INTERNATIONAL COLLEGE OF PHARMACEUTICAL INNOVATION
国际创新药学院

Introduction to Medicines 1

Course	**BSc(Pharm) & BSc (ATT)**
Year	**2024-2025 I**
Module	**Medicines 1**
Lecturer	**Prof. Zhiyuan Zhong**

LEARNING OUTCOMES

1. Describe the difference between a drug, dosage form and excipient
2. List the four scientific areas that together form the pharmaceutical sciences
3. Summarise the role of pharmaceutics in the development of medicines using aspirin as an example
4. List the functions of regulatory agencies in the development of new medicines
5. Find basic medicines information on the HPRA webpage (aspirin and nicotine)

MEDICINES 1

- **Module Lecturer**
  - Dr. Zhiyuan Zhong (ICPI)
  - Dr. Congcong Xu (ICPI)
  - Dr. Shi Du (ICPI)
- **Lab Instructor**
  - Dr. Congcong Xu (ICPI)
  - Dr. Shi Du (ICPI)
- **Moodle Technical Support**
  - Ceara Cooper (RCSI)

MODULE CONTENT

- Lectures (1 × 30 h)
  - On campus
- Laboratory practicals (6 × 2/3 h)
  - On campus
- Learning units (2 × 2 h and 2 × 1 h tutorials)
- Tutorials (5 × 1 h)
  - On campus

SECTION 1: PHARMACEUTICAL DOSAGE FORMS

Introduction to Pharmaceutics: Medicines 1
Therapeutic Modalities: the Nature of Disease and the Purpose of Therapy 1
Therapeutic Modalities: the Nature of Disease and the Purpose of Therapy 2
Routes of Administration 1
Routes of Administration 2
Routes of Administration 3
Pharmaceutical Dosage Forms 1
Pharmaceutical Dosage Forms 2
States of Matter and the Physical Behaviour of Drugs 1
States of Matter and the Physical Behaviour of Drugs 2
Physical Behaviour of Drug Solids 1
Physical Behaviour of Drug Solids 2
Physical Behaviour of Drug Solids 3
Pharmaceutical Dosage Forms Tutorial

SECTION 2: PHARMACEUTICAL CALCULATIONS

- Expressions of concentration and dilutions
- Learning unit 1: 2:43:55
- Learning Unit 2: 1:43:50
- Test Yourself Quiz: 30 MCQ
- Tutorial

SECTION 3: SOLUBILITY & PERMEABILITY IN DOSAGE FORM DEVELOPMENT

Diffusion From Pill to Target Receptor
Solubility Phenomena 1
Solubility Phenomena 2
Solubility Phenomena 3
Solubility and pH 1
Solubility and pH 2
Dissolution 1
Dissolution 2
Biological Barriers to Drug Absorption 1
Biological Barriers to Drug Absorption 2
Druglikeness and Biopharmaceutics Classification System 1
Druglikeness and Biopharmaceutics Classification System 2
Solubility Enhancement Strategies 1
Solubility Enhancement Strategies 2
Solubility Enhancement Strategies 3
Solubility, Permeability and the BCS Tutorial

SECTION 4: ANALYSIS IN PHARMACEUTICAL SCIENCE

Tools of Analysis of Drugs and Medicines 1
Tools of Analysis of Drugs and Medicines 2
Pharmaceutical Analysis Tutorial

SUPPORT
UPLOADED RECORDINGS, CLASS QUESTIONS & TUTORIALS

- Questions can be asked during lectures or the 10 minutes at the end of each lecture.

- If you are having difficulty with material, contact module lecturer for offline discussions.

- If you would like content revisited in a tutorial, email revision topics to the module lecturer or the class representative.

Pharmaceutical Dosage Forms Tutorial
Pharmaceutical Calculations Tutorial
Solubility, Permeability and the BCS Tutorial
Pharmaceutical Analysis Tutorial
Module Review Tutorial

LABORATORY PRACTICALS

- Requirements:
  - Laboratory coat
  - Safety glasses
  - Calculator

- Location
  - 6 × 3 h, ICPI Lab (Third Floor, ICPI building)
  - Lab manuals will be provided in advance of the first practical
  - All laboratory practicals must be written up in the allocated laboratory time and will be graded formatively
  - Attendance of lab practicals is compulsory

LABORATORY PRACTICAL DATES

For Pharm students:

DAY	TITLE	SECTION	LECTURER
2024/10/16	Introduction to Good Compounding Practices	1,2	Xu C & Du S
2024/10/30	QC Testing of Iron	2,4	Xu C & Du S
2024/11/13	Factors Influencing Solubility	2,3	Xu C & Du S
2024/11/27	Factors Influencing Dissolution	2,3	Xu C & Du S
2024/12/11	Quality testing of a solid dosage form	2,4	Xu C & Du S
2024/12/25	Preparation of Aspirin Tablets	2,4	Xu C & Du S

For ATT students:

DAY	TITLE	SECTION	LECTURER
2024/10/18	Introduction to Good Compounding Practices	1,2	Xu C & Du S
2024/11/01	QC Testing of Iron	2,4	Xu C & Du S
2024/11/15	Factors Influencing Solubility	2,3	Xu C & Du S
2024/11/29	Factors Influencing Dissolution	2,3	Xu C & Du S
2024/12/13	Quality testing of a solid dosage form	2,4	Xu C & Du S
2024/12/27	Preparation of Aspirin Tablets	2,4	Xu C & Du S

ASSESSMENT

- 40% Continuous Assessment (10% Quiz + 30% Lab practicals)

- 60% Summative Assessment (Final exam)

CONTINUOUS ASSESSMENT EXAMINATIONS (40%)

Post Practical Quizzes (30%)

- 10 MCQ per lab
- 6 lab practicals (each Lab work 5%)

TITLE	SECTION	LECTURER	GRADE
Introduction to Good Compounding Practices	1,2	Xu C & Du S	5%
QC Testing of Iron	2,4	Xu C & Du S	5%
Preparation of Aspirin Tablets	2,3	Xu C & Du S	5%
Factors Influencing Solubility	2,3	Xu C & Du S	5%
Factors Influencing Dissolution	2,4	Xu C & Du S	5%
Quality testing of a solid dosage form	2,4	Xu C & Du S	5%

Lab Test (10%)

