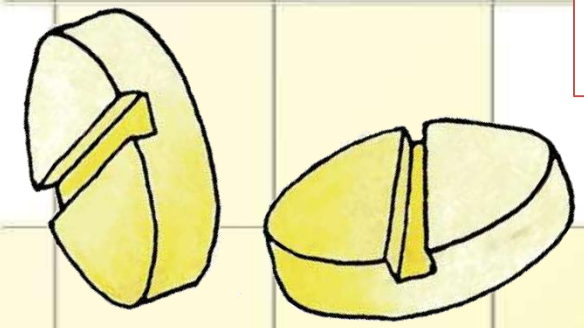
Tablets

Ms. Pratiksha Jayaswal
Assistant Professor
Faculty of Pharmaceutical Sciences
Rama University, KANPUR (U.P.)

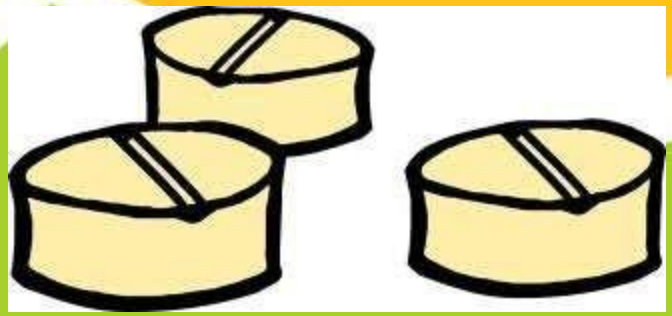
CONTENTS

- DEFINITION OF TABLETS
- ADVANTAGES
- DISADVANTAGES
- TABLET INGREDIENTS
- GRANULATION TECHNIQUES
- PROBLEMS DURING PRODUCTION
- EVALUATION OF TABLETS

INTRODUCTION



- **Tablet is defined as a compressed solid dosage form containing medicaments with or without excipients.**
- **Tablets are solid dosage forms, prepared by compressing a drug or a mixture of drugs, with or without diluents.**



ADVANTAGES

Cost is lowest of all oral dosage forms.

Lighter and compact.

Easiest and cheapest to package and strip.

No risk in choking.

Overcome unacceptable taste of drug.

Quick disintegration and dissolution of dosage form.

ADVANTAGES

- Improved bioavailability can be achieved.
- Avoid first pass metabolism due to pre-gastric absorption.
- Odour and bitter taste can be masked by coating techniques.
- Suitable for large scale production.

DISADVANTAGES

Difficult to swallow in case of children and unconscious patients.

Some drugs resist compression into dense compacts, owing to amorphous nature, low density characters.

Drugs with poor wetting, slow dissolution properties.

Bitter tasting drugs, drugs with an objectionable odour or drugs that are sensitive to oxygen may require encapsulation or coating.

TABLET INGREDIENTS

1. DILUENT

- Diluents are fillers used to make required bulk of the tablet.
- Ex: Lactose, Starch, Dextrose, Mannitol.

2.BINDER AND ADHESIVE

- Added either in dry or wet- form to form granules or cohesive compacts.
- Ex: Acacia, Starch, CMC, PVP.

3.DISINTEGRANTS

- Added to facilitate breaking or disintegration in the GIT.
- Ex: Starch, Cellulose, Clays.

4.LUBRICANTS

- Intended to prevent adhesion of the tablet materials to the surface of dies and punches.
- Ex: Stearic acid, Magnesium stearate, Talc, Surfactants.

5.Glidant

- Intended to promote flow of granules or powder material by reducing the friction.
- Ex: Corn Starch, Talc.

6. Colouring agent

- Production of more elegant product.
- Ex: Brilliant blue, Indigotene, Erythrosine.

7. Flavoring agent

- To impart flavour or odour.
- Ex: Menthol, Vanilla, Liquorice, Citrus fruits flavour, Anise oil, Clove oil.

