



Dosage Form Design

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No	Lecture title	Hr
1.	Pharmaceutical consideration: The need for the dosage form.	1
2.	General consideration for the dosage form.	3
3.	Pre-formulation; physical description, microscopic examination.	2
4.	Melting point; phase rule; particle size; polymorphism; solubility.	2
5.	Permeability; pH; partition coefficient; pka; stability; kinetics; shelf life.	2
6.	Rate reaction; enhancing stability.	2
7.	Formulation consideration: Excipients; definition and types; appearance; palatability; flavoring.	2
8.	Sweetening; coloring pharmaceuticals; preservatives; sterilization; preservatives selection.	2
9.	Biopharmaceutical considerations: Principle of drug absorption; dissolution of the drugs.	4
10.	Bioavailability and bioequivalency; FDA requirements.	3
11.	Assessment of bioavailability; bioequivalence among drug products.	3
12.	Pharmacokinetic principles: Half life; clearance; dosage regimen considerations.	4



Objectives

- List **reasons** for the incorporation of drugs into various **dosage forms**
- Compare the **advantages / disadvantages** of various drug DFs
- Describe the information needed in **preformulation studies** to characterize a drug substance for possible inclusion into a dosage form
- Describe the **mechanisms** of drug **degradation** and provide examples of each



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Objectives

- Describe the purpose and general protocol for **accelerated stability studies**
- Summarize approaches employed to stabilize drugs in pharmaceutical dosage forms
- Calculate rate reactions for various liquid dosage forms
- Categorize various pharmaceutical ingredients and excipients

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Objectives

- Discuss key data points in a **blood plasma concentration–time curve**.
- Differentiate between the terms **biopharmaceutics**, **bioavailability**, and **bioequivalence**
- Discuss the importance of a drug's **dissolution rate** following the oral administration of a solid dosage form
- Perform various **basic pharmacokinetic** calculations
- List the factors that a pharmacist must consider when determining a **dosage regimen** for a specific patient

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Module construction

Theory Lectures:

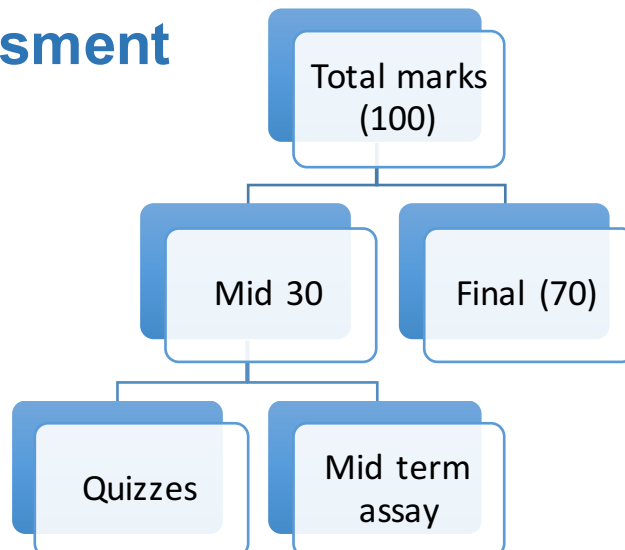
2 hr /week



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Module Assessment

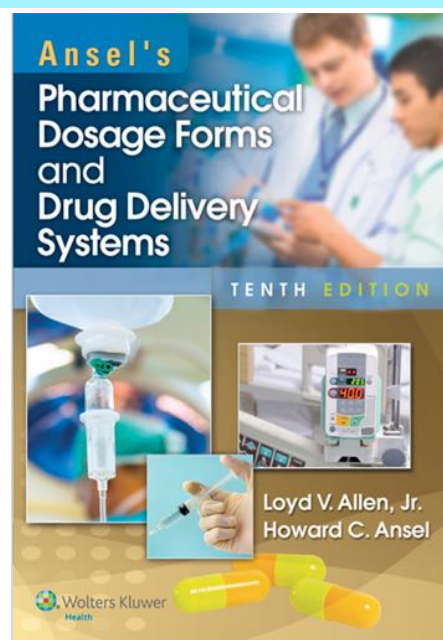


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References

1. ***Pharmaceutical Dosage Forms and Drug Delivery Systems*** by **Haward A. Ansel**; 10th edition.
2. ***Lecture notes from College web site:***
<http://pharmacy.uobasrah.edu.iq>





Introduction

1. Understand the **principles** and factors that influence **dosage forms design**.
2. Learn about the **applications** of these principles in the practice of **pharmaceutical industry**.



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Pharmaceutical dosage form

- **Dosage form**: it is the formulation to which drug is included with the excipients
- A drug can not be given alone.
- **Excipients** solubilize, suspend, thicken, dilute, emulsify, stabilize, preserve, colour, flavour, and fashion medicinal agents into efficacious and appealing dosage forms.



Pharmaceutical dosage form:

- Proper dosage form design ensures obtaining the required features like:
 - **Stability**
 - **Compatibility**
 - **Efficacy**
 - **Elegance**
 - **Easy administration by the patient.**
 - **Etc..**



The need for the dosage form

- Most drugs administered in small quantities (mg or μg) too small to be formulated as a tablet or cap.
 - **Volume would be so small.**
 - A filler here is needed.

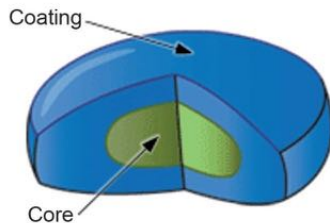
Drug	Usual dose (mg)	Category
Betaxolol	10	Antianginal
Enalapril	5	Antihypertensive
Clonazepam	1	Anticonvulsant
Digoxin	0.25	Carditonic
Levothyroxine	0.1	Thyroid



The need for the dosage form

- To **protect** the drug substance from the **destructive** influences of atmospheric oxygen or humidity.

Coating



Sealed ampoules



The need for the dosage form

- To protect the drug substance from the destructive influence of gastric acid after oral administration.
 - Enteric-coated tablets.

