

Unit-II whole sale and Retail sale of drugs.

Whole sale :- whole sale of drug is selling drugs to a person who can sell it again.

- for whole sale of drug, a person requires license from License Authority

- separate license needs to be issued for drugs of C.I.C. & X and drugs other than C.I.C.

X

Applications for license to sell drugs by wholesaler:-

- Application for grant or renewal of a license to sell by wholesale should be made to Licensing Authority in form IGAH with fee of Rupees 500.

- Application for the license for Schedule C & C changes in form IBB.
- Application for others license for drug use filled by 20BB.

Records of purchase of a drug intended for Resale or Sold by wholesale :-

- Date of Purchase
- Name, Address & the No of Relevant license Held by the person from who purchased

- The name of drug, the quantity & batch no.
- The name of Manufacturers of drug.
- Purchase Bills including cash or credit memo should be serially No. by the licensee & maintained.

conditions of licence:-

- An adequate premises for storage of drugs atleast 10 sq m with all the required facilities.

- The storage should be under Maintenance of a Registered pharmacist.
- drugs are sold only to a licensed Retail sellers.

- drugs cannot be sold to a Medical Institute Hospital Research Institute

- Records of drug purchased & sale needs to be Maintained for 3 yrs from date of sale & purchase.

- License should be displayed on premises.

Condition of Biological Clr. of wholesale

- Adequate Premises, with greater than 1am² area with proper storage facility.
- drug sold only to Retailer Having license!
- Premises should be in charge of Reg. Pharmacist
- Record of purchase & sale
 - should be Maintained for 3 yrs from date of issue
- license should displayed on premises
- conditions or classes of drug prohibited for whole sale:
 - misbranded, spurious & adulterated drugs & drugs not of standard quality,
 - Any patent medicine
 - Any drug which claims to cure or prevent any disease or ailments as described in schedule J
 - Any drug manu. as imposed in contravention to the act.

Page No. _____
Date _____

Packaging of Patent Medicines

- Patent medicines should be imported in container intended for retail sales after getting a written permission from licensing authority at least 3 months prior to date of import and imports use made within a period of 12 months from the date of issue such permission for retail sale of imported drug.
- Pack size of retail drug should be prescribed in schedule P1.
- These are 2 types of license for retail sale.
 1. general license
 2. Restricted license
- Drug whose date of expiry has been over.
- drug intended for supply to central govt Health scheme or govt. Hospital institution.
- physician sample.

Page No. 16
Date _____

Retail Sale: - Retail sale means a sale to a Hospital or dispensary, or a medical educational or Research Institute or to any other person other than a sale by way of wholesale dealing."

- All categories of drugs are sold under this license.
- scheduled c/c drugs
 - scheduled x drugs
 - drugs other than c/c ex
- Conditions :-
1. Adequate premises that fulfill all the requirements of 'pharmacy' as per Schedule N
 2. If any change in staff members, it should be reported to authority
 3. License should be displayed on premises
 4. Money belonging to c/c category should be stored properly
 5. Sale of schedule x drug should be recorded separately on Register.
 6. Veterinary drug should be stored separately as it must have a label only for clinical use!
 7. Expired drugs should not be stocked / selected

- a. Money should be sold only to prescription Holders.
1. If the drugs are given loose, others than Bulk packaging, envelope must have name of drug, quantity, storage conditions and Name & Address of pharmacy.

"Restricted License"

- Issued to an Applicant without fixed premises and qualified staff to dispense or compound drug.

- drugs belonging to schedule c/c ex are not sold under Restricted license.

- 'Restricted license' - issued to an applicant without fixed premises and qualified staff to dispense or compound drug

The license granted subject to following conditions:-

- must have adequate premises & facilities for proper storage of drugs and under the supervision of qualified person.