8. Sweetening agent

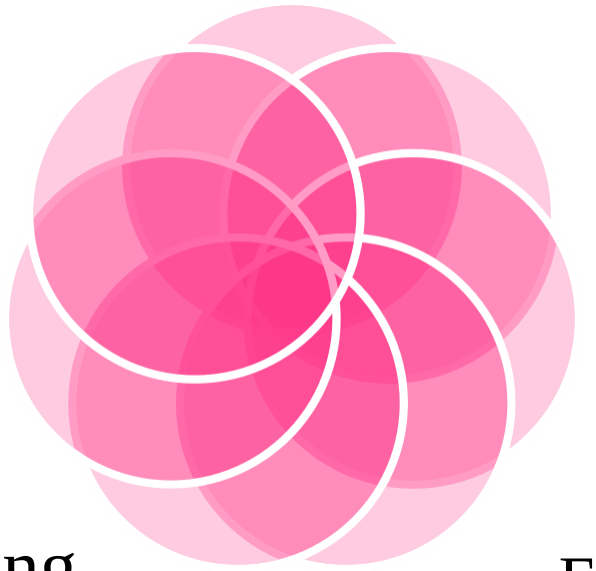
- To mask the bitter taste of drugs.
- Ex: Mannitol, Lactose, Aspartame.

EXCIEPIENTS
- *functions*

Impart weight, accuracy, & volume.

Facilitate dosage form design.

Improve solubility.



Increase patient acceptability.

Increase stability.

Modifying drug release.

Enhance bioavailability .

Different types of Tablets

(A) Tablets ingested orally:

1. Compressed tablets. e.g. Paracetamol tablets.

2. Multiple compressed tablets.

3. Repeat action tablets.

4. Delayed release tablets.

5. Sugar coated tablets, e.g. Multivitamin tablet.

6. Film coated tablets, e.g. Metronidazole tablet.

7. Chewable tablets, e.g. Antacid tablets.

(B) Tablets used in oral cavity

1. Buccal tablets, e.g. Vitamin-c tablet

2. Sublingual tablets.

3. Troches or lozenges.

4. Dental cone.

(c)Tablets administered by other route

1. Implantation tablets.

2. Vaginal tablets, e.g. Clotrimazole tablets.

PREPARATION OF TABLETS

TABLETING METHODS

Dry methods

- Direct compression
- Dry granulation

Wet methods

- Wet granulation

Direct compression

Tablets are compressed directly from powder blends of the active ingredient and suitable excipients

No pretreatment of the powder blends by wet or dry granulation procedures is necessary

DRY GRANULATION

1. **Milling/Screening.**
2. **Pre-blending.**
3. **Slugging/roller compaction.**
4. **Dry screening.**
5. **Blending of lubricant.**
6. **Compression.**

WET GRANULATION

1. Milling/Screening.
2. Pre-blending.
3. Addition of binder.
4. Screening of wet mass.
5. Drying of the wet granules.
6. Screening of dry granules.
7. Blending of lubricant (and disintegrant).
8. Compression.

Tablet compression equipments

Single Punch Machine (Tablets)

