Pharmacy Council of India

New Delhi

Rules & Syllabus for the Bachelor

of Pharmacy (B. Pharm) Course

[Framed under Regulation 6, 7 & 8 of the Bachelor of

Pharmacy (B. Pharm) course regulations 2014]

**CHAPTER- I: REGULATIONS**

**1. Short Title and Commencement**

These regulations shall be called as “The Revised Regulations for the B. Pharm. Degree

Program (CBCS)of the Pharmacy Council of India, New Delhi”. They shall come into

effect from the Academic Year 2016-17. The regulations framed are subject to

modifications from time to time by Pharmacy Council of India.

**2. Minimum qualification for admission**

**2.1 First year B. Pharm:**

Candidate shall have passed 10+2 examination conducted by the respective

state/central government authorities recognized as equivalent to 10+2 examination

by the Association of Indian Universities (AIU) with English as one of the

subjects and Physics, Chemistry, Mathematics (P.C.M) and or Biology (P.C.B /

P.C.M.B.) as optional subjects individually. Any other qualification approved by

the Pharmacy Council of India as equivalent to any of the above examinations.

**2.2. B. Pharm lateral entry (to third semester):**

A pass in D. Pharm. course from an institution approved by the Pharmacy Council

of India under section 12 of the Pharmacy Act.

**3. Duration of the program**

The course of study for B.Pharm shall extend over a period of eight semesters (four

academic years) and six semesters (three academic years) for lateral entry students. The

curricula and syllabi for the program shall be prescribed from time to time by Pharmacy

Council of India, New Delhi.

**4. Medium of instruction and examinations**

Medium of instruction and examination shall be in English.

**5. Working days in each semester**

Each semestershall consist of not less than 100 working days. The odd semesters shall be

conducted from the month of June/July to November/December and the even semesters

shall be conducted from December/January to May/June in every calendar year.

**6. Attendance and progress**

A candidate is required to put in at least 80% attendance in individual courses

considering theory and practical separately. The candidate shall complete the prescribed

course satisfactorily to be eligible to appear for the respective examinations.

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**7. Program/Course credit structure**

As per the philosophy of Credit Based Semester System, certain quantum of academic

work viz. theory classes, tutorial hours, practical classes, etc. are measured in terms of

credits. On satisfactory completion of the courses, a candidate earns credits. The amount

of credit associated with a course is dependent upon the number of hours of instruction

per week in that course. Similarly, the credit associated with any of the other academic,

co/extra-curricular activities is dependent upon the quantum of work expected to be put

in for each of these activities per week.

**7.1. Credit assignment**

**7.1.1. Theory and Laboratory courses**

Courses are broadly classified as Theory and Practical. Theory courses consist of

lecture (L) and /or tutorial (T) hours, and Practical (P) courses consist of hours

spent in the laboratory. Credits (C) for a course is dependent on the number of

hours of instruction per week in that course, and is obtained by using a multiplier

of one (1) for lecture and tutorial hours, and a multiplier of half (1/2) for practical

(laboratory) hours. Thus, for example, a theory course having three lectures and

one tutorial per week throughout the semester carries a credit of 4. Similarly, a

practical having four laboratory hours per week throughout semester carries a

credit of 2.

**7.2. Minimum credit requirements**

The minimum credit points required for award of a B. Pharm. degree is 208.

These credits are divided into Theory courses, Tutorials, Practical, Practice

School and Projectover the duration of eight semesters. The credits are distributed

semester-wise as shown in Table IX. Courses generally progress in sequences,

building competencies and their positioning indicates certain academic maturity

on the part of the learners. Learners are expected to follow the semester-wise

schedule of courses given in the syllabus.

The lateral entry students shall get 52 credit points transferred from their D.

Pharm program. Such students shall take up additional remedial courses of

‘Communication Skills’ (Theory and Practical) and ‘Computer Applications in

Pharmacy’ (Theory and Practical) equivalent to 3 and 4 credit points respectively,

a total of 7 credit points to attain 59 credit points, the maximum of I and II

semesters.

**8. Academic work**

A regular record of attendance both in Theory and Practical shall be maintained by the

teaching staff of respective courses.

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**Course code Name of the course**

**No. of**

**hours**

**Tuto**

**rial**

**Credit**

**points**

BP101T

Human Anatomy and Physiology I–

Theory

3 1 4

BP102T Pharmaceutical Analysis I – Theory 3 1 4

BP103T Pharmaceutics I – Theory 3 1 4

BP104T Pharmaceutical Inorganic Chemistry –

Theory

3 1 4

BP105T Communication skills – Theory \* 2 - 2

BP106RBT

BP106RMT

Remedial Biology/

Remedial Mathematics – Theory\*

2 - 2

BP107P

Human Anatomy and Physiology –

Practical

4 - 2

BP108P Pharmaceutical Analysis I – Practical 4 - 2

BP109P Pharmaceutics I – Practical 4 - 2

BP110P Pharmaceutical Inorganic Chemistry –

Practical

4 - 2

BP111P Communication skills – Practical\* 2 - 1

BP112RBP Remedial Biology – Practical\* 2 - 1

**Total 32/34$/36# 4 27/29$/30#**

**9. Course of study**

The course of study for B. Pharm shall include Semester Wise Theory & Practical as

given in Table – I to VIII. The number of hours to be devoted to each theory, tutorial and

practical course in any semester shall not be less than that shown in Table – I to VIII.

**Table-I: Course of study for semester I**

#Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and

appearing for Remedial Biology (RB)course**.**

$Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and

appearing for RemedialMathematics (RM)course**.**

\* Non University Examination (NUE)

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**Table-II: Course of study for semester II**

**Course**

**Code**

**Name of the course**

**No. of**

**hours**

**Tutorial**

**Credit**

**points**

BP201T Human Anatomy and Physiology II – Theory 3 1 4

BP202T Pharmaceutical Organic Chemistry I – Theory 3 1 4

BP203T Biochemistry – Theory 3 1 4

BP204T Pathophysiology – Theory 3 1 4

BP205T Computer Applications in Pharmacy – Theory \* 3 - 3

BP206T Environmental sciences – Theory \* 3 - 3

BP207P Human Anatomy and Physiology II –Practical 4 - 2

BP208P Pharmaceutical Organic Chemistry I– Practical 4 - 2

BP209P Biochemistry – Practical 4 - 2

BP210P Computer Applications in Pharmacy – Practical\* 2 - 1

**Total 32 4 29**

**\***Non University Examination (NUE)

**Table-III: Course of study for semester III**

**Course**

**code**

**Name of the course**

**No. of**

**hours**

**Tutorial**

**Credit**

**points**

BP301T Pharmaceutical Organic Chemistry II – Theory 3 1 4

BP302T Physical Pharmaceutics I – Theory 3 1 4

BP303T Pharmaceutical Microbiology – Theory 3 1 4

BP304T Pharmaceutical Engineering – Theory 3 1 4

BP305P Pharmaceutical Organic Chemistry II – Practical 4 - 2

BP306P Physical Pharmaceutics I – Practical 4 - 2

BP307P Pharmaceutical Microbiology – Practical 4 - 2

BP 308P Pharmaceutical Engineering –Practical 4 - 2

**Total 28 4 24**

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**Table-IV: Course of study for semester IV**

**Course**

**code**

**Name of the course**

**No. of**

**hours**

**Tutorial**

**Credit**

**points**

BP401T Pharmaceutical Organic Chemistry III– Theory 3 1 4

BP402T Medicinal Chemistry I – Theory 3 1 4

BP403T Physical Pharmaceutics II – Theory 3 1 4

BP404T Pharmacology I – Theory 3 1 4

BP405T Pharmacognosy and Phytochemistry I– Theory 3 1 4

BP406P Medicinal Chemistry I – Practical 4 - 2

BP407P Physical Pharmaceutics II – Practical 4 2

BP408P Pharmacology I – Practical 4 - 2

BP409P Pharmacognosy and Phytochemistry I – Practical 4 - 2

**Total 31 5 28**

**Table-V: Course of study for semester V**

**Course**

**code**

**Name of the course**

**No. of**

**hours**

**Tutorial**

**Credit**

**points**

BP501T Medicinal Chemistry II – Theory 3 1 4

BP502T Industrial PharmacyI– Theory 3 1 4

BP503T Pharmacology II – Theory 3 1 4

BP504T Pharmacognosy and Phytochemistry II– Theory 3 1 4

BP505T Pharmaceutical Jurisprudence – Theory 3 1 4

BP506P Industrial PharmacyI – Practical 4 - 2

BP507P Pharmacology II – Practical 4 - 2

BP508P Pharmacognosy and Phytochemistry II –

Practical

4 - 2

**Total 27 5 26**

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**Table-VI: Course of study for semester VI**

**Course**

**code**

**Name of the course**

**No. of**

**hours**

**Tutorial**

**Credit**

**points**

BP601T Medicinal Chemistry III – Theory 3 1 4

BP602T Pharmacology III – Theory 3 1 4

BP603T Herbal Drug Technology – Theory 3 1 4

BP604T

Biopharmaceutics and Pharmacokinetics –

Theory

3 1 4

BP605T Pharmaceutical Biotechnology – Theory 3 1 4

BP606T Quality Assurance –Theory 3 1 4

BP607P Medicinal chemistry III – Practical 4 - 2

BP608P Pharmacology III – Practical 4 - 2

BP609P Herbal Drug Technology – Practical 4 - 2

**Total 30 6 30**

**Table-VII: Course of study for semester VII**

**Course**

**code**

**Name of the course**

**No. of**

**hours**

**Tutorial**

**Credit**

**points**

BP701T Instrumental Methods of Analysis – Theory 3 1 4

BP702T Industrial PharmacyII – Theory 3 1 4

BP703T Pharmacy Practice – Theory 3 1 4

BP704T Novel Drug Delivery System – Theory 3 1 4

BP705P Instrumental Methods of Analysis – Practical 4 - 2

BP706PS Practice School\* 12 - 6

**Total 28 5 24**

**\*** Non University Examination (NUE)

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**Table-VIII: Course of study for semester VIII**

**Course**

**code**

**Name of the course**

**No. of**

**hours**

**Tutorial**

**Credit**

**points**

BP801T Biostatistics and Research Methodology 3 1 4

BP802T Social and Preventive Pharmacy 3 1 4

BP803ET Pharma Marketing Management

BP804ET Pharmaceutical Regulatory Science

BP805ET Pharmacovigilance

BP806ET

Quality Control and Standardization of

Herbals

BP807ET Computer Aided Drug Design

BP808ET Cell and Molecular Biology

BP809ET Cosmetic Science

BP810ET Experimental Pharmacology

BP811ET Advanced Instrumentation Techniques

3 + 3 =

6

1 + 1 = 2

4 + 4 =

8

BP812ET Dietary Supplements and Nutraceuticals

BP813PW Project Work 12 - 6

**Total 24 4 22**

**Table-IX: Semester wise credits distribution**

**Semester Credit Points**

I **27/29$/30#**

II 29

III 26

IV 28

V 26

VI 26

VII 24

VIII 22

Extracurricular/ Co curricular activities 01\*

**Total credit points for the program 209/211$/212#**

\* The credit points assigned for extracurricular and or co-curricular activities shall be given by the

Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this

credit point shall be defined by the colleges fromtime to time.

$Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing

for RemedialMathematics course**.**

#Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for

Remedial Biology course**.**

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**10. Program Committee**

1. The B. Pharm. program shall have a Program Committee constituted by the Head

of the institution in consultation with all the Heads of the departments.

2. The composition of the Program Committee shall be as follows:

A senior teacher shall be the Chairperson; One Teacher from each department

handling B.Pharm courses; and four student representatives of the program (one

from each academic year), nominated by the Head of the institution.

3. Duties of the Program Committee:

i. Periodically reviewing the progress of the classes.

ii. Discussing the problems concerning curriculum, syllabus and the conduct of

classes.

iii. Discussing with the course teachers on the nature and scope of assessment for

the course and the same shall be announced to the students at the beginning of

respective semesters.

iv. Communicating its recommendation to the Head of the institution on

academic matters.

v. The Program Committee shall meet at least thrice in a semester preferably at

the end of each Sessionalexam (Internal Assessment) and before the end

semester exam.

**11. Examinations/Assessments**

The scheme for internal assessment and end semester examinations is given in Table – X.

**11.1. End semester examinations**

The End Semester Examinations for each theory and practical coursethrough semesters I

to VIII shall beconducted by the university except for the subjects with asterix symbol (\*)

in table I and II for which examinations shall be conducted by the subject experts at

college level and the marks/grades shall be submitted to the university.

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**Internal Assessment End Semester Exams**

**Sessional Exams**

**Course**

**code Name of the course Continuous**

**Mode Marks Duration**

**Total Marks Duration**

**Total**

**Marks**

BP101T Human Anatomy and

Physiology I– Theory

10 15 1 Hr 25 75 3 Hrs 100

BP102T Pharmaceutical Analysis I –

Theory

10 15 1 Hr 25 75 3 Hrs 100

BP103T Pharmaceutics I – Theory 10 15 1 Hr 25 75 3 Hrs 100

BP104T Pharmaceutical Inorganic

Chemistry – Theory

10 15 1 Hr 25 75 3 Hrs 100

BP105T Communication skills –

Theory \*

5 10 1 Hr 15 35 1.5 Hrs 50

BP106RBT

BP106RMT

Remedial Biology/

Mathematics – Theory\*

5 10 1 Hr 15 35 1.5 Hrs 50

BP107P Human Anatomy and

Physiology – Practical

5 10 4 Hrs 15 35 4 Hrs 50

BP108P Pharmaceutical Analysis I –

Practical

5 10 4 Hrs 15 35 4 Hrs 50

BP109P Pharmaceutics I – Practical 5 10 4 Hrs 15 35 4 Hrs 50

BP110P Pharmaceutical Inorganic

Chemistry – Practical

5 10 4 Hrs 15 35 4 Hrs 50

BP111P Communication skills –

Practical\*

5 5 2 Hrs 10 15 2 Hrs 25

BP112RBP Remedial Biology –

Practical\*

5 5 2 Hrs 10 15 2 Hrs 25

**Total 70/75$/80# 115/125$/130# 23/24$/26#**

**Hrs**

**185/200$/210# 490/525$/**

**540#**

**31.5/33$/**

**35# Hrs**

**675/725$/**

**750#**

**Semester I**

**Tables-X: Schemes for internal assessments and end semester examinations semester wise**

#ApplicableONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course**.**

$ApplicableONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for RemedialMathematics (RM)course**.**

**\*** Non University Examination (NUE)

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**Semester II**

**Internal Assessment End Semester Exams**

**Sessional Exams**

**Course**

**code Name of the course Continuous**

**Mode Marks Duration**

**Total Marks Duration**

**Total**

**Marks**

BP201T

Human Anatomy and Physiology

II – Theory

10 15 1 Hr 25 75 3 Hrs 100

BP202T

Pharmaceutical Organic

Chemistry I – Theory

10 15 1 Hr 25 75 3 Hrs 100

BP203T Biochemistry – Theory 10 15 1 Hr 25 75 3 Hrs 100

BP204T Pathophysiology – Theory 10 15 1 Hr 25 75 3 Hrs 100

BP205T

Computer Applications in

Pharmacy – Theory\*

10 15 1 Hr 25 50 2 Hrs 75

BP206T Environmental sciences – Theory\* 10 15 1 Hr 25 50 2 Hrs 75

BP207P

Human Anatomy and Physiology

II –Practical

5 10 4 Hrs 15 35 4 Hrs 50

BP208P

Pharmaceutical Organic

Chemistry I– Practical

5 10 4 Hrs 15 35 4 Hrs 50

BP209P Biochemistry – Practical 5 10 4 Hrs 15 35 4 Hrs 50

BP210P Computer Applications in

Pharmacy – Practical\*

5 5 2 Hrs 10 15 2 Hrs 25

**Total 80 125 20 Hrs 205 520 30 Hrs 725**

**\*** The subject experts at college level shall conduct examinations

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**Semester III**

**Internal Assessment End Semester Exams**

**Sessional Exams**

**Course**

**code**

**Name of the course Continuous**

**Mode Marks Duration**

**Total Marks Duration**

**Total**

**Marks**

BP301T

Pharmaceutical Organic

Chemistry II – Theory

10 15 1 Hr 25 75 3 Hrs 100

BP302T PhysicalPharmaceuticsI –Theory 10 15 1 Hr 25 75 3 Hrs 100

BP303T

Pharmaceutical Microbiology –

Theory

10 15 1 Hr 25 75 3 Hrs 100

BP304T

Pharmaceutical Engineering –

Theory

10 15 1 Hr 25 75 3 Hrs 100

BP305P

Pharmaceutical Organic

Chemistry II – Practical

5 10 4 Hr 15 35 4 Hrs 50

BP306P Physical Pharmaceutics I –

Practical

5 10 4 Hr 15 35 4 Hrs 50

BP307P

Pharmaceutical Microbiology –

Practical

5 10 4 Hr 15 35 4 Hrs 50

BP308P

Pharmaceutical Engineering –

Practical

5 10 4 Hr 15 35 4 Hrs 50

**Total 60 100 20 160 440 28Hrs 600**

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**Semester IV**

**Internal Assessment End Semester Exams**

**Sessional Exams**

**Course**

**code**

**Name of the course Continuous**

**Mode Marks Duration**

**Total Marks Duration**

**Total**

**Marks**

BP401T

Pharmaceutical Organic

Chemistry III– Theory

10 15 1 Hr 25 75 3 Hrs 100

BP402T Medicinal Chemistry I – Theory 10 15 1 Hr 25 75 3 Hrs 100

BP403T Physical Pharmaceutics II –

Theory

10 15 1 Hr 25 75 3 Hrs 100

BP404T Pharmacology I – Theory 10 15 1 Hr 25 75 3 Hrs 100

BP405T Pharmacognosy I – Theory 10 15 1 Hr 25 75 3 Hrs 100

BP406P Medicinal Chemistry I – Practical 5 10 4 Hr 15 35 4 Hrs 50

BP407P Physical Pharmaceutics II –

Practical

5 10 4 Hrs 15 35 4 Hrs 50

BP408P Pharmacology I – Practical 5 10 4 Hrs 15 35 4 Hrs 50

BP409P Pharmacognosy I – Practical 5 10 4 Hrs 15 35 4 Hrs 50

**Total 70 115 21 Hrs 185 515 31 Hrs 700**

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**Semester V**

**Internal Assessment End Semester Exams**

**Sessional Exams**

**Course**

**code**

**Name of the course Continuous**

**Mode Marks Duration**

**Total Marks Duration**

**Total**

**Marks**

BP501T Medicinal Chemistry II – Theory 10 15 1 Hr 25 75 3 Hrs 100

BP502T Industrial PharmacyI– Theory 10 15 1 Hr 25 75 3 Hrs 100

BP503T Pharmacology II – Theory 10 15 1 Hr 25 75 3 Hrs 100

BP504T Pharmacognosy II – Theory 10 15 1 Hr 25 75 3 Hrs 100

BP505T

Pharmaceutical Jurisprudence –

Theory

10 15 1 Hr 25 75 3 Hrs 100

BP506P Industrial PharmacyI– Practical 5 10 4 Hr 15 35 4 Hrs 50

BP507P Pharmacology II – Practical 5 10 4 Hr 15 35 4 Hrs 50

BP508P Pharmacognosy II – Practical 5 10 4 Hr 15 35 4 Hrs 50

**Total 65 105 17 Hr 170 480 27 Hrs 650**

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**Semester VI**

**Internal Assessment End Semester Exams**

**Sessional Exams**

**Course**

**code**

**Name of the course Continuous**

**Mode Marks Duration**

**Total Marks Duration**

**Total**

**Marks**

BP601T Medicinal Chemistry III – Theory 10 15 1 Hr 25 75 3 Hrs 100

BP602T Pharmacology III – Theory 10 15 1 Hr 25 75 3 Hrs 100

BP603T

Herbal Drug Technology –

Theory

10 15 1 Hr 25 75 3 Hrs 100

BP604T

Biopharmaceutics and

Pharmacokinetics – Theory

10 15 1 Hr 25 75 3 Hrs 100

BP605T

Pharmaceutical Biotechnology–

Theory

10 15 1 Hr 25 75 3 Hrs 100

BP606T Quality Assurance– Theory 10 15 1 Hr 25 75 3 Hrs 100

BP607P

Medicinal chemistry III –

Practical

5 10 4 Hrs 15 35 4 Hrs 50

BP608P Pharmacology III – Practical 5 10 4 Hrs 15 35 4 Hrs 50

BP609P

Herbal Drug Technology –

Practical

5 10 4 Hrs 15 35 4 Hrs 50

**Total 75 120 18 Hrs 195 555 30 Hrs 750**

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**Semester VII**

**Internal Assessment End Semester**

**Exams**

**Sessional Exams**

**Course**

**code Name of the course**

**Continuous**

**Mode Marks Duration**

**Total Marks Duration**

**Total**

**Marks**

BP701T

Instrumental Methods of Analysis

– Theory

10 15 1 Hr 25 75 3 Hrs 100

BP702T Industrial Pharmacy – Theory 10 15 1 Hr 25 75 3 Hrs 100

BP703T Pharmacy Practice – Theory 10 15 1 Hr 25 75 3 Hrs 100

BP704T Novel Drug Delivery System –

Theory

10 15 1 Hr 25 75 3 Hrs 100

BP705 P

Instrumental Methods of Analysis

– Practical

5 10 4 Hrs 15 35 4 Hrs 50

BP706 PS Practice School\* 25 - - 25 125 5 Hrs 150

**Total 70 70 8Hrs 140 460 21 Hrs 600**

**\*** The subject experts at college level shall conduct examinations

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**Semester VIII**

**Internal Assessment End Semester Exams**

**Sessional Exams**

**Course**

**code**

**Name of the course Continuous**

**Mode Marks Duration**

**Total Marks Duration**

**Total**

**Marks**

BP801T

Biostatistics and Research

Methodology – Theory

10 15 1 Hr 25 75 3 Hrs 100

BP802T

Social and Preventive Pharmacy

– Theory

10 15 1 Hr 25 75 3 Hrs 100

BP803ET

Pharmaceutical Marketing –

Theory

BP804ET

Pharmaceutical Regulatory

Science – Theory

BP805ET Pharmacovigilance – Theory

BP806ET

Quality Control and

Standardization of Herbals –

Theory

BP807ET Computer Aided Drug Design –

Theory

BP808ET Cell and Molecular Biology –

Theory

BP809ET Cosmetic Science – Theory

BP810ET Experimental Pharmacology –

Theory

BP811ET Advanced Instrumentation

Techniques – Theory

10 + 10

= 20

15 + 15 =

30

1 + 1 =

2 Hrs

25 + 25 =

50

75 + 75

= 150

3 + 3 = 6

Hrs

100 +

100 =

200

BP812PW Project Work - - - - 150 4 Hrs 150

**Total 40 60 4 Hrs 100 450 16 Hrs 550**

17

18

**11.2. Internal assessment: Continuous mode**

The marks allocated for Continuous mode of Internal Assessment shall be

awarded as per the scheme given below.

**Table-XI:Scheme for awarding internal assessment: Continuous mode**

**Theory**

**Criteria Maximum**

**Marks**

Attendance (Refer Table – XII) 4 2

Academic activities (Average of any 3 activities e.g. quiz, assignment,

open book test, field work, group discussion and seminar)

3 1.5

Student – Teacher interaction 3 1.5

**Total 10 5**

**Practical**

Attendance (Refer Table – XII) 2

Based on Practical Records, Regular viva voce, etc. 3

**Total 5**

**Table- XII: Guidelines for the allotment of marks for attendance**

**Percentage of Attendance Theory Practical**

95 – 100 4 2

90 – 94 3 1.5

85 – 89 2 1

80 – 84 1 0.5

Less than 80 0 0

**11.2.1. Sessional Exams**

Two Sessional exams shall be conducted for each theory / practical course as per the

schedule fixed by the college(s). The scheme of question paper for theory and practical

Sessional examinations is given below. The average marks of two Sessional exams shall

be computed for internal assessment as per the requirements given in tables – X.

Sessional exam shall be conducted for 30 marks for theory and shall be computed

for 15 marks. Similarly Sessional exam for practical shall be conducted for 40 marks and

shall be computed for 10 marks.

**Question paper pattern for theory Sessional examinations**

**For subjects having University examination**

I. Multiple Choice Questions (MCQs) = 10 x 1 = 10

OR OR

Objective Type Questions (5 x 2) = 05 x 2 = 10

(Answer all the questions)

I. Long Answers (Answer 1 out of 2) = 1 x 10 = 10

II. Short Answers (Answer 2 out of 3) = 2 x 5 = 10

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Total = 30 marks

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**For subjects having Non University Examination**

I. Long Answers (Answer 1 out of 2) = 1 x 10 = 10

II. Short Answers (Answer 4 out of 6) = 4 x 5 = 20

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Total = 30 marks

**------------------**

**Question paper pattern for practical sessional examinations**

I. Synopsis = 10

II. Experiments = 25

III. Viva voce = 05

Total =

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40 marks

**------------------**

**12. Promotion and award of grades**

A student shall be declared PASSand eligible for getting gradein a course of

B.Pharm.program if he/she secures at least 50% marks in that particular course including

internal assessment.For example, to be declared as PASS and to get grade, the student has

to secure a minimum of 50 marks for the total of 100 including continuous mode of

assessment and end semester theory examination and has to secure a minimum of 25

marks for the total 50 including internal assessment and end semester practical

examination.

**13. Carry forward of marks**

In case a studentfails to secure the minimum 50% in any Theory or Practical course as

specified in 12,then he/she shall reappear for the end semester examinationof that course.

However his/her marks of the Internal Assessmentshallbe carried overand he/she shall be

entitled for grade obtained by him/her on passing.

