



GPAT BOOSTER

SUBJECT - PHARMACEUTICS

TOPIC - TABLET

DEFINITION • CLASSIFICATION • DEFECTS





TABLET



1. DEFINITION

According to Indian Pharmacopoeia, tablets are solid, flat or biconvex unit dosage forms prepared by compressing a drug or a mixture of drugs, with or without diluents.

2. TYPES AND CLASSES OF TABLETS

A. Tablets ingested orally	B. Tablets used in the oral cavity	C. Tablets administered by other route	D. Tablets used to prepare solution
• compressed or standard compressed tablets • multiple compressed tablets – layered tablets and compression-coated tablets • chewable tablets • sugar- and chocolate-coated tablets • film-coated tablets • repeat-action tablets • delayed-action and enteric-coated tablets • controlled-release tablets	• buccal and sublingual tablets • troches and lozenges • dental cones	• implantation tablets • vaginal tablets	• effervescent tablets • dispersing tablets • hypodermic tablets • tablet triturates

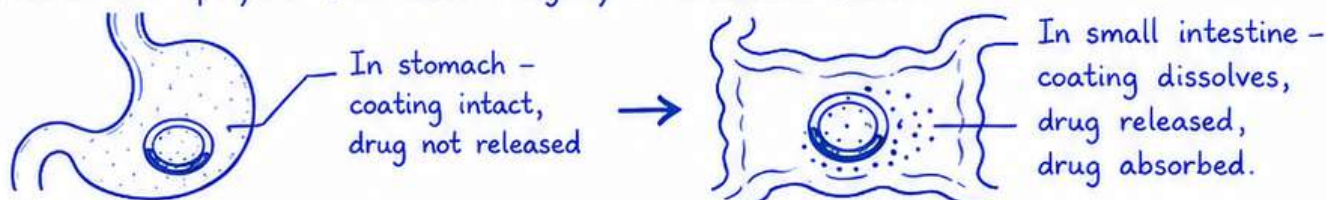
3. CHEWABLE TABLET

- intended to be chewed in the mouth.
- shows negative heat of solution.
- commonly used for children.
- examples: chewable aspirin tablets, antacid tablets, anthelmintics.
- disintegrant is not required.



4. DELAYED-ACTION TABLET & ENTERIC-COATED TABLET

- intended to release the drug after a time delay or after passing from one part of the GI tract to another.
- not all delayed-action tablets are enteric.
- enteric coating polymers: cellulose acetate phthalate, polyvinyl acetate phthalate, HPMC phthalate.
- these polymers remain insoluble in gastric media.
- mechanism: polymer film loses integrity in intestinal fluid.



TABLET FORMULATION - DILUENTS



1. Diluent -

- Diluents are fillers used to provide the required bulk when the drug dose is inadequate.
- Some drugs like aspirin and certain antibiotics need no filler because dose is sufficient.

2. Maillard Reaction -

- Chemical incompatibility between amine drugs and lactose in the presence of a metal stearate lubricant.
- Leads to tablet discoloration.
- Anhydrous lactose has advantage because it does not undergo Maillard reaction.

3. Lactose -

- Low-cost diluent; may discolor in presence of amine drugs.

4. Spray-dried Lactose -

- Has direct-compression properties and good flow; prone to darkening in presence of moisture and amines due to furfuraldehyde; use a neutral or acidic lubricant.

5. Sorbitol -

- Optical isomer of mannitol.

6. Sugar-Based Diluents / Sucrose -

- Trade names: Sugartab, Nu-Tab, Dipac
- Sugartab: 90-93% sucrose + 7-10% invert sugar
- Dipac: 97% sucrose + 3% modified dextrin
- Nu-Tab: 95% sucrose + 4% invert sugar with a small amount of corn starch and magnesium stearate.

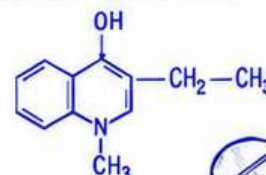
7. Microcrystalline Cellulose - also acts as a disintegrant; two grades: PH-101 (powder), PH-102 (granules).