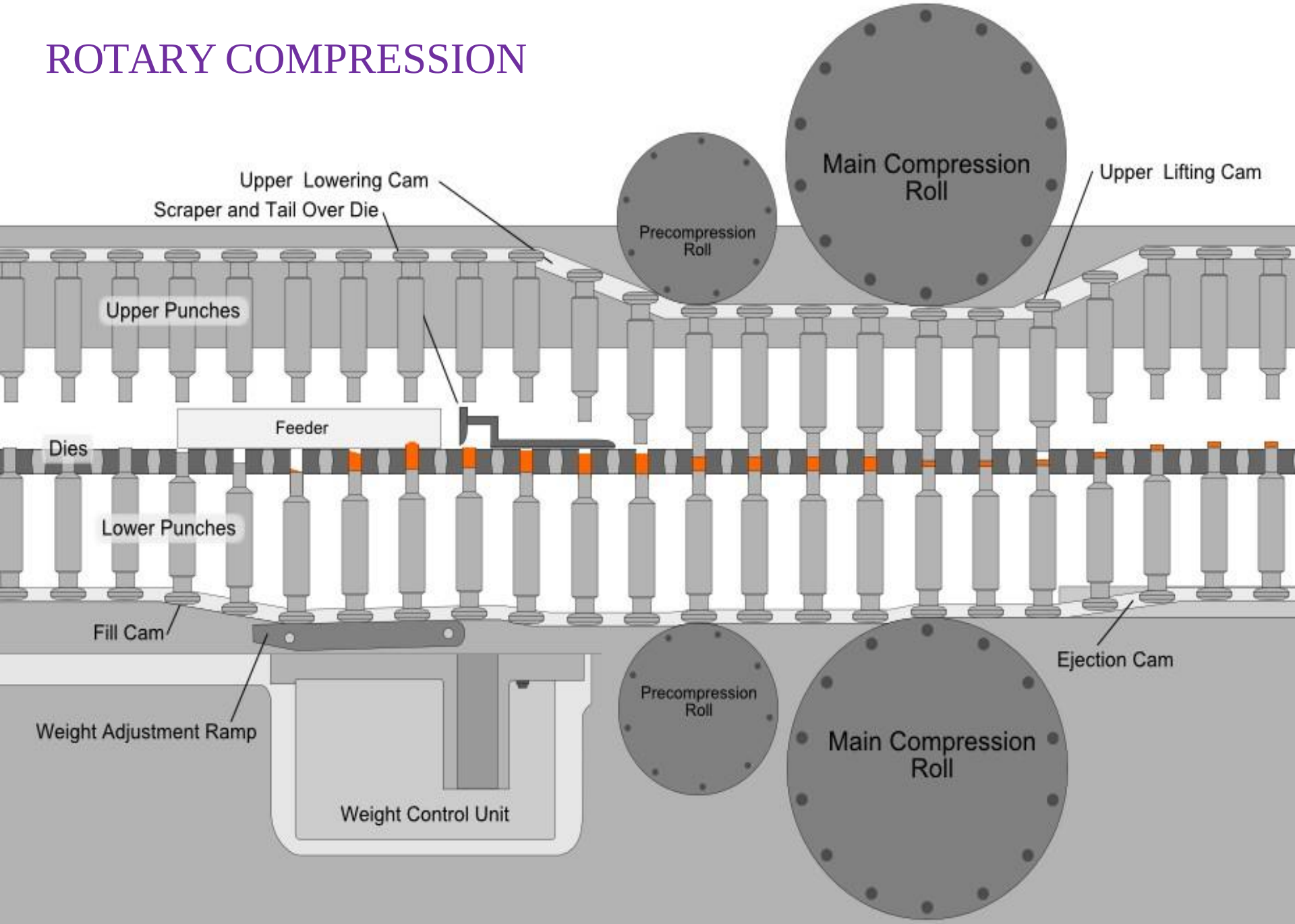
Upper and Lower Collar

Collar locker

top punch

bottom punch

ROTARY COMPRESSION



Processing Problems

PROCESSING PROBLEMS

Various problems arise during manufacture of tablets. They are:

- Capping
- Lamination
- Picking
- Sticking
- Mottling

Processing Problems

1.CAPPING :

Complete or partial loss of top and bottom crowns of a tablet from the main body is called capping.