**14. Improvement of internal assessment**

A studentshall have the opportunity to improvehis/her performance only oncein the

Sessional exam component of the internal assessment. The re-conduct of the Sessional

exam shall be completed before the commencement of next end semester theory

examinations.

**15. Re-examination of end semester examinations**

Reexamination ofend semester examinationshall be conducted as per the schedule given

in table XIII. The exact dates of examinations shall be notified from time to time.

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**Table-XIII: Tentative schedule of end semester examinations**

**Semester For Regular Candidates For Failed Candidates**

I, III, V and VII November / December May / June

II, IV, VI and VIII May / June November / December

**Question paper pattern for end semester theory examinations**

**For 75 marks paper**

I. Multiple Choice Questions(MCQs) = 20 x 1 = 20

OR OR

Objective Type Questions (10 x 2) = 10 x 2 = 20

(Answer all the questions)

II. Long Answers (Answer 2 out of 3) = 2 x 10 = 20

III. Short Answers (Answer 7 out of 9) = 7 x 5 = 35

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Total = 75 marks

**------------------**

**For 50 marks paper**

I. Long Answers (Answer 2 out of 3) = 2 x 10 = 20

II. Short Answers (Answer 6 out of 8) = 6 x 5 = 30

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Total = 50 marks

**------------------**

**For 35 marks paper**

I. Long Answers (Answer 1 out of 2) = 1 x 10 =10

II. Short Answers (Answer 5 out of 7) = 5 x 5 = 25

------------------

Total = 35 marks

**------------------**

**Question paper pattern for end semester practical examinations**

I. Synopsis = 5

II. Experiments = 25

III. Viva voce = 5

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Total = 35 marks

**------------------**

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**16. Academic Progression:**

No student shall be admitted to any examination unless he/she fulfills the norms given in

6. Academic progression rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I, II and III semesters till the

IV semester examinations. However, he/she shall not be eligible to attend the courses of

V semester until all the courses of I and II semesters are successfully completed.

A student shall be eligible to carry forward all the courses of III, IV and V semesters till

the VI semester examinations. However, he/she shall not be eligible to attend the courses

of VII semester until all the courses of I, II, III and IV semesters are successfully

completed.

A student shall be eligible to carry forward all the courses of V, VI and VII semesters till

the VIII semester examinations. However, he/she shall not be eligible to get the course

completion certificate until all the courses of I, II, III, IV, V and VI semesters are

successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses

of I to VIII semesters within the stipulated time period as per the norms specified in 26.

A lateral entry student shall be eligible to carry forward all the courses of III, IV and V

semesters till the VI semester examinations. However, he/she shall not be eligible to

attend the courses of VII semester until all the courses of III and IV semesters are

successfully completed.

A lateral entry student shall be eligible to carry forward all the courses of V, VI and VII

semesters till the VIII semester examinations. However, he/she shall not be eligible to get

the course completion certificate until all the courses of III, IV, V and VI semesters are

successfully completed.

A lateral entry student shall be eligible to get his/her CGPA upon successful completion

of the courses of III to VIII semesters within the stipulated time period as per the norms

specified in 26.

Any student who hasgiven more than 4 chances for successful completion of I / III

semester courses and more than 3 chances for successful completion of II / IV semester

courses shall be permitted to attend V / VII semester classes ONLY during the

subsequent academic year as the case may be. In simpler terms there shall NOT be any

ODD BATCH for any semester.

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Note: Grade ABshould be considered as failed and treated as one head for deciding

academic progression. Such rules are also applicable for those students who fail to

register for examination(s) of any course in any semester.

**17. Grading of performances**

**17.1. Letter grades and grade points allocations:**

Based on the performances, each student shall be awarded a final letter grade at the end

of the semester for each course.The letter grades and their corresponding grade points are

given in Table – XII.

**Table – XII: Letter grades and grade points equivalent to**

**Percentage of marks and performances**

**Percentage of**

**Marks Obtained**

**Letter Grade Grade Point Performance**

90.00 – 100 O 10 Outstanding

80.00 – 89.99 A 9 Excellent

70.00 – 79.99 B 8 Good

60.00 – 69.99 C 7 Fair

50.00 – 59.99 D 6 Average

Less than 50 F 0 Fail

Absent AB 0 Fail

A learner who remains absent for any end semester examination shall be assigned a letter

grade of ABand a corresponding grade point of zero. He/she should reappear for the said

evaluation/examination in due course.

**18. The Semester grade point average (SGPA)**

The performance of a student in a semester is indicated by a number called ‘Semester

Grade Point Average’ (SGPA). The SGPA is the weighted average of the grade points

obtainedin all the courses by the student during the semester. For example, if a student

takes five courses(Theory/Practical) in a semester with credits C1, C2, C3, C4 and C5

and the student’s grade pointsin these courses are G1, G2, G3, G4 and G5, respectively,

and then students’ SGPA is equal to:

**C1G1 + C2G2 + C3G3 + C4G4+ C5G5**

**SGPA = --------------------------------------------------**

**C1 + C2 + C3 + C4+ C5**

The SGPA is calculated to two decimal points.It should be noted that, the SGPA for any

semester shall take into consideration the F and ABSgrade awarded in that semester. For

example if a learner has a F or ABS grade in course 4, theSGPA shall then be computed

as:

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**C1G1 + C2G2 + C3G3 + C4\* ZERO + C5G5**

**SGPA = ------------------------------------------------------**

**C1 + C2 + C3 + C4+ C5**

**19. Cumulative Grade Point Average (CGPA)**

The CGPA is calculated with the SGPA of all the VIII semesters to two decimal points

and is indicated in final grade report card/final transcript showing the grades of all VIII

semesters and their courses. The CGPA shall reflect the failed statusin case of F

grade(s),till the course(s) is/are passed. When the course(s)is/are passedby obtaining a

pass grade on subsequent examination(s) theCGPA shall only reflect the new grade and

not the fail grades earned earlier.The CGPA is calculated as:

**C1S1 + C2S2 + C3S3 + C4S4+ C5S5+ C6S6+ C7S7+ C8S8**

**CGPA= -------------------------------------------------------------------------**

**C1 + C2 + C3 + C4+ C5+ C6+ C7+ C8**

where C1, C2, C3,…. is the total number of credits for semester I,II,III,…. and S1,S2, S3,….is

the SGPA of semester I,II,III,…. .

**20. Declaration of class**

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction = CGPA of. 7.50 and above

First Class = CGPA of 6.00 to 7.49

Second Class = CGPA of 5.00 to 5.99

**21. Project work**

All the students shall undertake a projectunder the supervision of a teacher and submit a

report. The area of the project shall directly relate any one of the elective subject opted by

the student in semester VIII. The project shall be carried out in group not exceeding 5 in

number. The project report shall be submitted in triplicate (typed & bound copy not less

than 25 pages).

The internal and external examiner appointed by the University shall evaluate the project

at the time of the Practical examinations of other semester(s). Students shall be evaluated

in groups for four hours (i.e., about half an hour for a group of five students). The

projects shall be evaluated as per the criteria given below.

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***Evaluation of Dissertation Book:***

Objective(s) of the work done 15 Marks

Methodology adopted 20 Marks

Results and Discussions 20 Marks

Conclusions and Outcomes 20 Marks

**Total 75 Marks**

***Evaluation of Presentation:***

Presentation of work 25 Marks

Communication skills 20 Marks

Question and answer skills 30 Marks

**Total 75 Marks**

*Explanation*: The 75 marks assigned to the dissertation book shall be same for all the

students in a group. However, the 75 marks assigned for presentation shall be awarded

based on the performance of individual students in the given criteria.

**22. Industrial training (Desirable)**

Every candidate shall be required to work for at least 150 hours spread over four weeks in

a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control

department, Quality Assurance department, Analytical laboratory, Chemical

manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical

Research Organization, Community Pharmacy, etc. After the Semester – VI and before

the commencement of Semester – VII, and shall submit satisfactory report of such work

and certificate duly signed by the authority of training organization to the head of the

institute.

**23. Practice School**

In the VII semester, every candidate shall undergo practice school for a period of 150

hours evenly distributed throughout the semester. The student shall opt any one of the

domains for practice school declared by the program committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate)

on the practice school he/she attended (not more than 25 pages). Along with the exams of

semester VII, the report submitted by the student, knowledge and skills acquired by the

student through practice school shall be evaluated by the subject experts at college

leveland grade point shall be awarded.

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**24. Award of Ranks**

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates

who fail in one or more courses during the B.Pharm program shall not be eligible for

award of ranks.Moreover, the candidates should have completed the B. Pharm program in

minimum prescribed number of years, (four years) for the award of Ranks.

**25. Award of degree**

Candidates who fulfill the requirements mentioned above shall be eligible for award of

degree during the ensuing convocation.

**26. Duration for completion of the program of study**

The duration for the completion of the program shall be fixed as double the actual

duration of the program and the students have to pass within the said period, otherwise

they have to get fresh Registration.

**27. Re-admission after break of study**

Candidate who seeks re-admission to the program after break of study has to get the

approval from the university by paying a condonation fee.

No condonation is allowed for the candidate who has more than 2 years of break up

period and he/she has to rejoin the program by paying the required fees.

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**CHAPTER - II: SYLLABUS**

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**Semester I**

28

**BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)**

**45 Hours**

**Scope:** This subject is designed to impart fundamental knowledge on the structure and

functions of the various systems of the human body. It also helps in understanding both

homeostatic mechanisms. The subject provides the basic knowledge required to

understand the various disciplines of pharmacy.

**Objectives**: Upon completion of this course the student should be able to

1. Explain the gross morphology, structure and functions of various organs of the human

body.

2. Describe the various homeostatic mechanisms and their imbalances.

3. Identify the various tissues and organs of different systems of human body.

4. Perform the various experiments related to special senses and nervous system.

5. Appreciate coordinated working pattern of different organs of each system

**Course Content:**

**Unit I 10 hours**

 **Introduction to human body**

Definition and scope of anatomy and physiology, levels of structural

organization and body systems, basic life processes, homeostasis, basic

anatomical terminology.

 **Cellular level of organization**

Structure and functions of cell, transport across cell membrane, cell

division, cell junctions. General principles of cell communication,

intracellular signaling pathway activation by extracellular signal

molecule, Forms of intracellular signaling: a) Contact-dependent b)

Paracrine c) Synaptic d) Endocrine

 **Tissue level of organization**

Classification of tissues, structure, location and functions of epithelial,

muscular and nervous and connective tissues.

**Unit II**

 **Integumentary system**

Structure and functions of skin

 **Skeletal system**

Divisions of skeletal system, types of bone, salient features and functions

of bones of axial and appendicular skeletal system

Organization of skeletal muscle, physiology of muscle contraction,

neuromuscular junction

**10 hours**

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 **Joints**

Structural and functional classification, types of joints movements and its

articulation

**Unit III 10 hours**

 **Body fluids and blood**

 Body fluids, composition and functions of blood, hemopoeisis, formation of

hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors,

transfusion, its significance and disorders of blood, Reticulo endothelial system.

 **Lymphatic system**

Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of

lymphatic system

**Unit IV 08 hours**

**Peripheral nervous system**:

Classification of peripheral nervous system: Structure and functions of

sympathetic and parasympathetic nervous system.

Origin and functions of spinal and cranial nerves.

 **Special senses**

Structure and functions of eye, ear, nose and tongue and their disorders.

**Unit V 07 hours**

 **Cardiovascular system**

Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of

artery, vein and capillaries, elements of conduction system of heart and heart beat, its

regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of

blood pressure, pulse, electrocardiogram and disorders of heart.

30

**BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)**

**4 Hours/week**

Practical physiology is complimentary to the theoretical discussions in

physiology. Practicals allow the verification of physiological processes discussed

in theory classes through experiments on living tissue, intact animals or normal

human beings. This is helpful for developing an insight on the subject**.**

1. Study of compound microscope.

2. Microscopic study of epithelial and connective tissue

3. Microscopic study of muscular and nervous tissue

4. Identification of axial bones

5. Identification of appendicular bones

6. Introduction to hemocytometry.

7. Enumeration of white blood cell (WBC) count

8. Enumeration of total red blood corpuscles (RBC) count

9. Determination of bleeding time

10. Determination of clotting time

11. Estimation of hemoglobin content

12. Determination of blood group.

13. Determination of erythrocyte sedimentation rate (ESR).

14. Determination of heart rate and pulse rate.

15. Recording of blood pressure.

**Recommended Books (Latest Editions)**

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee

brothers medical publishers, New Delhi.

2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill

Livingstone, New York

3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins

Co,Riverview,MI USA

4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH,

U.S.A.

5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.

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6. Textbook of Human Histology by Inderbir Singh, Jaypee brother’s medical publishers,

New Delhi.

7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother’s medical publishers,

New Delhi.

8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma,

Jaypee brother’s medical publishers, New Delhi.

**Reference Books (Latest Editions)**

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,

Riverview, MI USA

2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH,

U.S.A.

3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

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**BP102T. PHARMACEUTICAL ANALYSIS (Theory)**

**45 Hours**

**Scope**: This course deals with the fundamentals of analytical chemistry and principles of

electrochemical analysis of drugs

**Objectives:** Upon completion of the course student shall be able to

 understand the principles of volumetric and electro chemical analysis

 carryout various volumetric and electrochemical titrations

 develop analytical skills

**Course Content:**

**UNIT-I 10 Hours**

**(a) Pharmaceutical analysis**- Definition and scope

i) Different techniques of analysis

ii) Methods of expressing concentration

iii) Primary and secondary standards.

iv) Preparation and standardization of various molar and normal solutions-

Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate,

sulphuric acid, potassium permanganate and ceric ammonium sulphate

**(b)Errors:** Sources of errors, types of errors, methods of minimizing errors,

accuracy, precision and significant figures

(c)Pharmacopoeia, Sources of impurities in medicinal agents,limit tests.

**UNIT-II 10 Hours**

 **Acid base titration**: Theories of acid base indicators, classification of

acid base titrations and theory involved in titrations of strong, weak, and

very weak acids and bases, neutralization curves

 **Non aqueous titration**: Solvents, acidimetry and alkalimetry titration and

estimation of Sodium benzoate and Ephedrine HCl

**UNIT-III 10 Hours**

 **Precipitation titrations**: Mohr’s method, Volhard’s, Modified

Volhard’s, Fajans method, estimation of sodium chloride.

 **Complexometric titration**: Classification, metal ion indicators, masking

and demasking reagents, estimation of Magnesium sulphate, and calcium

gluconate.

 **Gravimetry**: Principle and steps involved in gravimetric analysis. Purity

of the precipitate: co-precipitation and post precipitation, Estimation of

barium sulphate.

 Basic Principles,methods and application of diazotisation titration.

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**UNIT-IV 08 Hours**

**Redox titrations**

(a) Concepts of oxidation and reduction

(b) Types of redox titrations (Principles and applications)

Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with

potassium iodate

**UNIT-V 07 Hours**

 **Electrochemical methods of analysis**

 **Conductometry**- Introduction, Conductivity cell, Conductometric

titrations, applications.

 **Potentiometry -** Electrochemical cell, construction and working

of reference (Standard hydrogen, silver chloride electrode and

calomel electrode) and indicator electrodes (metal electrodes and

glass electrode), methods to determine end point of potentiometric

titration and applications.

 **Polarography** - Principle, Ilkovic equation, construction and

working of dropping mercury electrode and rotating platinum

electrode, applications

34

**BP108P. PHARMACEUTICAL ANALYSIS (Practical)**

**4 Hours / Week**

I **Limit Test of the following**

(1) Chloride

(2) Sulphate

(3) Iron

(4) Arsenic

II **Preparation and standardization of**

(1) Sodium hydroxide

(2) Sulphuric acid

(3) Sodium thiosulfate

(4) Potassium permanganate

(5) Ceric ammonium sulphate

III **Assay of the following compounds along with Standardization of Titrant**

(1) Ammonium chloride by acid base titration

(2) Ferrous sulphate by Cerimetry

(3) Copper sulphate by Iodometry

(4) Calcium gluconate by complexometry

(5) Hydrogen peroxide by Permanganometry

(6) Sodium benzoate by non-aqueous titration

(7) Sodium Chloride by precipitation titration

IV **Determination of Normality by electro-analytical methods**

(1) Conductometric titration of strong acid against strong base

(2) Conductometric titration of strong acid and weak acid against strong base

(3) Potentiometric titration of strong acid against strong base

**Recommended Books: (Latest Editions)**

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone

Press of University of London

2. A.I. Vogel, Text Book of Quantitative Inorganic analysis

3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry

4. Bentley and Driver's Textbook of Pharmaceutical Chemistry

5. John H. Kennedy, Analytical chemistry principles

6. Indian Pharmacopoeia.

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**BP103T. PHARMACEUTICS- I (Theory)**

**45 Hours**

**Scope:** This course is designed to impart a fundamental knowledge on the preparatory

pharmacy with arts and science of preparing the different conventional dosage forms.

**Objectives:** Upon completion of this course the student should be able to:

 Know the history of profession of pharmacy

 Understand the basics of different dosage forms, pharmaceutical incompatibilities and

pharmaceutical calculations

 Understand the professional way of handling the prescription

 Preparation of various conventional dosage forms

**Course Content:**

**UNIT – I 10 Hours**

 **Historical background and development of profession of pharmacy**: History

of profession of Pharmacy in India in relation to pharmacy education, industry

and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP,

USP and Extra Pharmacopoeia.

 **Dosage forms:** Introduction to dosage forms, classification and definitions

 **Prescription:** Definition, Parts of prescription, handling of Prescription and

Errors in prescription.

 **Posology:** Definition, Factors affecting posology. Pediatric dose calculations

based on age, body weight and body surface area.

**UNIT – II 10 Hours**

 **Pharmaceutical calculations**: Weights and measures – Imperial & Metric

system, Calculations involving percentage solutions, alligation, proof spirit and

isotonic solutions based on freezing point and molecular weight.

 **Powders:** Definition, classification, advantages and disadvantages,Simple &

compound powders – official preparations, dusting powders, effervescent,

efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.

 **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms.

Excipients used in formulation of liquid dosage forms. Solubility enhancement

techniques

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**UNIT – III 08 Hours**

 **Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes,

Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and

Lotions.

 **Biphasic liquids:**

 **Suspensions:** Definition, advantages and disadvantages, classifications,

Preparation of suspensions; Flocculated and Deflocculated suspension & stability

problems and methods to overcome.

 **Emulsions:** Definition, classification, emulsifying agent, test for the identification

of type ofEmulsion, Methods of preparation & stability problems and methods to

overcome.

**UNIT – IV 08 Hours**

 **Suppositories**: Definition, types, advantages and disadvantages, types of bases,

methods of preparations. Displacement value & its calculations, evaluation of

suppositories.

 **Pharmaceutical incompatibilities**: Definition, classification, physical, chemical

and therapeutic incompatibilities with examples.

**UNIV – V 07 Hours**

 **Semisolid dosage forms:** Definitions, classification, mechanisms and factors

influencing dermal penetration of drugs. Preparation of ointments, pastes, creams

and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid

dosages forms

37

**BP109P. PHARMACEUTICSI (Practical)**

**1 . Syrups**

a) Syrup IP’66

b) Compound syrup of Ferrous Phosphate BPC’68

**3 Hours / week**

**2. Elixirs** a) Piperazine citrate elixir

b) Paracetamol pediatric elixir

**3.Linctus** a) Terpin Hydrate Linctus IP’66

**4. Solutions**

b) Iodine Throat Paint (Mandles Paint)

a) Strong solution of ammonium acetate

b) Cresol with soap solution

c) Lugol’s solution

**5. Suspensions**

a) Calamine lotion

b) Magnesium Hydroxide mixture

c) Aluminimum Hydroxide gel

**6. Emulsions** a) Turpentine Liniment

b) Liquid paraffin emulsion

**7. Powders and Granules**

a) ORS powder (WHO)

b) Effervescent granules

c)Dusting powder

d)Divded powders

**8. Suppositories**

a) Glycero gelatin suppository

b) Coca butter suppository

c) Zinc Oxide suppository

**8. Semisolids**

a) Sulphur ointment

b) Non staining-iodine ointment with methyl salicylate

c) Carbopal gel

**9. Gargles and Mouthwashes**

a) Iodine gargle

b) Chlorhexidine mouthwash

**Recommended Books: (Latest Editions)**

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1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott

Williams andWalkins, New Delhi.

2. Carter S.J., Cooper and Gunn’s-Dispensing for Pharmaceutical Students, CBS publishers,

New Delhi.

3. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone,

Edinburgh.

4. Indian pharmacopoeia.

5. British pharmacopoeia.

6. Lachmann. Theory and Practice of Industrial Pharmacy,Lea& Febiger Publisher, The

University of Michigan.

7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott

Williams, New Delhi.

8. Carter S.J., Cooper and Gunn’s. Tutorial Pharmacy, CBS Publications, New Delhi.

9. E.A. Rawlins, Bentley’s Text Book of Pharmaceutics, English Language Book Society,

Elsevier Health Sciences, USA.

10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC,

New York.

11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker,

INC, New York.

12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and

Suspensions, Marcel Dekker, INC, New York.

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**BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)**

**45 Hours**

**Scope**: This subject deals with the monographs of inorganic drugs and pharmaceuticals.

**Objectives:** Upon completion of course student shall be able to

 know the sources of impurities and methods to determine the impurities in inorganic

drugs and pharmaceuticals

 understand the medicinal and pharmaceutical importance of inorganic compounds

**Course Content**:

**UNIT I 10 Hours**

 **Impurities in pharmaceutical substances:** History of Pharmacopoeia,

Sources and types of impurities, principle involved in the limit test for

Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test

for Chloride and Sulphate

**General methods of preparation**, assay for the compounds superscripted

with **asterisk (\*),** properties and medicinal uses of inorganic compounds

belonging to the following classes

**UNIT II 10 Hours**

 **Acids, Bases and Buffers:** Buffer equations and buffer capacity in general,

buffers in pharmaceutical systems, preparation, stability, buffered isotonic

solutions, measurements of tonicity, calculations and methods of adjusting

isotonicity.

 **Major extra and intracellular electrolytes**: Functions of major

physiological ions, Electrolytes used in the replacement therapy: Sodium

chloride\*, Potassium chloride, Calcium gluconate\* and Oral Rehydration Salt

(ORS), Physiological acid base balance.

 **Dental products**: Dentifrices, role of fluoride in the treatment of dental

caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc

eugenol cement.

**UNIT III 10 Hours**

 **Gastrointestinal agents**

**Acidifiers:** Ammonium chloride\* and Dil. HCl

**Antacid:** Ideal properties of antacids, combinations of antacids, Sodium

40

Bicarbonate\*, Aluminum hydroxide gel, Magnesium hydroxide mixture

**Cathartics:** Magnesium sulphate, Sodium orthophosphate, Kaolin and

Bentonite

**Antimicrobials**: Mechanism, classification, Potassium permanganate, Boric

acid, Hydrogen peroxide\*, Chlorinated lime\*, Iodine and its preparations

**UNIT IV 08 Hours**

 **Miscellaneous compounds**

**Expectorants:** Potassium iodide, Ammonium chloride\*.

**Emetics**: Copper sulphate\*, Sodium potassium tartarate

**Haematinics:** Ferrous sulphate\*, Ferrous gluconate

**Poison and Antidote:** Sodium thiosulphate\*, Activated charcoal, Sodium

nitrite333

**Astringents**: Zinc Sulphate, Potash Alum

**UNIT V 07 Hours**

 **Radiopharmaceuticals**: Radio activity, Measurement of radioactivity,

Properties of α, β, γ radiations, Half life, radio isotopes and study of radio

isotopes - Sodium iodide I131, Storage conditions, precautions &

pharmaceutical application of radioactive substances.

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**BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)**

**4 Hours / Week**

I **Limit tests for following ions**

Limit test for Chlorides and Sulphates

Modified limit test for Chlorides and Sulphates

Limit test for Iron

Limit test for Heavymetals

Limit test for Lead

Limit test for Arsenic

II **Identification test**

Magnesium hydroxide

Ferrous sulphate

Sodium bicarbonate

Calcium gluconate

Copper sulphate

III **Test for purity**

Swelling power of Bentonite

Neutralizing capacity of aluminum hydroxide gel

Determination of potassium iodate and iodine in potassium Iodide

IV **Preparation of inorganic pharmaceuticals**

Boric acid

Potash alum

Ferrous sulphate

**Recommended Books (Latest Editions)**

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II,

Stahlone Press of University of London, 4th edition.

2. A.I. Vogel, Text Book of Quantitative Inorganic analysis

3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition

4. M.L Schroff, Inorganic Pharmaceutical Chemistry

5. Bentley and Driver's Textbook of Pharmaceutical Chemistry

6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry

7. Indian Pharmacopoeia

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**BP105T.COMMUNICATION SKILLS (Theory)**

**30 Hours**

**Scope:** This course will prepare the young pharmacy student to interact effectively with

doctors, nurses, dentists, physiotherapists and other health workers. At the end of this

course the student will get the soft skills set to work cohesively with the team as a team

player and will add value to the pharmaceutical business.