All lab practicals and pharmaceutical calculations learning units

- 25 SAQ/VSAQ
- ***Only students that attend lab practicals can achieve marks for lab practicals****

END OF SEMESTER EXAMINATIONS (60%)

Type	Question and time	Module %
	Section B (Pharmaceutics)	
MCQs	30 (1.5 min per MCQ)	20 %
VSAQ/SAQ	25 (2.5 min per VSAQ/SAQ)	40 %

SUMMATIVE ASSESSMENT DATE: TBC

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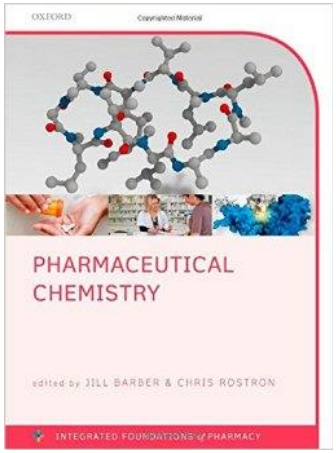
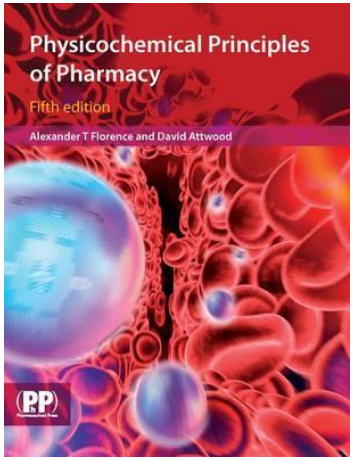
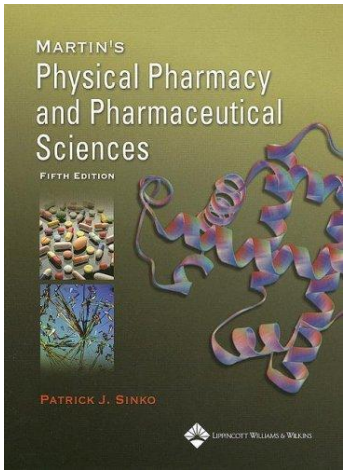
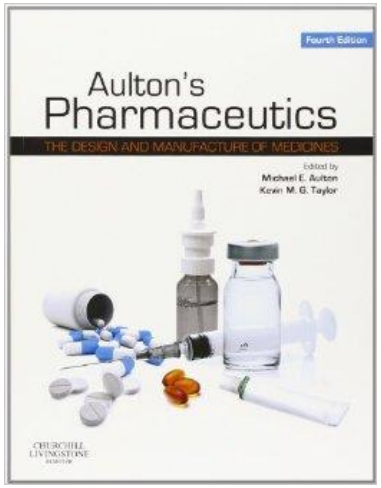
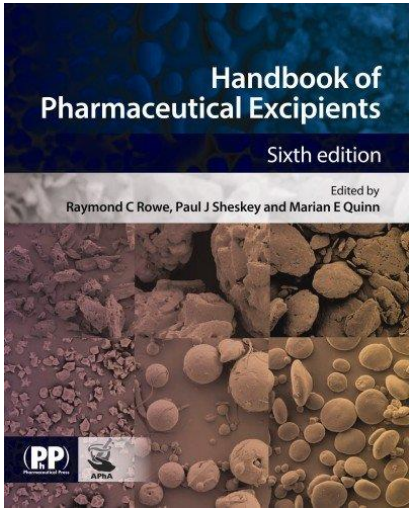
RECOMMENDED READING

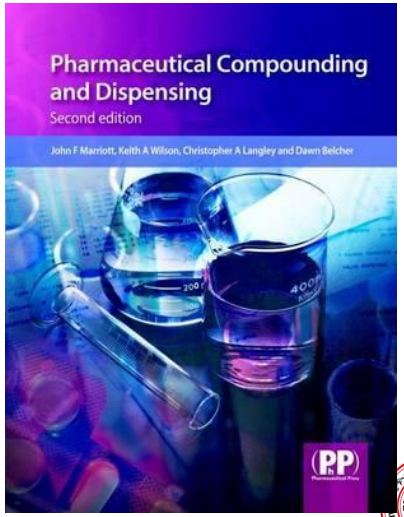












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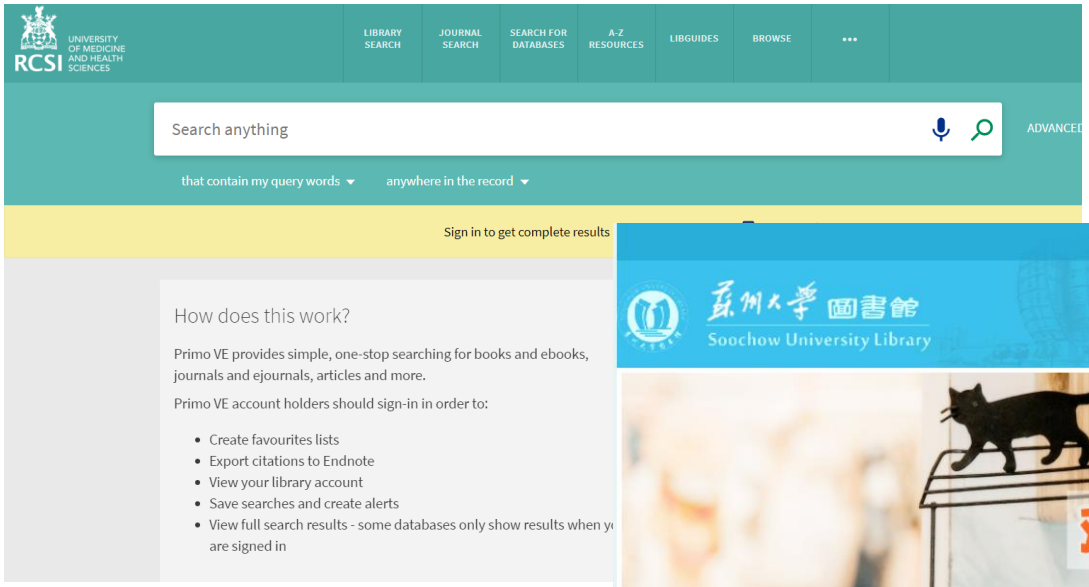
EBOOKS