- Licensee must fulfil requirement as per schedule N
- Must obtain the permission to sale
- addition categories of drug.
- C.R.A. & Schedule drug.
- Must maintain records of sale.
- Must allow in respect to inspect.
- Must allow in respect to check the records the promises and to check the records.
- Licensee must inform to licensing authority about change in qualified staff.
- [Prosecution must taken during storage of controlled drugs.]

Rule of Schedule I & Schedule II drugs

- 1) drugs specified in schedule I & II should be sold only on prescription of RMP
- 2) in case of such drug
 - prescription should be duplicate & should return for 2 yrs.
- 3) sign of customer with witness on cash & credit bill
- 4) Maintained Register of sell & purchase to upto date.

5) at a time of supply in register

- 1) date of supply
 - 2) bill no
 - 3) Name of drugs, its manufacturers name & batch no.
 - 4) Name & address of purchaser
 - 5) date of prescription & address of RMP
 - 6) sign of pharmacist in supervision of supply is made.
- mentioned in Register

- offences & Penalties of sale of drugs

offence	imprisonment	Penalty
	lifelong	₹ 1000

sale, stocking, exhibition or offers for sale of drugs likely to cause death or grievous	imprisonment	fine
--	--------------	------

Hurt as per sec. 320

sale, stocking, exhibition or offers of sale of adulterated drug	1-3 year (1st conviction) or 2-6 year (2nd) or subsequent	≥ ₹ 5000 or ₹ 10,000 (subsec.)
--	---	--------------------------------------

sale, stocking, exhibition or offer of sale of spurious drug	8-5 yrs (1st conviction) or 10 yrs (subsec.)	≥ ₹ 50000
--	---	-----------

①

Pharmaceuticals & "J.P". "B.P". "D.S.P" etc.

Page No. 19
Date

failure to keep records upto 1428 upto 1000

or disclosed required information

use of govt. analyst upto 10 yrs upto 2000

Report or C.R. Report for advertising

• Labelling & Packing of drugs

⇒ general Labelling Requirements :-

① Name of drug along with trade name,

e.g.,
Pacetamol 1P-tablets
metam-tablets

② Net quantity - i.e., 10 tabs or 20 ml liquid dosage or 50 gm powder etc.

⇒ Special Labelling Requirements :-

① for C.I.C. drugs → ① Potency in units (biological products) ② Toxicity tested passed

② quantity per unit tablet
- " per 15 ml oral syrup
- " per millilitres of Paracetamol dose

③ for Schedule A drugs → caution!

"Intoxicant" It is dangerous to

e.g.,
Sunpharma Ltd
Halal Syr Lc No. 45

"extosomal use" → No caution required

- ② Schedule H :- (i) for "internal use" e.g.
drugs not in Range of
Narcotic & Psychotropic

drugs

- (ii) - for "internal use" (i) Rx on top of
But in Range of Narcotic (ii) left corner
e.g. Psychotropic drug

(iii) Scheduled - H-drug

↳ 'N.Rx' on top left corner (i) (ii)

Points same (iii) warning:- To be

sold at retail only

or, Prescription of Rx

- (iv) for "external use"
→ "only for external use"

- ③ Scheduled & → "internal use" → 'N.Rx' on top
drugs left corner

- schedule x-drugs

→ external use:-
"only for external" - warning:- Not to be

sold on Retail without
use"

Prescription of Rx.

- ④ Ophthalmic Proprietary → solid suspension → use it within a

ointment opening of container

- Not for injection

- caution:- If irritation occurs stop the use &
consult a physician

- keep the container tightly closed

- do not touch the tip of container

⑤ Labelling of Homoeopathic Medicines.

⇒ Label contains word Homoeopathic medicine
- Name of Medicine or drug specified in
Homoeopathic pharmacopoeias of India, US etc.

- Potency of medicine

- In case of Homoeopathic Medicine, contains
2 or more ingredients. Name & their
individual potency should mention in

Metric system.

- Name & Address of manufacturer.

- If contain alcohol, the alcohol content
in % volume in terms of ethyl alcohol

should be stated on label.