**Objectives:**

Upon completion of the course the student shall be able to

1. Understand the behavioral needs for a Pharmacist to function effectively in the

areas of pharmaceutical operation

2. Communicate effectively (Verbal and Non Verbal)

3. Effectivelymanage the team as a team player

4. Develop interview skills

5. Develop Leadership qualities and essentials

**Course content:**

**UNIT – I 07 Hours**

 **Communication Skills:** Introduction, Definition, The Importance of Communication,

The Communication Process – Source, Message, Encoding, Channel, Decoding,

Receiver, Feedback, Context

 **Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural

Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological

Barriers, Emotional barriers

 **Perspectives in Communication:** Introduction, Visual Perception, Language, Other

factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

**UNIT – II 07 Hours**

 **Elements of Communication:** Introduction, Face to Face Communication - Tone of

Voice, Body Language (Non-verbal communication), Verbal Communication, Physical

Communication

 **Communication Styles:** Introduction, The Communication Styles Matrix with example

for each -Direct Communication Style, Spirited Communication Style, Systematic

Communication Style, Considerate Communication Style

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**UNIT – III 07 Hours**

 **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an

Active Listener, Listening in Difficult Situations

 **Effective Written Communication:** Introduction, When and When Not to Use Written

Communication - Complexity of the Topic, Amount of Discussion’ Required, Shades of

Meaning, Formal Communication

 **Writing Effectively:** Subject Lines, Put the Main Point First, Know Your Audience,

Organization of the Message

**UNIT – IV 05 Hours**

 **Interview Skills:** Purpose of an interview, Do’s and Dont’s of an interview

 **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your

Presentation, Delivering Your Presentation, Techniques of Delivery

**UNIT – V 04 Hours**

 **Group Discussion:** Introduction, Communication skills in group discussion, Do’s and

Dont’s of group discussion

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**BP111P.COMMUNICATION SKILLS (Practical)**

**2 Hours / week**

Thefollowing learning modules are to be conducted using wordsworth® English language

lab software

**Basic communication covering the following topics**

Meeting People

Asking Questions

Making Friends

What did you do?

Do’s and Dont’s

**Pronunciations covering the following topics**

Pronunciation (Consonant Sounds)

Pronunciation and Nouns

Pronunciation (Vowel Sounds)

**Advanced Learning**

Listening Comprehension / Direct and Indirect Speech

Figures of Speech

Effective Communication

Writing Skills

Effective Writing

Interview Handling Skills

E-Mail etiquette

Presentation Skills

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**Recommended Books: (Latest Edition)**

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition,

Pearson Education, 2011

2. Communication skills, Sanjay Kumar, Pushpalata, 1stEdition, Oxford Press, 2011

3. Organizational Behaviour, Stephen .P. Robbins, 1stEdition, Pearson, 2013

4. Brilliant- Communication skills, Gill Hasson, 1stEdition, Pearson Life, 2011

5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala

Swamy Ramesh, 5thEdition, Pearson, 2013

6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green

hall, 1st Edition Universe of Learning LTD, 2010

7. Communication skills for professionals, Konar nira, 2ndEdition, New arrivals –

PHI, 2011

8. Personality development and soft skills, Barun K Mitra, 1stEdition, Oxford Press,

2011

9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd,

2011

10. Soft skills and professional communication, Francis Peters SJ, 1stEdition, Mc Graw

Hill Education, 2011

11. Effective communication, John Adair, 4thEdition, Pan Mac Millan,2009

12. Bringing out the best in people, Aubrey Daniels, 2ndEdition, Mc Graw Hill, 1999

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**BP 106RBT.REMEDIAL BIOLOGY (Theory)**

**30 Hours**

**Scope:** To learn and understand the components of living world, structure and functional

system of plant and animal kingdom.

**Objectives:** Upon completion of the course, the student shall be able to

 know the classification and salient features of five kingdoms of life

 understand the basic components of anatomy & physiology of plant

 know understand the basic components of anatomy & physiology animal with

special reference to human

**UNIT I 07 Hours**

**Living world:**

 Definition and characters of living organisms

 Diversity in the living world

 Binomial nomenclature

 Five kingdoms of life and basis of classification. Salient features of Monera,

Potista, Fungi, Animalia and Plantae, Virus,

**Morphology of Flowering plants**

 Morphology of different parts of flowering plants – Root, stem, inflorescence,

flower, leaf, fruit, seed.

 General Anatomy of Root, stem, leaf of monocotyledons & Dicotylidones.

**UNIT II 07 Hours**

**Body fluids and circulation**

 Composition of blood, blood groups, coagulation of blood

 Composition and functions of lymph

 Human circulatory system

 Structure of human heart and blood vessels

 Cardiac cycle, cardiac output and ECG

**Digestion and Absorption**

 Human alimentary canal and digestive glands

 Role of digestive enzymes

 Digestion, absorption and assimilation of digested food

**Breathing and respiration**

 Human respiratory system

 Mechanism of breathing and its regulation

 Exchange of gases, transport of gases and regulation of respiration

 Respiratory volumes

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**UNIT III 07 Hours**

**Excretory products and their elimination**

 Modes of excretion

 Human excretory system- structure and function

 Urine formation

 Rennin angiotensin system

**Neural control and coordination**

 Definition and classification of nervous system

 Structure of a neuron

 Generation and conduction of nerve impulse

 Structure of brain and spinal cord

 Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

**Chemical coordination and regulation**

 Endocrine glands and their secretions

 Functions of hormones secreted by endocrine glands

**Human reproduction**

 Parts of female reproductive system

 Parts of male reproductive system

 Spermatogenesis and Oogenesis

 Menstrual cycle

**UNIT IV 05 Hours**

**Plants and mineral nutrition:**

 Essential mineral, macro and micronutrients

 Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

**Photosynthesis**

 Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting

photosynthesis.

**UNIT V 04 Hours**

**Plant respiration:**Respiration, glycolysis, fermentation (anaerobic).

**Plant growth and development**

 Phases and rate of plant growth, Condition of growth,Introduction to plant growth

regulators

**Cell - The unit of life**

 Structure and functions of cell and cell organelles.Cell division

**Tissues**

 Definition, types of tissues, location and functions.

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**Text Books**

a. Text book of Biology by S. B. Gokhale

b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

**Reference Books**

a. A Text book of Biology by B.V. Sreenivasa Naidu

b. A Text book of Biology by Naidu and Murthy

c. Botany for Degree students By A.C.Dutta.

d.Outlines of Zoology byM. Ekambaranatha ayyer and T. N. Ananthakrishnan.

e. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

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**BP112RBP.REMEDIAL BIOLOGY (Practical)**

1. Introduction to experiments in biology

a) Study of Microscope

b) Section cutting techniques

c) Mounting and staining

d) Permanent slide preparation

2. Study of cell and its inclusions

3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications

4. Detailed study of frog by using computer models

5. Microscopic study and identification of tissues pertinent to Stem, Root

Leaf, seed, fruit and flower

6. Identification of bones

7. Determination of blood group

8. Determination of blood pressure

9. Determination of tidal volume

**30 Hours**

**Reference Books**

1. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.

2. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and

S.P.Shriwastava.

3. Biology practical manual according to National core curriculum .Biology forum of

Karnataka. Prof .M.J.H.Shafi

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**BP 106RMT.REMEDIAL MATHEMATICS (Theory)**

**30 Hours**

**Scope:** This is an introductory course in mathematics. This subject deals with the

introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical

geometry, Calculus, differential equation and Laplace transform.

**Objectives:**Upon completion of the course the student shall be able to:-

**1.** Know the theory and their application in Pharmacy

**2.** Solve the different types of problems by applying theory

**3.** Appreciate the important application of mathematics in Pharmacy

**Course Content:**

**UNIT – I 06 Hours**

 **Partial fraction**

Introduction, Polynomial, Rational fractions, Proper and Improper fractions,

Partial fraction , Resolving into Partial fraction, Application of Partial

Fraction in Chemical Kinetics and Pharmacokinetics

 **Logarithms**

Introduction, Definition, Theorems/Properties of logarithms, Common

logarithms, Characteristic and Mantissa, worked examples, application of

logarithm to solve pharmaceutical problems.

 **Function***:*

Real Valued function, Classification of real valued functions,

 **Limits and continuity** :

Introduction , Limit of a function, Definition of limit of a function ( - 

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definition) , lim

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sin  1,

*x**a x*  *a* 0 

**UNIT –II 06 Hours**

 **Matrices and Determinant:**

Introduction matrices, Types of matrices, Operation on matrices,

Transpose of a matrix, Matrix Multiplication, Determinants, Properties of

determinants , Product of determinants, Minors and co-Factors, Adjoint

or adjugate of a square matrix , Singular and non-singular matrices,

Inverse of a matrix, Solution of system of linear of equations using matrix

method, Cramer’s rule, Characteristic equation and roots of a square

matrix, Cayley–Hamilton theorem,Applicationof Matrices in solving

Pharmacokinetic equations

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**UNIT – III 06 Hours**

 **Calculus**

**Differentiation** : Introductions, Derivative of a function, Derivative of a

constant, Derivative of a product of a constant and a function , Derivative

of the sum or difference of two functions, Derivative of the product of two

functions (product formula), Derivative of the quotient of two functions

(Quotient formula) – **Without Proof**, Derivative of *xn w.r.t*x,where *n* is any

rational number, Derivative of *ex,*, Derivative of loge *x ,* Derivative of

*ax*

*,*Derivative of trigonometric functions from first principles **(without**

**Proof)**, Successive Differentiation, Conditions for a function to be a

maximum or a minimum at a point. Application

**UNIT – IV 06 Hours**

 **Analytical Geometry**

**Introduction:** Signs of the Coordinates, Distance formula,

**Straight Line** : Slope or gradient of a straight line, Conditions for

parallelism and perpendicularity of two lines, Slope of a line joining two

points, Slope – intercept form of a straight line

**Integration:**

Introduction, Definition, Standard formulae, Rules of integration , Method of

substitution, Method of Partial fractions, Integration by parts, definite

integrals, application

**UNIT-V 06 Hours**

 **Differential Equations** : Some basic definitions, Order and degree,

Equations in separable form , Homogeneous equations, Linear

Differential equations, Exact equations, **Application in solving**

**Pharmacokinetic equations**

 **Laplace Transform** : Introduction, Definition, Properties of Laplace

transform, Laplace Transforms of elementary functions, Inverse

Laplace transforms, Laplace transform of derivatives, Application to

solve Linear differential equations, **Application in solving Chemical**

**kinetics and Pharmacokinetics equations**

**Recommended Books (Latest Edition)**

1. Differential Calculus by Shanthinarayan

2. Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa

Gowda D.H.

3. Integral Calculus by Shanthinarayan

4. Higher Engineering Mathematics by Dr.B.S.Grewal

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**Semester II**

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**BP 201T. HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)**

**45 Hours**

**Scope:** This subject is designed to impart fundamental knowledge on the structure and

functions of the various systems of the human body. It also helps in understanding both

homeostatic mechanisms. The subject provides the basic knowledge required to

understand the various disciplines of pharmacy.

**Objectives**: Upon completion of this course the student should be able to:

1. Explain the gross morphology, structure and functions of various organs of the

human body.

2. Describe the various homeostatic mechanisms and their imbalances.

3. Identify the various tissues and organs of different systems of human body.

4. Perform the hematological tests like blood cell counts, haemoglobin estimation,

bleeding/clotting time etc and also record blood pressure, heart rate, pulse and

respiratory volume.

5. Appreciate coordinated working pattern of different organs of each system

6. Appreciate the interlinked mechanisms in the maintenance of normal functioning

(homeostasis) of human body.

**Course Content:**

**Unit I 10 hours**

 **Nervous system**

Organization of nervous system, neuron, neuroglia, classification and

properties of nerve fibre, electrophysiology, action potential,

nerve impulse, receptors, synapse, neurotransmitters.

Central nervous system: Meninges, ventricles of brain and

cerebrospinal fluid.structure and functions of brain (cerebrum, brain

stem, cerebellum), spinal cord (gross structure, functions of afferent

and efferent nerve tracts,reflex activity)

**Unit II 06 hours**

 **Digestive system**

Anatomy of GI Tract with special reference to anatomy and functions of stomach,

( Acid production in the stomach, regulation of acid production through

parasympathetic nervous system, pepsin role in protein digestion) small intestine

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and large intestine, anatomy and functions of salivary glands, pancreas and liver,

movements of GIT, digestion and absorption of nutrients and disorders of GIT.

 **Energetics**

Formation and role of ATP, Creatinine Phosphate and BMR.

**Unit III**

 **Respiratory system 10 hours**

Anatomy of respiratory system with special reference to anatomy of lungs,

mechanism of respiration, regulation of respiration

Lung Volumes and capacities transport of respiratory gases, artificial respiration,

and resuscitation methods.

 **Urinary system**

Anatomy of urinary tract with special reference to anatomy of kidney and

nephrons, functions of kidney and urinary tract, physiology of urine formation,

micturition reflex and role of kidneys in acid base balance, role of RAS in kidney

and disorders of kidney.

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**Unit IV 10 hours**

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 **Endocrine system**

Classification of hormones, mechanism of hormone action, structure

and functions of pituitary gland, thyroid gland, parathyroid gland,

adrenal

gland, pancreas, pineal gland, thymus and their disorders.

**Unit V 09 hours**

 **Reproductive system**

Anatomy of male and female reproductive system, Functions of male and female

reproductive system, sex hormones, physiology of menstruation, fertilization,

spermatogenesis, oogenesis, pregnancy and parturition

 **Introduction to genetics**

Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

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**BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)**

**4 Hours/week**

Practical physiology is complimentary to the theoretical discussions in

physiology. Practicals allow the verification of physiological processes discussed

in theory classes through experiments on living tissue, intact animals or normal

human beings. This is helpful for developing an insight on the subject**.**

1. To study the integumentary and special senses using specimen, models, etc.,

2. To study the nervous system using specimen, models, etc.,

3. To study the endocrine system using specimen, models, etc

4. To demonstrate the general neurological examination

5. To demonstrate the function of olfactory nerve

6. To examine the different types of taste.

7. To demonstrate the visual acuity

8. To demonstrate the reflex activity

9. Recording of body temperature

10. To demonstrate positive and negative feedback mechanism.

11. Determination of tidal volume and vital capacity.

12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive

systems with the help of models, charts and specimens.

13. Recording of basal mass index .

14. Study of family planning devices and pregnancy diagnosis test.

15. Demonstration of total blood count by cell analyser

16. Permanent slides of vital organs and gonads.

**Recommended Books (Latest Editions)**

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee

brothers medical publishers, New Delhi.

2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill

Livingstone, New York

3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins

Co,Riverview,MI USA

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4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH,

U.S.A.

5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.

6. Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers,

New Delhi.

7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New

Delhi.

8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma,

Jaypee brother’s medical publishers, New Delhi.

**Reference Books:**

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,

Riverview, MI USA

2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH,

U.S.A.

3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

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**BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)**

**45 Hours**

**Scope:** This subject deals with classification and nomenclature of simple organic

compounds, structural isomerism, intermediates forming in reactions, important physical

properties, reactions and methods of preparation of these compounds. The syllabus also

emphasizes on mechanisms and orientation of reactions.

**Objectives:** Upon completion of the course the student shall be able to

1. write the structure, name and the type of isomerism of the organic compound

2. write the reaction, name the reaction and orientation of reactions

3. account for reactivity/stability of compounds,

4. identify/confirm the identification of organic compound

**Course Content**:

General methods of preparation and reactions of compounds superscripted with asterisk (\*) to be

explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples

and differences

**UNIT-I 07 Hours**

 **Classification, nomenclature and isomerism**

Classification of Organic Compounds

Common and IUPAC systems of nomenclature of organic compounds

(up to 10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds

**UNIT-II10 Hours**

 **Alkanes\*, Alkenes\* and Conjugated dienes\***

SP3 hybridization in alkanes, Halogenation of alkanes, uses of paraffins.

Stabilities of alkenes, SP2 hybridization in alkenes

E1 and E2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of

carbocations, Saytzeffs orientation and evidences. E1 verses E2 reactions, Factors affecting E1

and E2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff’s

orientation, free radical addition reactions of alkenes, Anti Markownikoff’s orientation.

Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition

reactions of conjugated dienes, allylic rearrangement

**UNIT-III10 Hours**

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 **Alkyl halides\***

SN1 and SN2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and

rearrangement of carbocations.

SN1 versus SN2 reactions, Factors affecting SN1 and SN2 reactions

Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene,

dichloromethane, tetrachloromethane and iodoform.

 **Alcohols\*-** Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol,

chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol

**UNIT-IV10 Hours**

 **Carbonyl compounds\* (Aldehydes and ketones)**

Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation,

Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin

condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone,

Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde.

**UNIT-V 08 Hours**

 **Carboxylic acids\***

Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative

tests for carboxylic acids ,amide and ester

Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic

acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and

Acetyl salicylic acid

 **Aliphatic amines\* -** Basicity, effect of substituent on Basicity. Qualitative test, Structure and

uses of Ethanolamine, Ethylenediamine, Amphetamine

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**BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)**

**4 Hours / week**

1. Systematic qualitative analysis of unknown organic compounds like

1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation

and unsaturation, etc.

2. Detection of elements like Nitrogen, Sulphur and Halogen by

Lassaigne’s test

3. Solubility test

4. Functional group test like Phenols, Amides/ Urea, Carbohydrates,

Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters,

Aromatic and Halogenated Hydrocarbons, Nitro compounds and

Anilides.

5. Melting point/Boiling point of organic compounds

6. Identification of the unknown compound from the literature using

melting point/ boiling point.

7. Preparation of the derivatives and confirmation of the unknown

compound bymelting point/ boiling point.

8. Minimum 5 unknown organic compounds to be analysed systematically.

2. Preparation of suitable solid derivatives from organic compounds

3. Construction of molecular models

**Recommended Books (Latest Editions)**

1. Organic Chemistry byMorrison and Boyd

2. Organic Chemistry by I.L. Finar , Volume-I

3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.

4. Organic Chemistry by P.L.Soni

5. Practical Organic Chemistry byMann and Saunders.

6. Vogel’s text book of Practical Organic Chemistry

7. Advanced Practical organic chemistry by N.K.Vishnoi.

8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

9. Reaction and reaction mechanism by Ahluwaliah/Chatwal.

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**BP203 T. BIOCHEMISTRY (Theory)**

**45 Hours**

**Scope**: Biochemistry deals with complete understanding of the molecular levels of the

chemical process associated with living cells. The scope of the subject is providing

biochemical facts and the principles to understand metabolism of nutrient molecules in

physiological and pathological conditions. It is also emphasizing on genetic organization

of mammalian genome and hetero & autocatalytic functions of DNA.

**Objectives:** Upon completion of course student shell able to

1. Understand the catalytic role of enzymes, importance of enzyme inhibitors in

design of new drugs, therapeutic and diagnostic applications of enzymes.

2. Understand the metabolism of nutrient molecules in physiological and

pathological conditions.

3. Understand the genetic organization of mammalian genome and functions of

DNA in the synthesis of RNAs and proteins.

**Course Content**:

**UNIT I 08 Hours**

 **Biomolecules**

Introduction, classification, chemical nature and biological role of

carbohydrate, lipids, nucleic acids, amino acids and proteins.

 **Bioenergetics**

Concept of free energy, endergonic and exergonic reaction, Relationship

between free energy, enthalpy and entropy; Redox potential.

Energy rich compounds; classification; biological significances of ATP

and cyclic AMP

**UNIT II 10 Hours**

 **Carbohydrate metabolism**

Glycolysis – Pathway, energetics and significance

Citric acid cycle- Pathway, energetics and significance

HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase

(G6PD) deficiency

Glycogen metabolism Pathways and glycogen storage diseases (GSD)

Gluconeogenesis- Pathway and its significance

Hormonal regulation of blood glucose level and Diabetes mellitus

 **Biological oxidation**

Electron transport chain (ETC) and its mechanism.

Oxidative phosphorylation & its mechanism and substrate

phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers

level

**UNIT III 10 Hours**

 **Lipid metabolism**

β-Oxidation of saturated fatty acid (Palmitic acid)

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Formation and utilization of ketone bodies; ketoacidosis

De novo synthesis of fatty acids (Palmitic acid)

Biological significance of cholesterol and conversion of cholesterol into

bile acids, steroid hormone and vitamin D

Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis,

fatty liver and obesity.

 **Amino acid metabolism**

General reactions of amino acid metabolism: Transamination,

deamination & decarboxylation, urea cycle and its disorders

Catabolism of phenylalanine and tyrosine and their metabolic disorders

(Phenyketonuria, Albinism, alkeptonuria, tyrosinemia)

Synthesis and significance of biological substances; 5-HT, melatonin,

dopamine, noradrenaline, adrenaline

Catabolism of heme; hyperbilirubinemia and jaundice

**UNIT IV 10 Hours**

 **Nucleic acid metabolism and genetic information transfer**

Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease

Organization of mammalian genome

Structure of DNA and RNA and their functions

DNA replication (semi conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

62

**UNIT V 07 Hours**

 **Enzymes**

Introduction, properties, nomenclature and IUB classification of enzymes

Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

Enzyme inhibitors with examples

Regulation of enzymes: enzyme induction and repression, allosteric

enzymes regulation

Therapeutic and diagnostic applications of enzymes and isoenzymes

Coenzymes –Structure and biochemical functions

**BP 209 P. BIOCHEMISTRY (Practical)**

**4 Hours / Week**

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose,

Sucrose and starch)

2. Identification tests for Proteins (albumin and Casein)

3. Quantitative analysis of reducing sugars (DNSA method) and Proteins

(Biuret method)

4. Qualitative analysis of urine for abnormal constituents

5. Determination of blood creatinine

6. Determination of blood sugar

7. Determination of serum total cholesterol

8. Preparation of buffer solution and measurement of pH

9. Study of enzymatic hydrolysis of starch

10. Determination of Salivary amylase activity

11. Study the effect of Temperature on Salivary amylase activity.

12. Study the effect of substrate concentration on salivary amylase activity.

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**Recommended Books (Latest Editions)**

1. Principles of Biochemistry by Lehninger.

2. Harper’s Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.

3. Biochemistry by Stryer.

4. Biochemistry by D. Satyanarayan and U.Chakrapani

5. Textbook of Biochemistry by Rama Rao.

6. Textbook of Biochemistry by Deb.

7. Outlines of Biochemistry by Conn and Stumpf

8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.

9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)

10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.

11. Practical Biochemistry by Harold Varley.

**BP 204T.PATHOPHYSIOLOGY (THEORY)**

**45Hours**

**Scope:** Pathophysiology is the study of causes of diseases and reactions of the body to

such disease producing causes.This course is designed to impart a thorough knowledge of

the relevant aspects of pathology of various conditions with reference to its

pharmacological applications, and understanding of basic pathophysiological

mechanisms. Hence it will not only help to study the syllabus of pathology, but also to

get baseline knowledge required to practice medicine safely, confidently, rationally and

effectively.

**Objectives:** Upon completion of the subject student shall be able to –

1. Describe the etiology and pathogenesis of the selected disease states;

2. Name the signs and symptoms of the diseases; and

3. Mention the complications of the diseases.

**Course content:**

**Unit I 10Hours**

 **Basic principles of Cell injury and Adaptation:**

Introduction, definitions, Homeostasis, Components and Types of Feedback systems,

Causes of cellular injury**,**Pathogenesis (Cell membrane damage, Mitochondrial damage,

Ribosome damage, Nuclear damage)**,**Morphology of cell injury – Adaptive changes

(Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia)**,**Cell swelling, Intra cellular

accumulation, Calcification, Enzyme leakage and Cell Death Acidosis

&Alkalosis,Electrolyte imbalance

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 **Basic mechanism involved in the process of inflammation and repair:**

Introduction, Clinical signs of inflammation, Different types of Inflammation,Mechanism

of Inflammation – Alteration in vascular permeability and blood flow, migration of

WBC’s,Mediators of inflammation,Basic principles of wound healing in the

skin,Pathophysiology of Atherosclerosis

**Unit II 10Hours**

 **Cardiovascular System:**

Hypertension, congestive heart failure, ischemic heart disease (angina,myocardial

infarction, atherosclerosis and arteriosclerosis)

 **Respiratory system:**Asthma, Chronic obstructive airways diseases.

 **Renal system:**Acute and chronic renal failure .

**Unit II 10Hours**

 **Haematological Diseases:**

Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia,

thalasemia, hereditary acquired anemia, hemophilia

 **Endocrine system:** Diabetes, thyroid diseases, disorders of sex hormones

 **Nervous system:** Epilepsy, Parkinson’s disease, stroke, psychiatric disorders:

depression, schizophrenia and Alzheimer’s disease.

 **Gastrointestinal system:** Peptic Ulcer

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**Unit IV 8 Hours**

 Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver

disease.

 **Disease of bones and joints:** Rheumatoid arthritis, osteoporosis and gout

 **Principles of cancer:** classification, etiology and pathogenesis of cancer

 **Diseases of bones and joints:**Rheumatoid Arthritis, Osteoporosis,Gout

 **Principles of Cancer:** Classification, etiology and pathogenesis of Cancer

**Unit V 7 Hours**

 **Infectious diseases:**Meningitis,Typhoid, Leprosy, Tuberculosis

Urinary tract infections

 **Sexually transmitted diseases:**AIDS, Syphilis, Gonorrhea

**Recommended Books (Latest Editions)**

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1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins &Cotran Pathologic Basis of

Disease; South Asia edition; India; Elsevier; 2014.

2. HarshMohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.

3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman’s The Pharmacological Basis of

Therapeutics; 12th edition; New York; McGraw-Hill; 2011.

4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B

(John Burnard); Best and Taylor’s Physiological basis of medical practice; 12th ed;

united states;

5. William and Wilkins, Baltimore;1991 [1990 printing].

6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston;Davidson’s Principles and Practice

of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.

7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders

Company; 2010.

8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey;

Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill

Medical; 2014.

9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia;

WB Saunders Company; 1997.

10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London;

Churchill Livingstone publication; 2003.