Cause: **Improper/Deep concave punches.**

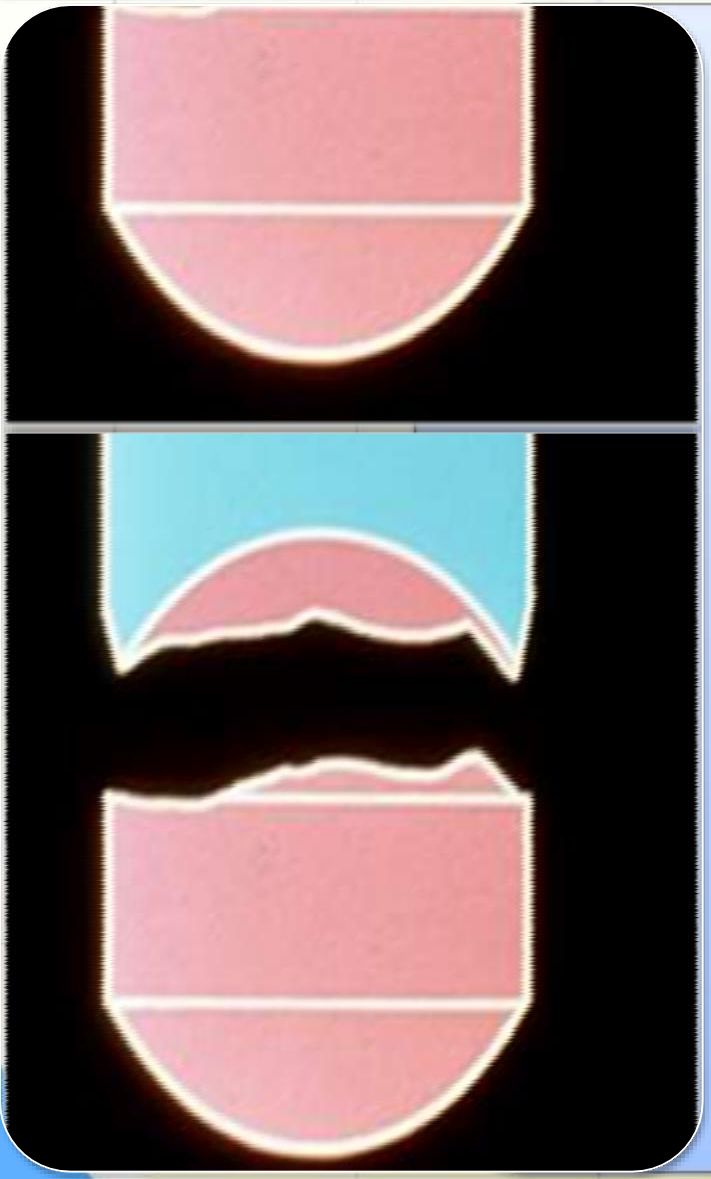
Remedy: **Better to use flat punches.**

2.LAMINATION:

The separation of a tablet into two or more distinct layers is called lamination.

Cause: **Air entrapment , Deep concave punch.**

Remedy: **By pre-compression ,Reducing final compression force ,Using flat punch ,Using hygroscopic materials to maintain proper moisture level.**



3.Picking :

Surface materials of the tablet stick to the punch and get removed from the tablet surface. This is known as **picking.**

Cause:

•Because of engraving on the punch tips like small enclosed areas in the letters like “A”, “B”, “D”, “O”, “Q” etc

Remedy:

•Lettering should be designed as large as possible, even the tablet size can be increased by reformulation

4.Sticking:

Sticking refers to the condition in which tablet materials adhere to the die wall.

Cause: over wetting or excessive film tackiness

Remedy: Reduction in liquid application rate

5.Mottling:

It is an unequal distribution of colors on a tablet with light and dark areas on tablet surface.

Cause: 1. Use of a drug whose color differs from tablet excipients.

2. Use of a drug whose dehydration products are colored.

Remedy: 1. The use of colorant.

2. Disperse a dry colour additive during powder binding steps.

EVALUATION OF TABLETS

TYPES OF TABLET EVALUATION

1. General appearance
2. Weight variation test
3. Content uniformity test
4. Hardness test
5. Friability test
6. Disintegration test
7. Dissolution Test

1.GENERAL APPEARANCE :

The general appearance of a tablet is essential for consumer acceptance. it involves:

- **Size & Shape :** Tablet thickness should be controlled within a ± 5% variation of standard value.
- **Unique identification marking:** These markings include company name or symbol, product code, product name etc.
- **Organoleptic properties:** Color distribution must be uniform in comparison with the color of the standard.

2.WEIGHT VARIATION TEST:

weigh randomly 20 tablets individually in a batch.

↓

Determine the average weight of 20 tablets.

↓

Compare individual tablet weight to average weight

- As per I.P. ,

❑ **If the tablet weight is,**

❑ **< 80mg , % deviation allowed up to 10%**

80-250mg , % deviation allowed up to 7.5%

> 250mg , % deviation allowed up to 5%

If any of the tablet deviates, another 10 tablets are selected from the same batch and the procedure is repeated.

Of 30 tablets , not more than 1 tablet should deviate.

3.Content uniformity test:

It is used to ensure that every tablet contains the amount of drug substance intended with little variation.

Procedure:

- 10 tablets are assayed,
- 9 tablets should have % limit of 85-115%.
- If more than 1 tablet deviates from 85-115%,
- Another 20 tablets are assayed
- Not more than 1 tablet should have the % limit of 75-125%

4. Hardness test:

It is defined as the force required to break a tablet in a diametric compression . Tablet requires a certain amount of strength or hardness and resistance to friability to withstand mechanical shocks of handling in manufacture, packaging and shipping

Types of hardness testers used.

