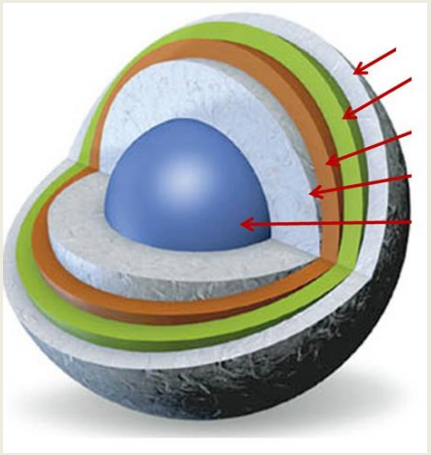
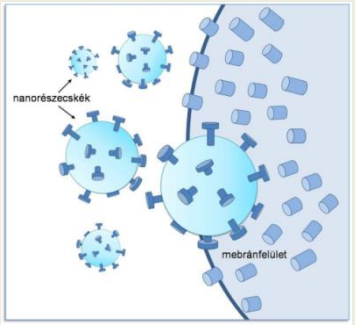
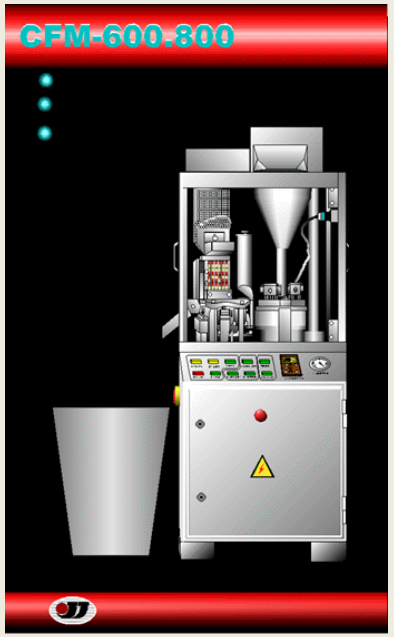
Introduction to Pharmaceutical Technology







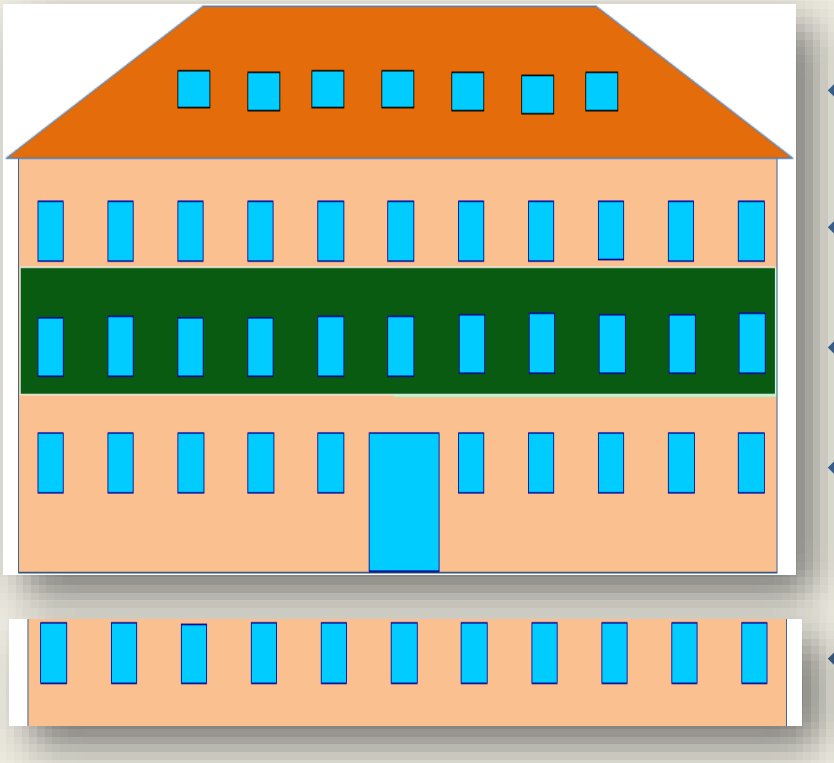
Institute of Pharmaceutical Technololgy and Biopharmacy

University of Pécs

Faculty of Pharmacy

H-7624 Pécs, Rókus str.2.