**Recommended Journals**

1. The Journal of Pathology. ISSN: 1096-9896 (Online)

2. The American Journal of Pathology. ISSN: 0002-9440

3. Pathology. 1465-3931 (Online)

4. International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171

(Online)

5. Indian Journal of Pathology and Microbiology. ISSN-0377-4929.

66

**BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)**

**30 Hrs (2 Hrs/Week)**

**Scope**: This subject deals with the introduction Database, Database Management system,

computer application in clinical studies and use of databases.

**Objectives:** Upon completion of the course the student shall be able to

1. know the various types of application of computers in pharmacy

2. know the various types of databases

3. know the various applications of databases in pharmacy

**Course content:**

**UNIT – I 06 hours**

**Number system**: Binary number system, Decimal number system, Octal

number system, Hexadecimal number systems, conversion decimal to

binary, binary to decimal, octal to binary etc, binary addition, binary

subtraction – One’s complement ,Two’s complement method, binary

multiplication, binary division

**Concept of** I**nformation Systems and Software : I**nformation gathering,

requirement and feasibility analysis, data flow diagrams, process

specifications, input/output design, process life cycle, planning and

managing the project

**UNIT –II 06 hours**

**Web technologies**:Introduction to HTML, XML,CSS and

Programming languages, introduction to web servers and Server

Products

Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

**UNIT – III 06 hours**

**Application of computers in Pharmacy** – Drug information storage and

retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital

and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems,

barcode medicine identification and automated dispensing of drugs, mobile

technology and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System,

Pharma Information System

67

**UNIT – IV 06 hours**

**Bioinformatics:** Introduction, Objective of Bioinformatics, Bioinformatics

Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine

Discovery

**UNIT-V 06 hours**

**Computers as data analysis in Preclinical development**:

Chromatographic dada analysis(CDS), Laboratory Information management

System (LIMS) and Text Information Management System(TIMS)

68

**BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)**

1. Design a questionnaire using a word processing package to gather information

about a particular disease.

2. Create a HTML web page to show personal information.

3 Retrieve the information of a drug and its adverse effects using online tools

4 Creating mailing labels Using Label Wizard , generating label in MS WORD

5 Create a database in MS Access to store the patient information with the required

fields Using access

6. Design a form in MS Access to view, add, delete and modify the patient record in

the database

7. Generating report and printing the report from patient database

8. Creating invoice table using – MS Access

9. Drug information storage and retrieval using MS Access

10. Creating and working with queries in MS Access

11. Exporting Tables, Queries, Forms and Reports to web pages

12. Exporting Tables, Queries, Forms and Reports to XML pages

**Recommended books (Latest edition):**

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600

South Washington Square, USA, (215) 922-1330.

2. Computer Application in Pharmaceutical Research and Development –Sean Ekins –

Wiley-Interscience, A John Willey and Sons, INC., Publication, USA

3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and

Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)

4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server,

DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7,

Ansari Road, Daryagani, New Delhi - 110002

69

**BP 206 T. ENVIRONMENTAL SCIENCES (Theory)**

**30 hours**

**Scope:**Environmental Sciences is the scientific study of the environmental system and

the status of its inherent or induced changes on organisms. It includes not only the study

of physical and biological characters of the environment but also the social and cultural

factors and the impact of man on environment.

**Objectives:** Upon completion of the course the student shall be able to**:**

1. Create the awareness about environmental problems among learners.

2. Impart basic knowledge about the environment and its allied problems.

3. Develop an attitude of concern for the environment.

4. Motivate learner to participate in environment protection and environment

improvement.

5. Acquire skills to help the concerned individuals in identifying and solving

environmental problems.

6. Strive to attain harmony with Nature.

**Course content:**

**Unit-I 10hours**

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food

resources; e) Energy resources; f) Land resources: Role of an individual in

conservation of natural resources.

**Unit-II 10hours**

Ecosystems

 Concept of an ecosystem.

 Structure and function of an ecosystem.

 Introduction, types, characteristic features, structure and function of

the ecosystems: Forest ecosystem; Grassland ecosystem; Desert

ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans,

estuaries)

**Unit- III 10hours**

Environmental Pollution: Air pollution; Water pollution; Soil pollution

70

**Recommended Books (Latest edition):**

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers,

Bangalore

2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.

3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd.,

Ahmedabad – 380 013, India,

4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p

5. Clark R.S., Marine Pollution, Clanderson Press Oxford

6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001,

Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p

7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.

8. Down of Earth, Centre for Science and Environment

71

**SEMESTER III**

72

**BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)**

**45 Hours**

**Scope:** This subject deals with general methods of preparation and reactions of some

organic compounds. Reactivity of organic compounds are also studied here. The syllabus

emphasizes on mechanisms and orientation of reactions. Chemistry of fats and oils are

also included in the syllabus.

**Objectives:** Upon completion of the course the student shall be able to

1. write the structure, name and the type of isomerism of the organic compound

2. write the reaction, name the reaction and orientation of reactions

3. account for reactivity/stability of compounds,

4. prepare organic compounds

**Course Content**:

General methods of preparation and reactions of compounds superscripted with asterisk (\*) to be

explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples

and differences

**UNIT I 10 Hours**

 **Benzene and its derivatives**

**A.** Analytical, synthetic and other evidences in the derivation of structure

of benzene, Orbital picture, resonance in benzene, aromatic

characters, Huckel’s rule

**B.** Reactions of benzene - nitration, sulphonation, halogenationreactivity,

Friedelcrafts alkylation- reactivity, limitations,

Friedelcrafts acylation.

**C.** Substituents, effect of substituents on reactivity and orientation of

mono substituted benzene compounds towards electrophilic

substitution reaction

**D.** Structure and uses of DDT, Saccharin, BHC and Chloramine

**UNIT II 10 Hours**

 **Phenols\*** - Acidity of phenols, effect of substituents on acidity, qualitative

tests, Structure and uses of phenol, cresols, resorcinol, naphthols

 **Aromatic Amines\* -** Basicity of amines, effect of substituents on basicity,

and synthetic uses of aryl diazonium salts

 **Aromatic Acids\* –**Acidity, effect of substituents on acidity and

important reactions of benzoic acid.

**UNIT III**

**10 Hours**

 **Fats and Oils**

a. Fatty acids – reactions.

73

b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying

oils.

c. Analytical constants – Acid value, Saponification value, Ester value,

Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and

principle involved in their determination.

**UNIT IV 08 Hours**

 **Polynuclear hydrocarbons:**

a. Synthesis, reactions

b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene,

Diphenylmethane, Triphenylmethane and their derivatives

**UNIT V 07 Hours**

 **Cyclo alkanes\***

Stabilities – Baeyer’s strain theory, limitation of Baeyer’s strain theory,

Coulson and Moffitt’s modification, Sachse Mohr’s theory (Theory of

strainless rings), reactions of cyclopropane and cyclobutane only

74

**BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)**

**4 Hrs/week**

I Experiments involving laboratory techniques

 Recrystallization

 Steam distillation

II Determination of following oil values (including standardization of

reagents)

 Acid value

 Saponification value

 Iodine value

III **Preparation of compounds**

 Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol

/Aniline by acylation reaction.

 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/

 Acetanilide by halogenation (Bromination) reaction.

 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid /

Nitro benzene by nitration reaction.

 Benzoic acid from Benzyl chloride by oxidation reaction.

 Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by

hydrolysis reaction.

 1-Phenyl azo-2-napthol from Aniline by diazotization and coupling

reactions.

 Benzil from Benzoin by oxidation reaction.

 Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction

 Cinnammic acid from Benzaldehyde by Perkin reaction

 *P*-Iodo benzoic acid from *P*-amino benzoic acid

**Recommended Books (Latest Editions)**

1. Organic Chemistry byMorrison and Boyd

2. Organic Chemistry by I.L. Finar , Volume-I

3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.

4. Organic Chemistry by P.L.Soni

5. Practical Organic Chemistry byMann and Saunders.

6. Vogel’s text book of Practical Organic Chemistry

7. Advanced Practical organic chemistry by N.K.Vishnoi.

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8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

**BP302T. PHYSICAL PHARMACEUTICS-I (Theory)**

**45Hours**

**Scope:** The course deals with the various physica and physicochemical properties, and

principles involved in dosage forms/formulations. Theory and practical

components of the subject help the student to get a better insight into various

areas of formulation research and development, and stability studies of

pharmaceutical dosage forms.

**Objectives:** Upon the completion of the course student shall be able to

1. Understand various physicochemical properties of drug molecules in the

designing the dosage forms

2. Know the principles of chemical kinetics & to use them for stability testing nad

determination of expiry date of formulations

3. Demonstrate use of physicochemical properties in the formulation

development and evaluation of dosage forms.

**Course Content:**

**UNIT-I 10 Hours**

**Solubility of drugs:** Solubility expressions, mechanisms of solute solvent interactions,

ideal solubility parameters, solvation & association, quantitative approach to the factors

influencing solubility of drugs, diffusion principles in biological systems. Solubility

of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions)

Raoult’s law, real solutions. Partiallymiscible liquids, Critical solution temperature and

applications. Distribution law, its limitations and applications

**UNIT-II 10Hours**

**States of Matter and properties of matter:**State of matter, changes in the state of matter,

latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols

– inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solidcrystalline,

amorphous & polymorphism.

**Physicochemical properties of drug molecules:** Refractive index, optical rotation,

dielectric constant, dipole moment, dissociation constant, determinations and applications

**UNIT-III 08 Hours**

**Surface and interfacial phenomenon:** Liquid interface, surface & interfacial tensions,

surface free energy, measurement of surface & interfacial tensions, spreading coefficient,

adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation,

detergency, adsorption at solid interface.

76

**UNIT-IV 08Hours**

**Complexation and protein binding:** Introduction, Classification of Complexation,

Applications, methods of analysis, protein binding, Complexation and drug action,

crystalline structures of complexes and thermodynamic treatment of stability constants.

**UNIT-V 07 Hours**

**pH, buffers and Isotonic solutions:** Sorensen’s pH scale, pH determination

(electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity,

buffers in pharmaceutical and biological systems, buffered isotonic solutions.

77

**BP306P. PHYSICAL PHARMACEUTICS – I (Practical)**

1. Determination the solubility of drug at room temperature

**4 Hrs/week**

2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch

equation.

3. Determination of Partition co- efficient of benzoic acid in benzene and water

4. Determination of Partition co- efficient of Iodine in CCl4 and water

5. Determination of % composition of NaCl in a solution using phenol-water system by

CST method

6. Determination of surface tension of given liquids by drop count and drop weight

method

7. Determination of HLB number of a surfactant by saponification method

8. Determination of Freundlich and Langmuir constants using activated char coal

9. Determination of critical micellar concentration of surfactants

10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine

complex by solubilitymethod

11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine

complex by pH titration method

**Recommended Books: (Latest Editions)**

1. Physical Pharmacy by Alfred Martin

2. Experimental Pharmaceutics by Eugene, Parott.

3. Tutorial Pharmacy by Cooper and Gunn.

4. Stocklosam J. Pharmaceutical Calculations, Lea &Febiger, Philadelphia.

5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to

3, MarcelDekkar Inc.

6. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse

systems, volume 1, 2, 3. Marcel Dekkar Inc.

7. Physical Pharmaceutics by Ramasamy C and ManavalanR.

8. LaboratoryManual of Physical Pharmaceutics, C.V.S. Subramanyam, J.

Thimma settee

9. Physical Pharmaceutics by C.V.S. Subramanyam

10. Test book of Physical Phramacy, by Gaurav Jain & Roop K. Khar

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**BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)**

**Scope:**

**45Hours**

 Study of all categories of microorganisims especially for the production of alchol

antibiotics, vaccines, vitamins enzymes etc..

**Objectives:** Upon completion of the subject student shall be able to;

1. Understand methods of identification, cultivation and preservation of

various microorganisms

2. To understand the importance and implementation of sterlization in

pharmaceutical processing and industry

3. Learn sterility testing of pharmaceutical products.

4. Carried out microbiological standardization of Pharmaceuticals.

5. Understand the cell culture technology and its applications in pharmaceutical

industries.

**Course content:**

**Unit I 10 Hours**

Introduction, history of microbiology, its branches, scope and its

importance.

Introduction to Prokaryotes and Eukaryotes

Study of ultra-structure and morphological classification of bacteria,

nutritional requirements, raw materials used for culture media and physical

parameters for growth, growth curve, isolation and preservation methods

for pure cultures, cultivation of anaerobes, quantitative measurement of

bacterial growth (total & viable count).

Study of different types of phase constrast microscopy, dark field

microscopy and electron microscopy.

**Unit II 10 Hours**

Identification of bacteria using staining techniques (simple, Gram’s &Acid

fast staining) and biochemical tests (IMViC).

Study of principle, procedure, merits, demerits and applications of physical,

chemical gaseous,radiation and mechanical method of sterilization.

Evaluation of the efficiency of sterilization methods.

79

Equipments employed in large scale sterilization.

Sterility indicators.

**Unit III 10 Hours**

Study of morphology, classification, reproduction/replication and

cultivation of Fungi and Viruses.

Classification and mode of action of disinfectants

Factors influencing disinfection, antiseptics and their evaluation. For

bacteriostatic and bactericidal actions

Evaluation of bactericidal & Bacteriostatic.

Sterility testing of products (solids, liquids, ophthalmic and other sterile

products) according to IP, BP and USP.

**Unit IV 08 Hours**

Designing of aseptic area, laminar flow equipments; study of different

sources of contamination in an aseptic area and methods of prevention,

clean area classification.

Principles and methods of different microbiological assay. Methods for

standardization of antibiotics, vitamins and amino acids.

Assessment of a new antibiotic.

**Unit V 07Hours**

Types of spoilage, factors affecting the microbial spoilage of

pharmaceutical products, sources and types of microbial contaminants,

assessment of microbial contamination and spoilage.

Preservation of pharmaceutical products using antimicrobial agents,

evaluation of microbial stability of formulations.

Growth of animal cells in culture, general procedure for cell culture,

Primary, established and transformed cell cultures.

Application of cell cultures in pharmaceutical industry and research.

80

**BP 307P.PHARMACEUTICAL MICROBIOLOGY (Practical)**

**4 Hrs/week**

1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator,

laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator,

microscopes used in experimental microbiology.

2. Sterilization of glassware, preparation and sterilization of media.

3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.

4. Staining methods- Simple, Grams staining and acid fast staining (Demonstration with

practical).

5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other

techniques.

6. Microbiological assay of antibiotics by cup plate method and other methods

7. Motility determination by Hanging drop method.

8. Sterility testing of pharmaceuticals.

9. Bacteriological analysis of water

10. Biochemical test.

**Recommended Books (Latest edition)**

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific

publications, Oxford London.

2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors,

Delhi.

3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.

4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.

5. Rose: Industrial Microbiology.

6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan

7. Cooper and Gunn’s: Tutorial Pharmacy, CBS Publisher and Distribution.

8. Peppler: Microbial Technology.

9. I.P., B.P., U.S.P.- latest editions.

10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai

11. Edward: Fundamentals of Microbiology.

12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi

13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

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**BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)**

**45 Hours**

**Scope:** This course is designed to impart a fundamental knowledge on the art and science

of various unit operations used in pharmaceutical industry.

**Objectives:** Upon completion of the course student shall be able:

1. To know various unit operations used in Pharmaceutical industries.

2. To understand the material handling techniques.

3. To perform various processes involved in pharmaceutical manufacturing process.

4. To carry out various test to prevent environmental pollution.

5. To appreciate and comprehend significance of plant lay out design for optimum

use of resources.

6. To appreciate the various preventive methods used for corrosion control in

Pharmaceutical industries.

**Course content:**

**UNIT-I 10 Hours**

 **Flow of fluids:** Types of manometers, Reynolds number and its significance,

Bernoulli’s theorem and its applications, Energy losses, Orifice meter,

Venturimeter, Pitot tube and Rotometer.

 **Size Reduction:** Objectives, Mechanisms & Laws governing size reduction,

factors affecting size reduction, principles, construction, working, uses, merits and

demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end

runner mill.

 **Size Separation:** Objectives, applications & mechanism of size separation,

official standards of powders, sieves, size separation Principles, construction,

working, uses, merits and demerits of Sieve shaker, cyclone separator, Air

separator, Bag filter & elutriation tank.

**UNIT-II 10 Hours**

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 **Heat Transfer:** Objectives, applications & Heat transfer mechanisms. Fourier’s

law, Heat transfer by conduction, convection & radiation. Heat interchangers &

heat exchangers.

82

 **Evaporation:** Objectives, applications and factors influencing evaporation,

differences between evaporation and other heat process. principles, construction,

working, uses, merits and demerits of Steam jacketed kettle, horizontal tube

evaporator, climbing film evaporator, forced circulation evaporator, multiple

effect evaporator& Economy of multiple effect evaporator.



 **Distillation:** Basic Principles and methodology of simple distillation,flash

distillation, fractional distillation, distillation under reduced pressure, steam

distillation & molecular distillation

**UNIT- III 08 Hours**

 **Drying:** Objectives, applications & mechanism of drying process, measurements

& applications of Equilibrium Moisture content, rate of drying curve. principles,

construction, working, uses, merits and demerits of Tray dryer, drum dryer spray

dryer, fluidized bed dryer, vacuum dryer, freeze dryer.

 **Mixing:** Objectives, applications & factors affecting mixing, Difference between

solid and liquid mixing, mechanism of solid mixing, liquids mixing and

semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits

of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer,

planetarymixers, Propellers, Turbines, Paddles & Silverson Emulsifier,

**UNIT-IV 08 Hours**

 **Filtration:** Objectives, applications, Theories & Factors influencing filtration,

filter aids, filter medias. Principle, Construction, Working, Uses, Merits and

demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter &

Cartridge filter, membrane filters and Seidtz filter.

 **Centrifugation:** Objectives, principle & applications of Centrifugation,

principles, construction, working, uses, merits and demerits of Perforated basket

centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super

centrifuge.

**UNIT- V 07 Hours**

 **Materials of pharmaceutical plant construction, Corrosion and its**

**prevention:** Factors affecting during materials selected for Pharmaceutical plant

construction, Theories of corrosion, types of corrosion and there prevention.

Ferrous and nonferrous metals, inorganic and organic non metals, basic of

material handling systems.

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**Recommended Books: (Latest Editions)**

1. Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest

edition.

2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson-

Latest edition.

3. Unit operation of chemical engineering – Mcabe Smith, Latest edition.

4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest

edition.

5. Remington practice of pharmacy- Martin, Latest edition.

6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.

7. Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.

8. Cooper and Gunn’s Tutorial pharmacy, S.J. Carter, Latest edition.

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**BP308P - PHARMACEUTICAL ENGINEERING (Practical)**

**4 Hours/week**

I. Determination of radiation constant of brass, iron, unpainted and painted glass.

II. Steam distillation – To calculate the efficiency of steam distillation.

III. To determine the overall heat transfer coefficient by heat exchanger.

IV. Construction of drying curves (for calcium carbonate and starch).

V. Determination of moisture content and loss on drying.

VI. Determination of humidity of air – i) From wet and dry bulb temperatures –use of

Dew point method.

VII. Description of Construction working and application of Pharmaceutical

Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill,

de humidifier.

VIII. Size analysis by sieving – To evaluate size distribution of tablet granulations –

Construction of various size frequency curves including arithmetic

andlogarithmic probability plots.

IX. Size reduction: To verify the laws of size reduction using ball mill and

determining Kicks, Rittinger’s, Bond’s coefficients, power requirement and

critical speed of Ball Mill.

X. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer

and such othermajor equipment.

XI. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration

and Thickness/ viscosity

XII. To study the effect of time on the Rate of Crystallization.

XIII. To calculate the uniformity Index for given sample by using Double Cone

Blender.

85

**SEMESTER IV**

86

**BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)**

**45 Hours**

**Scope:** This subject imparts knowledge on stereo-chemical aspects of organic compounds

and organic reactions, important named reactions, chemistry of important hetero cyclic

compounds. It also emphasizes on medicinal and other uses of organic compounds.

**Objectives**: At the end of the course, the student shall be able to

1. understand the methods of preparation and properties of organic compounds

2. explain the stereo chemical aspects of organic compounds and stereo chemical

reactions

3. know the medicinal uses and other applications of organic compounds

**Course Content:**

**Note: To emphasize on definition, types, mechanisms, examples, uses/applications**

**UNIT-I 10 Hours**

**Stereo isomerism**

Optical isomerism –

Optical activity, enantiomerism, diastereoisomerism, meso compounds

Elements of symmetry, chiral and achiral molecules

DL system of nomenclature of optical isomers, sequence rules, RS system of

nomenclature of optical isomers

Reactions of chiral molecules

Racemic modification and resolution of racemic mixture.

Asymmetric synthesis: partial and absolute

**UNIT-II 10 Hours**

Geometrical isomerism

Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems)

Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane.

Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical

activity.

Stereospecific and stereoselective reactions

**UNIT-III 10 Hours**

87

**Heterocyclic compounds:**

Nomenclature and classification

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrrole, Furan, and Thiophene

Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene

**UNIT-IV 8 Hours**

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrazole, Imidazole, Oxazole and Thiazole.

Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine

Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

**UNIT-V 07 Hours**

**Reactions of synthetic importance**

Metal hydride reduction (NaBH4 and LiAlH4), Clemmensen reduction, Birch

reduction, Wolff Kishner reduction.

Oppenauer-oxidation and Dakin reaction.

Beckmanns rearrangement and Schmidt rearrangement.

Claisen-Schmidt condensation

**Recommended Books (Latest Editions)**

1. Organic chemistry by I.L. Finar, Volume-I & II.

2. A text book of organic chemistry – Arun Bahl, B.S. Bahl.

3. Heterocyclic Chemistry by Raj K. Bansal

4. Organic Chemistry byMorrison and Boyd

5. Heterocyclic Chemistry by T.L. Gilchrist

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**BP402T. MEDICINAL CHEMISTRY – I (Theory)**

**45 Hours**

**Scope:** This subject is designed to impart fundamental knowledge on the structure,

chemistry and therapeutic value of drugs. The subject emphasizes on structure activity

relationships of drugs, importance of physicochemical properties and metabolism of

drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each

class.

**Objectives:** Upon completion of the course the student shall be able to

1. understand the chemistry of drugs with respect to their pharmacological activity

2. understand the drug metabolic pathways, adverse effect and therapeutic value of

drugs

3. know the Structural Activity Relationship (SAR) of different class of drugs

4. write the chemical synthesis of some drugs

**Course Content**:

**Study of the development of the following classes of drugs, Classification, mechanism of**

**action, uses of drugs mentioned in the course, Structure activity relationship of selective**

**class of drugs as specified in the course and synthesis of drugs superscripted (\*)**

**UNIT- I 10 Hours**

**Introduction to Medicinal Chemistry**

**History and development of medicinal chemistry**

**Physicochemical properties in relation to biological action**

Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein

binding, Chelation, Bioisosterism, Optical and Geometrical isomerism.

**Drug metabolism**

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

**UNIT- II 10 Hours**

**Drugs acting on Autonomic Nervous System**

**Adrenergic Neurotransmitters:**

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

**Sympathomimetic agents: SAR of Sympathomimetic agents**

Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine\*, Dopamine,

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Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline,

Salbutamol\*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

 Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine,

Propylhexedrine.

 Agents with mixed mechanism: Ephedrine, Metaraminol.

**Adrenergic Antagonists:**

**Alpha adrenergic blockers:** Tolazoline\*, Phentolamine,

Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

**Beta adrenergic blockers:** SAR of beta blockers, Propranolol\*,

Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol,

Labetolol, Carvedilol.

**UNIT-III 10 Hours**

**Cholinergic neurotransmitters:**

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

**Parasympathomimetic agents: SAR of Parasympathomimetic agents**

**Direct acting agents:** Acetylcholine, Carbachol\*, Bethanechol,

Methacholine, Pilocarpine.

**Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible):**

Physostigmine, Neostigmine\*, Pyridostigmine, Edrophonium chloride,

Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, Echothiophate

iodide, Parathione, Malathion.

**Cholinesterase reactivator:** Pralidoxime chloride.

**Cholinergic Blocking agents: SAR of cholinolytic agents**

**Solanaceous alkaloids and analogues:** Atropine sulphate, Hyoscyamine

sulphate, Scopolamine hydrobromide, Homatropine hydrobromide,

Ipratropium bromide\*.

**Synthetic cholinergic blocking agents:** Tropicamide, Cyclopentolate

hydrochloride, Clidinium bromide, Dicyclomine hydrochloride\*,

Glycopyrrolate, Methantheline bromide, Propantheline bromide,

Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride,

Procyclidine hydrochloride\*, Tridihexethyl chloride, Isopropamide iodide,

Ethopropazine hydrochloride.

**UNIT- IV 08 Hours**

**Drugs acting on Central Nervous System**

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**A. Sedatives and Hypnotics:**

**Benzodiazepines:** SAR of Benzodiazepines, Chlordiazepoxide, Diazepam\*,

Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem

**Barbiturtes:** SAR of barbiturates, Barbital\*, Phenobarbital, Mephobarbital,

Amobarbital, Butabarbital, Pentobarbital, Secobarbital

**Miscelleneous:**

Amides & imides: Glutethmide.

Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

**B. Antipsychotics**

**Phenothiazeines:** SAR of Phenothiazeines - Promazine hydrochloride,

Chlorpromazine hydrochloride\*, Triflupromazine, Thioridazine

hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate,

Trifluoperazine hydrochloride.

**Ring Analogues of Phenothiazeines:** Chlorprothixene, Thiothixene,

Loxapine succinate, Clozapine.