1. Monsanto hardness tester .
2. Strong cob tester.
3. Pfizer tester.

TABLET HARNESS TESTER (MONSANO TYPE)

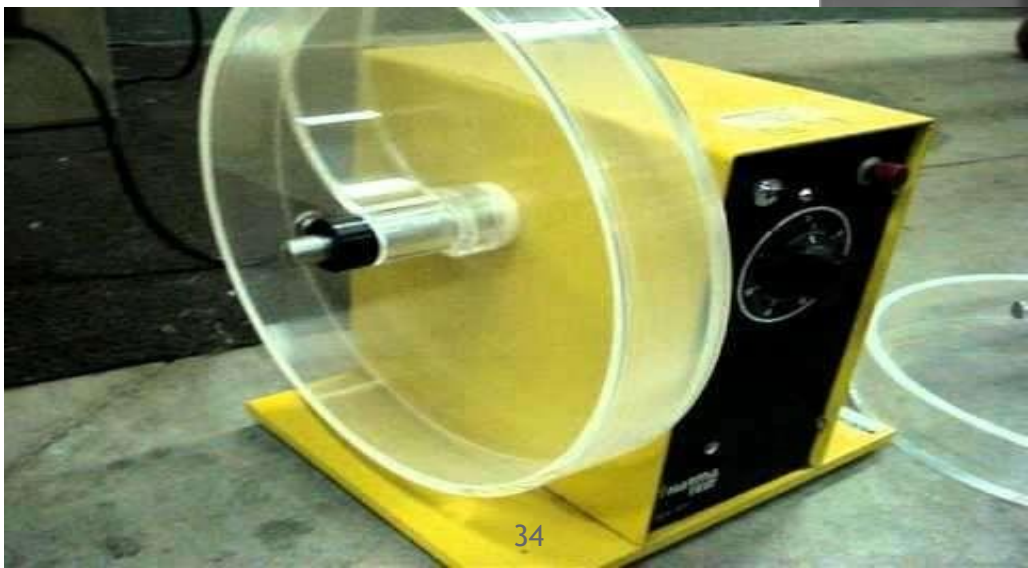
For, Conventional tablets hardness : 2.5- 5 kg/cm^2

Dispersible/ chewable tablets hardness: 2.25- 2.5 kg/cm^2

Extended release tablets hardness : 5- 7.5 kg/cm^2

5. Friability test:

- The instrument used is ***Roche friabilator.***
- It consists of a drum having 280-290mm diameter with a thickness of 30mm. A drum is mounted on a horizontal axis of a drive motor.
- Drum is operated at a speed of 25rpm.&Allowed revolutions for each tablet is 100.
- ***Allowable range: loss 0.5 - 1% weight***



6.Disintegration test:

Disintegration is the breakdown of tablet crust into finely divided particulate matter or into granules once the tablet is exposed to the gastric fluids .

Type of tablets	Time Of disintegration
uncoated conventional tablets	*15min*
sugar coated tablets	*60 min.*
film coated tablets	30 min

7.Dissolution Test (U.S.P.): It is the solubilization of the drug or active moiety in to the dissolution media.

Different types of dissolution apparatus:

Apparatus -I-Rotating Basket type.

Apparatus -II- Rotating Paddle type.

Apparatus-3-Reciprocating cylindrical type.