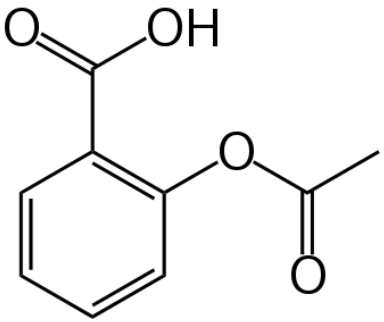
https://rcsidublin.primo.exlibrisgroup.com/discovery/search?vid=353RCSI_INST:RCSI&lang=en



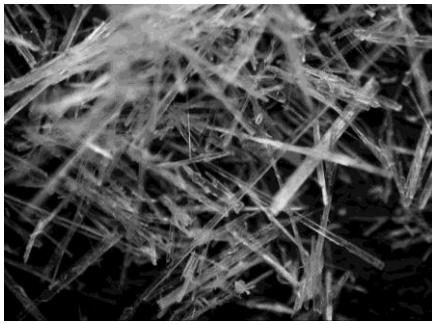
https://library.suda.edu.cn/

Resources can be found at RCSI library or Soochow University library.

WHAT IS A DRUG?



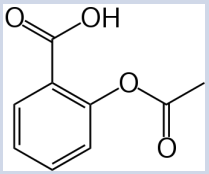
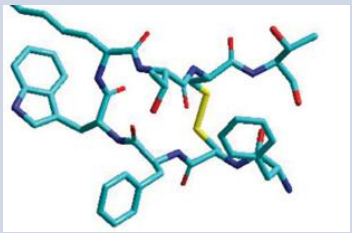
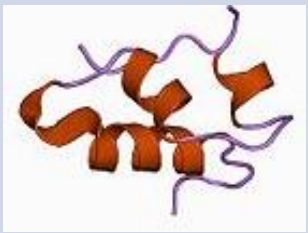
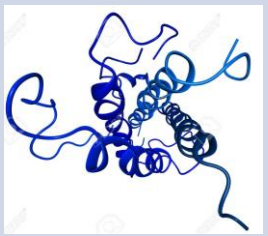
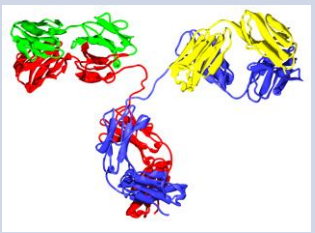
- A drug can be defined as a chemical substance that interacts with a part of the body to alter an existing physiological or biochemical process



- A drug can be used in the diagnosis, mitigation, treatment, cure or prevention of diseases in humans or other animals

- A drug is the principle active ingredient within a medicine (termed Active Pharmaceutical Ingredient)

DRUGS RANGE IN SIZE AND COMPLEXITY

Attribute	Aspirin	Octreotide	Insulin	hGH	IgG (Rituximab)
SIZE					
ATOMS	21	137	797	3000	25,000
COMPLEXITY					

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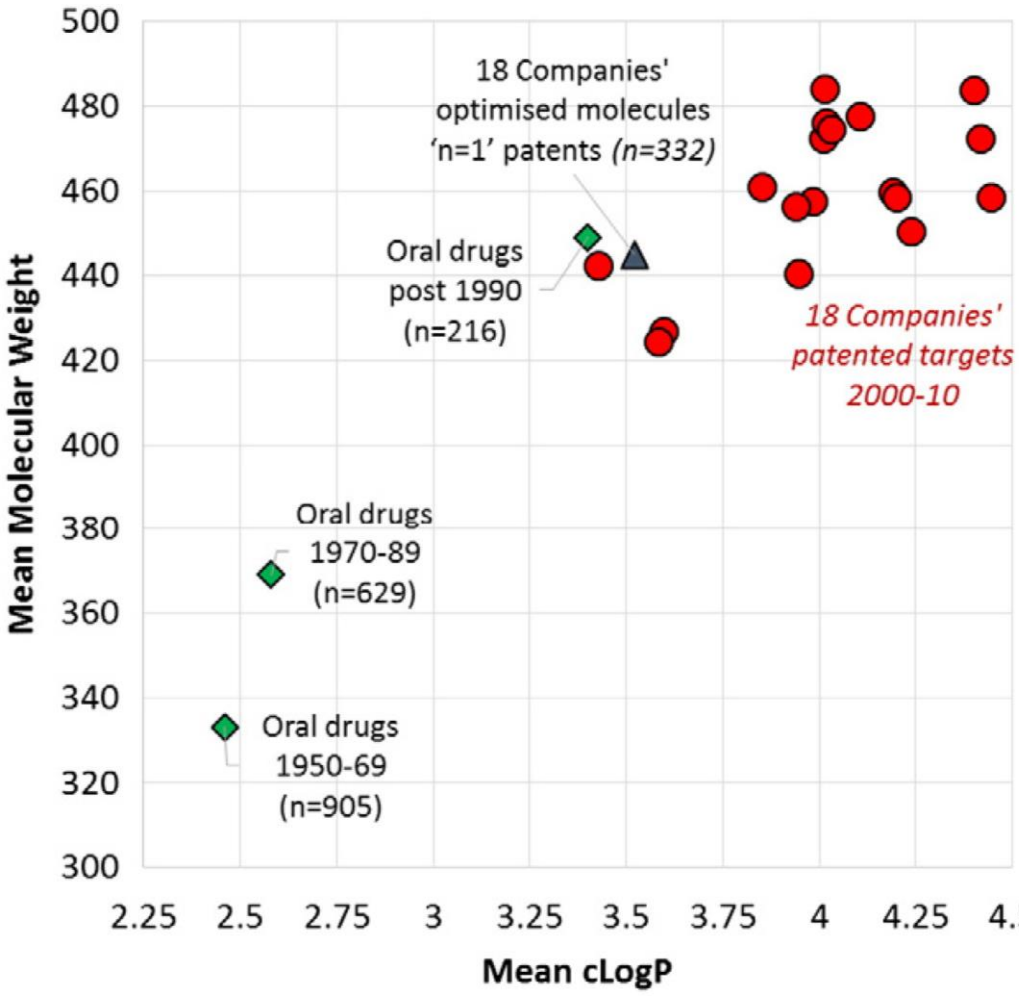
LEADS ARE GETTING LARGE AND MORE COMPLEX



Leeson PD (2016) *Adv Drug Deliver Rev* 101, 22-33

RCSI

WHAT IS A MEDICINE?