**Fluro buterophenones:** Haloperidol, Droperidol, Risperidone.

**Beta amino ketones:** Molindone hydrochloride.

**Benzamides:** Sulpieride.

**C. Anticonvulsants:** SAR of Anticonvulsants**,** mechanism of anticonvulsant

action

**Barbiturates**: Phenobarbitone, Methabarbital. **Hydantoins:**

Phenytoin\*, Mephenytoin, Ethotoin **Oxazolidine diones:**

Trimethadione, Paramethadione **Succinimides:**

Phensuximide, Methsuximide, Ethosuximide\* **Urea and**

**monoacylureas**: Phenacemide, Carbamazepine\*

**Benzodiazepines**: Clonazepam

**Miscellaneous:** Primidone, Valproic acid , Gabapentin, Felbamate

**UNIT – V 07 Hours**

**Drugs acting on Central Nervous System**

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**General anesthetics:**

**Inhalation anesthetics:** Halothane\*, Methoxyflurane, Enflurane,

Sevoflurane, Isoflurane, Desflurane.

**Ultra short acting barbitutrates:** Methohexital sodium\*, Thiamylal

sodium, Thiopental sodium.

**Dissociative anesthetics:** Ketamine hydrochloride.\*

**Narcotic and non-narcotic analgesics**

**Morphine and related drugs:** SAR of Morphine analogues, Morphine

sulphate, Codeine, Meperidine hydrochloride, Anilerdine hydrochloride,

Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate\*,

Methadone hydrochloride\*, Propoxyphene hydrochloride, Pentazocine,

Levorphanol tartarate.

**Narcotic antagonists:** Nalorphine hydrochloride, Levallorphan tartarate,

Naloxone hydrochloride.

**Anti-inflammatory agents:** Sodium salicylate, Aspirin, Mefenamic acid\*,

Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepriac, Diclofenac,

Ketorolac, Ibuprofen\*, Naproxen, Piroxicam, Phenacetin, Acetaminophen,

Antipyrine, Phenylbutazone.

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**BP406P. MEDICINAL CHEMISTRY – I (Practical)**

**4 Hours/Week**

**I Preparation of drugs/ intermediates**

1 1,3-pyrazole

2 1,3-oxazole

3 Benzimidazole

4 Benztriazole

5 2,3- diphenyl quinoxaline

6 Benzocaine

7 Phenytoin

8 Phenothiazine

9 Barbiturate

**II Assay of drugs**

1 Chlorpromazine

2 Phenobarbitone

3 Atropine

4 Ibuprofen

5 Aspirin

6 Furosemide

**III Determination of Partition coefficient for any two drugs**

**Recommended Books (Latest Editions)**

1. Wilson and Giswold’s Organic medicinal and Pharmaceutical Chemistry.

2. Foye’s Principles of Medicinal Chemistry.

3. Burger’s Medicinal Chemistry, Vol I to IV.

4. Introduction to principles of drug design- Smith and Williams.

5. Remington’s Pharmaceutical Sciences.

6. Martindale’s extra pharmacopoeia.

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7. Organic Chemistry by I.L. Finar, Vol. II.

8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.

9. Indian Pharmacopoeia.

10. Text book of practical organic chemistry- A.I.Vogel.

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**BP 403 T. PHYSICAL PHARMACEUTICS-II (Theory)**

**45Hours**

**Scope:** The course deals with the various physica and physicochemical properties, and

principles involved in dosage forms/formulations. Theory and practical

components of the subject help the student to get a better insight into various

areas of formulation research and development, and stability studies of

pharmaceutical dosage forms.

**Objectives:** Upon the completion of the course student shall be able to

1. Understand various physicochemical properties of drug molecules in the

designing the dosage forms

2. Know the principles of chemical kinetics & to use them for stability testing nad

determination of expiry date of formulations

3. Demonstrate use of physicochemical properties in the formulation

development and evaluation of dosage forms.

**Course Content:**

**UNIT-I 07 Hours**

**Colloidal dispersions:** Classification of dispersed systems & their general

characteristics, size & shapes of colloidal particles, classification of colloids &

comparative account of their general properties. Optical, kinetic & electrical properties.

Effect of electrolytes, coacervation, peptization& protective action.

**UNIT-II 10 Hours**

**Rheology:** Newtonian systems, law of flow, kinematic viscosity, effect of temperature,

non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy in

formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers

**Deformation of solids:** Plastic and elastic deformation, Heckel equation, Stress, Strain,

Elastic Modulus

**UNIT-III 10 Hours**

**Coarse dispersion:** Suspension, interfacial properties of suspended particles, settling in

suspensions, formulation of flocculated and deflocculated suspensions. Emulsions and

theories of emulsification, microemulsion and multiple emulsions; Stability of emulsions,

preservation of emulsions, rheological properties of emulsions and emulsion

formulation by HLB method.

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**UNIT-IV 10Hours**

**Micromeretics:** Particle size and distribution, mean particle size, number and weight

distribution, particle number, methods for determining particle size by different

methods, counting and separation method, particle shape, specific surface, methods for

determining surface area, permeability, adsorption, derived properties of powders,

porosity, packing arrangement, densities, bulkiness & flow properties.

**UNIT-V 10 Hours**

**Drug stability:** Reaction kinetics: zero, pseudo-zero, first & second order, units of basic

rate constants, determination of reaction order. Physical and chemical factors influencing

the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength,

dielectric constant, specific & general acid base catalysis, Simple numerical problems.

Stabilization of medicinal agents against common reactions like hydrolysis & oxidation.

Accelerated stability testing in expiration dating of pharmaceutical dosage forms.

Photolytic degradation and its prevention

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**BP 407P. PHYSICAL PHARMACEUTICS- II (Practical)**

**3 Hrs/week**

1. Determination of particle size, particle size distribution using sieving method

2. Determination of particle size, particle size distribution using Microscopic method

3. Determination of bulk density, true density and porosity

4. Determine the angle of repose and influence of lubricant on angle of repose

5. Determination of viscosity of liquid using Ostwald’s viscometer

6. Determination sedimentation volume with effect of different suspending agent

7. Determination sedimentation volume with effect of different concentration of

single suspending agent

8. Determination of viscosity of semisolid by using Brookfield viscometer

9. Determination of reaction rate constant first order.

10. Determination of reaction rate constant second order

11. Accelerated stability studies

**Recommended Books: (Latest Editions)**

1. Physical Pharmacy by Alfred Martin, Sixth edition

2. Experimental pharmaceutics by Eugene, Parott.

3. Tutorial pharmacy by Cooper and Gunn.

4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.

5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3,

Marcel Dekkar Inc.

6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1,

2, 3. Marcel Dekkar Inc.

7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

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**BP 404 T. PHARMACOLOGY-I (Theory)**

**45 Hrs**

**Scope:** The main purpose of the subject is to understand what drugs do to the living

organisms and how their effects can be applied to therapeutics. The subject covers the

information about the drugs like, mechanism of action, physiological and biochemical

effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion

(pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses,

contraindications and routes of administration of different classes of drugs.

**Objectives:** Upon completion of this course the student should be able to

1. Understand the pharmacological actions of different categories of drugs

2. Explain the mechanism of drug action at organ system/sub cellular/

macromolecular levels.

3. Apply the basic pharmacological knowledge in the prevention and treatment of

various diseases.

4. Observe the effect of drugs on animals by simulated experiments

5. Appreciate correlation of pharmacology with other bio medical sciences

**Course Content:**

**UNIT-I 08 hours**

**1. General Pharmacology**

**a.** Introduction to Pharmacology- Definition, historical landmarks and scope of

pharmacology, nature and source of drugs, essential drugs concept and routes of

drug administration, Agonists, antagonists( competitive and non competitive), spare

receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.

**b.** Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and

excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination

**UNIT-II 12 Hours**

**General Pharmacology**

a. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories

and classification of receptors, regulation of receptors. drug receptors interactions

signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor,

transmembrane enzyme linked receptors, transmembrane JAK-STAT binding

receptor and receptors that regulate transcription factors, dose response

relationship, therapeutic index, combined effects of drugs and factors modifying

drug action.

b. Adverse drug reactions.

c. Drug interactions (pharmacokinetic and pharmacodynamic)

d. Drug discovery and clinical evaluation of new drugs -Drug discovery phase,

preclinical evaluation phase, clinical trial phase, phases of clinical trials and

pharmacovigilance.

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**UNIT-III 10 Hours**

**2**. **Pharmacology of drugs acting on peripheral nervous system**

a. Organization and function of ANS.

b.Neurohumoral transmission,co-transmission and classification of neurotransmitters.

c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.

d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).

e. Local anesthetic agents.

f. Drugs used in myasthenia gravis and glaucoma

**UNIT-IV 08 Hours**

**3. Pharmacology of drugs acting on central nervous system**

a. Neurohumoral transmission in the C.N.S.special emphasis on importance of various

neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.

b. General anesthetics and pre-anesthetics**.**

c. Sedatives, hypnotics and centrally acting muscle relaxants.

d. Anti-epileptics

e. Alcohols and disulfiram

**UNIT-V 07 Hours**

**3. Pharmacology of drugs acting on central nervous system**

a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents,

anti-manics and hallucinogens.

b. Drugs used in Parkinsons disease and Alzheimer’s disease.

c. CNS stimulants and nootropics.

d. Opioid analgesics and antagonists

e. Drug addiction, drug abuse, tolerance and dependence.

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**BP 408 P.PHARMACOLOGY-I (Practical)**

**4Hrs/Week**

1. Introduction to experimental pharmacology.

2. Commonly used instruments in experimental pharmacology.

3. Study of common laboratory animals.

4. Maintenance of laboratory animals as per CPCSEA guidelines.

5. Common laboratory techniques. Blood withdrawal, serum and plasma separation,

anesthetics and euthanasia used for animal studies.

6. Study of different routes of drugs administration in mice/rats.

7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping

time in mice.

8. Effect of drugs on ciliary motility of frog oesophagus

9. Effect of drugs on rabbit eye.

10. Effects of skeletal muscle relaxants using rota-rod apparatus.

11. Effect of drugs on locomotor activity using actophotometer.

12. Anticonvulsant effect of drugs byMES and PTZ method.

13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.

14. Study of anxiolytic activity of drugs using rats/mice.

15. Study of local anesthetics by different methods

*Note: All laboratory techniques and animal experiments are demonstrated by simulated*

*experiments by softwares and videos*

**Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale’s

Pharmacology,.Churchil Livingstone Elsevier

2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc

Graw-Hill

3. Goodman and Gilman’s, The Pharmacological Basis of Therapeutics

4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A.

K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott

Williams &Wilkins

5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott’s Illustrated Reviews-

Pharmacology

100

6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical

Publishers (P) Ltd, New Delhi.

7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher

8. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,

9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company,

Kolkata.

10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

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**BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)**

**45 Hours**

**Scope:** The subject involves the fundamentals of Pharmacognosy like scope, classification of

crude drugs, their identification and evaluation, phytochemicals present in them and their

medicinal properties.

**Objectives:** Upon completion of the course, the student shall be able

1. to know the techniques in the cultivation and production of crude drugs

2. to know the crude drugs, their uses and chemical nature

3. know the evaluation techniques for the herbal drugs

4. to carry out the microscopic and morphological evaluation of crude drugs

**Course Content:**

**UNIT-I 10 Hours**

**Introduction to Pharmacognosy:**

(a) Definition, history, scope and development of Pharmacognosy

(b) Sources of Drugs – Plants, Animals, Marine & Tissue culture

(c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and

mucilages, oleoresins and oleo- gum -resins).

**Classification of drugs:**

Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero

taxonomical classification of drugs

**Quality control of Drugs of Natural Origin:**

Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical,

chemical and biological methods and properties.

Quantitative microscopy of crude drugs including lycopodium spore method, leafconstants,

camera lucida and diagrams of microscopic objects to scale with camera lucida.

**UNIT-II 10 Hours**

**Cultivation, Collection, Processing and storage of drugs of natural origin:**

Cultivation and Collection of drugs of natural origin

Factors influencing cultivation of medicinal plants.

Plant hormones and their applications.

Polyploidy, mutation and hybridization with reference to medicinal plants

**Conservation of medicinal plants**

**UNIT-III 07 Hours**

**Plant tissue culture:**

Historical development of plant tissue culture, types of cultures, Nutritional requirements,

growth and their maintenance.

Applications of plant tissue culture in pharmacognosy.

Edible vaccines

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**UNIT IV 10 Hours**

**Pharmacognosy in various systems of medicine:**

Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda,

Unani, Siddha, Homeopathy and Chinese systems of medicine.

**Introduction to secondary metabolites:**

Definition, classification, properties and test for identification of Alkaloids, Glycosides,

Flavonoids, Tannins, Volatile oil and Resins

**UNIT V 08 Hours**

Study of biological source, chemical nature and uses of drugs of natural origin containing

following drugs

**Plant Products:**

Fibers - Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

**Primary metabolites:**

General introduction, detailed study with respect to chemistry, sources, preparation,

evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical

Aids and/or Medicines for the following Primarymetabolites:

**Carbohydrates:** Acacia, Agar, Tragacanth, Honey

**Proteins and Enzymes :** Gelatin, casein, proteolytic enzymes (Papain, bromelain,

serratiopeptidase, urokinase, streptokinase, pepsin).

**Lipids(Waxes, fats, fixed oils)** : Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax

**Marine Drugs:**

Novel medicinal agents from marine sources

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**BP408 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)**

**4 Hours/Week**

1. Analysis of crude drugs by chemical tests: **(**i)Tragaccanth (ii) Acacia (iii)Agar (iv)

Gelatin (v) starch (vi) Honey (vii) Castor oil

2. Determination of stomatal number and index

3. Determination of vein islet number, vein islet termination and paliside ratio.

4. Determination of size of starch grains, calcium oxalate crystals by eye piece

micrometer

5. Determination of Fiber length and width

6. Determination of number of starch grains by Lycopodium spore method

7. Determination of Ash value

8. Determination of Extractive values of crude drugs

9. Determination of moisture content of crude drugs

10. Determination of swelling index and foaming

**Recommended Books: (Latest Editions)**

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co.,

London, 2009.

2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and

Febiger, Philadelphia, 1988.

3. Text Book of Pharmacognosy by T.E. Wallis

4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers &

Distribution, New Delhi.

5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition,

Nirali Prakashan, New Delhi.

6. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New

Delhi.

7. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New

Delhi, 2007

8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae

9. Anatomy of Crude Drugs byM.A. Iyengar

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**SEMESTERV**

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**BP501T. MEDICINAL CHEMISTRY – II (Theory)**

**45 Hours**

**Scope:** This subject is designed to impart fundamental knowledge on the structure,

chemistry and therapeutic value of drugs. The subject emphasizes on structure activity

relationships of drugs, importance of physicochemical properties and metabolism of

drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each

class.

**Objectives:** Upon completion of the course the student shall be able to

1. Understand the chemistry of drugs with respect to their pharmacological activity

2. Understand the drug metabolic pathways, adverse effect and therapeutic value of

drugs

3. Know the Structural Activity Relationship of different class of drugs

4. Study the chemical synthesis of selected drugs

**Course Content**:

**Study of the development of the following classes of drugs, Classification,**

**mechanism of action, uses of drugs mentioned in the course, Structure activity**

**relationship of selective class of drugs as specified in the course and synthesis of**

**drugs superscripted (\*)**

**UNIT- I 10 Hours**

**Antihistaminic agents:** Histamine, receptors and their distribution in the

humanbody

**H1–antagonists:** Diphenhydramine hydrochloride\*, Dimenhydrinate,

Doxylamines cuccinate, Clemastine fumarate, Diphenylphyraline hydrochloride,

Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine

hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine

hydrochloride\*, Phenidamine tartarate, Promethazine hydrochloride\*,

Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate,

Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

**H2-antagonists:** Cimetidine\*, Famotidine, Ranitidin.

**Gastric Proton pump inhibitors:** Omeprazole, Lansoprazole, Rabeprazole,

Pantoprazole

**Anti-neoplastic agents:**

**Alkylating agents:** Meclorethamine\*, Cyclophosphamide, Melphalan,

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Chlorambucil, Busulfan, Thiotepa

**Antimetabolites:** Mercaptopurine\*, Thioguanine, Fluorouracil, Floxuridine,

Cytarabine, Methotrexate\*, Azathioprine

**Antibiotics:** Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

**Plant products:** Etoposide, Vinblastin sulphate, Vincristin sulphate

**Miscellaneous:** Cisplatin, Mitotane.

**UNIT – II 10 Hours**

**Anti-anginal**:

**Vasodilators:** Amyl nitrite, Nitroglycerin\*, Pentaerythritol tetranitrate, Isosorbide

dinitrite\*, Dipyridamole.

**Calcium channel blockers:** Verapamil, Bepridil hydrochloride, Diltiazem

hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

**Diuretics:**

Carbonic anhydrase inhibitors: Acetazolamide\*, Methazolamide,

Dichlorphenamide.

Thiazides: Chlorthiazide\*, Hydrochlorothiazide, Hydroflumethiazide,

Cyclothiazide,

Loop diuretics: Furosemide\*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

**Anti-hypertensive Agents**: Timolol, Captopril, Lisinopril, Enalapril, Benazepril

hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,\* Clonidine

hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium

nitroprusside, Diazoxide,Minoxidil, Reserpine, Hydralazine hydrochloride.

**UNIT- III 10 Hours**

**Anti-arrhythmic Drugs**: Quinidine sulphate, Procainamide hydrochloride,

Disopyramide phosphate\*, Phenytoin sodium, Lidocaine hydrochloride,

Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide hydrochloride,

Amiodarone, Sotalol.

**Anti-hyperlipidemic agents**: Clofibrate, Lovastatin, Cholesteramine and

Cholestipol

**Coagulant & Anticoagulants**: Menadione, Acetomenadione, Warfarin\*,

Anisindione, clopidogrel

**Drugs used in Congestive Heart Failure:** Digoxin, Digitoxin, Nesiritide,

Bosentan, Tezosentan.

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**UNIT- IV 08 Hours**

**Drugs acting on Endocrine system**

Nomenclature, Stereochemistry and metabolism of steroids

**Sex hormones**: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol,

Oestrione, Diethyl stilbestrol.

**Drugs for erectile dysfunction:** Sildenafil, Tadalafil.

**Oral contraceptives:** Mifepristone, Norgestril, Levonorgestrol

**Corticosteroids:** Cortisone, Hydrocortisone, Prednisolone, Betamethasone,

Dexamethasone

**Thyroid and antithyroid drugs**: L-Thyroxine, L-Thyronine, Propylthiouracil,

Methimazole.

**UNIT – V 07 Hours**

**Antidiabetic agents:**

Insulin and its preparations

Sulfonyl ureas: Tolbutamide\*, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acrabose, Voglibose.

**Local Anesthetics:** SAR of Local anesthetics

**Benzoic Acid derivatives**; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine,

Piperocaine.

**Amino Benzoic acid derivatives**: Benzocaine\*, Butamben, Procaine\*, Butacaine,

Propoxycaine, Tetracaine, Benoxinate.

**Lidocaine/Anilide derivatives**: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

**Miscellaneous**: Phenacaine, Diperodon, Dibucaine.\*

**Recommended Books (Latest Editions)**

1. Wilson and Giswold’s Organic medicinal and Pharmaceutical Chemistry.

2. Foye’s Principles of Medicinal Chemistry.

3. Burger’s Medicinal Chemistry, Vol I to IV.

4. Introduction to principles of drug design- Smith and Williams.

5. Remington’s Pharmaceutical Sciences.

6. Martindale’s extra pharmacopoeia.

7. Organic Chemistry by I.L. Finar, Vol. II.

8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.

9. Indian Pharmacopoeia.

10. Text book of practical organic chemistry- A.I.Vogel.

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**BP 502 T. Industrial PharmacyI (Theory)**

**45 Hours**

**Scope**: Course enables the student to understand and appreciate the influence of

pharmaceutical additives and various pharmaceutical dosage forms on the performance of

the drug product.

**Objectives:** Upon completion of the course the student shall be able to

1. Know the various pharmaceutical dosage forms and their manufacturing

techniques.

2. Know various considerations in development of pharmaceutical dosage forms

3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their

quality

**Course content:**

**3 hours/ week**

**UNIT-I 07 Hours**

**Preformulation Studies:** Introduction to preformulation, goals and objectives, study of

physicochemical characteristics of drug substances.

***a. Physical properties:*** Physical form (crystal & amorphous), particle size, shape, flow

properties, solubility profile (pKa, pH, partition coefficient), polymorphism

***b. Chemical Properties:*** Hydrolysis, oxidation, reduction, racemisation, polymerization

BCS classification of drugs & its significant

Application of preformulation considerations in the development of solid, liquid oral and

parenteral dosage forms and its impact on stability of dosage forms.

**UNIT-II 10 Hours**

**Tablets:**

a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients,

Formulation of tablets, granulation methods, compression and processing problems.

Equipments and tablet tooling.

b. Tablet coating: Types of coating, coating materials, formulation of coating

composition, methods of coating, equipment employed and defects in coating.

c. Quality control tests: In process and finished product tests

**Liquid orals:** Formulation and manufacturing consideration of syrups and elixirs

suspensions and emulsions; Filling and packaging; evaluation of liquid orals

official in pharmacopoeia

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**UNIT-III 08 Hours**

**Capsules:**

a. ***Hard gelatin capsules:*** Introduction, Production of hard gelatin capsule shells. size

of capsules, Filling, finishing and special techniques of formulation of hard gelatin

capsules, manufacturing defects. In process and final product quality control tests

for capsules.

b. ***Soft gelatin capsules:*** Nature of shell and capsule content, size of

capsules,importance of base adsorption and minim/gram factors, production, in

process and final product quality control tests. Packing, storage and stability testing

of soft gelatin capsules and their applications.

**Pellets:** Introduction, formulation requirements, pelletization process, equipments for

manufacture of pellets

**UNIT-IV 10 Hours**

**Parenteral Products:**

a. Definition, types, advantages and limitations. Preformulation factors and essential

requirements, vehicles, additives, importance of isotonicity

b. Production procedure, production facilities and controls,

aseptic processing

c. Formulation of injections, sterile powders, large volume parenterals and

lyophilized products.

d. Containers and closures selection, filling and sealing of ampoules, vials and infusion

fluids. Quality control tests of parenteral products.

**Ophthalmic Preparations:** Introduction, formulation considerations; formulation of eye

drops, eye ointments and eye lotions; methods of preparation; labeling, containers;

evaluation of ophthalmic preparations

**UNIT-V 10 Hours**

**Cosmetics:** Formulation and preparation of the following cosmetic preparations:

lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and

sunscreens.

**Pharmaceutical Aerosols:** Definition, propellants, containers, valves, types of aerosol

systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality

control and stability studies.

**Packaging Materials Science:** Materials used for packaging of pharmaceutical products,

factors influencing choice of containers, legal and official requirements for containers,

stability aspects of packaging materials, quality control tests.

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**BP 506 P. Industrial PharmacyI (Practical)**

1. Preformulation studies on paracetamol/asparin/or any other drug

2. Preparation and evaluation of Paracetamol tablets

3. Preparation and evaluation of Aspirin tablets

4. Coating of tablets- film coating of tables/granules

5. Preparation and evaluation of Tetracycline capsules

6. Preparation of Calcium Gluconate injection

7. Preparation of Ascorbic Acid injection

8. Qulaity control test of (as per IP) marketed tablets and capsules

9. Preparation of Eye drops/ and Eye ointments

10. Preparation of Creams (cold / vanishing cream)

11. Evaluation of Glass containers (as per IP)

**4 Hours/week**

**Recommended Books: (Latest Editions)**

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman

&J.B.Schwartz

2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman &

Lachman

3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman

4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition

5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical

Science (RPS)

6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman

7. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill

livingstone, Latest edition

8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger,

Philadelphia, 5thedition, 2005

9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition,

Marcel Dekker Series, Vol 107.

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**BP503.T. PHARMACOLOGY-II (Theory)**

**45 Hours**

**Scope:** This subject is intended to impart the fundamental knowledge on various aspects

(classification, mechanism of action, therapeutic effects, clinical uses, side effects and

contraindications) of drugs acting on different systems of body and in addition,emphasis

on the basic concepts of bioassay.

**Objectives:** Upon completion of this course the student should be able to

1. Understand the mechanism of drug action and its relevance in the treatment of

different diseases

2. Demonstrate isolation of different organs/tissues from the laboratory animals by

simulated experiments

3. Demonstrate the various receptor actions using isolated tissue preparation

4. Appreciate correlation of pharmacology with related medical sciences

**Course Content:**

**UNIT-I 10hours**

**1. Pharmacology of drugs acting on cardio vascular system**

a. Introduction to hemodynamic and electrophysiology of heart.

b. Drugs used in congestive heart failure

c. Anti-hypertensive drugs.

d. Anti-anginal drugs.

e. Anti-arrhythmic drugs.

f. Anti-hyperlipidemic drugs.

**UNIT-II 10hours**

**1. Pharmacology of drugs acting on cardio vascular system**

a. Drug used in the therapy of shock.

b. Hematinics, coagulants and anticoagulants.

c. Fibrinolytics and anti-platelet drugs

d. Plasma volume expanders

**2. Pharmacology of drugs acting on urinary system**

a. Diuretics

b. Anti-diuretics.

**UNIT-III 10hours**

**3. Autocoids and related drugs**

a. Introduction to autacoids and classification

b. Histamine, 5-HT and their antagonists.

c. Prostaglandins, Thromboxanes and Leukotrienes.

d. Angiotensin, Bradykinin and Substance P.

e. Non-steroidal anti-inflammatory agents

f. Anti-gout drugs

g. Antirheumatic drugs

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**UNIT-IV 08hours**

**5. Pharmacology of drugs acting on endocrine system**

a. Basic concepts in endocrine pharmacology.

b. Anterior Pituitary hormones- analogues and their inhibitors.

c. Thyroid hormones- analogues and their inhibitors.

d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and

Vitamin-D.

d. Insulin, Oral Hypoglycemic agents and glucagon.

e. ACTH and corticosteroids.