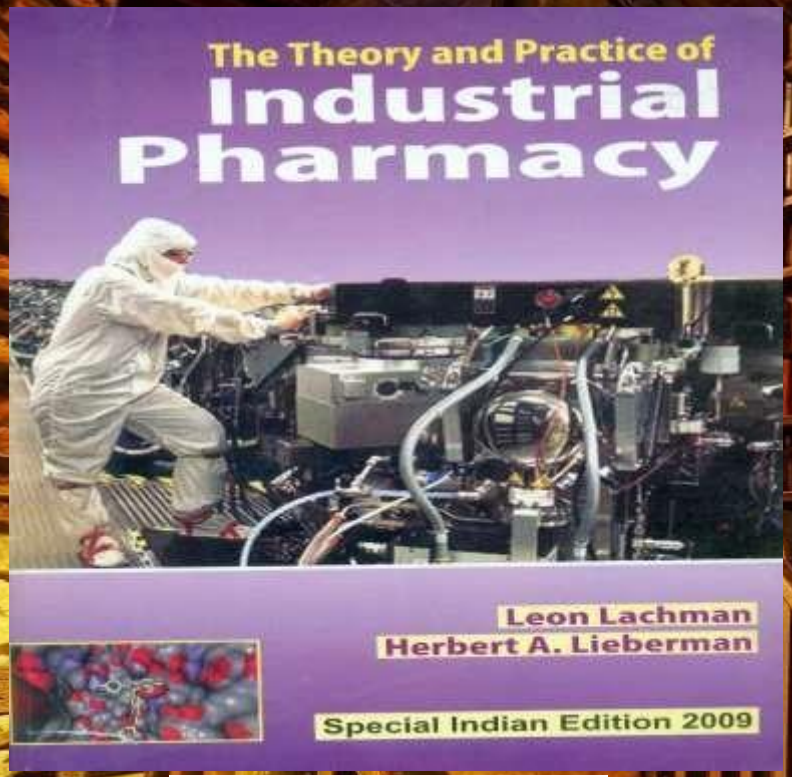
Apparatus-4-Flow through cell.

Apparatus-5-Paddle over disk.

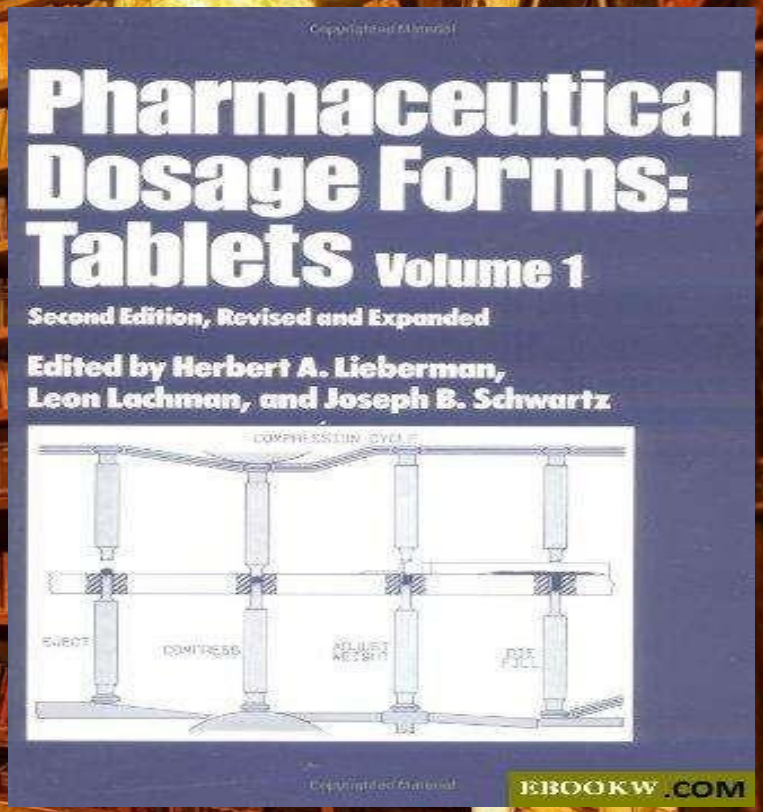
Apparatus-6-Cylindrical apparatus.

Apparatus-7-Reciprocating disc apparatus.

REFERENCES



Page no: 293 to 334.