- A medicine is a pharmaceutical dosage form
- A pharmaceutical dosage form is the form that a medicine is taken by a patient e.g. tablet, syrup, injection, ointment
- A drug is often combined in a suitable manner with other ingredients (termed excipients) that together form a unique formulation
- Each formulation has a distinct composition

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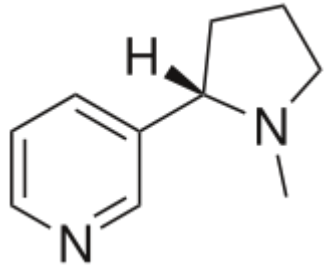
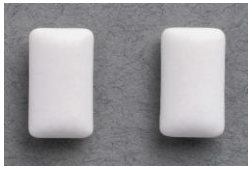
ANY DRUG MAY EXIST IN A NUMBER OF DIFFERENT FORMULATIONS



Nicotine



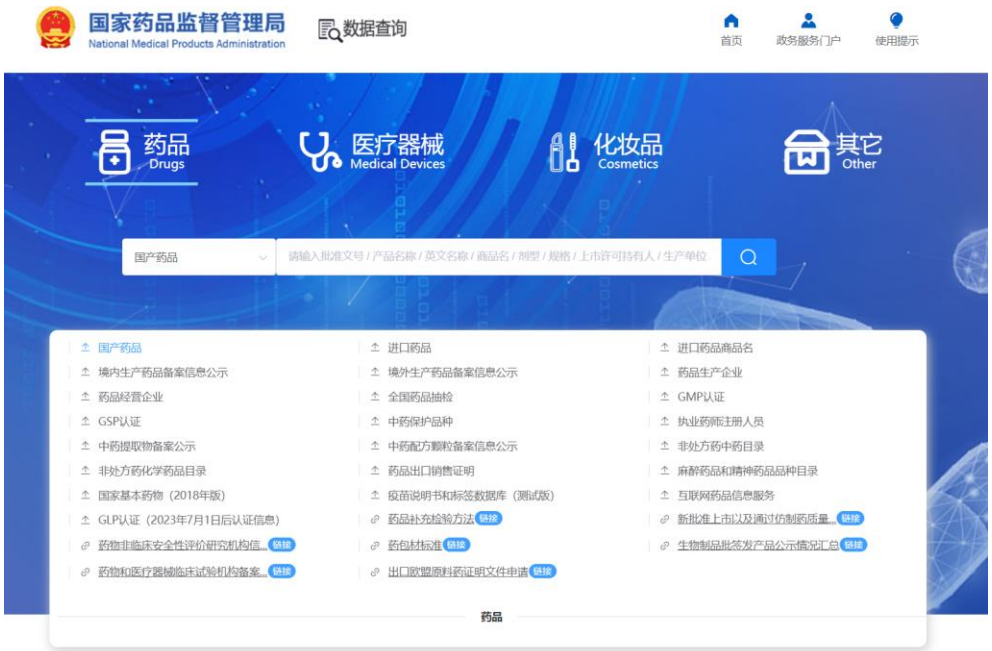
Patients don't take drugs…

They take dosage forms

REGULATIONS EXIST TO ENSURE THE QUALITY OF MEDICINES

Ireland: Health Products Regulatory Authority

China: National Medical Products Administration



Country	Regulatory Authority
US	Food and Drug Administration (US FDA)
UK	Medicines and Health care products regulatory Agency (MHRA)
India	Central Drugs Standard Control Organization Drug controller general of India (DCGI)
Australia	Therapeutic Goods Administration (TGA)
Japan	Japanese Ministry of health, Labour and Welfare (MHLW)
Canada	Health Canada
Brazil	Agency Nacional degradation Vigilancia Sanitaria (ANVISA)
South Africa	Medicines Control Council (MCC)
Europe	European Directorate for Quality of Medicines (EDQM)
	European Medicines Evaluation agencies (EMEA)

QUALITIES OF AN IDEAL DOSAGE FORM

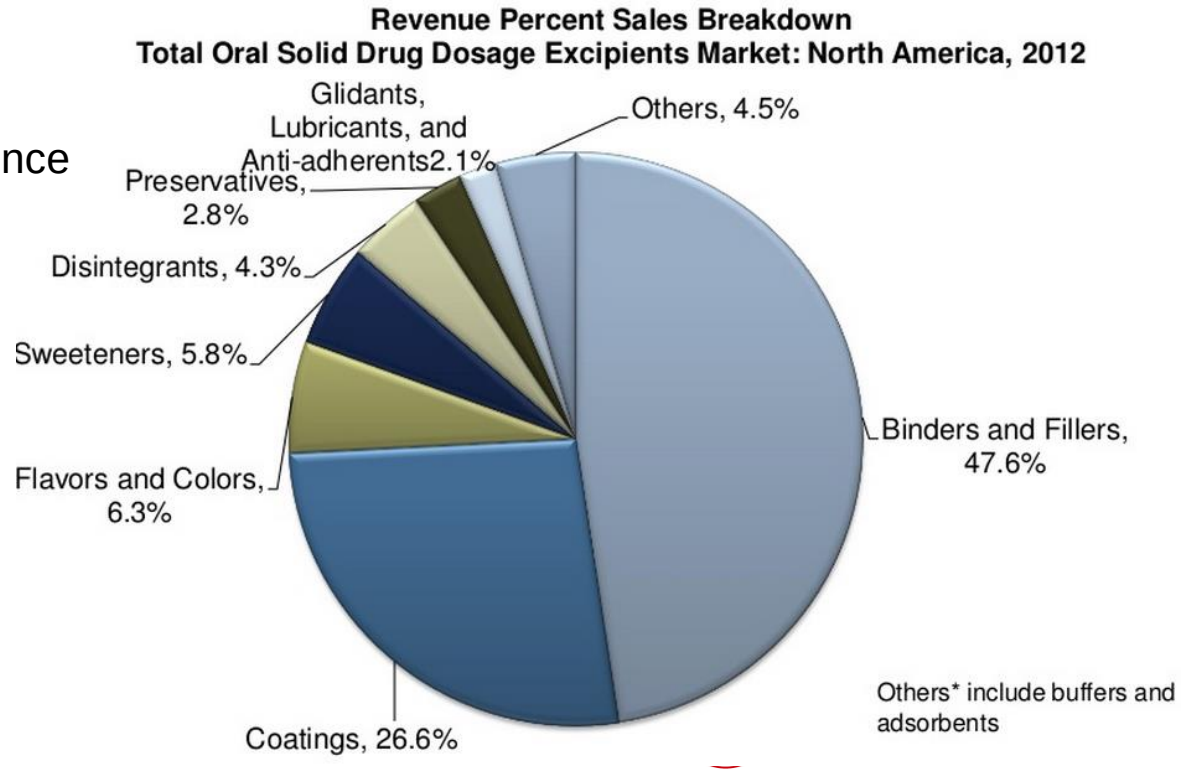
1. One dose in a manageable size unit
2. Palatable or comfortable
3. Stable chemically, microbiologically and physically
4. Convenient and easy to use
5. Release the drug to the receptors in a timely fashion with minimal side effects and the optimal duration
6. Capable of large scale manufacture