⑥ Labelling of Ayurvedic & Siddha & unani drugs

⇒ The labelling of Ayurvedic, Siddha & unani
drugs as follows.

- Should contain true list of all ingredients with
Botanical name of plant used ingredients
along with plant parts.

- quantity of each ingredient

- Reference method of preparation - detailed in

standard text

- if provided list of ingredients contained
in the medicine is large, can't enumerate
detailed on label.

An example of a procedure type of ^{Part No. 21}
 Intended to be studied by experts of ^{Date}
 Schedule

- Then, addition information should be

Enclosed with packing

=> If it is made up from substance
 Mention in schedule (c) that label
 contain cautions-

+ be taken under Medical supervision
 in both Hindi & English language

② Labelling of cosmetics:-

1) On both inner & outer label should indicate

- Name of cosmetic
- Name & Address of manufacturer

2) outer label :- indicate net content of

Packaging

inner label :- proper direction of safe use

- Wearing, caution,
- Special direction

According cosmetic & their ingredients

3) It should indicates

- Batch No

- Month & year of mfg
- Mfg lic No.

4) some general labelling requires to it.

Specimen labels for drugs & remedies

All the details mentioned on the container's label & it should be properly visible on the inner most container having the drug to present by every following coloring in which the contained is packed.

=> draw the format of it according to me in exam.

Packing of drug :-

1) Schedule X :- + 100 unit doses in case of tub capsule drug - 300 ml in case of liquid oral prep

- 5ml in injection

2) Biological :- if imported ^{as} imported - imported drug - dispersed drug

cfc

List of permitted colour :-

- only natural colouring agent are permitted under

- rule 26 of prosecution of food adulteration

1955

- H.C. section 3 of drug cosmetics Act, 1940

- Rule 197 of drug & cosmetics Rules, 1945
 will be used for Approved, standard, & unapproved drugs.

- Preservatives & coloring Agent should be
mentioned on label

e.g. specified colour in drug & cosmetic, etc.

① Natural colour

e.g. Annatto, chlorophyll,
carotene, Red oxide of iron,

Yellow oxide of iron,
Titanium oxide

Black oxide of iron.

Titanium dioxide.

Black oxide of iron.

② Artificial colour

e.g. curcumin,
Riboflavin

③ Coal-tar colour

e.g. N.C.,
fast green

F.C.F - 42053

Yellow

sun set yellow FCF - 15985

Red
Erythrosine - 15430

orange

Orange or - 16230.

Offences & Penalties of Labelling & Packaging

Offences

Penalty

Imprisonment

Adulterated drug (sec 17-A)

14 days imprisonment
or 10,000/-

Sprinkler drug (sec 17-B) used by person cause death or

5 yrs imprisonment or 3 yrs

Harm of Body

Not referred to in sec 17-A
imprisonment 5 yrs

Any drug deemed to be adulterated sec 17-A

imprisonment 5 yrs

Not referred to in sec 17-A

imprisonment 5 yrs

Penalty for non-disclosure of Name of manufacturer

14220 1000/-

Penalty for not keeping record, etc, or non-

disclosure of information

Penalty for use of draft

14220 1000/-

Penalty for Manufacture, Advertiser's Report for Advertising

34200 5000/-

Penalty for Manufacture, labelling of drug or cosmetics

34200 5000/-

Penalty for Manufacture, Advertiser's Report for Advertising

34200 5000/-

Penalty for Manufacture, Advertiser's Report for Advertising

34200 5000/-

Penalty for Manufacture, Advertiser's Report for Advertising

34200 5000/-

Penalty for Manufacture, Advertiser's Report for Advertising

34200 5000/-

Penalty for Manufacture, Advertiser's Report for Advertising

34200 5000/-

Administration Bodies of D&C Act :-

Date _____
Page No. 23
Date _____

(A) Advisory Board :-

- drug technical advisory board - DTAB
- drug committee
- drug consulting committee

(B) Analytical Board :-

- central drug laboratory
- drug control laboratory
- govt. analyst

(C) executives Board :-

- licensing Authorities
- controlling Authorities
- drug inspectors
- customs collection.