**UNIT-V 07hours**

**5. Pharmacology of drugs acting on endocrine system**

a. Androgens and Anabolic steroids.

b. Estrogens, progesterone and oral contraceptives.

c. Drugs acting on the uterus.

**6. Bioassay**

a. Principles and applications of bioassay.

b.Types of bioassay

c. Bioassay of insulin, oxytocin, vasopressin, ACTH,d-tubocurarine,digitalis, histamine

and 5-HT

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**BP 507 P. PHARMACOLOGY-II (Practical)**

**4Hrs/Week**

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.

2. Effect of drugs on isolated frog heart.

3. Effect of drugs on blood pressure and heart rate of dog.

4. Study of diuretic activity of drugs using rats/mice.

5. DRC of acetylcholine using frog rectus abdominis muscle.

6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus

abdominis muscle and rat ileum respectively.

7. Bioassay of histamine using guinea pig ileum by matching method.

8. Bioassay of oxytocin using rat uterine horn by interpolation method.

9. Bioassay of serotonin using rat fundus strip by three point bioassay.

10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.

11. Determination of PA2 value of prazosin using rat anococcygeus muscle (by

Schilds plot method).

12. Determination of PD2 value using guinea pig ileum.

13. Effect of spasmogens and spasmolytics using rabbit jejunum.

14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema

model.

15. Analgesic activity of drug using central and peripheral methods

*Note: All laboratory techniques and animal experiments are demonstrated by simulated*

*experiments by softwares and videos*

**Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale’s Pharmacology,

Churchil Livingstone Elsevier

2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc

Graw-Hill.

3. Goodman and Gilman’s, The Pharmacological Basis of Therapeutics

4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A.

K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point

Lippincott Williams & Wilkins.

5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott’s Illustrated Reviews-

Pharmacology.

6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical

Publishers (P) Ltd, New Delhi.

7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher

8. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert.

9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company,

Kolkata.

10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

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**BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)**

**45Hours**

**Scope:** The main purpose of subject is to impart the students the knowledge of how the

secondary metabolites are produced in the crude drugs, how to isolate and identify and

produce them industrially. Also this subject involves the study of producing the plants and

phytochemicals through plant tissue culture, drug interactions and basic principles of

traditional system of medicine

**Objectives:** Upon completion of the course, the student shall be able

1. to know the modern extraction techniques, characterization and identification of the

herbal drugs and phytoconstituents

2. to understand the preparation and development of herbal formulation.

3. to understand the herbal drug interactions

4. to carryout isolation and identification of phytoconstituents

**Course Content:**

**UNIT-I 7 Hours**

**Metabolic pathways in higher plants and their determination**

a) Brief study of basic metabolic pathways and formation of different secondary metabolites

through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.

b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

**UNIT-II 14 Hours**

General introduction, composition, chemistry & chemical classes, biosources, therapeutic

uses and commercial applications of following

secondary metabolites:

**Alkaloids:** Vinca, Rauwolfia, Belladonna, Opium,

**Phenylpropanoids and Flavonoids:** Lignans, Tea, Ruta

**Steroids, Cardiac Glycosides & Triterpenoids**: Liquorice, Dioscorea, Digitalis

**Volatile oils**: Mentha, Clove, Cinnamon, Fennel, Coriander,

**Tannins:** Catechu, Pterocarpus

**Resins:** Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

**Glycosides:** Senna, Aloes, Bitter Almond

**Iridoids, Other terpenoids & Naphthaquinones:** Gentian, Artemisia, taxus, carotenoids

**UNIT-III 06 Hours**

Isolation, Identification and Analysis of Phytoconstituents

a) Terpenoids: Menthol, Citral, Artemisin

b) Glycosides: Glycyrhetinic acid & Rutin

c) Alkaloids: Atropine,Quinine,Reserpine,Caffeine

d) Resins: Podophyllotoxin, Curcumin

**UNIT-IV 10 Hours**

Industrial production, estimation and utilization of the following phytoconstituents:

Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine,

Taxol, Vincristine and Vinblastine

**UNIT V 8 Hours**

**Basics of Phytochemistry**

Modern methods of extraction, application of latest techniques like Spectroscopy,

chromatography and electrophoresis in the isolation, purification and identification of crude

drugs.

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**BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)**

**4 Hours/Week**

1. Morphology, histology and powder characteristics & extraction & detection of:

Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander

2. Exercise involving isolation & detection of active principles

a. Caffeine - from tea dust.

b. Diosgenin from Dioscorea

c. Atropine from Belladonna

d. Sennosides from Senna

3. Separation of sugars by Paper chromatography

4. TLC of herbal extract

5. Distillation of volatile oils and detection of phytoconstitutents by TLC

6. Analysis of crude drugs by chemical tests: **(**i) Asafoetida (ii) Benzoin (iii)

Colophony (iv) Aloes (v) Myrrh

**Recommended Books: (Latest Editions)**

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co.,

London, 2009.

2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers &

Distribution, New Delhi.

3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition,

Nirali Prakashan, New Delhi.

4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New

Delhi.

5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New

Delhi, 2007

6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.

7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi,

2005.

8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.

9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.

10. The formulation and preparation of cosmetic, fragrances and flavours.

11. Remington’s Pharmaceutical sciences.

12. Text Book of Biotechnology by Vyas and Dixit.

13. Text Book of Biotechnology by R.C. Dubey.

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**BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)**

**Scope:** This course is designed to impart basic knowledge on important

legislations related to the profession of pharmacy in India.

**45 Hours**

**Objectives**: Upon completion of the course, the student shall be able to understand:

1. The Pharmaceutical legislations and their implications in the development and

marketing of pharmaceuticals.

2. Various Indian pharmaceutical Acts and Laws

3. The regulatory authorities and agencies governing the manufacture and sale of

pharmaceuticals

4. The code of ethics during the pharmaceutical practice

**Course Content:**

**UNIT-I 10 Hours**

**Drugs and Cosmetics Act, 1940 and its rules 1945:**

Objectives, Definitions, Legal definitions of schedules to the Act and

Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under

license or permit. Offences and penalties**.**

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs,

Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan

license and repacking license.

**UNIT-II 10 Hours**

**Drugs and Cosmetics Act, 1940 and its rules 1945.**

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA)

Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

Labeling & Packing of drugs- General labeling requirements and specimen labels for

drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs

Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing

authorities, controlling authorities, Drugs Inspectors

**UNIT-III 10 Hours**

 **Pharmacy Act –1948**: Objectives, Definitions, Pharmacy Council of India; its

constitution and functions, Education Regulations, State and Joint state pharmacy

councils; constitution and functions, Registration of Pharmacists, Offences and

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Penalties

 **Medicinal and Toilet Preparation Act –1955**: Objectives, Definitions, Licensing,

Manufacture In bond and Outside bond, Export of alcoholic preparations,

Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.

Offences and Penalties.

 **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**: Objectives,

Definitions, Authorities and Officers, Constitution and Functions of narcotic &

Psychotropic Consultative Committee, National Fund for Controlling the Drug

Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production

of poppy straw, manufacture, sale and export of opium, Offences and Penalties

**UNIT-IV 08 Hours**

 **Study of Salient Features of Drugs and Magic Remedies Act and its**

**rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of

Exempted advertisements, Offences and Penalties

 **Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional

Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of

Animals, Performance of Experiments, Transfer and acquisition of animals for

experiment, Records, Power to suspend or revoke registration, Offences and Penalties

 **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-

2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations,

Retail price and ceiling price of scheduled formulations, National List of Essential

Medicines (NLEM)

**UNIT-V 07 Hours**

 **Pharmaceutical Legislations –** A brief review, Introduction, Study of drugs enquiry

committee, Health survey and development committee, Hathi committee and

Mudaliar committee

 **Code of Pharmaceutical ethics** D efinition, Pharmacist in relation to his job, trade,

medical profession and his profession, Pharmacist’s oath

 **Medical Termination of Pregnancy Act**

 **Right to Information Act**

 **Introduction to Intellectual Property Rights (IPR)**

**Recommended books: (Latest Edition)**

1. Forensic Pharmacy by B. Suresh

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2. Text book of Forensic Pharmacy by B.M. Mithal

3. Hand book of drug law-byM.L. Mehra

4. A text book of Forensic Pharmacy by N.K. Jain

5. Drugs and Cosmetics Act/Rules by Govt. of India publications.

6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.

7. Narcotic drugs and psychotropic substances act by Govt. of India publications

8. Drugs and Magic Remedies act by Govt. of India publication

9.Bare Acts of the said laws published by Government. Reference books (Theory)

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**SEMESTERVI**

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**BP601T. MEDICINAL CHEMISTRY – III (Theory)**

**45 Hours**

**Scope**: This subject is designed to impart fundamental knowledge on the structure,

chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of

rational drug design like quantitative structure activity relationship (QSAR), Prodrug

concept, combinatorial chemistry and Computer aided drug design (CADD). The subject

also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects,

Structure Activity Relationships (SAR), therapeutic uses and synthesis of important

drugs.

**Objectives:** Upon completion of the course student shall be able to

1. Understand the importance of drug design and different techniques of drug

design.

2. Understand the chemistry of drugs with respect to their biological activity.

3. Know the metabolism, adverse effects and therapeutic value of drugs.

**4.** Know the importance of SAR of drugs.

**Course Content**:

**Study of the development of the following classes of drugs, Classification, mechanism of**

**action, uses of drugs mentioned in the course, Structure activity relationship of selective**

**class of drugs as specified in the course and synthesis of drugs superscripted by (\*)**

**UNIT – I 10 Hours**

**Antibiotics**

Historical background, Nomenclature, Stereochemistry, Structure activity

relationship, Chemical degradation classification and important products of

the following classes.

**β-Lactam antibiotics:** Penicillin, Cepholosporins, β- Lactamase inhibitors,

Monobactams

**Aminoglycosides:** Streptomycin, Neomycin, Kanamycin

**Tetracyclines:** Tetracycline,Oxytetracycline, Chlortetracycline,

Minocycline, Doxycycline

**UNIT – II 10 Hours**

**Antibiotics**

Historical background, Nomenclature, Stereochemistry, Structure activity

relationship, Chemical degradation classification and important products of

the following classes.

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**Macrolide:** Erythromycin Clarithromycin, Azithromycin.

**Miscellaneous:** Chloramphenicol\*, Clindamycin.

**Prodrugs:** Basic concepts and application of prodrugs design.

**Antimalarials:** Etiology of malaria.

**Quinolines:** SAR, Quinine sulphate, Chloroquine\*, Amodiaquine,

Primaquine phosphate, Pamaquine\*, Quinacrine hydrochloride, Mefloquine.

**Biguanides and dihydro triazines:** Cycloguanil pamoate, Proguanil.

**Miscellaneous:** Pyrimethamine, Artesunete, Artemether, Atovoquone.

**UNIT – III 10 Hours**

**Anti-tubercular Agents**

**Synthetic anti tubercular agents:** Isoniozid\*, Ethionamide, Ethambutol,

Pyrazinamide, Para amino salicylic acid.\*

**Anti tubercular antibiotics:** Rifampicin, Rifabutin, Cycloserine

Streptomycine, Capreomycin sulphate.

**Urinary tract anti-infective agents**

**Quinolones:** SAR of quinolones, Nalidixic Acid,Norfloxacin, Enoxacin,

Ciprofloxacin\*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin,

Moxifloxacin

**Miscellaneous:** Furazolidine, Nitrofurantoin\*, Methanamine.

**Antiviral agents:**

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine

trifluoride, Acyclovir\*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine,

Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir,

Ritonavir.

**UNIT – IV 08 Hours**

**Antifungal agents:**

**Antifungal antibiotics:** Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

**Synthetic Antifungal agents:** Clotrimazole, Econazole, Butoconazole,

Oxiconazole Tioconozole, Miconazole\*, Ketoconazole, Terconazole,

Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate\*.

**Anti-protozoal Agents:** Metronidazole\*, Tinidazole, Ornidazole, Diloxanide,

Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

**Anthelmintics:** Diethylcarbamazine citrate\*, Thiabendazole, Mebendazole\*,

Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.

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**Sulphonamides and Sulfones**

Historical development, chemistry, classification and SAR of Sulfonamides:

Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide\*,

Sulphapyridine, Sulfamethoxaole\*, Sulphadiazine, Mefenide acetate,

Sulfasalazine.

**Folate reductase inhibitors:** Trimethoprim\*, Cotrimoxazole.

**Sulfones:** Dapsone\*.

**UNIT – V 07 Hours**

**Introduction to Drug Design**

Various approaches used in drug design.

Physicochemical parameters used in quantitative structure activity

relationship (QSAR) such as partition coefficient, Hammet’s electronic

parameter, Tafts steric parameter and Hansch analysis.

Pharmacophore modeling and docking techniques.

**Combinatorial Chemistry:** Concept and applications

chemistry: solid phase and solution phase synthesis.

of combinatorial

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**BP607P. MEDICINAL CHEMISTRY- III (Practical)**

**4 Hours / week**

**I Preparation of drugs and intermediates**

1 Sulphanilamide

2 7-Hydroxy, 4-methyl coumarin

3 Chlorobutanol

4 Triphenyl imidazole

5 Tolbutamide

6 Hexamine

**II Assay of drugs**

1 Isonicotinic acid hydrazide

2 Chloroquine

3 Metronidazole

4 Dapsone

5 Chlorpheniramine maleate

6 Benzyl penicillin

**III** Preparation of medicinally important compounds or intermediates byMicrowave

irradiation technique

**IV** Drawing structures and reactions using chem draw®

**V** Determination of physicochemical properties such as logP, clogP, MR, Molecular

weight, Hydrogen bond donors and acceptors for class of drugs course content

using drug design software Drug likeliness screening (Lipinskies RO5)

**Recommended Books (Latest Editions)**

1. Wilson and Giswold’s Organic medicinal and Pharmaceutical Chemistry.

2. Foye’s Principles of Medicinal Chemistry.

3. Burger’s Medicinal Chemistry, Vol I to IV.

4. Introduction to principles of drug design- Smith and Williams.

5. Remington’s Pharmaceutical Sciences.

6. Martindale’s extra pharmacopoeia.

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7. Organic Chemistry by I.L. Finar, Vol. II.

8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.

9. Indian Pharmacopoeia.

10. Text book of practical organic chemistry- A.I.Vogel.

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**BP602 T. PHARMACOLOGY-III (Theory)**

**45 Hours**

**Scope:** This subject is intended to impart the fundamental knowledge on various aspects

(classification, mechanism of action, therapeutic effects, clinical uses, side effects and

contraindications) of drugs acting on respiratory and gastrointestinal system, infectious

diseases, immuno-pharmacology and in addition,emphasis on the principles of

toxicology and chronopharmacology.

**Objectives:** Upon completion of this course the student should be able to:

1. understand the mechanism of drug action and its relevance in the treatment of

different infectious diseases

2. comprehend the principles of toxicology and treatment of various poisoningsand

3. appreciate correlation of pharmacology with related medical sciences.

**Course Content:**

**UNIT-I 10hours**

**1. Pharmacology of drugs acting on Respiratory system**

a. Anti -asthmatic drugs

b. Drugs used in the management of COPD

c. Expectorants and antitussives

d. Nasal decongestants

e. Respiratory stimulants

**2. Pharmacology of drugs acting on the Gastrointestinal Tract**

a. Antiulcer agents.

b. Drugs for constipation and diarrhoea.

c. Appetite stimulants and suppressants.

d. Digestants and carminatives.

e. Emetics and anti-emetics.

**UNIT-II 10hours**

**3. Chemotherapy**

a. General principles of chemotherapy.

b. Sulfonamides and cotrimoxazole.

c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides,

quinolones and fluoroquinolins, tetracycline and aminoglycosides

**UNIT-III 10hours**

**3. Chemotherapy**

a. Antitubercular agents

b. Antileprotic agents

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c. Antifungal agents

d. Antiviral drugs

e.Anthelmintics

f. Antimalarial drugs

g. Antiamoebic agents

**UNIT-IV 08hours**

**3. Chemotherapy**

l. Urinary tract infections and sexually transmitted diseases.

m. Chemotherapy of malignancy.

**4. Immunopharmacology**

a. Immunostimulants

b. Immunosuppressant

Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

**UNIT-V 07hours**

**5. Principles of toxicology**

**a.** Definition and basic knowledge of acute, subacute and chronic toxicity.

**b.** Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity

and mutagenicity

**c.** General principles of treatment of poisoning

**d.** Clinical symptoms and management of barbiturates, morphine,

organophosphosphorus compound and lead, mercury and arsenic poisoning.

**6. Chronopharmacology**

a. Definition of rhythm and cycles.

b. Biological clock and their significance leading to chronotherapy.

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**BP 608 P. PHARMACOLOGY-III (Practical)**

**4Hrs/Week**

1. Dose calculation in pharmacological experiments

2. Antiallergic activity by mast cell stabilization assay

3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and

NSAIDS induced ulcer model.

4. Study of effect of drugs on gastrointestinal motility

5. Effect of agonist and antagonists on guinea pig ileum

6. Estimation of serum biochemical parameters by using semi- autoanalyser

7. Effect of saline purgative on frog intestine

8. Insulin hypoglycemic effect in rabbit

9. Test for pyrogens ( rabbit method)

10. Determination of acute oral toxicity (LD50) of a drug from a given data

11. Determination of acute skin irritation / corrosion of a test substance

12. Determination of acute eye irritation / corrosion of a test substance

13. Calculation of pharmacokinetic parameters from a given data

14. Biostatistics methods in experimental pharmacology( student’s t test, ANOVA)

15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon

Signed Rank test)

*\*Experiments are demonstrated by simulated experiments/videos*

**Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale’s Pharmacology,

Churchil Livingstone Elsevier

2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc

Graw-Hill

3. Goodman and Gilman’s, The Pharmacological Basis of Therapeutics

4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A.

K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott

Williams &Wilkins

5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott’s Illustrated Reviews-

Pharmacology

6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical

Publishers (P) Ltd, New Delhi.

7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher

Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,

8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company,

Kolkata,

9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

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**BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)**

**45 hours**

**Scope:** This subject gives the student the knowledge of basic understanding of herbal drug

industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics,

natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing

Practices (GMP), patenting and regulatory issues of herbal drugs

**Objectives:** Upon completion of this course the student should be able to:

1. understand raw material as source of herbal drugs from cultivation to herbal drug

product

2. know the WHO and ICH guidelines for evaluation of herbal drugs

3. know the herbal cosmetics, natural sweeteners, nutraceuticals

4. appreciate patenting of herbal drugs, GMP .

**Course content:**

**UNIT-I 11 Hours**

**Herbs as raw materials**

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation

Source of Herbs

Selection, identification and authentication of herbal materials

Processing of herbal raw material

**Biodynamic Agriculture**

Good agricultural practices in cultivation of medicinal plants including Organic farming.

Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

**Indian Systems of Medicine**

a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy

b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas,

Ghutika,Churna, Lehya and Bhasma.

**UNIT-II 7 Hours**

**Nutraceuticals**

General aspects, Market, growth, scope and types of products available in the market. Health

benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable

bowel syndrome and various Gastro intestinal diseases.

Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic,

Honey, Amla, Ginseng, Ashwagandha, Spirulina

**Herbal-Drug and Herb-Food Interactions:** General introduction to interaction and

classification. Study of following drugs and their possible side effects and interactions:

Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

**UNIT-III 10 Hours**

**Herbal Cosmetics**

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Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums

colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin

care, hair care and oral hygiene products.

**Herbal excipients:**

Herbal Excipients – Significance of substances of natural origin as excipients – colorants,

sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

**Herbal formulations :**

Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms

like phytosomes

**UNIT- IV 10 Hours**

**Evaluation of Drugs** WHO & ICH guidelines for the assessment of herbal drugs

Stability testing of herbal drugs.

**Patenting and Regulatory requirements of natural products:**

a) Definition of the terms: Patent, IPR, Farmers right, Breeder’s right, Bioprospecting and

Biopiracy

b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma

& Neem.

**Regulatory Issues** - Regulations in India (ASU DTAB, ASU DCC), Regulation of

manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

**UNIT-V 07 Hours**

**General Introduction to Herbal Industry**

Herbal drugs industry: Present scope and future prospects.

A brief account of plant based industries and institutions involved in work on medicinal and

aromatic plants in India.

S**chedule T – GoodManufacturing Practice of Indian systems of medicine**

Components of GMP (Schedule – T) and its objectives

Infrastructural requirements, working space, storage area, machinery and equipments,

standard operating procedures, health and hygiene, documentation and records.

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**BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)**

**4 hours/ week**

1. To perform preliminary phytochemical screening of crude drugs.

2. Determination of the alcohol content of Asava and Arista

3. Evaluation of excipients of natural origin

4. Incorporation of prepared and standardized extract in cosmetic formulations like creams,

lotions and shampoos and their evaluation.

5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures

and tablets and their evaluation as per Pharmacopoeial requirements.

6. Monograph analysis of herbal drugs from recent Pharmacopoeias

7. Determination of Aldehyde content

8. Determination of Phenol content

9. Determination of total alkaloids

**Recommended Books: (Latest Editions)**

1. Textbook of Pharmacognosy by Trease & Evans.

2. Textbook of Pharmacognosy by Tyler, Brady & Robber.

3. Pharmacognosy by Kokate, Purohit and Gokhale

4. Essential of Pharmacognosy by Dr.S.H.Ansari

5. Pharmacognosy & Phytochemistry by V.D.Rangari

6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in

Indian Medicine & Homeopathy)

7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of

Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

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**BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS**

**(Theory)**

45 Hours

**Scope:**This subject is designed to impart knowledge and skills of Biopharmaceutics

and pharmacokinetics and their applications in pharmaceutical development, design of

dose and dosage regimen and in solving the problems arised therein.

**Objectives:** Upon completion of the course student shall be able

to:

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and

their significance.

2. Use of plasma drug concentration-time data to calculate the pharmacokinetic

parameters to describe the kinetics of drug absorption, distribution,

metabolism, excretion, elimination.

3. To understand the concepts of bioavailability and bioequivalence of drug

products and their significance.

4. Understand various pharmacokinetic parameters, their significance &

applications.

**Course**

**Content:**

**UNIT-I 10**

**Hours**

**Introduction**

**Biopharmaceutics**

**to**

**Absorption**; Mechanisms of drug absorption through GIT, factors influencing drug

absorption though GIT, absorption of drug from Non per oral extra-vascular

routes, **Distribution** Tissue permeability of drugs, binding of drugs, apparent, volume

of drug distribution, plasma and tissue protein binding of drugs, factors affecting

protein-drug binding. Kinetics of protein binding, Clinical significance of protein

binding of drugs

**UNIT- II 10**

**Hours**

**Elimination:** Drug metabolism and basic understanding metabolic pathways renal

excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal

routes of drug excretion of drugs

**Bioavailability and Bioequivalence:** Definition and Objectives of bioavailability,

absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug

dissolution models, *in-vitro*-*in-vivo* correlations, bioequivalence studies, methods to

enhance the dissolution rates and bioavailability of poorly soluble drugs.

**UNIT- III 10 Hours**

**Pharmacokinetics:** Definition and introduction to Pharmacokinetics, Compartment

models, Non compartment models, physiological models, One compartment open

model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra

vascular administrations. Pharmacokinetics parameters - KE ,t1/2,Vd,AUC,Ka, Clt and

CLR- definitions methods of eliminations, understanding of their significance and

application

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**UNIT- IV 08 Hours**

***Multicompartment models:*** Two compartment open model. IV bolus

Kinetics of multiple dosing, steady state drug levels, calculation of loading and

mainetnance doses and their significance in clinical settins.

**UNIT- V 07 Hours**

**Nonlinear Pharmacokinetics:** a. Introduction, b. Factors causing Non-linearity.

c. Michaelis-menton method of estimating parameters, Explanation with example of

drugs.

**Recommended Books: (Latest Editions)**

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.

2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari

3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew

B.C.YU 4th edition,Prentice-Hall Inernational edition.USA

4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and

Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi

5. Pharmacokinetics: ByMilo Glbaldi Donald, R. Mercel Dekker Inc.

6. Hand Book of Clinical Pharmacokinetics, ByMilo Gibaldi and Laurie Prescott by

ADIS Health Science Press.

7. Biopharmaceutics; By Swarbrick

8. Clinical Pharmacokinetics, Concepts and Applications: ByMalcolm Rowland and

9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.

10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack,

Publishing Company,Pennsylvania 1989.

11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition

Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and

Basel, 1987.

12. Remington’s Pharmaceutical Sciences, ByMack Publishing Company,

Pennsylvnia

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**Scope:**

**BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)**

**45 Hours**

 Biotechnology has a long promise to revolutionize the biological sciences and

technology.

 Scientific application of biotechnology in the field of genetic engineering,

medicine and fermentation technologymakes the subject interesting.

 Biotechnology is leading to new biological revolutions in diagnosis, prevention

and cure of diseases, new and cheaper pharmaceutical drugs.

 Biotechnology has already produced transgenic crops and animals and the future

promises lot more.

 It is basically a research-based subject.

**Objectives:** Upon completion of the subject student shall be able to;

1. Understanding the importance of Immobilized enzymes in Pharmaceutical

Industries

2. Genetic engineering applications in relation to production of pharmaceuticals

3. Importance of Monoclonal antibodies in Industries

4. Appreciate the use of microorganisms in fermentation technology

**Unit I 10 Hours**

a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.

b) Enzyme Biotechnology- Methods of enzyme immobilization and applications.

c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries.

d) Brief introduction to Protein Engineering.

e) Use of microbes in industry. Production of Enzymes- General consideration -

Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.

f) Basic principles of genetic engineering.