Page no:88 to 121

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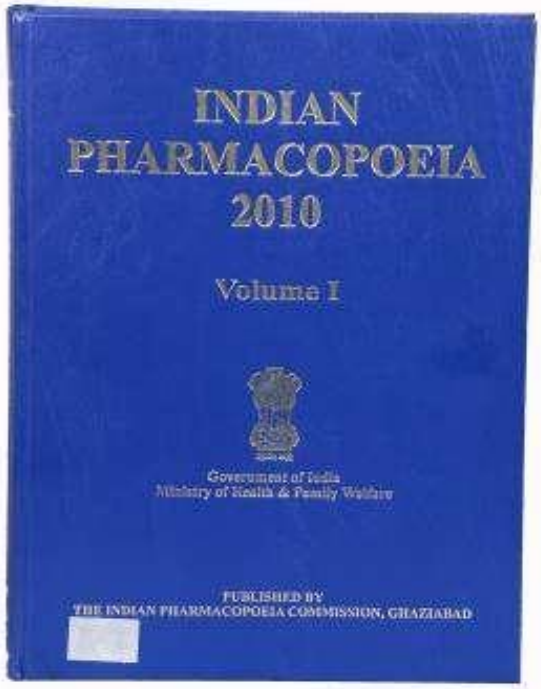
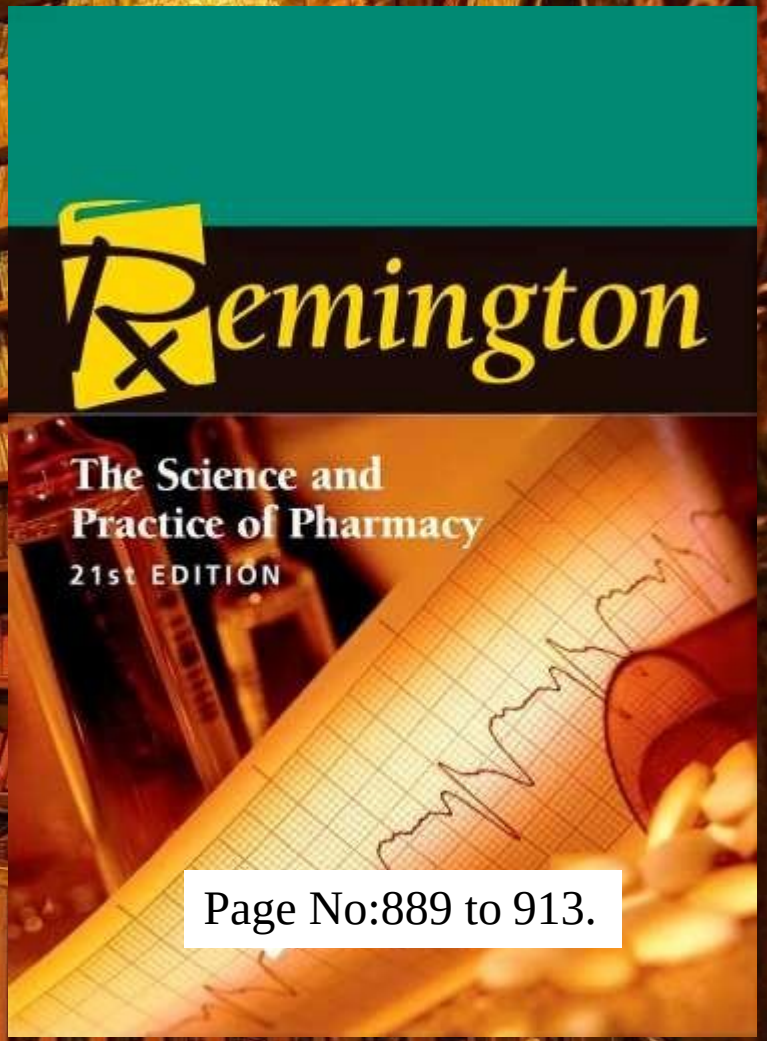


page No: 751 to 754



Page No:889 to 913.