DIAB :- drug technical Advisory Board :-

- It is constituted by central govt

constitution :- formed by 105 members

- A pharmacology teacher from any university or college elected by elective committee of PCI.

3 → ex-officio

5 → nominated

5 → elected

- A medicine teacher from any university or college elected by elective committee of MCI.

- 2 use nominated that are in charge of drug control in states.
- 2 use govt. Analyst
- one person from pharmaceutical industry is nominated by central govt

Nominated - 5

ex-officio :-

- 1) director general of health services - chairman

- 2) drug controllers of India - member
- secretary

- 1) director general of health services - chairman
- 2) drug controllers of India - member
- secretary

(4) one person is elected by Indian Council of Medical Association.

(5) one pharmacologist is elected by Indian Council of Medical Research.

functions of DTAB :-

- (1) It gives advice to central & state govt on technical matters.
- (2) It makes changes of amendment in act after consulting with Govt.

Note:-

1. Nominated & elected members hold the office for 3 yrs & also eligible for re-nomination & re-election.
2. Central Govt appoints a secretary of Board and other legal stuff.
3. Board also appoint sub-committees & may appoint persons who are not Board member either temp or period not exceeding 3 yrs.

through consultative committee (CC)

It is constituted by the central govt in order to secure uniformity in act throughout India.

It also called as Advisory committee for the central & state govt & the DTB.

constitution:-

- ① two representative from ^{central} state govt.
- ② one representative (nominee) of each state govt.

functions:-

- ① To advise the central govt, state govt & draw Technical Advisory Board on any other matters tending to secure uniformity throughout India.
- ② Draws consultative committee shall meet when required.
- ③ It has power to regulate its own procedure.

Central drug laboratory - CDL :-

The central drug laboratory established in Calcutta under the control of director appointed by govt.

Central govt.

- In every state has laboratory for analysis and testing of drugs & cosmetics manufactured or sold in particular area.

- These laboratories use busy in analysis of samples sent by D.I. or any person or purchasers on payment of necessary fees.

functions :-

- testing and analysis of drug samples sent by court or custom collector
- testing of drugs that are imported from others countries

- collection, storage & distribution of International standards.

Development & Maintenance of National Reference Standards

- advises the Indian drug control administration regarding quality & toxicity of drugs.

- Training of drug analysis.

Some samples are not tested by CDL :-

- analysis of cosmetics is carried out at central drug testing lab (CDTL) at Mumbai, Chennai, Hyderabad
- 1. Biological samples are not tested by CDL, they are sent to Central Research Institute, Kushtkuli
- 2. Biological products for Veterinary use are tested at Central Veterinary Research Institute, Izatnagar
- 3. Condoms are tested at CIVL (Central Indian Pharmaceutical Lab.)
- 4. Blood & Blood Related products are tested at National Institute of Communicable Diseases.

Procedure :-

- Sealed samples along with memorandum close sent by court to CDL
- On receiving sample, director has to record condition of seal
- After performing analysis, report are sent to court.

Government Analyst :-

- gout analyst in relation to Ayurvedic, Siddha or. Unani drugs a person appointed by central or state govt. under section 33-F letter.
- After notification in official gazette, state govt. appoint persons having sufficient qualification to be govt. Analyst for such aspects in state.

Qualifications :-

- A graduate in sci. Pharmacy/ medicine with 3 yrs Post graduate experience in testing of drug or 2 yrs training at CDL
- A Post graduate in sci. Pharmacy/ medicine with 3 yrs of experience of drug testing or 2 yrs training at CDL
- Association diploma of institution of chemist, India, with "analysis of drugs and pharmaceuticals", 3 yrs of experience in drug testing in laboratory under control of gout Analyst or Approved Institute.