**Unit II 10 Hours**

a) Study of cloning vectors, restriction endonucleases and DNA ligase.

b) Recombinant DNA technology. Application of genetic engineering in medicine.

c) Application of r DNA technology and genetic engineering in the production of:

i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin.

d) Brief introduction to PCR

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**Unit III 10 Hours**

Types of immunity- humoral immunity, cellular immunity

a) Structure of Immunoglobulins

b) Structure and Function of MHC

c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.

d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine,

antitoxins, serum-immune blood derivatives and other products relative to immunity.

e) Storage conditions and stability of official vaccines

f) Hybridoma technology- Production, Purification and Applications

g) Blood products and Plasma Substituties.

**Unit IV 08Hours**

a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting.

b) Genetic organization of Eukaryotes and Prokaryotes

c) Microbial genetics including transformation, transduction, conjugation, plasmids and

transposons.

d) Introduction to Microbial biotransformation and applications.

**e)** Mutation: Types of mutation/mutants.

**Unit V 07 Hours**

a) Fermentation methods and general requirements, study of media, equipments,

sterilization methods, aeration process, stirring.

b) Large scale production fermenter design and its various controls.

c) Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid,

Griseofulvin,

d) Blood Products: Collection, Processing and Storage of whole human blood, dried

human plasma, plasma Substituties.

**Recommended Books (Latest edition):**

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications

of RecombinantDNA: ASM Press Washington D.C.

2. RA Goldshy et. al., : Kuby Immunology.

3. J.W. Goding: Monoclonal Antibodies.

4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal

Society of Chemistry.

5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.

6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific

Publication.

7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology,

2nd edition, Aditya books Ltd., New Delhi

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**BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)**

**45 Hours**

**Scope:** This course deals with the various aspects of quality control and quality

assurance aspects of pharmaceutical industries. It deals with the important aspects like

cGMP, QC tests, documentation, quality certifications and regulatory affairs.

**Objectives:** Upon completion of the course student shall be able to:

 understand the cGMP aspects in a pharmaceutical industry

 appreciate the importance of documentation

 understand the scope of quality certifications applicable to pharmaceutical

industries

 understand the responsibilities of QA & QC departments

**Course content:**

**UNIT – I 10 Hours**

**Quality Assurance and Quality Management concepts:** Definition and concept of Quality

control, Quality assurance and GMP

**Total Quality Management (TQM):** Definition, elements, philosophies

**ICH Guidelines**: purpose, participants, process of harmonization, Brief overview of QSEM,

with special emphasis on Q-series guidelines, ICH stability testing guidelines

**Quality by design (QbD)**: Definition, overview, elements of QbD program, tools

**ISO 9000 & ISO14000**: Overview, Benefits, Elements, steps for registration

**NABL accreditation** : Principles and procedures

**UNIT - II 10 Hours**

**Organization and personnel:** Personnel responsibilities, training, hygiene and personal records.

**Premises:** Design, construction and plant layout, maintenance, sanitation, environmental

control, utilities and maintenance of sterile areas, control of contamination.

**Equipments and raw materials:** Equipment selection, purchase specifications, maintenance,

purchase specifications and maintenance of stores for raw materials.

**UNIT – III 10 Hours**

**Quality Control:** Quality control test for containers, rubber closures and secondary packing

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materials.

**Good Laboratory Practices:** General Provisions, Organization and Personnel, Facilities,

Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a

Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

**UNIT – IV 08 Hours**

**Complaints:** Complaints and evaluation of complaints, Handling of return good, recalling and

waste disposal.

**Document maintenance in pharmaceutical industry:** Batch Formula Record, Master Formula

Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and

documents, distribution records.

**UNIT – V 07 Hours**

**Calibration and Validation:** Introduction, definition and general principles of calibration,

qualification and validation, importance and scope of validation, types of validation, validation

master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General

principles of Analytical method Validation.

**Warehousing:** Good warehousing practice, materials management

**Recommended Books: (Latest Edition)**

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.

2. Good Laboratory Practice Regulations, 2nd Edition, SandyWeinberg Vol. 69.

3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related

materials Vol IWHO Publications.

4. A guide to Total QualityManagement- Kushik Maitra and Sedhan K Ghosh

5. How to Practice GMP’s – P P Sharma.

6. ISO 9000 and Total QualityManagement – Sadhank G Ghosh

7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis

and Quality specification for Pharmaceutical Substances, Excipients and Dosage

forms

8. Good laboratory Practices – Marcel Deckker Series

9. ICH guidelines, ISO 9000 and 14000 guidelines

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**SEMESTERVII**

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**BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)**

**45 Hours**

**Scope:** This subject deals with the application of instrumental methods in qualitative and

quantitative analysis of drugs. This subject is designed to impart a fundamental

knowledge on the principles and instrumentation of spectroscopic and chromatographic

technique. This also emphasizes on theoretical and practical knowledge on modern

analytical instruments that are used for drug testing.

**Objectives:** Upon completion of the course the student shall be able to

1. Understand the interaction of matter with electromagnetic radiations and its

applications in drug analysis

2. Understand the chromatographic separation and analysis of drugs.

3. Perform quantitative & qualitative analysis of drugs using various analytical

instruments.

**Course Content:**

**UNIT –I 10 Hours**

**UV Visible spectroscopy**

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on

absorption spectra, Beer and Lambert’s law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors-

Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component

analysis

**Fluorimetry**

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external

conversions, factors affecting fluorescence, quenching, instrumentation and

applications

**UNIT –II 10 Hours**

**IR spectroscopy**

Introduction, fundamental modes of vibrations in poly atomic molecules, sample

handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell,

Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

**Flame Photometry-**Principle, interferences, instrumentation and applications

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**Atomic absorption spectroscopy**- Principle, interferences, instrumentation and

applications

**Nepheloturbidometry**- Principle, instrumentation and applications

**UNIT –III 10 Hours**

**Introduction to chromatography**

**Adsorption and partition column chromatography-**Methodology, advantages,

disadvantages and applications.

**Thin layer chromatography-** Introduction, Principle, Methodology, Rf values,

advantages, disadvantages and applications.

**Paper chromatography-**Introduction, methodology, development techniques,

advantages, disadvantages and applications

**Electrophoresis**– Introduction, factors affecting electrophoretic mobility, Techniques

of paper, gel, capillary electrophoresis, applications

**UNIT –IV 08 Hours**

**Gas chromatography -** Introduction, theory, instrumentation, derivatization,

temperature programming, advantages, disadvantages and applications

**High performance liquid chromatography (HPLC)-**Introduction, theory,

instrumentation, advantages and applications.

**UNIT –V 07 Hours**

**Ion exchange chromatography-** Introduction, classification, ion exchange resins,

properties, mechanism of ion exchange process, factors affecting ion exchange,

methodology and applications

**Gel chromatography-** Introduction, theory, instrumentation and applications

**Affinity chromatography-** Introduction, theory, instrumentation and applications

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**BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)**

**4 Hours/Week**

1 Determination of absorption maxima and effect of solvents on absorption

maxima of organic compounds

2 Estimation of dextrose by colorimetry

3 Estimation of sulfanilamide by colorimetry

4 Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy

5 Assay of paracetamol by UV- Spectrophotometry

6 Estimation of quinine sulfate by fluorimetry

7 Study of quenching of fluorescence

8 Determination of sodium by flame photometry

9 Determination of potassium by flame photometry

10 Determination of chlorides and sulphates by nephelo turbidometry

11 Separation of amino acids by paper chromatography

12 Separation of sugars by thin layer chromatography

13 Separation of plant pigments by column chromatography

14 Demonstration experiment on HPLC

15 Demonstration experiment on Gas Chromatography

**Recommended Books (Latest Editions)**

1. Instrumental Methods of Chemical Analysis by B.K Sharma

2. Organic spectroscopy by Y.R Sharma

3. Text book of Pharmaceutical Analysis by Kenneth A. Connors

4. Vogel’s Text book of Quantitative Chemical Analysis by A.I. Vogel

5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake

6. Organic Chemistry by I. L. Finar

7. Organic spectroscopy byWilliam Kemp

8. Quantitative Analysis of Drugs by D. C. Garrett

9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi

10. Spectrophotometric identification of Organic Compounds by Silverstein

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**BP 702 T. INDUSTRIAL PHARMACYII (Theory)**

**45 Hours**

**Scope:** This course is designed to impart fundamental knowledge on pharmaceutical

product development and translation from laboratory to market

**Objectives:** Upon completion of the course, the student shall be able to:

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms

2. Understand the process of technology transfer from lab scale to commercial batch

3. Know different Laws and Acts that regulate pharmaceutical industry

4. Understand the approval process and regulatory requirements for drug products

**Course Content:**

**UNIT-I 10 Hours**

**Pilot plant scale up techniques:** General considerations - including significance of

personnel requirements, space requirements, raw materials, Pilot plant scale up

considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC

guidelines, Introduction to platform technology

**UNIT-II 10 Hours**

**Technology development and transfer:** WHO guidelines for Technology Transfer(TT):

Terminology, Technology transfer protocol, Quality risk management, Transfer from R

& D to production (Process, packaging and cleaning), Granularity of TT Process (API,

excipients, finished products, packaging materials) Documentation, Premises and

equipments, qualification and validation, quality control, analytical method transfer,

Approved regulatory bodies and agencies, Commercialization - practical aspects and

problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE /

SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs,

legal issues

**UNIT-III 10 Hours**

**Regulatory affairs:** Introduction, Historical overview of Regulatory Affairs, Regulatory

authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs

Professionals

**Regulatory requirements for drug approval:** Drug Development Teams, Non-Clinical

Drug Development, Pharmacology, Drug Metabolism and Toxicology, General

considerations of Investigational New Drug (IND) Application, Investigator’s Brochure

(IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research

Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for

FDA Submissions, Management of Clinical Studies.

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**UNIT-IV 08 Hours**

**Quality management systems:** Quality management & Certifications: Concept of

Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out

of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality

systems standards, ISO 14000, NABL, GLP

**UNIT-V 07 Hours**

**Indian Regulatory Requirements:** Central Drug Standard Control Organization

(CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of

Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for

New Drugs.

**Recommended Books: (Latest Editions)**

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available

at http,//en.wikipedia.org/wiki/Regulatory\_ Affairs.

2. International Regulatory Affairs Updates, 2005. available at

http://www.iraup.com/about.php

3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide

for Prescription Drugs, Medical Devices, and Biologics’ Second Edition.

4. Regulatory Affairs brought by learning plus, inc. available at

http.//www.cgmp.com/ra.htm.

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**BP 703T. PHARMACY PRACTICE (Theory)**

**45 Hours**

**Scope:** In the changing scenario of pharmacy practice in India, for successful practice of

Hospital Pharmacy, the students are required to learn various skills like drug distribution,

drug information, and therapeutic drug monitoring for improved patient care. In

community pharmacy, students will be learning various skills such as dispensing of

drugs, responding to minor ailments by providing suitable safe medication, patient

counselling for improved patient care in the community set up.

**Objectives:** Upon completion of the course, the student shall be able to

1. know various drug distribution methods in a hospital

2. appreciate the pharmacy stores management and inventory control

3. monitor drug therapy of patient through medication chart review and clinical

review

4. obtain medication history interview and counsel the patients

5. identify drug related problems

6. detect and assess adverse drug reactions

7. interpret selected laboratory results (as monitoring parameters in therapeutics) of

specific disease states

8. know pharmaceutical care services

9. do patient counseling in community pharmacy;

10. appreciate the concept of Rational drug therapy.

**Unit I: 10 Hours**

**a) Hospital and it’s organization**

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals,

Classification based on clinical and non- clinical basis, Organization Structure of a

Hospital, and Medical staffs involved in the hospital and their functions.

**b) Hospital pharmacy and its organization**

Definition, functions of hospital pharmacy, Organization structure, Location, Layout

and staff requirements, and Responsibilities and functions of hospital pharmacists.

**c) Adverse drug reaction**

Classifications - Excessive pharmacological effects, secondary pharmacological

effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity

following sudden withdrawal of drugs, Drug interaction- beneficial interactions,

adverse interactions, and pharmacokinetic drug interactions, Methods for detecting

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drug interactions, spontaneous case reports and record linkage studies, and Adverse

drug reaction reporting and management.

**d**) **Community Pharmacy**

Organization and structure of retail and wholesale drug store, types and design, Legal

requirements for establishment and maintenance of a drug store, Dispensing of

proprietary products, maintenance of records of retail and wholesale drug store.

**Unit II: 10 Hours**

**a) Drug distribution system in a hospital**

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy

and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of

controlled drugs.

**b) Hospital formulary**

Definition, contents of hospital formulary, Differentiation of hospital formulary and

Drug list, preparation and revision, and addition and deletion of drug from hospital

formulary.

**c) Therapeutic drug monitoring**

Need for Therapeutic Drug Monitoring, Factors to be considered during the

Therapeutic DrugMonitoring, and Indian scenario for Therapeutic Drug Monitoring.

**d) Medication adherence**

Causes of medication non-adherence, pharmacist role in the medication adherence,

and monitoring of patient medication adherence.

**e) Patient medication history interview**

Need for the patient medication history interview, medication interview forms.

**f) Community pharmacy management**

Financial, materials, staff, and infrastructure requirements.

**Unit III: 10 Hours**

**a) Pharmacy and therapeutic committee**

Organization, functions, Policies of the pharmacy and therapeutic committee in

including drugs into formulary, inpatient and outpatient prescription, automatic stop

order, and emergency drug list preparation.

**b) Drug**

**information services**

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Drug and Poison information centre, Sources of drug information, Computerised

services, and storage and retrieval of information.

**c) Patient**

**counseling**

Definition of patient counseling; steps involved in patient counseling, and Special

cases that require the pharmacist

**d) Education and training program in the hospital**

Role of pharmacist in the education and training program, Internal and external

training program, Services to the nursing homes/clinics, Code of ethics for community

pharmacy, and Role of pharmacist in the interdepartmental communication and

community health education.

**e) Prescribed medication order and communication skills**

Prescribed medication order- interpretation and legal requirements, and

Communication skills- communication with prescribers and patients.

**Unit IV 8 Hours**

**a) Budget**

**preparation and implementation**

Budget preparation and implementation

**b) Clinical Pharmacy**

Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and

responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart

review, clinical review, pharmacist intervention, Ward round participation, Medication

history and Pharmaceutical care.

Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

**c) Over the counter (OTC) sales**

Introduction and sale of over the counter, and Rational use of common over the

counter medications.

**Unit V 7 Hours**

**a) Drug store management and inventory control**

Organisation of drug store, types of materials stocked and storage conditions, Purchase

and inventory control: principles, purchase procedure, purchase order, procurement

and stocking, Economic order quantity, Reorder quantity level, and Methods used for

the analysis of the drug expenditure

**b) Investigational use of drugs**

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Description, principles involved, classification, control, identification, role of hospital

pharmacist, advisory committee.

**c) Interpretation of Clinical Laboratory Tests**

Blood chemistry, hematology, and urinalysis

**Recommended Books (Latest Edition):**

1. Merchant S.H. and Dr. J.S.Quadry. *A textbook of hospital pharmacy*, 4th ed.

Ahmadabad: B.S. Shah Prakakshan; 2001.

2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. *A textbook of Clinical*

*Pharmacy Practice- essential concepts and skills,* 1st ed. Chennai: Orient

Longman Private Limited; 2004.

3. William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger;

1986.

4. Tipnis Bajaj. *Hospital Pharmacy*, 1st ed. Maharashtra: Career Publications; 2008.

5. Scott LT. *Basic skills in interpreting laboratory data*, 4thed*.* American Society of

Health System Pharmacists Inc; 2009.

6. Parmar N.S. *Health Education and Community Pharmacy,* 18th ed. India: CBS

Publishers & Distributers; 2008.

**Journals:**

1. Therapeutic drug monitoring. ISSN: 0163-4356

2. Journal of pharmacy practice. ISSN : 0974-8326

3. American journal of health system pharmacy. ISSN: 1535-2900 (online)

4. Pharmacy times (Monthly magazine)

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**BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)**

**45 Hours**

**Scope:** This subject is designed to impart basic knowledge on the area of novel drug

delivery systems.

**Objectives:** Upon completion of the course student shall be able

1. To understand various approaches for development of novel drug delivery systems.

2. To understand the criteria for selection of drugs and polymers for the development of

Novel drug delivery systems, their formulation and evaluation

**Course content:**

**Unit-I 10 Hours**

**Controlled drug delivery systems**: Introduction, terminology/definitions and rationale,

advantages, disadvantages, selection of drug candidates.Approaches to design controlled

release formulations based on diffusion, dissolution and ion exchange principles.

Physicochemical and biological properties of drugs relevant to controlled release

formulations

**Polymers:** Introduction, classification, properties, advantages and application of

polymers in formulation of controlled release drug delivery systems.

**Unit-II 10 Hours**

**Microencapsulation:** Definition, advantages and disadvantages, microspheres

/microcapsules, microparticles, methods of microencapsulation, applications

**Mucosal Drug Delivery system:** Introduction, Principles of bioadhesion /

mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and

formulation considerations of buccal delivery systems

**Implantable Drug Delivery Systems:**Introduction, advantages and disadvantages,

concept of implantsand osmotic pump

**Unit-III 10 Hours**

**Transdermal Drug Delivery Systems:** Introduction, Permeation through skin, factors

affecting permeation, permeation enhancers, basic components of TDDS, formulation

approaches

**Gastroretentive drug delivery systems:** Introduction, advantages, disadvantages,

approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive

systems and their applications

**Nasopulmonary drug delivery system:** Introduction to Nasal and Pulmonary routes of

drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays,

nebulizers

**Unit-IV 08 Hours**

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**Targeted drug Delivery:** Concepts and approaches advantages and disadvantages,

introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their

applications

**Unit-V 07 Hours**

**Ocular Drug Delivery Systems:** Introduction, intra ocular barriers and methods to

overcome –Preliminary study, ocular formulations and ocuserts

**Intrauterine Drug Delivery Systems:** Introduction, advantages and disadvantages,

development of intra uterine devices (IUDs) and applications

**Recommended Books: (Latest Editions)**

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,

Marcel Dekker, Inc., New York, 1992.

2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,

Inc., New York, 1992.

3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley

Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim

4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors,

New Delhi, First edition 1997 (reprint in 2001).

5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances,

Vallabh Prakashan, New Delhi, First edition 2002.

**Journals**

1. Indian Journal of Pharmaceutical Sciences (IPA)

2. Indian Drugs (IDMA)

3. Journal of Controlled Release (Elsevier Sciences)

4. Drug Development and Industrial Pharmacy (Marcel & Decker)

5. International Journal of Pharmaceutics (Elsevier Sciences)

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**SEMESTERVIII**

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**BP801T. BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)**

**45 Hours**

**Scope:** To understand the applications of Biostatics in Pharmacy. This subject deals with

descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability

theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA,

Introduction to Design of Experiments, Phases of Clinical trials and Observational and

Experimental studies, SPSS, R and MINITAB statistical software’s, analyzing the

statistical data using Excel**.**

**Objectives:** Upon completion of the course the student shall be able to

• Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of

Experiment)

• Know the various statistical techniques to solve statistical problems

• Appreciate statistical techniques in solving the problems**.**

**Course content:**

**Unit-I 10 Hours**

**Introduction:** Statistics, Biostatistics, Frequency distribution

**Measures of central tendency**: Mean, Median, Mode- Pharmaceutical examples

**Measures of dispersion**: Dispersion, Range, standard deviation, Pharmaceutical

problems

**Correlation**: Definition, Karl Pearson’s coefficient of correlation, Multiple correlation -

Pharmaceuticals examples

**Unit-II 10 Hours**

**Regression:** Curve fitting by the method of least squares, fitting the lines y= a + bx and x

= a + by, Multiple regression, standard error of regression– Pharmaceutical Examples

**Probability:**Definition of probability, Binomial distribution, Normal distribution,

Poisson’s distribution, properties - problems

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis,

sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard

error of mean (SEM) - Pharmaceutical examples

**Parametric test**: t-test(Sample, Pooled or Unpaired and Paired) , ANOVA, (One way

and Two way), Least Significance difference

**Unit-III 10 Hours**

**Non Parametric tests:** Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis

test, Friedman Test

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**Introduction to Research:** Need for research, Need for design of Experiments,

Experiential Design Technique, plagiarism

**Graphs:** Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph

**Designing the methodology:** Sample size determination and Power of a study, Report

writing and presentation of data, Protocol, Cohorts studies, Observational studies,

Experimental studies, Designing clinical trial, various phases.

**Unit-IV 8 Hours**

Blocking and confounding system for Two-level factorials

**Regression modeling:** Hypothesis testing in Simple and Multiple regressionmodels

**Introduction to Practical components of Industrial and Clinical Trials Problems**:

Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R -

Online Statistical Software’s to Industrial and Clinical trial approach

**Unit-V 7Hours**

**Design and Analysis of experiments:**

**Factorial Design:** Definition, 22, 23design. Advantage of factorial design

**Response Surface methodology**: Central composite design, Historical design,

Optimization Techniques

**Recommended Books (Latest edition):**

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton,

publisher Marcel Dekker Inc. NewYork.

2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha

3. Design and Analysis of Experiments –PHI Learning Private Limited, R.

Pannerselvam,

4. Design and Analysis of Experiments – Wiley Students Edition,

Douglas and C. Montgomery

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**BP 802T SOCIAL AND PREVENTIVE PHARMACY**

**Hours: 45**

**Scope:**

The purpose of this course is to introduce to students a number of health issues and their

challenges. This course also introduced a number of national health programmes. The

roles of the pharmacist in these contexts are also discussed.

**Objectives:**

After the successful completion of this course, the student shall be able to:

 Acquire high consciousness/realization of current issuesrelated to health and

pharmaceutical problems within the country and worldwide.

 Have a critical way of thinking based on current healthcare development.

 Evaluate alternative ways of solving problems related tohealth and

pharmaceutical issues

**Course content:**

**Unit I: 10 Hours**

**Concept of health and disease:** Definition, concepts and evaluation of public health.

Understanding the concept of prevention and control of disease, social causes of diseases

and social problems of the sick.

**Social and health education:** Food in relation to nutrition and health, Balanced diet,

Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

**Sociology and health:** Socio cultural factors related to health and disease, Impact of

urbanization on health and disease, Poverty and health

**Hygiene and health:** personal hygiene and health care; avoidable habits

**Unit II: 10 Hours**

**Preventive medicine:** General principles of prevention and control of diseases such as

cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken

guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer,

drug addiction-drug substance abuse

**Unit III: 10 Hours**

**National health programs, its objectives, functioning and outcome of the following:**

HIV AND AIDS control programme, TB, Integrated disease surveillance program

(IDSP), National leprosy control programme, National mental health program, National

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programme for prevention and control of deafness, Universal immunization programme,

National programme for control of blindness, Pulse polio programme.

**Unit IV: 08 Hours**

National health intervention programme for mother and child, National family welfare

programme, National tobacco control programme, National Malaria Prevention Program,

National programme for the health care for the elderly, Social health programme; role of

WHO in Indian national program

**Unit V: 07 Hours**

Community services in rural, urban and school health: Functions of PHC, Improvement

in rural sanitation, national urban health mission, Health promotion and education in

school.

**Recommended Books (Latest edition)*:***

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition,

2010, ISBN: 9789380704104, JAYPEE Publications

2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy

Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE

Publications

3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th

Edition, 2014, ISBN: 9789351522331, JAYPEE Publications

4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D,

Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE

Publications

5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011,

ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.

6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

**Recommended Journals:**

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

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**BP803ET. PHARMA MARKETING MANAGEMENT (Theory)**

**Scope:**

**45 Hours**

The pharmaceutical industry not only needs highly qualified researchers, chemists and,

technical people, but also requires skilled managers who can take the industry forward

by managing and taking the complex decisions which are imperative for the growth of the

industry. The Knowledge and Know-how of marketing management groom the people

for taking a challenging role in Sales and Product management.

**Course Objective:** The course aims to provide an understanding of marketing concepts

and techniques and their applications in the pharmaceutical industry.

**Unit I 10 Hours**

**Marketing:**

Definition, general concepts and scope of marketing; Distinction between marketing &

selling; Marketing environment; Industry and competitive analysis; Analyzing consumer

buying behavior; industrial buying behavior.

**Pharmaceutical market:**

Quantitative and qualitative aspects; size and composition of the market; demographic

descriptions and socio-psychological characteristics of the consumer; market

segmentation& targeting.Consumer profile; Motivation and prescribing habits of the

physician; patients' choice of physician and retail pharmacist.Analyzing the Market;Role

of market research.

**Unit II 10 Hours**

**Product decision:**

Classification, product line and product mix decisions, product life

cycle,product portfolio analysis; product positioning; New product decisions; Product

branding, packaging and labeling decisions, Product management in pharmaceutical

industry.

**Unit III 10 Hours**

**Promotion:**

Methods, determinants of promotional mix, promotional budget; An overview of

personal selling, advertising, direct mail, journals, sampling, retailing, medical

exhibition, public relations, online promotional techniques for OTC Products.

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**Unit IV 10 Hours**

**Pharmaceutical marketing channels:**

Designing channel, channel members, selecting the appropriate channel, conflict in

channels, physical distribution management: Strategic importance, tasks in physical

distribution management.

**Professional sales representative (PSR):**

Duties of PSR, purpose of detailing, selection and training, supervising, norms for

customer calls, motivating, evaluating, compensation and future prospects of the PSR.

**Unit V 10 Hours**

**Pricing:**

Meaning, importance, objectives, determinants of price; pricing methods and strategies,

issues in price management in pharmaceutical industry. An overview of DPCO

(Drug Price Control Order)and NPPA (National Pharmaceutical Pricing Authority).