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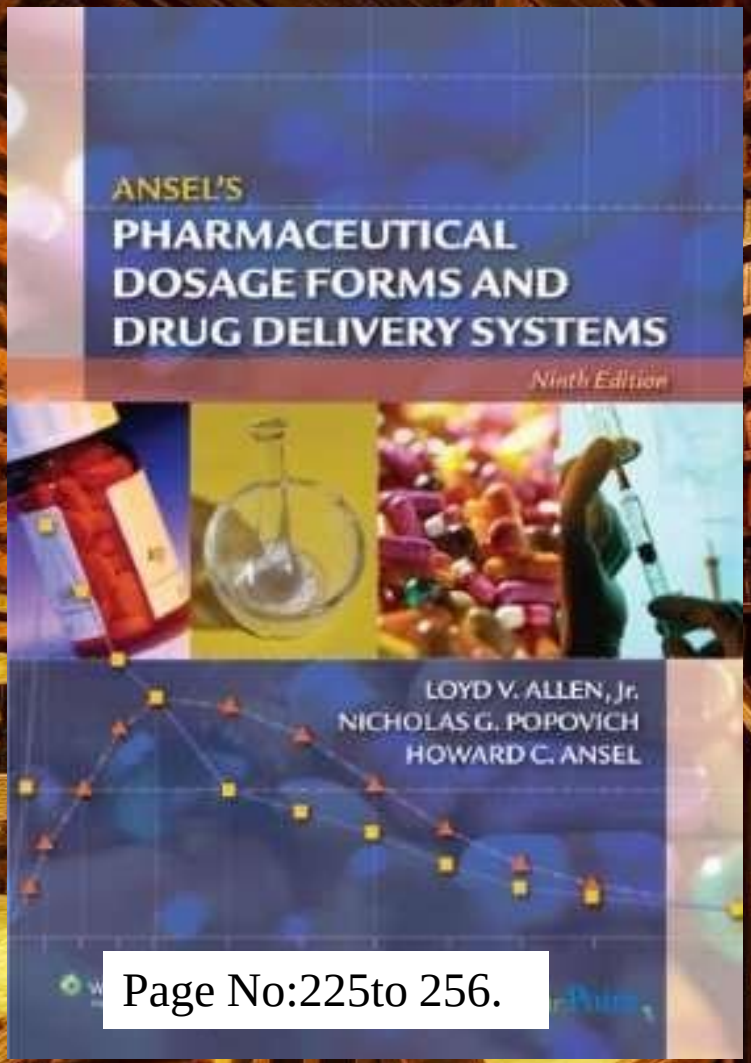
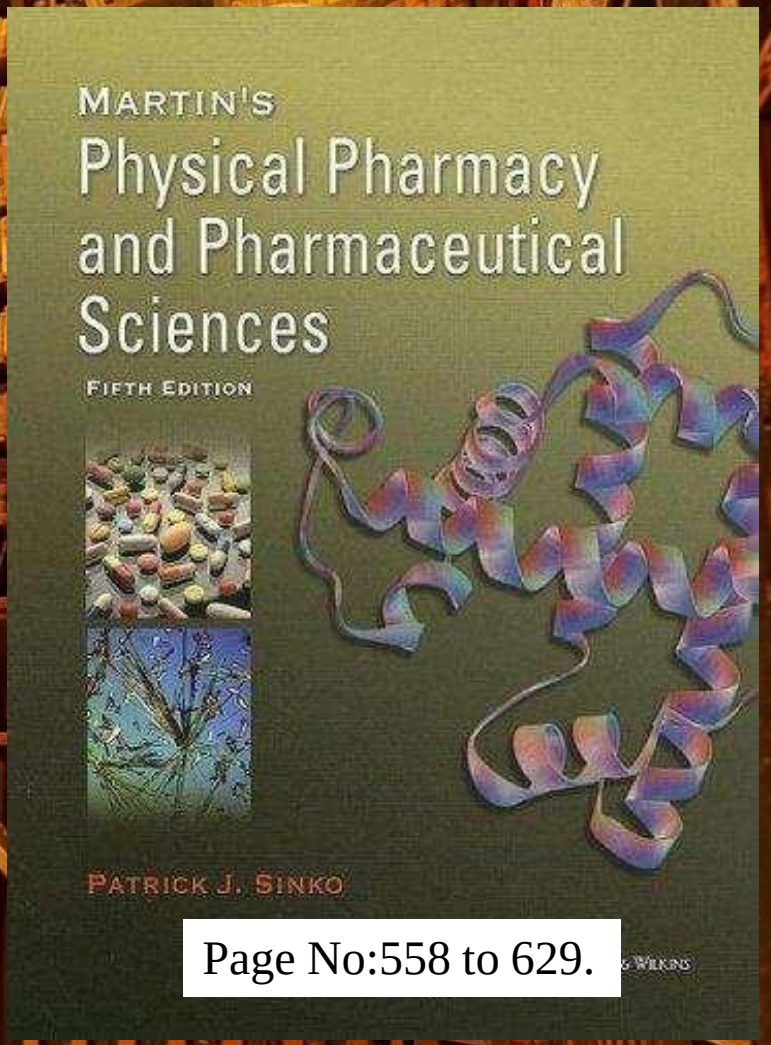


Page No:225to 256.



Page No:558 to 629.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Home
Page Down
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