Faculty of Pharmacy



Inst. of Pharmaceutical Biotechnology

Inst. of Pharmacognosy/Dept. of Pharmaceutics

Inst. of Pharmaceutical Technology and Biopharmacy

Inst. of Pharmaceutical Chemistry

Inst. of Pharmaceutical Biology/
Inst. of Pharmaceutical Technology and Biopharmacy – new lab.

Who is who

Institute of Pharmaceutical Technololgy and Biopharmacy

University of Pécs

Who is who ?

Course director:

Dr. Szilárd PÁL PhD

Senior Lecturer
Head of Institute of Pharmaceutical Technology and Biopharmacy

Who is who ?

Dr. Anna Takácsi-Nagy

assistant lecturer
responsible for english 3rd year

Important notes

Conditions for acceptance of the semester

- Students must fulfil requirements determined by the Code of Studies and Examinations
- Attendance of the lectures according to the Code of Studies and Examinations
  - 3 absences are allowed
  - In case of 4 or more absences the course is rejected!

Important notes

- During the semester students have to write three assessments and they have to reach 60% after average calculation.
- After two assessments if students reach average 60% taking into account both tests, writing the third assessment is not compulsory.
- Summarized average of all three assessments has to be above 60%.
- In case of confirmed absence from the assessment, re-take chance is possible for the student. Missing the re-take results 0% assessment.

Dates of tests

- 1. test: October 1
- 2. test: November 5
- 3. test: December 3

Education

Course literature

- theoretical knowledge

  - Aulton's Pharmaceutics – The Science of Dosage Form Design
  - Pharmaceutical Technology e-book (pdf) (on our website)
  - Lecture notes

- practical knowledge

  - Laboratory practices, notes

- theoretical + practical knowledge

http://gytk.pte.hu

our website includes:

- The program and material of lectures and laboratory education

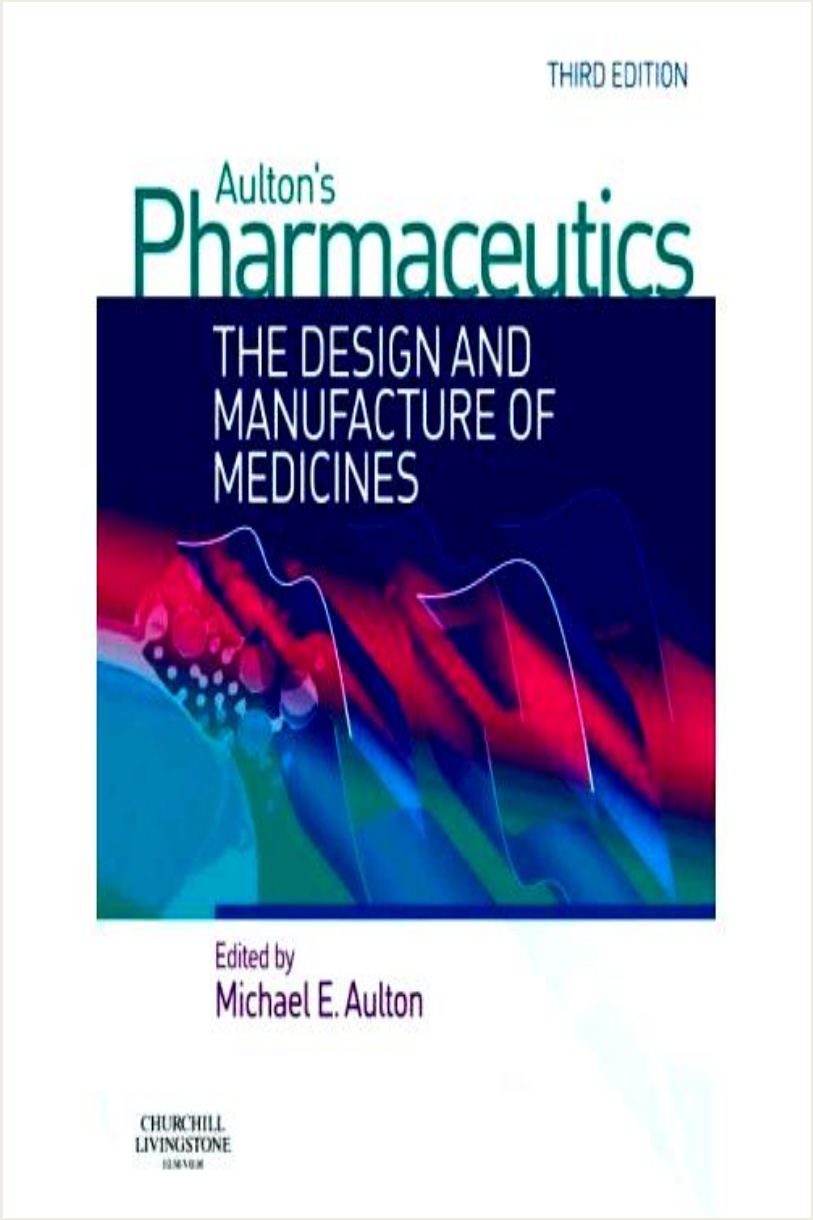
Education

Course literature

Aulton's

Pharmaceutics –

The Design and Manufacture of Medicines



What is the topic for today?

- **Introduction to the pharmaceutical terminology**
- **Introduction to the pharmaceutical technology**

Pharmaceutical technological terminology

(pharmaceutical terms)

Standard Term

European Pharmacopoeia Commission

STANDARD

TERMS

Introduction

and

Guidance for use

Ph. Hg. VIII. - Ph. Eur.

Medicines

Medicines are drug delivery systems for use in

- the diagnosis,
- treatment,
- or prevention of disease

in human or other animals.

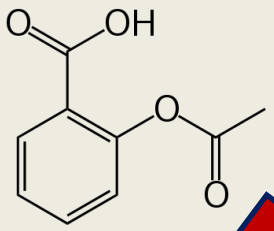
Characterization of medicines

Main requirements:

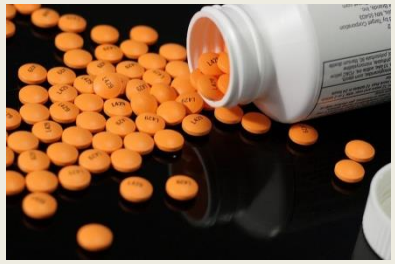
- **safety**,
- **efficacy** and
- **quality** (stability, content uniformity, reproducibility…)

in a convenient dosage forms (administration, liberation)

From API to DDS



2-acet-oxybenzoic acid



coated tablet

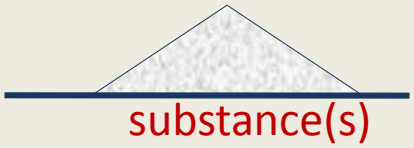
uncoated tablet

Main components of medicines

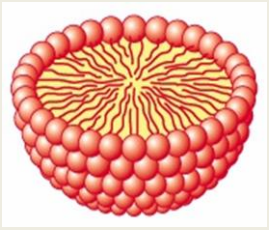
active ingredients

\+ adjuvants (excipients)

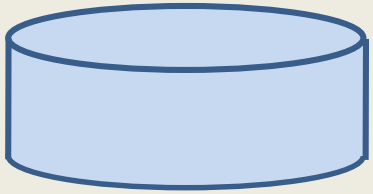
medicine



formulation



DDS



DDS

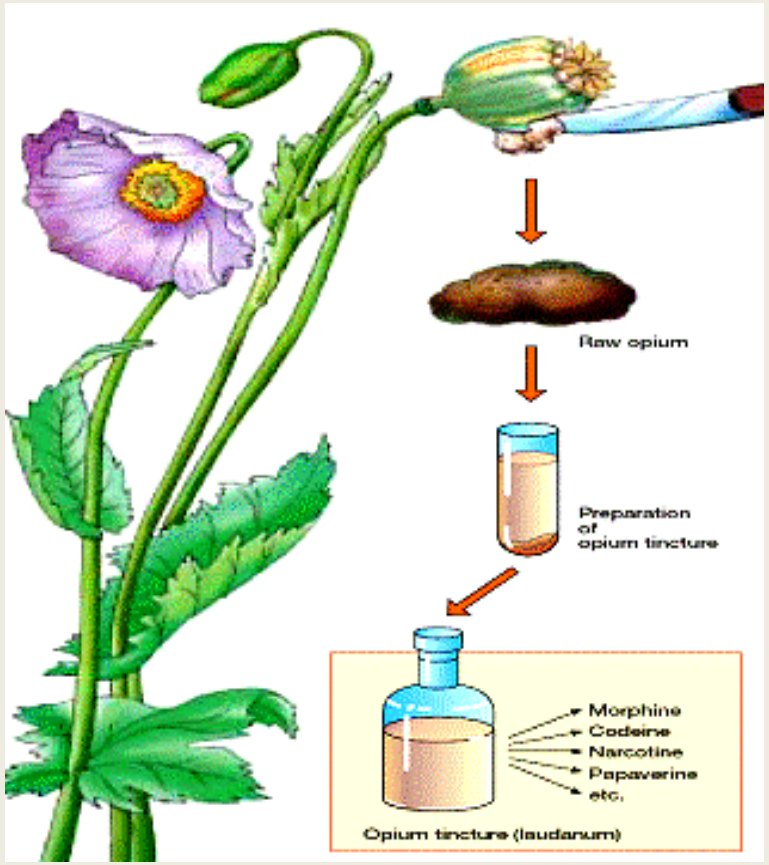
Medicines are very rarely drugs alone but require additives to insert them into dosage forms and this introduces the concept of formulation.