8. Important Brand Names and Chemical Names -

Brand Name	Chemical Name
Cerelose	Dextrose
Sta-Rx 1500	Directly compressible starch
Endex / Cellu-Tab	Hydrolysed starch
Primogel	Modified starch
Avicel	Microcrystalline cellulose
Emcocel / Vivacel	Cellulose
Pearlitol	Mannitol
Zeparox	Spray-dried lactose
Cab-o-sil / Aerosil / Syloid	Colloidal silica
Emcompress	Calcium hydrogen phosphate
Amberlite	Ion exchange resins
Polyplasdone	Crosslinked PVP
Dipac	97% sucrose + 3% modified dextrin
Nu-Tab	95% sucrose + 4% invert sugar
Sugartab	90-93% sucrose + 7-10% invert sugar
Microcellac	75% lactose + 25% microcrystalline cellulose
Cal-Tab	93% calcium sulphate + 7% vegetable gum



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BINDERS & DISINTEGRANTS



1. BINDERS AND ADHESIVES -

Added in dry or wet form to form granules or cohesive compacts for directly compressed tablets.

CHEMICAL NAME	COMMON BRAND / EXAMPLE
Carboxymethylcellulose sodium	Nymcel
Cellulose, microcrystalline	Avicel, Emcocoel, Vivacel
Ethyl cellulose	Aquacoat
HPMC	Methocel, Pharmacoat
Magnesium aluminium silicate	Pharmasorb, Veegum
Methylcellulose	Celacol, Methocel
Polydextrose	Litesse



2. DISINTEGRANTS - Added to facilitate breaking or disintegration of tablets when they contact water in the GIT.

3. SUPERDISINTEGRANTS - Swell up to ten-fold within 30 seconds on contact with water.

4. IMPORTANT DISINTEGRANTS -

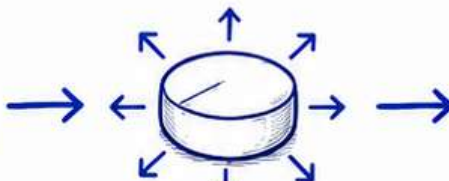
CHEMICAL NAME	COMMON BRAND / EXAMPLE
Cellulose, microcrystalline	Avicel, Emcocoel, Vivacel
Magnesium aluminium silicate	Veegum
Methyl cellulose	Celacol, Methocel
Sodium lauryl sulfate	Empicol
Polacrillin potassium	Amberlite
Sodium starch glycolate	Explotab, Primogel
Crospovidone	Kollidon CL, Polyplasdone XL
Croscarmellose sodium	Ac-di-sol, Solutab



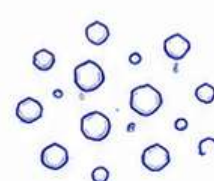
Tablet



Water



Swelling



Disintegration



LUBRICANTS, GLIDANTS & SWEETENING AGENTS



1. LUBRICANTS

Prevent adhesion of tablet material to dies and punches, reduce interparticle friction, and may improve flow of granulation.



Glyceryl palmitostearate	Precirol
Hydrogenated vegetable oil	Lubritab, Sterotex
PEG 4000 or 6000	Macrogols, Carbowax
Sodium lauryl sulfate	Empicol, Sterowet

- examples – stearic acid, magnesium stearate, talc, PEG, surfactants.

2. GLIDANTS

Promote flow of granules or powder by reducing friction between particles.

Cellulose	Elcema, Solka, Floc
Colloidal silicon dioxide	Aerosil, Cab-o-Sil, Syloid

- corn starch 5-10%.
- talc 5%.
- colloidal silica derivatives such as Cab-O-Sil, Syloid, Aerosil: 0.25-3%.

3. SWEETENING AGENTS

Cyclamate	carcinogenic, 70 times sweeter than sugar
Mannitol	used in chewable tablets; about 72 times sweeter than sugar
Saccharin	carcinogenic, 500 times sweeter than sugar
Aspartame	non-carcinogenic, 200 times sweeter than sugar
Neotame	non-caloric artificial sweetener; trade name Neutame
Sucralose	artificial sweetener; noncaloric because most ingested sucralose is not broken down by the body
Acesulfame potassium	also called acesulfame K or Ace K; calorie-free sugar substitute; trade names Sunett and Sweet One



TABLET COATING



1. Definition -

As per I.P., coated tablets are tablets coated with mixtures of substances such as resins, gums, inactive insoluble fillers, sugars, waxes, etc.