In order to ensure these qualities are routinely attained, pharmaceutical excipients are added to the drug or manufacturing process

PHARMACEUTICAL EXCIPIENTS

Pharmaceutical excipients are non-drug ingredients that are added to a dosage form to ensure the formulation routinely meets the qualities of an ideal dosage form

- Key functions
  - Ensure delivery (efficacy)
  - Ensure stability
  - Enable manufacture
  - Promote compliance/adherence



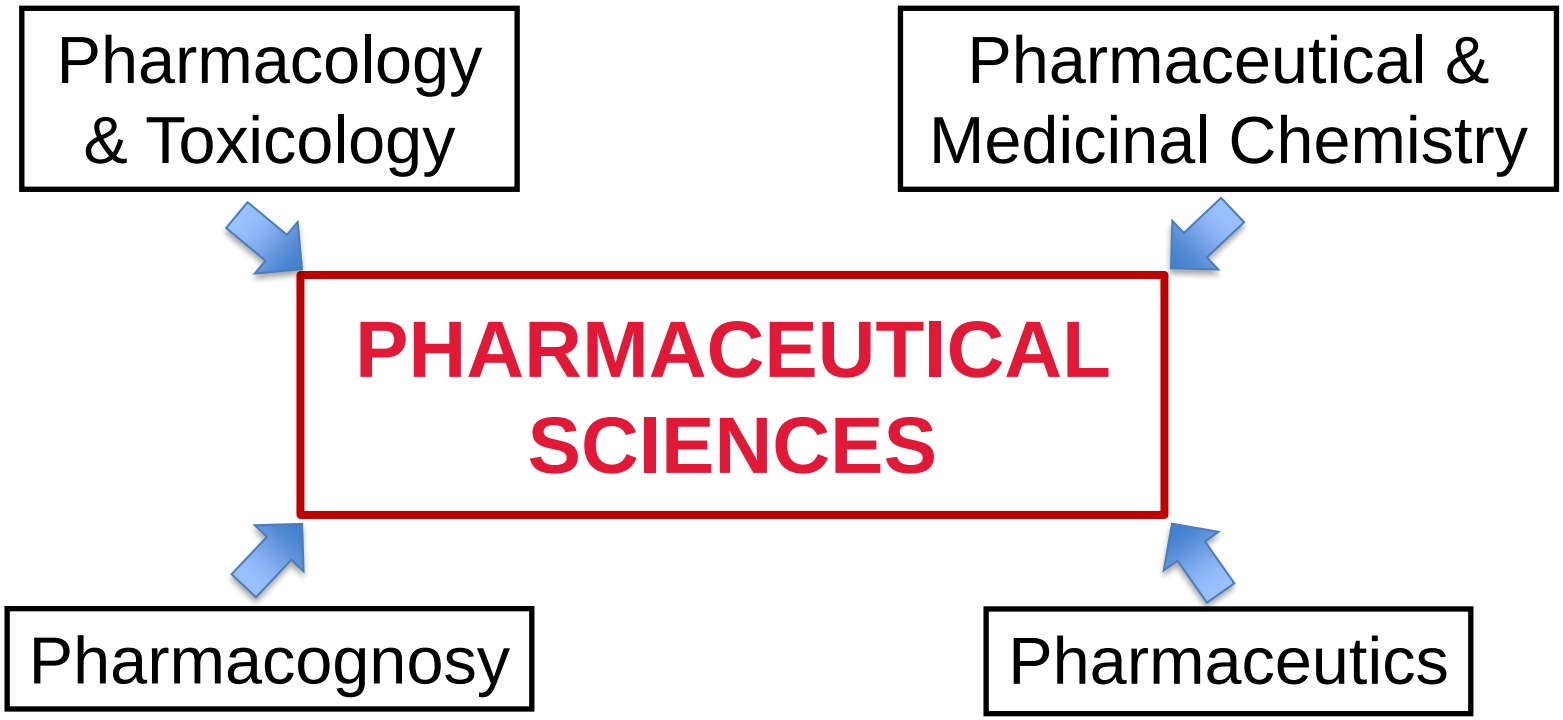
HANDBOOK OF PHARMACEUTICAL EXCIPIENTS

- Monographs on 250 excipients.
- Nonproprietary, chemical and commercial names
- Empirical formulas and molecular weights.
- Chemical and physical properties.
- Incompatibilities and interactions with other excipients and drug substances.
- Regulatory status
- Applications in pharmaceutical formulation or technology

EXCIPIENTS IN THE FORMULATION OF DISPERSIBLE ASPIRIN TABLETS

ASPIRIN TABLETS			
MATERIAL NAME	SCALE (MG/TABLET)	FUNCTION	QUALITY
ASPIRIN	325	ACTIVE	—
STARCH 1500	25.52	BINDER	Ensures that the tablet remains intact after compression
MICROCRYSTALLINE CELLULOSE	21.33	DISINTEGRANT	Promotes dispersion of the tablet into small particles
POWDERED CELLULOSE	6.33	GLIDANT	Improves flowability and promotes uniformity of content

