B.PHARM SEMESTER III · BP306T

BP306T Pharmaceutical Dosage Forms I

Unit II — Tablets & Tablet Coating

Final Study Notes · 12 Hours

Tablet excipients · Tooling · Manufacturing methods · Compression defects
In-process quality control · Finished-product evaluation · Tablet coating

Pills & Python
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Chapter 3 — Tablet Excipients, Tooling & Manufacturing Methods (Unit II)

3.1 Learning objectives

After studying this chapter, you will be able to:

1. Define a tablet and list its advantages and disadvantages.
2. Classify tablet excipients by role and give two examples of each.
3. Explain the mechanism of action of disintegrants, binders, lubricants, and glidants.
4. Identify the parts of tablet tooling (punches and die) and types of punch faces.
5. Compare wet granulation, dry granulation, and direct compression — process, equipment, and when each is used.
6. Describe the working of a rotary tablet press in three stages: filling, compression, ejection.
7. Draw and label a flowchart for wet granulation.

3.2 Definitions

- **Tablet:** A solid dosage form made by compressing powder or granules into a hard, flat or biconvex disc, containing drug plus excipients. The most popular dosage form in the world.
- **Compressed solid:** Any dosage form made by applying pressure to powders/granules — tablets are the main example.
- **Granules:** Small, uniform agglomerates of powder particles made to improve flow and compressibility — the usual feed for tablet machines.
- **Granulation:** The process of converting fine powders into granules.
- **Tooling:** The punch-and-die set that shapes the tablet inside the tablet press.
- **Compression:** Applying high pressure to granules in a die cavity to form a compact tablet.

Simple explanation: A tablet is just drug powder *squeezed very hard* into a small disc with the help of helper ingredients (excipients). Making tablets is like making atta ladoos — you mix ingredients, bind them so they hold shape, and press them into form. The tablet press is the machine that does the pressing, thousands of times per minute.

Advantages of tablets (why they dominate):

1. Accurate dose — every tablet has the same drug amount.
2. Cheap to make on a large scale.
3. Stable, light, easy to pack, carry, and store.
4. Easy to identify (shape, colour, embossing, scoring).
5. Good patient acceptance — easy to swallow, tasteless if coated.

Disadvantages/limitations:

1. Some drugs compress poorly or are damaged by compression.
2. Large tablets are hard for children and elderly to swallow.
3. Slow onset compared to liquids (must disintegrate and dissolve first).
4. Bitter drugs need coating (extra cost).

> **Key takeaway:** Tablets rule because they are accurate, cheap, stable, and convenient — but they need the right helpers (excipients) and the right machine (press + tooling).

3.3 Terminology (word bank)

Term	Meaning in one line
Diluent (filler)	Bulky excipient that increases tablet weight when the drug dose is tiny
Binder	Glues powder particles together so the tablet holds its shape
Disintegrant	Breaks the tablet apart in stomach fluid so the drug can dissolve
Superdisintegrant	Modern, highly efficient disintegrant effective at 2–5% (swells or wicks water fast)
Lubricant	Reduces friction so tablets eject smoothly and don't stick to punches
Glidant	Improves powder flow into the die (helps filling, not ejection)
Anti-adherent	Prevents granules sticking to punch faces
Adsorbent	Soaks up moisture or oils (keeps volatile/oily drugs manageable)
Punch	The steel tool that presses the powder (upper punch descends, lower punch forms the base)
Die	The steel cavity/block in which powder is compressed
Slugging	Dry granulation by compressing powder into large crude tablets (slugs), then milling
Roller compaction	Dry granulation by squeezing powder between two rollers into ribbons, then milling

3.4 Tablet excipients — roles and examples (the heart of this chapter)

Technical concept: Because most drug doses are a few milligrams, excipients form 90%+ of a tablet. Each excipient has a *role*; choosing the right one at the right level is formulation design.

3.4.1 Diluents (fillers)

- **Role:** Give bulk to the tablet when the drug dose is small; make a tablet big enough to handle.
- **Examples:** Lactose, microcrystalline cellulose (MCC), starch, mannitol, dibasic calcium phosphate, sorbitol.
- **Simple explanation:** If the drug dose is 5 mg, you can't make a 5 mg tablet — it would be a dust speck. Diluents are the "atta" that bulks it up to a handleable 200 mg tablet.
- **Selection hints:** Lactose — cheap, good compression (avoid with amine drugs — Maillard, see Ch. 2). MCC — excellent for direct compression. Mannitol — pleasant cooling taste, good for chewable tablets.

3.4.2 Binders

- **Role:** Stick powder particles together so granules/tablets don't crumble.
- **Examples:** Starch paste, polyvinylpyrrolidone (PVP/povidone), hydroxypropyl methylcellulose (HPMC), gelatin, acacia, methylcellulose.
- **Mechanism:** Binder solution coats particles; on drying, solid bridges form between particles — like Fevicol between two paper sheets.
- **Caution:** Too much binder → tablet too hard → won't disintegrate. Balance is everything.