Active ingredient (API, AI, DS)

Active ingredients are components in a drug which provide some pharmaceutical value, in contrast with the inactive ingredients, which act as carriers to make the drug easier for the body to process.

Active ingredient (API, AI, DS)

In the past, all medicines came from plants or animals. Although some important medicines still come from plants or animals (e.g. morphine), most medicines used today in the developed world are manufactured through chemical or biological processes.



Excipients

Excipients generally are pharmacologically inactive substances used as carriers for the active ingredients of medications or as adjuvants of manufacturing process or as regulators of liberation.

Its selection depends on

- technological,
- stability and/or
- biopharmaceutical reasons.

Types of excipients

- Fillers, diluents (to fill out the size of tablet)
- Binders (to hold the ingredients in a tablet together)
- Antiadherents (to reduce the adhesion)
- Lubricants (to prevent tablets sticking to the punches of tabletting machine)
- Glidants (to promote powder flow)
- Coatings (to coat tablets, granules...)
- Dissolution rate regulators (to change the of active species)
- Disintegrants (to ensure disintegration in GIT)
- Sorbents (to limit moisture sorbing)
- Preservatives (to extend shelf life and improve safety)
- Flavours (to mask unpleasant tasting)
- Sweeteners (to make the ingredients more palatable)
- Colours (to improve the appearance of a formulation)

Vehicle

A vehicle is the carrier, composed of one or more excipients, for the active substance(s) in a liquid preparation.

Ph. Hg. VIII. - Ph. Eur. 4, 4.1 és 4.2

Basis

A basis is the carrier, composed of one or more excipients, for the active substance(s) in semi-solid and solid preparations.

Ph. Hg. VIII. - Ph. Eur. 4, 4.1 és 4.2

Dosage form

The dosage form is the physical manifestation of a pharmaceutical product that contains the active ingredient(s) and/or excipient(s) that are intended to be delivered to the patient.