THE ROLE OF PHARMACEUTICAL SCIENCE IN THE DEVELOPMENT OF MEDICINES



WHY ARE PHARMACEUTICAL SCIENCES IMPORTANT TO PHARMACISTS

DOMAIN 3	SUPPLY OF MEDICINES	
Competency:	**3.1**	**Manufactures and compounds medicines**
Behaviours:	3.1.1	Remains up to date with and applies pharmaceutical knowledge on the requirements of formulating and compounding of medicines
	3.1.2	Demonstrates the ability to perform pharmaceutical calculations accurately
	3.1.3	Applies pharmaceutical knowledge to select the appropriate route of administration and dosage form for the medicine
	3.1.4	Applies pharmaceutical knowledge to select appropriate ingredients and excipients of the required quality standard for the manufacture and compounding of medicines
	3.1.5	Effectively uses technical skills to prepare pharmaceutical products as appropriate to their practice setting
	3.1.6	Prepares pharmaceutical products according to the standards required including local standard operating procedures (SOPs), guidelines, or good manufacturing practice (GMP) as appropriate
	3.1.7	Applies knowledge to ensure the appropriate quality controls and monitoring are in place
	3.1.8	Maintains appropriate records and documentation
	3.1.9	Demonstrates an understanding of the legislative framework and requirements that govern the manufacture of medicinal products, including GMP

WHAT IS PHARMACEUTICS?

In brief, pharmaceutics is about the conversion of drug substances into medicines suitable for administration by or to patients.

Physicochemical Principles of Pharmacy (Florence /Attwood)

The study of pharmaceutics provides the scientific foundation for the design and appropriate use of dosage forms and drug delivery systems.

Remington Education (Fox)

The word 'pharmaceutics' is used in pharmacy and pharmaceutical science to encompass many subject areas that are all associated with the steps to which a drug is subjected towards the end of its development, i.e. it is the stages that follow the discovery or synthesis or the drug, its isolation and purification, and testing for advantageous pharmacological effects and absence of serious toxicological problems. Put at its simplest – *pharmaceutics converts a drug into a medicine*.

Aulton's Pharmaceutics (Aulton and Taylor)

WHAT IS PHARMACEUTICS?

- Physical & chemical properties of drugs and medicines
- Preformulation science
- Formulation science
- Pharmaceutical calculations and metrology
- Pharmaceutical manufacturing technology
- Pharmaceutical analysis
- Biopharmaceutics and pharmacology
- Drug delivery
- Regulatory science

PHYSICAL AND CHEMICAL PROPERTIES OF DRUGS AND MEDICINES

- The physicochemical properties of a drug are critical in the design of a formulation that delivers the drug to its target tissues

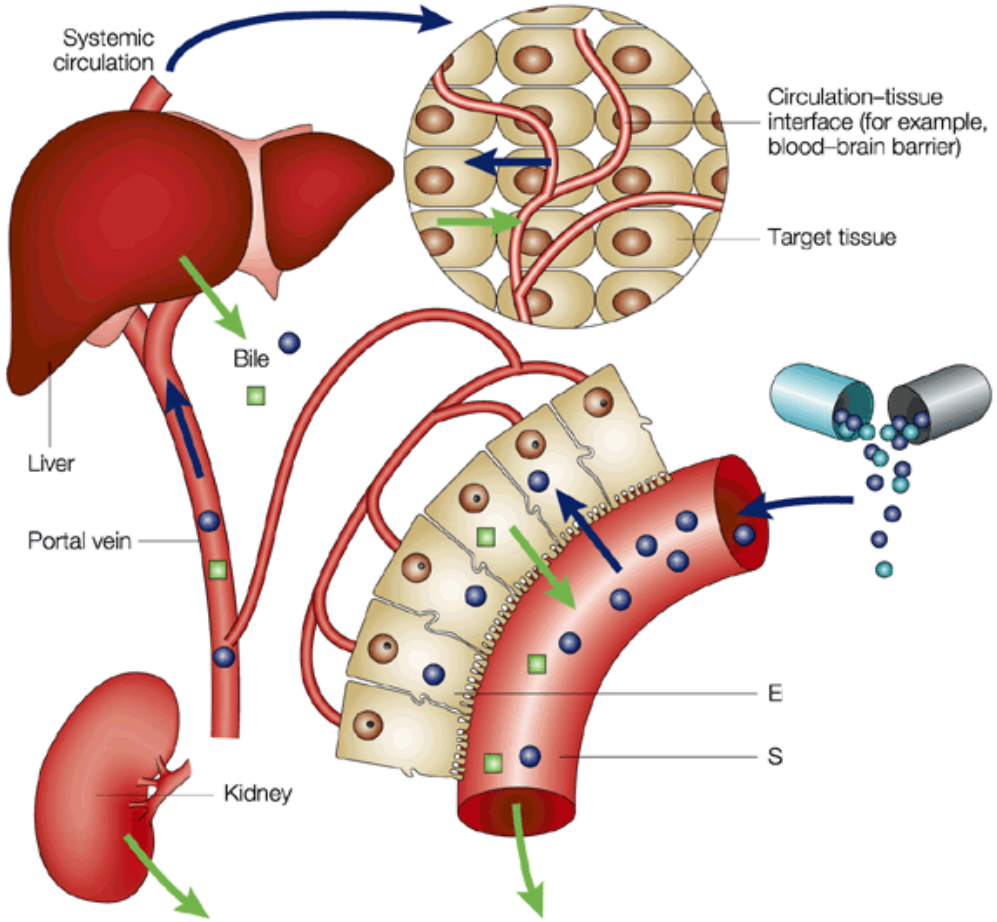
- These properties include:
  - Water solubility
  - Molecular weight
  - Stability in solid and liquid forms
  - Enzymatic degradation
  - Target receptor location
  - Selectivity