2. Types of tablet coating -

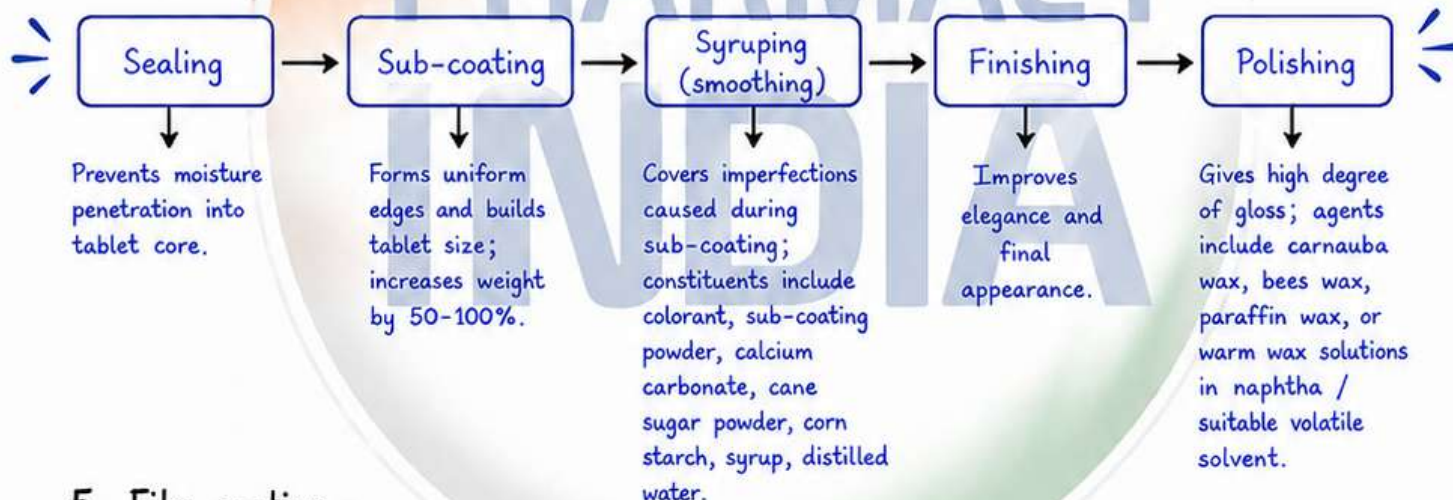
- Sugar coating;
- Film coating;
- Enteric coating.



3. Equipment used in coating -

- Perforated coating pans;
- Standard coating pans;
- Fluidized bed coater.

4. Sugar coating -



5. Film coating -

Single-stage process in which coating solution is sprayed onto a rotating tablet bed followed by drying.

6. Film forming agents -

Non-enteric film formers	Enteric film formers
HPMC, MHEC, EC, HPC, Povidone, SCMC, PG, Acrylate polymers.	CAP, Acrylate polymers, HPMCP, PVAP.

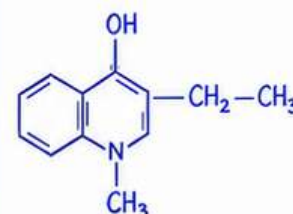


7. Types of coating pans -

Standard coating pans	Perforated coating pans
• Pellegrini pan • Immersion sword type pan • Immersion tube type pan	• Accela Cota pan • Hi-Coater • Dria coater • Glatt pan-coating • Huttlin butterfly pan