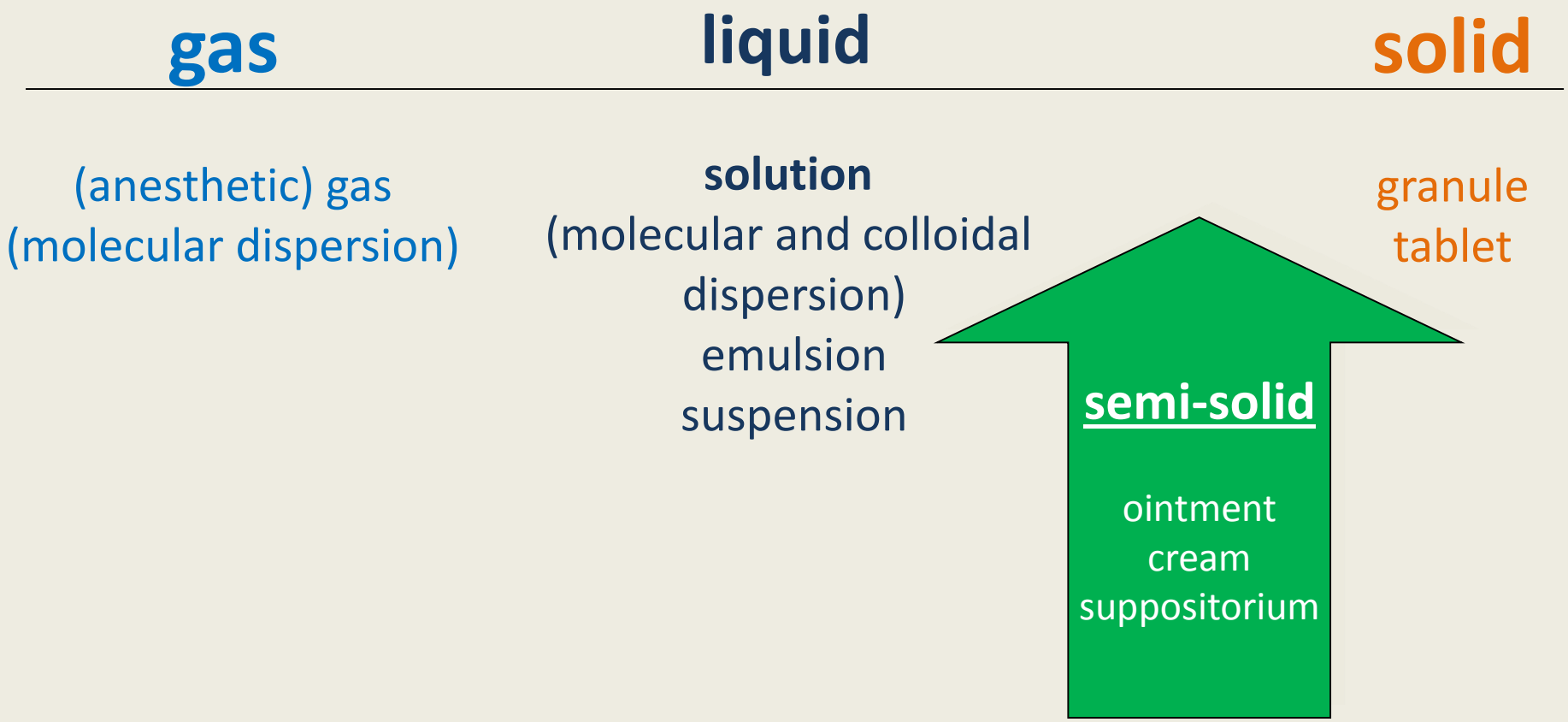
Pharmaceutical preparation in tablet form

Standard Terms were drawn up by the European Pharmacopoeia Commission

Classification of medicines

based on the consistency

Pharmaceutical Dosage Forms



Gases

- Medicinal gases, inhalation/volatile anaesthetics (vaporised before administration by inhalation)
- Aerodispersions of solid particles (e.g., antiasthmatic inhalations) or liquid particles (antiasthmatic inhalations or sprays)

Liquids

- Solutions – one homogenous phase, prepared by dissolving one or more solutes in a solvent
- Emulsions
  - a dispersion system consisting of two immiscible liquids
  - o/w or w/o
  - cloudy appearance
- Suspensions
  - a dispersion system where solid particles (dispersed phase) are dispersed in liquid phase (dispersion medium)
  - require shaking before administration

Semi-solid dosage forms

1- Unshaped (without specific physical shape)

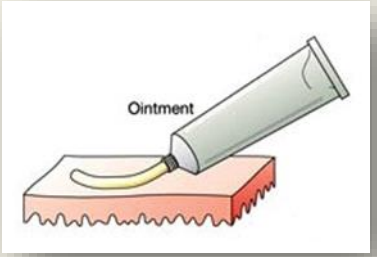
- Gels -a semi-solid systems in which a liquid phase is constrained within a 3D cross-linked matrix.

- Creams – semi-solid emulsion systems (o/w, w/o) containing more than 10% of water.