BARRIERS TO ORAL DRUG ABSORPTION

SOLUBILITY

PERMEABILITY

STABILITY



Roden DM, George AL, (2002) *Nat Rev Drug Discov* (1) 37-44

PREFORMULATION SCIENCE

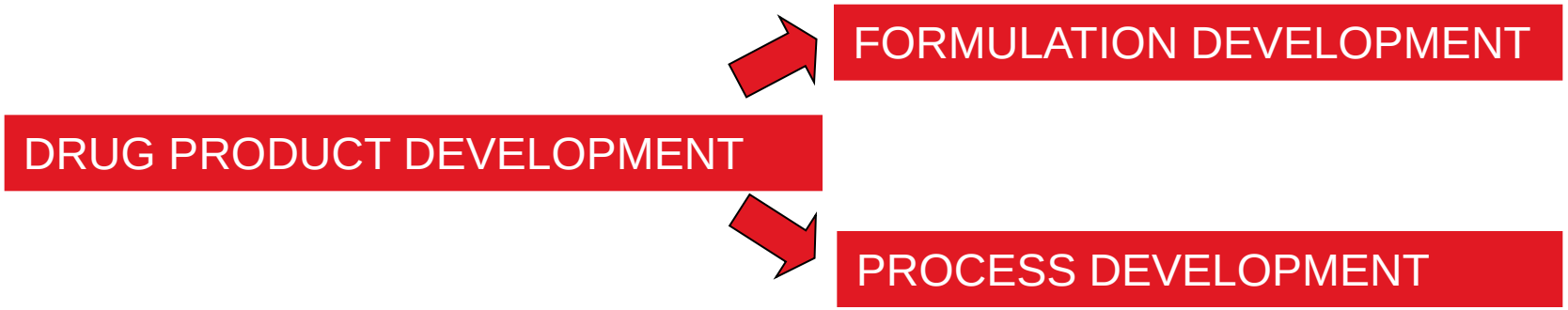
- Describes the physical and chemical characterisation of substances and mixtures used in pharmaceutical products
  - A promising lead in drug discovery and early R&D testing will not necessarily be applicable in production
  - Physicochemical information in preformulation is used in formulation development in concert with production/manufacturing

Table 24.2 Preformulation drug characterization

Test	Method/function/ characterization
1 Spectroscopy	Simple UV assay
2 Solubility	Phase solubility, purity
aqueous	Intrinsic solubility, pH effects
pK_a	Solubility control, salt formation
salts	Solubility, hygroscopicity, stability
solvents	Vehicles, extraction
partition coeff K_w^o	Lipophilicity, structure activity
dissolution	Biopharmaceutics
3 Melting point	DSC – polymorphism, hydrates, solvates
4 Assay development	UV, TLC, HPLC
5 Stability (in solution and solid state)	Thermal, hydrolysis, oxidation, photolysis, metal ions, pH
6 Microscopy	Morphology, particle size
7 Powder flow	Tablet and capsule formulation
bulk density	
angle of repose	
8 Compression properties	Excipient choice
9 Excipient compatibility	Excipient choice

FORMULATION SCIENCE

- The aim of formulation development is to select excipients that will provide a dosage form that has the required functionality and performance
- Traditionally an empirical science
- Today integrally linked with pre-formulation



PHARMACEUTICAL CALCULATIONS & METROLOGY

WHY?

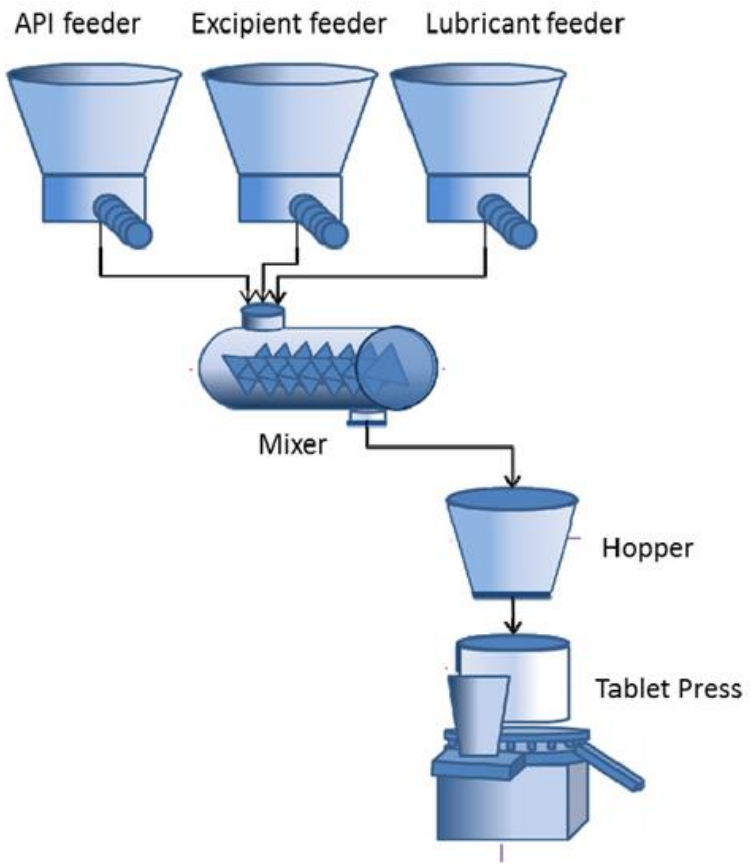
A miscalculation of medication dosage or incorrect conversion of concentration units represents a potential threat to both patient safety and clinical effectiveness

LEARNING UNITS

Systems of Units
Concentrations
Dilutions
Formulations
Calculation of doses
Calculations involving molecular weights

PHARMACEUTICAL MANUFACTURING TECHNOLOGY

- Industrial processes and procedures
- Unit operations
- Current Good manufacturing practice
- Quality control
- Process analytical technology (PAT)

