Introduction to pharmaceutical technology

Marie Wahlgren

Chapter 1

What is the topics of today

- **Introduction to the course**
- **Introduction to the project assignment**
- **How to choose a new drug formulation**

Contacts and other important information

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What I want you to learn during this course

- **Basic knowledge of pharmaceutical formulations**
- **How to evaluate the uptake of pharmaceutical components by the body**
- **The language used within the pharmaceutical industry**
- **The quality systems used by the pharmaceutical industry**
- **How to use all you already know about chemistry, biochemistry and chemical engineering in the field of drug product development**

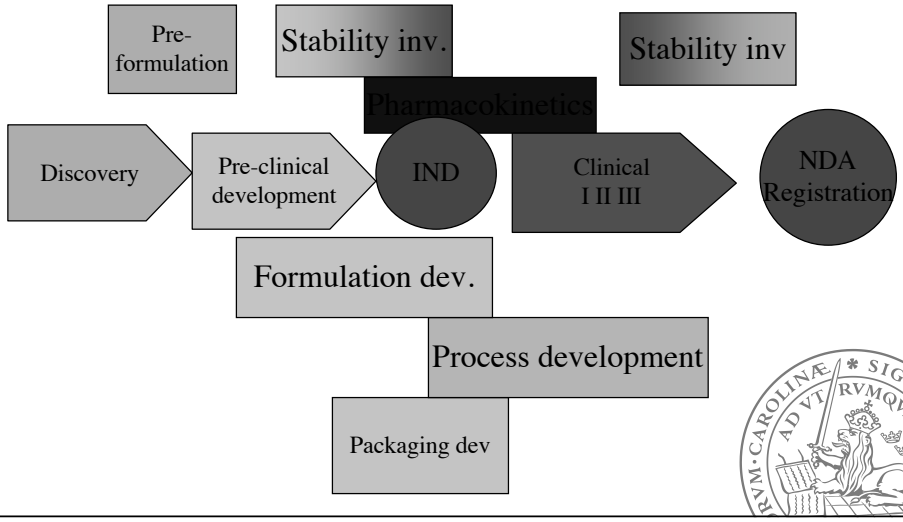
Course literature etc

- **Aulton: Pharmaceutics – The Science of Dosage Form Design**
- **A binder containing all the course SOPs and all the materials from my lectures**
- **The webpage of the course which includes**
  - **All the material in the binder**
  - **Links to other homepages**
  - **Templates for reports etc.**

The course is in English

- **I want you to think about whether this changes your learning tactics**
- **Do not hesitate to ask questions if you did not understood something during a lecture**
- **If you don't know the Swedish word for any of the things I talk about, ask**
- **As a help to you I will normally end every power point presentation with a list of important words. These are also listed on the webpage of the course.**

Development of a drug product - What will be taken up in the course



Quality demands that mimic those used in the industry

- **Why**
  - **To understand that the quality systems used in the pharmaceutical industry is part of becoming a pharmaceutical engineer**
  - **It is an advantage to be familiar with them when you start to work in the industry**
  - **Used in a sensible way they do improve your way of working**
- **How**
  - **We use SOPs to describe different parts of the course.**
  - **Laboratory work is documented according to standards used in the industry**
  - **Lectures will be given on such issues as that of validation**
  - **You'll be training on how to write specifications and production masters**

Changes in the course from last year

- It will be an oral exam not a written one
- I have changed the assignment to reduce the amount of work
- I have changed some lectures
- There are two versions of the hand outs

Oral exam

- Individual
- On your own questions
- You decide which grade you aim for
- Tomorrow we will train on writing questions

Oral exam

Grade	Criteria for grade
5	Questions that show that the student is able to have a deep understanding of important and complex concepts within the area of pharmaceutical technology
4	Questions that show that the student is able to link several important aspects of the course material to each other
3	Questions that require a basic understanding of important concepts
Unacceptable	Questions that only require one simple fact based answer

Exercises and laborative work

- **Two laboratory exercises (Introduction tomorrow at 13.15)**
  - **Production of tablets**
  - **Determination of log P or solubility**
- **One project assignment**
- **Two exercises to be carried out in seminar form**

Project assignment

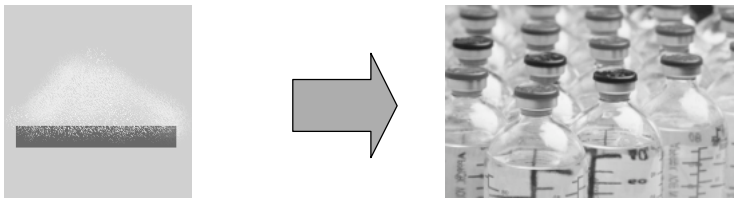
- **Describe the development of a drug product in three stages**
  - **Choice of a drug formulation**
  - **Description of the disease,the drug substance and the drug product**
  - **Description of the production process and of critical points for validation**
- **Starting point: description in article of an active substance**
- **Groups of 4-5 persons**
- **The assignment is described in SOP-2002.05**

Part 1

- **Choose a route of delivery and suggest a suitable drug formulation (for example tablet, capsule or gel)**
- **Be prepared to discuss your choice of product next Monday.**
- **Start now by reading the SOP.**
- **During the break you can choose an article and group, or you can sign up during today or tomorrow.**
  List on my door at the Department of Food Technology

Any questions on the project assignment?