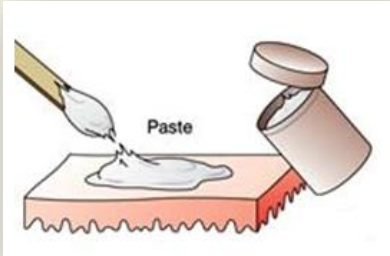
Semi-solid dosage forms

1- Unshaped (without specific physical shape)

- Ointments – semi-solid dosage forms preparations for external application to skin or mucous membranes



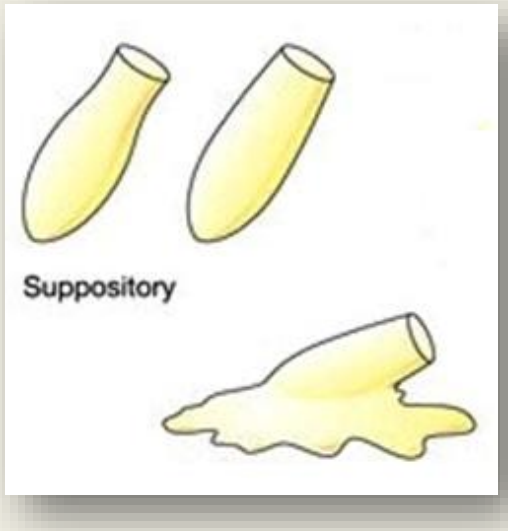
- Pastes – semi-solid dispersion system, where a solid particles (> 25%, e.g. ZnO) are dispersed in ointments



Semi-solid dosage forms

2- Shaped

- Suppositories (for rectal administration)



- Vaginal suppositories

Solid dosage forms

1- Unshaped

- powders for external/internal use

Solid dosage forms

2- Shaped

- **Tablets**

- **Capsules**

- **Implants** (sterile disks inserted surgically into body tissues and designed to release drug(s) over extended period of time)

- **Transdermal patches**

Classification of medicines

based on manufacture

Pharmaceutical preparations

- **Manufactured** in large scales by pharmaceutical industry (original and generic preparations)
- **Contemporaneous/magistral preparations** dispensed individually in pharmacies

Pharmaceutical preparations

1.1- Original pharmaceutical preparations

- undergo full and very extensive pharmacological/ toxicological and pharmaceutical pre-clinical and clinical development and evaluation

- particularly important is the proof of effectiveness and safety

Pharmaceutical preparations

1.2- Generic pharmaceutical preparations („authorized copies of original preparations“)

- Can be released after the expiration of the patent protection of the original preparation
- The approval for clinical use is easier due to the prior experience with the original preparation
- Must be pharmaceutically equivalent: same API, dose, pharmaceutical dosage form and the same route of administration as in original preparation
- Must be clinically bioequivalent: i.e. it must be of very close biopharmaceutical profile as original preparation. Pharmacokinetics (PK) parameters (C_{max}, t_{max}, AUC) are within 80-125 % range as compared with the original preparation.

Pharmaceutical preparations

2 –Magistral preparations compounded individually

- These preparations are compounded individually for a particular patient according to the physician's prescription in a pharmacy licensed for compounding
- In contrast to the past, they are used rather rarely and mostly in specific situations
- The major disadvantage is the lack of quality control and clinical investigations.

Formulation

Formulation is a preparation method of the specific structure of a preparation by proper pharmaceutical technological methods.

Formulation

Formulation studies then consider such factors as particle size, polymorphism, pH, and solubility, as all of these can influence liberation, bioavailability and hence the activity of a drug.

The drug must be combined with inactive additives by a method which ensures that the quantity of drug present is consistent in each dosage unit e.g. each tablet. The dosage should have a uniform appearance, with an acceptable taste, tablet hardness, or capsule disintegration.

Operation and procedure

The manufacturing procedures contain operations
e.g. mixing, filtering, drying, extracting…

An operation can be made by procedures
e.g. mixing with arm-stirrer or shaker…

*Discipline of **operation**:* theoretical knowledge or information about the manufacturing process

*Discipline of **procedure**:* the knowledge of the operation's application using an equipment

Classification of the operation

- *basic operation:* is an operation, which assists making other operations (e.g. crystallization, drying)

- *compiler operation:* when the substancies are mixed in one mass product (e.g. mixing)

- *final operation:* the operation, which is made as the last step (filling, coating, packaging)