Douy Inspectors (DI)

- 1. On Receipt of package of sample from DR. Inspector - It should comprise the seals on package with specimen seals & note its condition.
- 2. After the analysis of test, Report in triplicate together with full protocols and sent to be Investigators.
- 3. Gout Analyst has submit a report in form No. 3

A person appointed by central or state government for inspection of premise for sale or manufacturing of drug.

- DI has to keep all the information confidential & should not be disclosed.

Duties

- To test & analyze the drug sample sent by drug inspectors or other person under the Act.

Qualifications :-

- A graduate in pharmacy sci with following any higher qualification

experience,

① 16 month / 1.5 yrs experience in manufacturing or testing of drug.

(2) 3 yrs experience in inspection of manufacturing of drug.

=> for inspection of manufacture of substances in schedule c, DI must have

(1) At least 16 month experience in Manuf of least one of substance specified in schedule C.

(2) At least 15 month experience in testing one of the item in schedule C.

Duties

(1) To inspect the premises for sale of drugs
(2) to inspect the " Manufacture of drug.

- He take sample of drugs being manufactured or sold.
- Examines all the records of manufacture & sale of drugs.
- Performs investigation about any complaint for that premises.
- Powers :-
- can inspect any premises for sale of manufacture.
- can examine & seize the records document & Registers.
- can search a person believed to have secret about any drug that is being offence.

=> Procedure for withdrawal of samples:-

- He has to visit the premises on HIs
- does atleast once a yr.
- He checks all the conditions regarding license are fulfilled or not
- if point tendered is refused then seizes any stock of drug or cosmetic.

- He should issue the Receipt for sample to the concerned person, prescribed (form 16).

(2) He should inform to concerned person, for purpose of sample taking in (form 15).

for purpose of sample taking

- divide sample to 4 parts

- divide sample → addressed to the concerned person

1. one sample → send to Court Analyst
2. 2nd part → preserved for
3. 3rd " → production before court

No 4th part → witness

(3) inspectors sent to sample to govt Analyst by Registered post or by Hand in sealed pack enclosed together with memorandum in form 18

(4) If the confiscated drug is not in std. quality, it should be reported in court

e. Court may order destruction of drug under supervision of dI

(5) If the confiscated std. quality of drug, then should inspectors may report court and court further allow sale of drug.

e.g. Diphenhydramine

ethosuximide

paracetamol etc,

labeling of schedule Q medicines :- If any container a substance specified in schedule Q, will be labelled with the words

cution :- It is dangerous to take this preparation except under medical supervision, visibly printed & surrounded by line e.g., formut

℞ ABC Tablets

each uncoated tablets contains:-

A :- 2mg

B :- 2mg dosage :- As directed

C :- 2mg by physician, keep out of reach of children

SCHEDULE H PRESCRIPTION DRUG CAUTION :-

Not to be sold by Retail without the prescription of registered medical practitioner.

- takes only medical supervision only.

Schedule H & list of substances that should be sold by Retail only on prescription of RMP.

Sold by

RMP.

e.g.) Albendazole, Atorvastatin, carboplatin, ganavi, etc.)

Labelling of Medicines:-

- Symbol of Rx displayed on top left corner.
- OS

If the drug is come within the previous of Narcotic drugs & Psychotropic Sub. Act 1985.

labelled with symbol Not in Red colour on top left corner of label

- It should contain warning:-

To be sold by Retail on Prescription of RMP only

- If drug substance specified in H, then Rx with the Red colour at top left corner and formulation of H - substance mentioned in labelled

- warning - with Red border for H drug.

- It is dangerous to take this Rx without medical advice.

- Only dispensed with Prescription of RMP

=> draw the format of label.

On supply of drug specified in Schedule H to patient.

1. Should be recorded in a separate register.
2. Registers should include Name, address of prescriber, the name of patient, the name of drug & quantity supplied.
3. Record should meet Muttamed for 3455 of date of supply.

Supply of H, H₂ drug to RMP, Hospitals, Pharmacy e. Nursing Home.

- Should be only against signed order or written order of RMP.
- document should be preserved for 2 years.