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TABLET GRANULATION & PARTS OF TABLET MACHINE

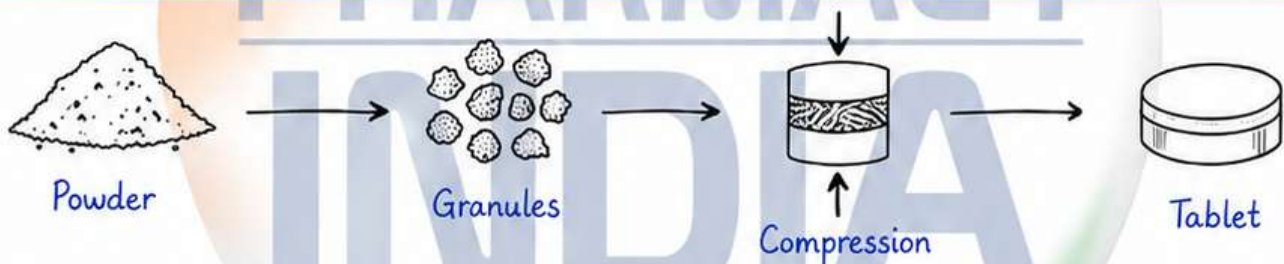


1. GRANULATION –

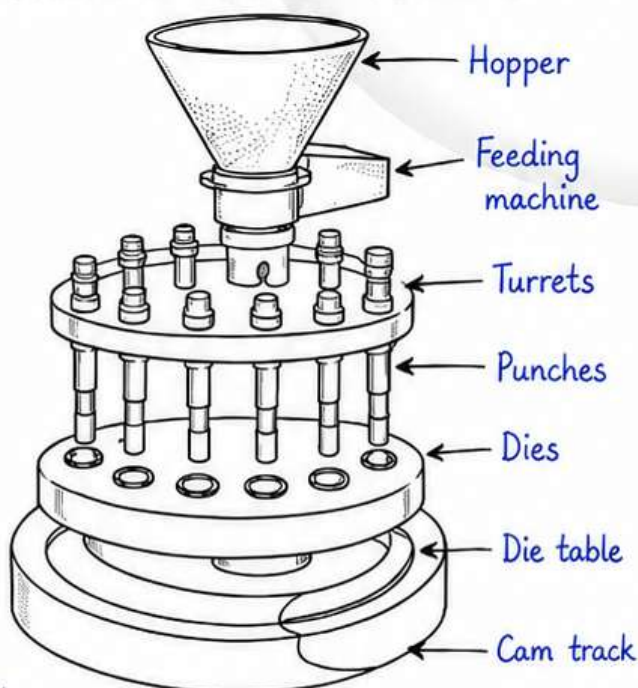
Granulation is the process in which small particles adhere together by forming bonds and produce large aggregates called granules.

2. METHODS OF GRANULATION –

A. DIRECT COMPRESSION	B. DRY GRANULATION	C. WET GRANULATION
- dry process - powdered tablet formulation is compressed directly without modifying the physical nature of material. - examples: ascorbic acid tablets, chewable antacid tablets.	- also called double compression or precompression. - accomplished by slugging and roller compaction. - examples: acetyl salicylic acid tablets, vitamin B complex.	- uses liquids to form compact masses. - examples: acetaminophen tablets, aluminium hydroxide chewable tablets.



3. PARTS OF TABLET MACHINE –



PART	FUNCTION
Hopper	holds and feeds granulation to be compressed.
Feeding machine	moves granulation from hopper to dies.
Turrets	hold upper and lower punches.
Punches	used for compression of granulation within the die.
Dies	define the size and shape of tablet.
Die table	portion holding the dies.
Cam track	guides movement of punches.



TABLET DEFECTS



1. INTRODUCTION

- During tablet manufacture, an industrial pharmacist may encounter several problems.
- Most visual defects are due to inadequate fines, inadequate moisture in granules, or faulty machine settings.
- Functional defects are due to faulty formulation.

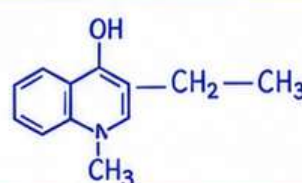
2. CLASSIFICATION & COMMON DEFECTS

PROCESS RELATED	FORMULATION RELATED	MACHINE RELATED
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COMMON DEFECTS – capping, lamination, cracking, chipping, sticking, picking, binding, mottling, double impression, bridging.

3. DEFINITIONS WITH REASONS

No.	Defect	Sketch	Definition	Reason
1.	Capping		separation of upper or lower segment of tablet from main body during ejection or handling.	air entrapment during compression and expansion on ejection.
2.	Lamination		separation of tablet into two or more horizontal layers.	air entrapment during compression and release on ejection, worsened by high turret speed.
3.	Chipping		breaking of tablet edges during ejection, handling, or coating.	incorrect machine settings, especially mis-set ejection take-off.
4.	Cracking		fine cracks on upper or lower central surface or rarely on side wall.	rapid expansion of tablets, especially with deep concave punches.
5.	Sticking		tablet material adheres to die wall or punch face.	improperly dried or improperly lubricated granules.
6.	Picking		small amount of material sticks to and is removed by punch face; more common on upper punch face.	especially problematic with embossed or engraved punches; granules improperly dried.
7.	Binding		tablet sticks in die and does not eject properly.	excess moisture in granules, lack of lubrication, or worn dies.
8.	Mottling		unequal distribution of color producing light or dark spots.	nonuniform color distribution or migration of dye.
9.	Double impression		occurs with engraved or monogram punches when upper punch rotates before final compression.	imprint received at compression; lower punch travels uncontrolled briefly before ejection.



EVALUATION OF TABLET - I



1. Evaluation of Tablet -

Non-official tests - General appearance (organoleptic, size and shape)

- general appearance (organoleptic, size and shape)
- hardness
- friability

Official tests

- weight variation
- content uniformity
- dissolution
- disintegration

2. Hardness - tablets require enough strength or hardness and resistance to friability to withstand mechanical shocks during manufacture, packing, and shipping; hardness is also termed crushing strength; tablet hardness testers:

- Pfizer tester
- Monsanto tester
- Erweka tester
- Strong-Cobb tester
- Schleuniger tester



3. Friability - official in USP but not in BP and IP; procedure: pre-weighed tablet sample is placed in friabilator, operate for 100 revolutions at 25 rpm for 4 minutes, tablets fall from 6-inch height; maximum mean weight loss not more than 1%.