**Emerging concepts in marketing:**

Vertical & Horizontal Marketing; RuralMarketing; Consumerism; Industrial Marketing;

Global Marketing.

**Recommended Books: (Latest Editions)**

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India,

New Delhi

2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata

MC GrawHill, New Delhi.

3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill

4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India

5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)

6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective,

IndianContext,Macmilan India, New Delhi.

7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi

8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel

Publications.

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**BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)**

**45Hours**

**Scope:** This course is designed to impart the fundamental knowledge on the regulatory

requirements for approval of new drugs, and drug products in regulated markets of

India & other countries like US, EU, Japan, Australia,UK etc. It prepares the students

to learn in detail on the regulatory requirements, documentation requirements, and

registration procedures for marketing the drug products.

**Objectives:** Upon completion of the subject student shall be able to;

1. Know about the process of drug discovery and development

2. Know the regulatory authorities and agencies governing the manufacture and sale

of pharmaceuticals

3. Know the regulatory approval process and their registration in Indian and

international markets

**Course content:**

**Unit I 10Hours**

**New Drug Discovery and development**

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical

activities, clinical studies, Innovator and generics, Concept of generics, Generic drug

product development.

**Unit II 10Hours**

**Regulatory Approval Process**

Approval processes and timelines involved in Investigational New Drug (IND), New

Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an

approved NDA / ANDA.

**Regulatory authorities and agencies**

Overview of regulatory authorities of India, United States, European Union, Australia,

Japan, Canada (Organization structure and types of applications)

**Unit III 10Hours**

**Registration of Indian drug product in overseas market**

Procedure for export of pharmaceutical products, Technical documentation, Drug Master

Files (DMF), Common Technical Document (CTD), electronic Common Technical

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Document (eCTD), ASEAN Common Technical Document (ACTD)research.

**Unit IV 08Hours**

**Clinical trials**

Developing clinical trial protocols, Institutional Review Board / Independent Ethics

committee - formation and working procedures, Informed consent process and

procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and

Monitoring clinical trials, Pharmacovigilance - safetymonitoring in clinical trials

**Unit V 07Hours**

**Regulatory Concepts**

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book,

Federal Register, Code of Federal Regulatory, Purple book

**Recommended books (Latest edition):**

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.

2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and

Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health

care Publishers.

3. New Drug Approval Process: Accelerating Global Registrations By Richard A

Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.

4. Guidebook for drug regulatory submissions / SandyWeinberg. By John Wiley &

Sons. Inc.

5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and

biologics /edited by Douglas J. Pisano, David Mantus.

6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and

Isader Kaufer, Marcel Dekker series, Vol.143

7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance

By Fay A. Rozovsky and Rodney K. Adams

8. Principles and Practices of Clinical Research, Second Edition Edited by John I.

Gallin and Frederick P. Ognibene

9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

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**BP 805T: PHARMACOVIGILANCE (Theory)**

**45 hours**

**Scope:** This paper will provide an opportunity for the student to learn about development of

pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario

of Pharmacovigilance, train students on establishing pharmacovigilance programme in an

organization, various methods that can be used to generate safety data and signal detection. This

paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

**Objectives:**

*At completion of this paper it is expected that students will be able to (know, do, and*

*appreciate):*

1. Why drug safety monitoring is important?

2. History and development of pharmacovigilance

3. National and international scenario of pharmacovigilance

4. Dictionaries, coding and terminologies used in pharmacovigilance

5. Detection of new adverse drug reactions and their assessment

6. International standards for classification of diseases and drugs

7. Adverse drug reaction reporting systems and communication in pharmacovigilance

8. Methods to generate safety data during pre clinical, clinical and post approval phases of

drugs’ life cycle

9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation

10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India

11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning

12. CIOMS requirements for ADR reporting

13. Writing case narratives of adverse events and their quality.

**Course Content**

**Unit I 10 Hours**

**Introduction to Pharmacovigilance**

 History and development of Pharmacovigilance

 Importance of safety monitoring of Medicine

 WHO international drug monitoring programme

 Pharmacovigilance Program of India(PvPI)

**Introduction to adverse drug reactions**

 Definitions and classification of ADRs

 Detection and reporting

 Methods in Causality assessment

 Severity and seriousness assessment

 Predictability and preventability assessment

 Management of adverse drug reactions

**Basic terminologies used in pharmacovigilance**

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 Terminologies of adverse medication related events

 Regulatory terminologies

**Unit II 10 hours**

**Drug and disease classification**

 Anatomical, therapeutic and chemical classification of drugs

 International classification of diseases

 Daily defined doses

 International Non proprietary Names for drugs

**Drug dictionaries and coding in pharmacovigilance**

 WHO adverse reaction terminologies

 MedDRA and Standardised MedDRA queries

 WHO drug dictionary

 Eudravigilance medicinal product dictionary

**Information resources in pharmacovigilance**

 Basic drug information resources

 Specialised resources for ADRs

**Establishing pharmacovigilance programme**

 Establishing in a hospital

 Establishment & operation of drug safety department in industry

 Contract Research Organisations (CROs)

 Establishing a national programme

**Unit III 10 Hours**

**Vaccine safety surveillance**

 Vaccine Pharmacovigilance

 Vaccination failure

 Adverse events following immunization

**Pharmacovigilance methods**

 Passive surveillance – Spontaneous reports and case series

 Stimulated reporting

 Active surveillance – Sentinel sites, drug event monitoring and registries

 Comparative observational studies – Cross sectional study, case control study and

cohort study

 Targeted clinical investigations

**Communication in pharmacovigilance**

 Effective communication in Pharmacovigilance

 Communication in Drug Safety Crisis management

 Communicating with Regulatory Agencies, Business Partners, Healthcare facilities &

Media

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**Unit IV 8 Hours**

**Safety data generation**

 Pre clinical phase

 Clinical phase

 Post approval phase (PMS)

**ICH Guidelines for Pharmacovigilance**

 Organization and objectives of ICH

 Expedited reporting

 Individual case safety reports

 Periodic safety update reports

 Post approval expedited reporting

 Pharmacovigilance planning

 Good clinical practice in pharmacovigilance studies

**Unit V 7 hours**

**Pharmacogenomics of adverse drug reactions**

 Genetics related ADR with example focusing PK parameters.

**Drug safety evaluation in special population**

 Paediatrics

 Pregnancy and lactation

 Geriatrics

**CIOMS**

 CIOMS Working Groups

 CIOMS Form

**CDSCO (India) and Pharmacovigilance**

 D&C Act and Schedule Y

 Differences in Indian and global pharmacovigilance requirements

**Recommended Books (Latest edition):**

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.

2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and

Bartlett Publishers.

3. Mann's Pharmacovigilance:Elizabeth B. Andrews, Nicholas, Wiley Publishers.

4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle,

Wiley Publishers.

5. An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.

6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert,Jones&

Bartlett Publishers.

7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel,

Sean Hennessy,Wiley Publishers.

8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G.

Parthasarathi, Karin NyfortHansen,Milap C. Nahata

9. National Formulary of India

10. Text Book of Medicine by Yashpal Munjal

11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK

Manna

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12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn

3=7297

13. http://www.ich.org/

14. http://www.cioms.ch/

15. http://cdsco.nic.in/

16. http://www.who.int/vaccine\_safety/en/

17. http://www.ipc.gov.in/PvPI/pv\_home.html

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**BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS**

**(Theory)**

**Scope:** In this subject the student learns about the various methods and guidelines for

evaluation and standardization of herbs and herbal drugs. The subject also provides an

opportunity for the student to learn cGMP, GAP and GLP in traditional system of

medicines.

**Objectives:** Upon completion of the subject student shall be able to;

1. know WHO guidelines for quality control of herbal drugs

2. know Quality assurance in herbal drug industry

3. know the regulatory approval process and their registration in Indian and

international markets

4. appreciate EU and ICH guidelines for quality control of herbal drugs

**Unit I 10 hours**

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage

forms

WHO guidelines for quality control of herbal drugs.

Evaluation of commercial crude drugs intended for use

**Unit II 10 hours**

**Quality assurance in herbal drug industry** of cGMP, GAP, GMP and GLP in

traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines

WHO Guidelines on GACP for Medicinal Plants.

**Unit III 10 hours**

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

**Unit IV 08 hours**

Stability testing of herbal medicines.Application of various chromatographic techniques

in standardization of herbal products.

Preparation of documents for new drug application and export registration

GMP requirements and Drugs & Cosmetics Act provisions.

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**Unit V 07 hours**

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

**Recommended Books: (Latest Editions**

1. Pharmacognosy by Trease and Evans

2. Pharmacognosy by Kokate, Purohit and Gokhale

3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier

Pub., 2006.

4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.

5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal

Products,

6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of

Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control

principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.

8. WHO. Quality Control Methods for Medicinal Plant Materials,World Health

Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal

Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO

Regional office for the Western Pacific, Manila, 1998.

9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn.

World Health Organization, Geneva, 1981.

10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health

Organization, Geneva, 1999.

11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative

Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health

Organization, Geneva, 2005.

12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for

Medicinal Plants. World Health Organization, Geneva, 2004.

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**BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)**

**45 Hours**

**Scope:** This subject is designed to provide detailed knowledge of rational drug design

process and various techniques used in rational drug design process.

**Objectives:** Upon completion of the course, the student shall be able to understand

 Design and discovery of lead molecules

 The role of drug design in drug discovery process

 The concept of QSAR and docking

 Various strategies to develop new drug like molecules.

 The design of new drug molecules using molecular modeling software

**Course Content:**

**UNIT-I 10 Hours**

**Introduction to Drug Discovery and Development**

Stages of drug discovery and development

**Lead discovery and Analog Based Drug Design**

Rational approaches to lead discovery based on traditional medicine,

Random screening, Non-random screening, serendipitous drug discovery,

lead discovery based on drug metabolism, lead discovery based on

clinical observation.

**Analog Based Drug Design:**Bioisosterism, Classification, Bioisosteric

replacement. Any three case studies

**UNIT-II 10 Hours**

**Quantitative Structure Activity Relationship (QSAR)**

SAR versus QSAR, History and development of QSAR, Types of

physicochemical parameters, experimental and theoretical approaches for

the determination of physicochemical parameters such as Partition

coefficient, Hammet’s substituent constant and Tafts steric constant.

Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like

COMFA and COMSIA.

**UNIT-III 10 Hours**

**Molecular Modeling and virtual screening techniques**

**Virtual Screening techniques:** Drug likeness screening, Concept of

pharmacophore mapping and pharmacophore based Screening,

**Molecular docking**: Rigid docking, flexible docking, manual docking,

Docking based screening. *De novo* drug design.

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**UNIT-IV 08 Hours**

**Informatics & Methods in drug design**

Introduction to Bioinformatics, chemoinformatics. ADME databases,

chemical, biochemical and pharmaceutical databases.

**UNIT-V 07 Hours**

**Molecular Modeling:** Introduction to molecular mechanics and quantum

mechanics.Energy Minimization methods and Conformational Analysis,

global conformational minima determination.

**Recommended Books (Latest Editions)**

1. Robert GCK, ed., “Drug Action at the Molecular Level” University Prak Press Baltimore.

2. Martin YC. “Quantitative Drug Design” Dekker, New York.

3. Delgado JN, Remers WA eds “Wilson & Gisvolds’s Text Book of Organic

Medicinal & Pharmaceutical Chemistry” Lippincott, New York.

4. Foye WO “Principles of Medicinal chemistry ‘Lea & Febiger.

5. Koro lkovas A, Burckhalter JH. “Essentials of Medicinal Chemistry” Wiley

Interscience.

6. Wolf ME, ed “The Basis of Medicinal Chemistry, Burger’s Medicinal Chemistry”

JohnWiley& Sons, New York.

7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University

Press.

8. Smith HJ, Williams H, eds, “Introduction to the principles of Drug Design”

Wright Boston.

9. Silverman R.B. “The organic Chemistry of Drug Design and Drug Action”

Academic Press New York.

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**BP808ET: CELL AND MOLECULAR BIOLOGY (Elective subject)**

**45 Hours**

**Scope:**

 Cell biology is a branch of biology that studies cells – their physiological

properties, their structure, the organelles they contain, interactions with their

environment, their life cycle, division, death and cell function.

 This is done both on a microscopic and molecular level.

 Cell biology research encompasses both the great diversity of single-celled

organisms like bacteria and protozoa, as well as the many specialized cells in

multi-cellular organismssuch as humans, plants, and sponges.

**Objectives:** Upon completion of the subject student shall be able to;

 Summarize cell and molecular biology history.

 Summarize cellular functioning and composition.

 Describe the chemical foundations of cell biology.

 Summarize the DNA properties of cell biology.

 Describe protein structure and function.

 Describe cellular membrane structure and function.

 Describe basic molecular genetic mechanisms.

 Summarize the Cell Cycle

**Course content:**

**Unit I 10Hours**

a) Cell and Molecular Biology: Definitions theory and basics and Applications.

b) Cell and Molecular Biology: History and Summation.

c) Properties of cells and cell membrane.

d) Prokaryotic versus Eukaryotic

e) Cellular Reproduction

f) Chemical Foundations – an Introduction and Reactions (Types)

**Unit II 10 Hours**

a) DNA and the Flow of Molecular Information

b) DNA Functioning

c) DNA and RNA

d) Types of RNA

e) Transcription and Translation

**Unit III 10 Hours**

a) Proteins: Defined **and** Amino Acids

b) Protein Structure

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c) Regularities in Protein Pathways

d) Cellular Processes

e) Positive Control and significance of Protein Synthesis

**Unit IV 08 Hours**

a) Science of Genetics

b) Transgenics and Genomic Analysis

c) Cell Cycle analysis

d) Mitosis and Meiosis

e) Cellular Activities and Checkpoints

**Unit V 07 Hours**

a) Cell Signals: Introduction

b) Receptors for Cell Signals

c) Signaling Pathways: Overview

d) Misregulation of Signaling Pathways

e) Protein-Kinases: Functioning

**Recommended Books (latest edition):**

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific

publications, Oxford London.

2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers &

Distributors, Delhi.

3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.

4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.

5. Rose: Industrial Microbiology.

6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan

7. Cooper and Gunn’s: Tutorial Pharmacy, CBS Publisher and Distribution.

8. Peppler: Microbial Technology.

9. Edward: Fundamentals of Microbiology.

10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi

11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly

company

12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and

Applications of RecombinantDNA: ASM Press Washington D.C.

13. RA Goldshy et. al., : Kuby Immunology.

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**BP809ET. COSMETIC SCIENCE(Theory)**

**45Hours**

**UNIT I 10Hours**

Classification of cosmetic and cosmeceutical products

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals

from cosmetics, cosmetics as quasi and OTC drugs

**Cosmetic excipients:** Surfactants, rheologymodifiers, humectants, emollients,

preservatives. Classification and application

**Skin:** Basic structure and function of skin.

**Hair:** Basic structure of hair. Hair growth cycle.

**Oral Cavity:** Common problem associated with teeth and gums**.**

**UNIT II 10 Hours**

**Principles of formulation and building blocks of skin care products:**

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream and their advantages and

disadvantages.Application of these products in formulation of cosmecuticals.

**Antiperspants & deodorants**- Actives & mechanism of action.

**Principles of formulation and building blocks of Hair care products:**

Conditioning shampoo, Hair conditioner,anti-dandruff shampoo.

Hair oils.

Chemistry and formulation of Para-phylene diamine based hair dye.

Principles of formulation and building blocks of oral care products:

Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

**UNIT III 10 Hours**

Sun protection, Classification of Sunscreens and SPF.

**Role of herbs in cosmetics:**

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

**Analytical cosmetics:** BIS specification and analytical methods for shampoo, skincream

and toothpaste**.**

**UNIT IV 08 Hours**.

Principles of Cosmetic Evaluation:Principles of sebumeter, corneometer. Measurement

of TEWL, Skin Color, Hair tensile strength, Hair combing properties

Soaps,and syndet bars. Evolution and skin benfits.

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**UNIT V 07 Hours**

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of

the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes

Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and

body odor.

Antiperspirants and Deodorants- Actives and mechanism of action

**References**

1) Harry’s Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.

2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th

Edition, Vandana Publications Pvt. Ltd., Delhi.

3) Text book of cosmelicology by Sanju Nanda & Roop K. Khar, Tata Publishers.

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**BP810 ET. PHARMACOLOGICAL SCREENINGMETHODS**

**45 Hours**

**Scope:**This subject is designed to impart the basic knowledge of preclinical studies in

experimental animals including design, conduct and interpretations of results.

**Objectives**

Upon completion of the course the student shall be able to,

 Appreciate the applications of various commonly used laboratory animals.

 Appreciate and demonstrate the various screening methods used in preclinical

research

 Appreciate and demonstrate the importance of biostatistics and researchmethodology

 Design and execute a research hypothesis independently

**Unit –I 08 Hours**

**Laboratory Animals:**

Study of CPCSEA and OECD guidelines for maintenance, breeding

and conduct of experiments on laboratory animals, Common lab

animals: Description and applications of different species and strains

of animals. Popular transgenic and mutant animals.

Techniques for collection of blood and common routes of drug

administration in laboratory animals, Techniques of blood collection

and euthanasia.

**Unit –II 10 Hours**

**Preclinical screening models**

a. Introduction: Dose selection, calculation and conversions,

preparation of drug solution/suspensions, grouping of animals and

importance of sham negative and positive control groups.

Rationale for selection of animal species and sex for the study.

b. **Study of screening animal models for**

Diuretics, nootropics, anti-Parkinson’s,antiasthmatics,

**Preclinical screening models:** for CNS activity- analgesic,

antipyretic,anti-inflammatory, general anaesthetics, sedative and

hypnotics, antipsychotic, antidepressant, antiepileptic,

antiparkinsonism, alzheimer’s disease

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**Unit –III**

**Preclinical screening models:** for ANS activity, sympathomimetics,

sympatholytics, parasympathomimetics, parasympatholytics, skeletal

muscle relaxants, drugs acting on eye, local anaethetics

**Unit –IV**

**Preclinical screening models:** for CVS activity- antihypertensives,

diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory,

coagulants, and anticoagulants

Preclinical screening models for other important drugs like antiulcer,

antidiabetic, anticancer and antiasthmatics.

**Research methodology and Bio-statistics**

Selection of research topic, review of literature, research hypothesis

and study design

Pre-clinical data analysis and interpretation using Students ‘t’ test

and One-way ANOVA. Graphical representation of data

**05Hours**

**Recommended Books (latest edition):**

1. Fundamentals of experimental Pharmacology-byM.N.Ghosh

2. Hand book of Experimental Pharmacology-S.K.Kulakarni

3. CPCSEA guidelines for laboratory animal facility.

4. Drug discovery and Evaluation by Vogel H.G.

5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta

6. Introduction to biostatistics and research methods by PSS Sundar Rao and J

Richard

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**BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES**

**45 Hours**

**Scope:** This subject deals with the application of instrumental methods in qualitative and

quantitative analysis of drugs. This subject is designed to impart advanced knowledge on

the principles and instrumentation of spectroscopic and chromatographic hyphenated

techniques. This also emphasizes on theoretical and practical knowledge on modern

analytical instruments that are used for drug testing.

**Objectives:**Upon completion of the course the student shall be able to

 understand the advanced instruments used and its applications in drug analysis

 understand the chromatographic separation and analysis of drugs.

 understand the calibration of various analytical instruments

 know analysis of drugs using various analytical instruments.

**Course Content:**

**UNIT-I 10 Hours**

**Nuclear Magnetic Resonance spectroscopy**

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical

shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and

applications

**Mass Spectrometry**- Principles, Fragmentation, Ionization techniques –

Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of

flight and Quadrupole, instrumentation, applications

**UNIT-II 10 Hours**

**Thermal Methods of Analysis**: Principles, instrumentation and applications

of ThermogravimetricAnalysis (TGA), Differential Thermal Analysis (DTA),

Differential Scanning Calorimetry (DSC)

**X-Ray Diffraction Methods:** Origin of X-rays, basic aspects of crystals, Xray

Crystallography, rotating crystal technique, single crystal diffraction,powder

diffraction, structural elucidation and applications.

**UNIT-III 10 Hours**

**Calibration and validation-**as per ICH and USFDA guidelines

**Calibration of following Instruments**

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer,

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Fluorimeter, Flame Photometer, HPLC and GC

**UNIT-IV 08 Hours**

**Radio immune assay:**Importance, various components, Principle, different

methods, Limitation and Applications of Radio immuno assay

**Extraction techniques**:General principle and procedure involved in the solid

phase extraction and liquid-liquid extraction

**UNIT-V 07 Hours**

**Hyphenated techniques**-LC-MS/MS, GC-MS/MS, HPTLC-MS.

**Recommended Books (Latest Editions)**

1. Instrumental Methods of Chemical Analysis by B.K Sharma

2. Organic spectroscopy by Y.R Sharma

3. Text book of Pharmaceutical Analysis by Kenneth A. Connors

4. Vogel’s Text book of Quantitative Chemical Analysis by A.I. Vogel

5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake

6. Organic Chemistry by I. L. Finar

7. Organic spectroscopy byWilliam Kemp

8. Quantitative Analysis of Drugs by D. C. Garrett

9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi

10. Spectrophotometric identification of Organic Compounds by Silverstein

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**BP 812 ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS**

**No. of hours :3 Tutorial:1 Credit point:4**

**Scope :**

This subject covers foundational topic that are important for understanding the need and

requirements of dietary supplements among different groups in the population.

**Objective:**

This module aims to provide an understanding of the concepts behind the theoretical

applications of dietary supplements. By the end of the course, students should be able to :

1. Understand the need of supplements by the different group of people to maintain

healthy life.

2. Understand the outcome of deficiencies in dietary supplements.

3. Appreciate the components in dietary supplements and the application.

4. Appreciate the regulatory and commercial aspects of dietary supplements including

health claims.

**UNIT I 07 hours**

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification

of Nutraceuticals, Health problems and diseases that can be prevented or cured by

Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis,

hypertension etc.

b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition

education in community.

c. Source, Name of marker compounds and their chemical nature, Medicinal uses and

health benefits of following used as nutraceuticals/functional foods: Spirulina,

Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

**UNIT II 15 hours**

Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature

medicinal benefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin

b) Sulfides: Diallyl sulfides, Allyl trisulfide.

c) Polyphenolics: Reservetrol

d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones

e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum

f) Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans

g) Tocopherols

h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats,

wheat bran, rice bran, sea foods, coffee, tea and the like.

**UNIT III 07 hours**

a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free

radicals in cells, damaging reactions of free radicals on lipids, proteins,

Carbohydrates, nucleic acids.

b) Dietary fibres and complex carbohydrates as functional food ingredients..

**UNIT IV 10 hours**

a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer,

Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage,

muscle damage. Free radicals involvement in other disorders. Free radicals theory of

ageing.

b) Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant

defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione

Vitamin C, Vitamin E, α- Lipoic acid, melatonin

Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.

c) Functional foods for chronic disease prevention

**UNIT V 06 hours**

a) Effect of processing, storage and interactions of various environmental factors on the

potential of nutraceuticals.

b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food

Safety. Adulteration of foods.

c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

**References:**

1. Dietetics by Sri Lakshmi

2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and

P.Faizal: BSPunblication.

3. Advanced Nutritional Therapies by Cooper. K.A., (1996).

4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).

5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn.,

Avery Publishing Group, NY (1997).

6. G. Gibson and C.williams Editors *2000 Functional foods* Woodhead Publ.Co.London.

7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.

8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good

Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional*

*Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.

9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)

10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth

edition. Lea and Febiger

**Semester VIII – Elective course on Pharmaceutical Product Development**

**No of Hours: 3 Tutorial:1 Credit points:4**

**Unit-I 10 Hours**

Introduction to pharmaceutical product development, objectives, regulations related to

preformulation, formulation development, stability assessment, manufacturing and

quality control testing of different types of dosage forms

**Unit-II 10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development

with a special reference to the following categories

i. Solvents and solubilizers

ii. Cyclodextrins and their applications

iii. Non - ionic surfactants and their applications

iv. Polyethylene glycols and sorbitols

v. Suspending and emulsifying agents

vi. Semi solid excipients

**Unit-III 10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development

with a special reference to the following categories

i. Tablet and capsule excipients

ii. Directly compressible vehicles

iii. Coat materials

iv. Excipients in parenteral and aerosols products

v. Excipients for formulation of NDDS

Selection and application of excipients in pharmaceutical formulations with specific

industrial applications

**Unit-IV 08 Hours**

Optimization techniques in pharmaceutical product development.A study of various

optimization techniques for pharmaceutical product development with specific

examples.Optimization by factorial designs and their applications.A study of QbD and its

application in pharmaceutical product development.

**Unit-V 07 Hours**

Selection and quality control testing of packaging materials for pharmaceutical product

development- regulatory considerations.

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**Recommended Books (Latest editions)**

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton,

CharlesBon; Marcel Dekker Inc.

2. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third

Edition,Informa Healthcare publishers.

3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman

andLeon Lachman; Marcel Dekker, Inc.

4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop

kKhar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors

Pvt.Ltd. 2013.

5. Martin’s Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by

Patrick J. Sinko, BI Publications Pvt. Ltd.

6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and

R. K.Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.

7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr.,

Nicholas B.Popovich, Howard C. Ansel, 9th Ed. 40

8. Aulton’s Pharmaceutics – The Design and Manufacture of Medicines, Michael E.

Aulton,3rd Ed.

9. Remington – The Science and Practice of Pharmacy, 20th Ed.

10. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman

andJoseph B. Schwartz

11. Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman,

Martin, M.R and Gilbert S. Banker.

12. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis

andH.A. Libermann.

13. Advanced Review Articles related to the topics.

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