Rules of dispensing of H/H₂ drugs

- Prescription should contain drug of H/H₂
- Must not dispensed more than once per prescription.

- At time of dispensing sign with name, address of prescriber, name & address of seller must present in prescription.

Schedule No:-

- It states about Requirements for an effective manufacturing unit
- It states about good Manufacturing practices
- It states about good quality of drugs.

(GMP) for to assure quality of drugs.

(I) Premises Requirements

(II) Plant & Equipment Requirements

(III) Premises Requirements

(IV) Production area :-

- Location :- factory should not be situated adjacent to open sewage or factory that produce disagreeable fumes.
- Building :- It should permit hygienic product

Walls should be of 6 feet ht & walls/floors washable & smooth.

Adequate Ventilation, Lightening & Humidity should be maintained.

Space should be adequate for placement of equipments, materials & movement of staff members to avoid risk of mixing.

Design is such that prevents entry of birds, insects & pests.

(B) Storage Area :-

sufficient area should be these to store various

materials like, starting material, finished material, packaging material, product in quarantine, say parts of machine etc.

separate space for under test, approval & rejected materials.

(C) Production area :-

- It should allow production in sequence of operations.
- This area should be maintained highly contamination free & moisture free.

(D) Quality control area :-

It should be independence of storage area and manufacturing area.

Separate laboratory with all essential equipment for physicochemical, Biological & Micro Biological Analysis

(E) plant & equipment Requirements :-

- This Requirements very on basis of manufacturing product

1. Solid unit dosage form (Tablets).

2. Formulating section - some

- Powder, Mix - oven,

- granulator

(b) compression section - 30m^2

- Pill machine.
- tablet inspection belt
- Hardness testers
- Weighing Balance

② Recommended Preparation :- (150m^2)

- storage equipment like Ampoules, Bottles etc.
- mixing & prep' tank
- filling & sealing unit
- leak testing equipment.

Schedule No:-

- It states about minimum equipment required
- to run a pharmacy efficiently.

④ Books :- J.P. - Drugs & cosmetics act

B.P. - Pharmacy Act
U.S.P. - Psychotropic & Narkotic act

⑤ general conditions:-

- Pharmacy store must be conducted by a Reg. pharmacist whose name should be displayed
- He/she should wear clean white clothes.

- ③ Area :- min area of 6m^2 is one person working & additional 8m^2 for each additional person
- Height at min 2.5 m.

- floors should be smooth & washable & walls plastered & painted,

(c) furniture :- It should be such that all category of drugs can kept separately

& their quality remains maintained.

- These should be a separate cupboard to keep poison, it should be locked.

Apparatus :-

- Weighing Balance - cork - Thermometer - Beaker - Distillation unit - evaporated plate - scissores - moisten pestle - watch glass - flasks - water bath - Beaker - filter paper - spirit lamp - measuring cylinder

① entrance :- An inscription should be these on entrance "pharmacy"

② premises :- It should be separated from:

- Personal use
- It should be well built, dry, well ventilated and well lit.

Schedule P :- contains expiry if drug i.e., it contains period life period of drugs date of manufacture in months between which the labelled

and date of expiry which shall not exceed potency period of drug specified under the condition of storage specified.

- o.s. - carbamycin Na Injection. Having life period of 24 months and stored at temp. Not exceeding 5°C

Schedule P₁ :- packing of drugs :-

Pack sizes of drugs for retail sale should be mentioned in schedule P₁.

⇒ Pack size of drugs not covers S.P. drugs as given below :-

- The pack sizes for tablets capsules of less than 10, such packing should be made by Integred no.

- Pack sizes of liquid oral Prepn → 30ml / 60ml / 100ml / 150ml. (Prelastic only)

⇒ Prelastic oral drops should be 5 | 10 | 15 ml

- Pack sizes for eye ear nasal should be 3 | 5 | 10 ml

- eye ointment 3 | 5 | 10 gm.

exempted from P₁ :-

- Pack sizes or dosage forms not covered by the foregoing provision of rule
- When formulation is imported as finished form
- Prepn intended Veterinary use.
- Intended for export.
- Physician samples.
- Pack sizes of large volume IV fluids.