What is pharmaceutical development?



- It is the road from active substance to a finished product in its primary packing material.
- This includes functional production methods and all necessary documentation

OR FDA's definition

"The aim of pharmaceutical development is to design a quality product and its manufacturing process to consistently deliver the intended performance of the product."

Why is formulation necessary

- Convenient
- To give the correct dose
- Protect the substance
- Alters the pharmacokinetic behaviour of the drug

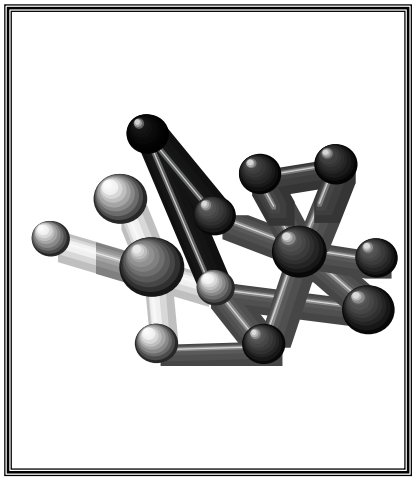
What determines the choice of formulation?

- **Patient**
  - **Child, adult or elderly person**
  - **Other diseases**
  - **Culture and habits**
- **Doctors or society**
  - **Price**
  - **Tradition**
  - **Insurance system**

Disease

- **Acute, long term or chronic.**
- **How serious the disease is.**
- **Local or systemic treatment.**
- **Self-treatment or treatment by healthcare professionals.**

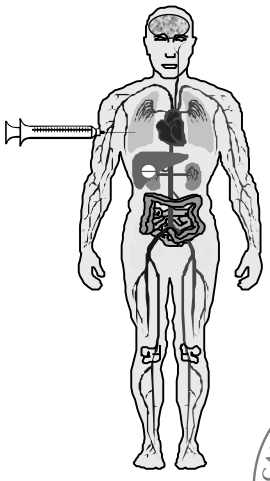
The active substance



- Behaviour in vivo
  - Uptake
  - Metabolism prior to uptake, the first-pass effects
  - Clearance
- Stability in vitro
  - Interactions with excipients and packing material
  - Sensitivity to moisture oxygen etc
- Physical and chemical properties
  - Solubility
  - Particle size

Delivery routs

- Oral
- Injection
- Lungs
- Nasal mucosa
- Topical
- Rectum
- Vaginal
- Ophthalmic



Delivery routes a brief guide

Formulation	First pass effects	Other enzymatic effects	Absorption	Other comments
Oral	yes	yes	Large area, active transport	Most common
Injection	no	no	IV 100%	Low patient compliance
Inhalation	no	yes	Large area Good adsorption	Difficult regulatory demands
Nasal	no	yes	Small area High clearance	Can reach the brain
Topical	no	yes	No active transport low permeability	Local delivery Controlled release
Rectal	no	Some but small	Small area low permeability	Good for children

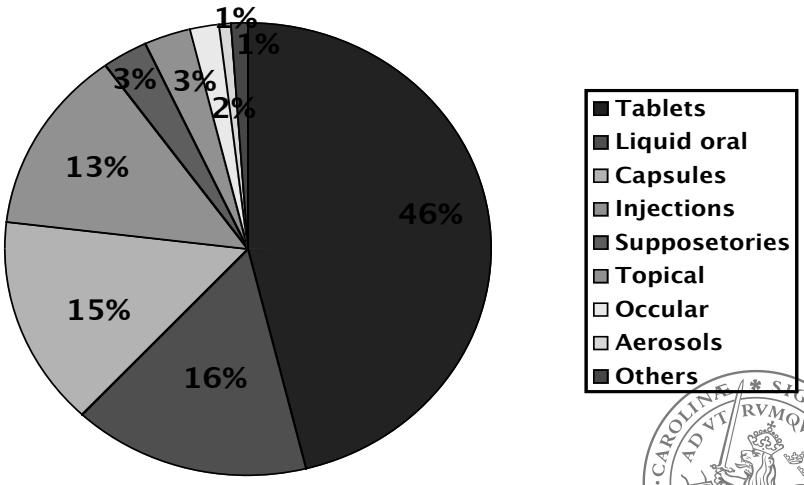
Choice of a formulation

Primary concerns

- **Desired pharmacokinetic profile**
- **Toxicity issues**
- **Patient compliance**
- **Properties of active substance**
  - **Solubility**
  - **Stability in vitro and in vivo**

- **Secondary concerns**
  - **Price**
  - **Time to market**
  - **Available facilities**
  - **The companies formulation platforms**
  - **Patents**

Common drug formulations



General rule

- **Keep it simple, stupid,**
  - **If a simple fast-release tablet does the job, use it.**
  - **Use approved excipients (excipient = all ingredients except the active substance)**

Terms to know from today's lecture

- **IND: Investigational New Drug**
- **NDA: New Drug Application**
  - **The milestones in drug development where authorities are contacted**
- **SOP standard operating procedure: written instructions**
- **First pass effect: the drug is metabolised in the liver before reaching the blood**
- **In-vitro: conducted in a glass contaner in contrast to in-vivo where the experiment is done on living organisms**
- **I.V intravenous- injection into the veins**
- **Topical: on the skin**