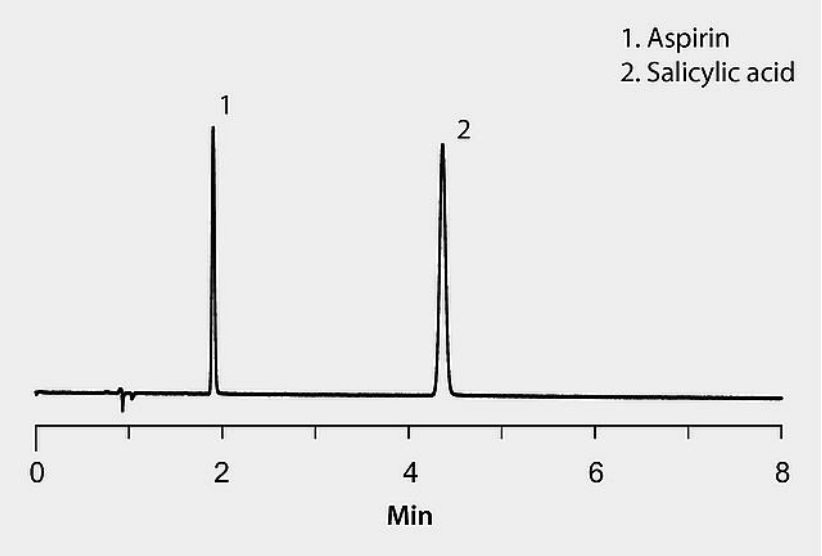


PHARMACEUTICAL ANALYSIS

QUALITATIVE ANALYSIS

QUANTITATIVE ANALYSIS

DRUG ANALYSIS
EXCIPIENT ANALYSIS
DOSAGE FORM ANALYSIS
IN VIVO ANALYSIS



STABILITY TESTING OF ASPIRIN USING RP-HPLC ANALYSIS

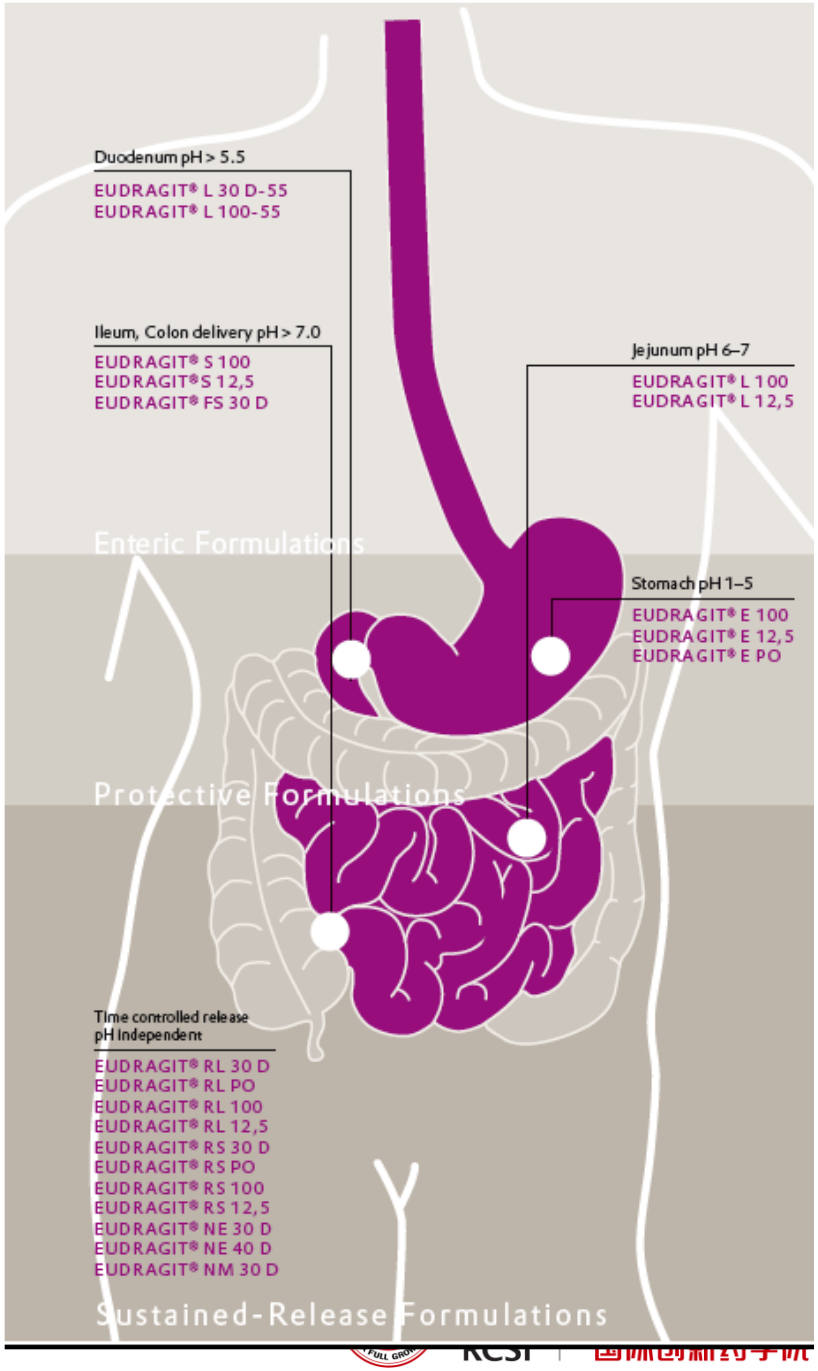
BIOPHARMACEUTICS & PHARMACOLOGY

- **PHARMACOLOGY**: study of the interaction of drugs with the human body
- **PHARMACODYNAMICS**: The branch of pharmacology concerned with the effect of therapeutic drugs on the body
- **PHARMACOKINETICS**: The branch of pharmacology concerned with the effect that the body has on therapeutic drugs (ADME)
- **BIOPHARMACEUTICS**: The study of factors affecting bioavailability of a drug and the use this information to optimise the pharmacological activity of drug products in clinical progression. Biopharmaceutics studies the relationship between physicochemical properties of drug within a dsage form and the various pharmacological , toxicological and efficacy observed after the administration of the dosage form

DRUG DELIVERY

- Drug delivery is a specialist area involving the design of Delivery systems that enable administration of a safe and efficacious dose of medicine to patients

E.G. ENTERIC COATING OF ASPIRIN



REGULATORY SCIENCE

- Health Products Regulatory Authority (https://www.HPRA.ie/)
  - Licensing of medicinal products for human use
  - Licensing of veterinary products
  - Licensing of wholesalers of human medicines
  - Licensing of manufacturers of human and veterinary medicines
  - Pharmacovigilance & Drugs safety monitoring
  - Clinical Trial Licensing
  - Inspection of wholesale and manufacturing sites
  - Regulation of medical devices
  - Regulation of blood and tissue products.
- European Medicines Agency (http://www.ema.europa.eu/ema/)
  - European marketing authorisation for medicinal products
  - Pharmacovigilance
  - Scientific advice and protocol assistance for companies developing new medicinal products
  - Publishes guidelines on quality, safety and efficacy testing requirements.
  - The Scientific Committees of the EMEA - 6 technical committees.
  - Committee for Human Medicinal Products (CHMP)..
  - Committee for Veterinary Medicinal Products (CVMP).
  - Committee for Orphan Medicinal Products (COMP). This
  - Committee for Herbal Medicinal Products (HMPC).
  - Committee for Advanced therapies (CAT).
  - The paediatric committee (PDCO).

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