Schedule :- T :- Regulations by Department (GMP)

of factory premises for Ayurvedic, Unani, Siddha drugs.

- This Manufacturing of drug carried out in premises under condition of schedule T.

- Only grant or renewal of license in form- D is allowed.

Details :-

- (i) the quality of Auro Materials used for manufacture of Ayurvedic, Siddha, Unani drug should be prescribed quantity.
- (ii) it is free from contamination.

3. Manufacturing process should be prescribed standards

4. Adequate quality control

5. Manufactured drug which is released for sale is of prescribed quality.

(A) Part I :- good Manufacturing Practices:

The manufacturing plant should have adequate space for :-

- Receiving & storing raw material.
- Manufacturing process areas.
- Quality control section.
- finished goods store
- office
- Rejected goods store.

Schedule :- (1)

(i) general requirements is general requirement which is necessary for manufacturing of Ayurvedic, Unani

drugs like location & surrounding,

- Building, water supply, dispensable

water, containers, cleaning, stores,

raw materials, packaging materials, working space

Health clothing, machinery & equipment, records, scheduling etc.

(ii) Requirement for sterile products:-
Manufacturing unit, precautions against contamination of mix.

Part II :- contains :-

1. list of recommended Machinery, equipment & minimum manufacturing premises required for the manufacture of various categories of Ayurvedic, Siddha, Unani medicines.

2. list of equipment recommended for in-House quality control section.

3. supplementary guidelines for manufacturing Siddha, Unani, & Ayurvedic medicine.

4. schedule (1) contains Manufacturing & Analytical Records of (i),

5. - schedule (i) contains Manufacturing & Analytical Records of (ii).

6. - schedule (ii) contains Manufacturing & Analytical Records of (iii).

7. - schedule (iii) contains Manufacturing & Analytical Records of (iv).

8. - schedule (iv) contains Manufacturing & Analytical Records of (v).

- Serial No

- Name of Product

- Ref. of Master formula Records.

- Lot | Batch size

- Lot | Batch No

- Date of commencement Manufacturing

- Date of completion of Manufacturing.

- Name of all ingredients & quantity.

- Name & duration of mixing

- date, time of mixing

- details of environmental controls like Room temp, relative humidity etc

- date of granulation

- Records of in-process control like mixing etc

- date of filling of tablets & capsules

- date of sealing | packing | polishing of Medicines

- date of labeling of label strip

- date & quantity released after seal of distribution.

- Quality transferred to warehouse

- Specimens of label strip

- date & quantity released after seal of distribution.

(II) Records of Raw Materials :-

Records of raw materials should be maintained including the date, time, invoice no, name & address of manufacturer | supplier, batch no, quantity, review, pack size, date of manufacture, date of expiry

(III) Records for pharmaceutical formulation & analytical methods

- clarity

- pH test

- Identification

- Vol in containers

- Any other test

• signature of analyst

• opinion & sign of approved Analyst

• results of assay

Schedule V :- Provides standards for patent or proprietary medicines.

details

- It contains vitamins for therapeutic or paediatric use

- In case of pharmaceutical product containing several API, they don't interfere with one another.

- Safety & therapeutic efficacy of product also not showing analytical errors.
- Patent shall comply with general requirements of dosage form under which it falls as given in IP. If it is not included in IP, it should be mentioned in other pharmacopeia.
- It comply with all ingredients like colour, consistency, stability, freedom from contamination with foreign matter or fungal growth.
- Content of Active ingredients, other than vitamins, enzymes & antibiotics, in patent or proprietary medicine should be less than 50% & not more than 100%.
- If medicine containing aspirin, then sulfuric acid test & then such Acid should be 0.75%.
- In case of soluble type at 15-3%.
- It should be tested for pyrogall test.
- It free from toxicity

Schedule X :- List of Narcotic drugs & Psychotropic substances to import drugs specified on schedule X (from R.A) should complete frost.