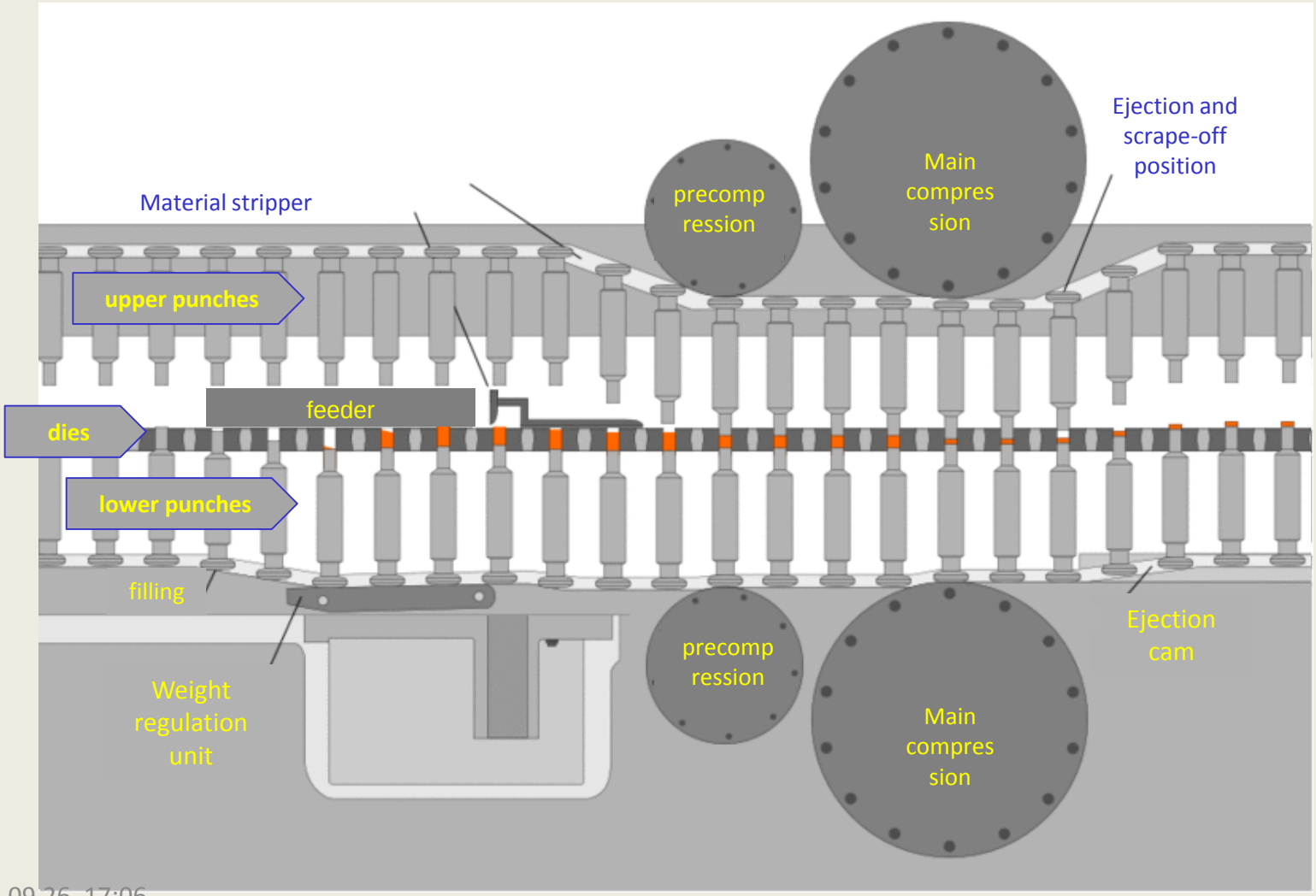
Pharmaceutical technology

Pharmaceutical technology is the multidisciplinary science of preparing pharmaceutical dosage forms.

Pharmaceutical technology combines knowledge and understanding of active ingredients, excipient substances, technological processes and equipment and plays a key role in developing new drugs.

Equipments

Rotary tablet-machine



Equipments

Capsule filling machine

Classification of medicines

based on biopharmacy

Routes of administration

The route of administration indicates the part of the body on which, through which or into which the medicinal product is to be introduced.

Two main routes:

- Systemic
- Local

Standard Terms were drawn up by the European Pharmacopoeia Commission

Classification of pharmaceutical dosage forms according to the route of administration

– for systemic administration
  - peroral (p.o.)
  - sublingual (s.l) and buccal
  - rectal
  - parenteral
  - transdermal
  - inhalation

Classification of pharmaceutical dosage forms according to the route of administration

– for local administration

- Topical

  Into/onto - the eye, nose, ear
  - the oral cavity
  - the vagina, rectum
  - the bronchi
  - the skin

- Local parenteral
- Oral (local effect within GIT; antacids, adsorbents)

Thank you for your attention!