4. Weight Variation -

IP	Limit	USP
Less than 85 mg	$\pm 10\%$	weighing 130 mg or less
85 mg to 250 mg	$\pm 7.5\%$	weighing 130-324 mg
Greater than 250 mg	$\pm 5\%$	weighing 324 mg or more

5. Content Uniformity -

- total tablets taken: 30
- at least 10 tablets are assayed by analytical technique
- test passes if 9 tablets contain 85-115% content and the 10th tablet may contain 75-125%
- if not satisfied, assay remaining 20 tablets none should fall outside 85-115%.



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EVALUATION OF TABLET-II



1. Disintegration -

- Apparatus - 6 test tubes, each about 3 inches long, with 10-mesh screens.
- Medium - 1 L beaker of water / 0.1 N HCl simulated gastric fluid.
- Temperature - $37 \pm 2^\circ\text{C}$.
- Movement - up and down through 5-6 inches.
- Frequency - 28-32 cycles per minute.
- Uncoated USP tablets (aspirin) - as low as 5 minutes.
- Enteric-coated tablets - no evidence of disintegration in simulated gastric fluid after 1 hour; then place in simulated intestinal fluid for 2 hours plus time specified in monograph.

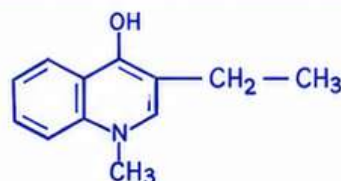
Dosage Form	Time Limit
uncoated tablet	15 minutes
film- and sugar-coated tablet	60 minutes
enteric-coated tablet	3 hours
hard gelatin capsule	30 minutes
soft gelatin capsule	60 minutes

2. Dissolution -

- Dissolution is the process by which a solid solute enters a solution.
- In pharmaceutical industry, it is the amount of drug substance that goes into solution per unit time under standardized conditions of liquid/solid interface, temperature, and solvent composition.

3. USP Apparatus -

Type	Description	Rotating Speed	Dosage Form
Type 1	Basket apparatus	50-120 rpm	conventional tablet, chewable tablet, controlled release
Type 2	Paddle apparatus	25-50 rpm	orally disintegrating tablet, chewable tablet, controlled release, suspension
Type 3	Reciprocating cylinder	6-35 rpm	controlled release, chewable tablet
Type 4	Flow-through cell	N/A	ER, poorly soluble API, powder, granules, microparticles, implants
Type 5	Paddle over disk	25-50 rpm	transdermal
Type 6	Cylinder	N/A	transdermal
Type 7	Reciprocating holder	30 rpm	CR





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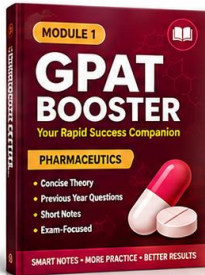
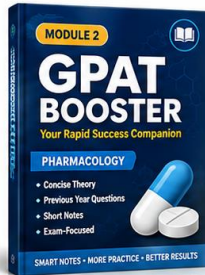
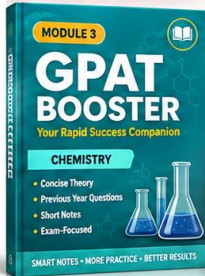
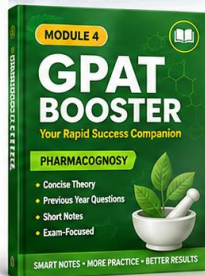
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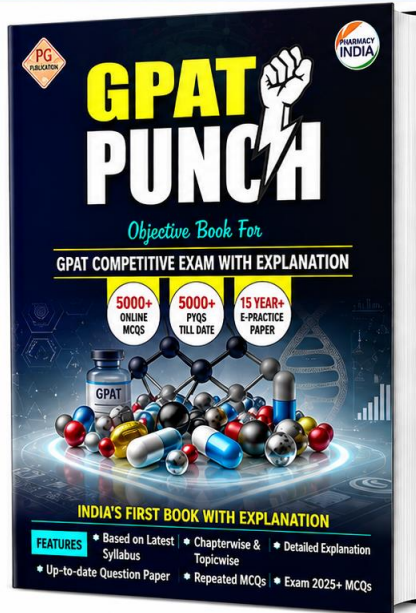
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