Labelling of Schedule X medicines:-

- The symbol of Rx or N.R in red colour top left corners of label.
- Contain warning:- To be sold by Retail on Prescription of RMP only.

Packing of Schedule X medicines:-

- Packing of schedule X should be marketed in packing not exceeding

- 100 unit doses in case of tablets / capsules
- 200 ml in the case of oral liquid preparation
- 5 ml in case of injection

Distribution of drugs specified on Schedule X:-

While distributing schedule X, the licensee shall maintain a separate record, mentioned following in it.

- 1) Name of drug
- 2) Batch No
- 3) Name & address of manufacturer
- 4) date of transaction
- 5) quantity of drug received
- 6) Name of purchaser
- 7) Balance quantity of drug at end of business day.

- 3) sign of person under supplied
the drugs have been
the drugs have been supplied

Schedule Y :-

- schedule Y provides guidelines for clinical trials of new drug in India.
- "Clinical trial" → systematic study of drug in human subject to verify its clinical, pharmacological & adverse effects & determine its safety.

2) Approval of clinical trials :-

- Before initiating a clinical trial it is necessary to get permission from Licensing Authority as per Rule no 21(B).

Phase 1 :- Human pharmacology

- such dose is given atleast 2 person at a time
- it is done to know the drug tolerance, P.D. & P.K & adverse reaction of drug.

Phase-2 (Therapeutic exploratory trial)

- such dose is given to 9-10 people at a time
- it is done to determine therapeutic uses of drug & efficient dosage.

Phase-3 (Therapeutic confirmatory trial)

- it is done to determine safety & therapeutic effect of drug among large no. people.
- it is the responsibility of investigator to check whether the procedure is under GCP, e.g. other protocols needs to be followed.

- such dose is given to about 100 people at a time.

→ After 3rd phase, the report signed with license submitted to license investigator is submitted for permission of authority and applied for phase IV marketing to conduct phase IV.

Phase - 4 Post-Marketing studies

- with all necessary indications, the newly approved drug is marketed.
- effects among people are recorded & after this phase the drug gets final approval for further manufacture & sale.

phase 0 of Human pharmacology phase

- 1 → Therapeutic exploratory
- 2 → Therapeutic confirmatory

- Part II B of Schedule F :-
- 1 → Post Marketing Survey.
 - 2 → Requirements for functioning & operation of Blood Bank & for prepn of Blood components.

① Blood Bank or Components:-

- general component :- in pt location &

- surroundings Building & Health, clothing & sunitation of stuff are explained.

Accommodation for Blood Bank:-

- 100 sq.m area for its operation should be required.
- 50 sq.m for prep of blood components.
- maintenance :- the premises should be maintained in a clean & proper manner to ensure adequate cleaning.
- equipment :- used in collection, processing, testing, storage & sale of blood and its components should be maintained and clean as per SOPs.
- equipment should be observed, standardized & calibrated on regulated schedule Basis as described in SOPs.
- supplies & reagents :- All supplies & reagents are used in testing, collection, processing, storage & distribution of blood & its components should be stored at proper temp in safe & hygienic place
- criteria for blood donation
- donor age group - 18-65 yrs.
- weight = Not less than 45 kg.
- temp & pulse should Normal.

4. systolic & diastolic B.P. are within Normal limit without medication.

5. Haemoglobin which shall not be less than 12.5 gm.

- 6. donor free from Acute respiratory disease.
- 7. donor should be free from any disease.
- 8. donor should be free from any blood transfusion disease.

9. arms & forearms of donors should be free from skin punctures or scurs.

(ii) Blood Donating Camps :-

organized by:

- A. A licensed designated Regional Blood transfusion centre.
- B. Indian Red cross society.
- C. A licensed Govt Blood Bank.