3.4.3 Disintegrants

- **Role:** Break the tablet into small particles in GI fluid so dissolution can start.
- **Examples:** Starch, sodium starch glycolate, croscarmellose sodium, crospovidone (the last three are *superdisintegrants*).
- **Mechanisms (three ways tablets break):**

1. **Swelling** — disintegrant swells with water and bursts the tablet (starch, sodium starch glycolate).
2. **Wicking (capillary action)** — water is sucked through pores, weakening bonds (crospovidone).
3. **Deformation recovery** — compressed particles spring back to shape when wet.

- **Analogy:** A disintegrant is like the "breaking news" inside a tablet — one drop of water and it shouts "break apart!"

3.4.4 Lubricants

- **Role:** Reduce friction between tablet and die wall/punch faces so tablets eject cleanly without sticking or picking.
- **Examples:** Magnesium stearate (most common), stearic acid, talc, calcium stearate.
- **Mechanism:** Forms a thin slippery film around granules — like oil on a dosa tawa so the dosa slides off.
- **Caution:** Too much lubricant (or over-mixing) coats particles so well that water can't enter → slow disintegration and dissolution. Use the minimum effective amount, mixed briefly at the end.

3.4.5 Glidants

- **Role:** Improve powder *flow* into the die (different from lubricants, which help *ejection*).
- **Examples:** Colloidal silicon dioxide (Aerosil), talc, starch.
- **Simple explanation:** Glidants are like tiny ball bearings between powder particles — they roll, so the powder flows.

3.4.6 Others

Excipient	Role	Examples
Adsorbents	Soak up moisture/oils	Silica, kaolin
Colourants	Identification, appeal	Iron oxides, permitted lake colours
Flavourants/sweeteners	Taste (chewable tablets)	Aspartame, saccharin, mint flavour
Anti-adherents	Stop sticking to punches	Talc, magnesium stearate

Common confusion: Lubricant vs glidant — the most mixed-up pair. Lubricant = helps tablet *leave* the die (ejection). Glidant = helps powder *enter* the die (flow). Magnesium stearate is mainly a lubricant; colloidal silicon dioxide is mainly a glidant.

Master table — excipients at a glance:

Excipient class	Role	2 examples	Key caution
Diluent	Bulk	Lactose, MCC	Lactose + amine drugs = browning
Binder	Glue particles	Starch paste, PVP	Excess → no disintegration
Disintegrant	Break tablet in fluid	Sodium starch glycolate, crospovidone	Needed for fast drug release
Lubricant	Easy ejection	Magnesium stearate, stearic acid	Excess → slow dissolution
Glidant	Good flow	Colloidal silicon dioxide, talc	—
Colour/flavour	Identity/taste	Iron oxide, aspartame	Permitted colours only

> **Key takeaway:** Every excipient earns its place by role. Wrong excipient or wrong amount = defective tablet.

3.5 Tooling — types and specifications

Technical concept: Tooling = the matched set of **upper punch, lower punch, and die** that forms each tablet. The die is a steel block with a precise cavity; powder fills the cavity; the upper punch descends and squeezes it against the lower punch; the lower punch then rises to eject the tablet.

> **Simple explanation:** Tooling is the "mould" of tablet-making — like the steel die that stamps coins. Change the tooling, and you change the tablet's size, shape, and markings.

Parts and their jobs:

- **Upper punch:** Moves down to compress; has the top marking/embossing.
- **Lower punch:** Forms the bottom of the die cavity; moves up to eject the finished tablet.
- **Die:** The cavity that decides tablet diameter and gives side-wall shape.

Types of punch faces (tip shapes):

1. **Flat-faced:** Flat tip → flat tablets (simple, but edges chip easily).
2. **Concave:** Curved tip → biconvex tablets (stronger edges, standard for most tablets).
3. **Bevel-edged:** Flat face with slanted edge → neat edge, less chipping.

- Punches can carry **embossing** (raised letters/logos) or **scoring** (a break-line) for identification and splitting.

Specifications (what is standardised): Punch dimensions — tip diameter, barrel diameter, working length — and die bore diameter are standardised in the industry (commonly called **B and D tooling** standards), so tooling from one manufacturer fits standard presses. Multi-tip punches (several small tips on one punch) make multiple mini-tablets per stroke.

Diagram — draw it: A vertical cross-section: hopper at top, feed frame, then the die as a rectangle with a cavity; upper punch above the cavity (arrow down, "compression"), lower punch inside the cavity (arrow up, "ejection"). Label: die cavity = decides tablet size; punch tip = decides shape/marking.

> **Key takeaway:** Tooling decides what the tablet *looks like*; the press decides how *hard* it is squeezed.

3.6 Manufacturing methods and equipment

Technical concept: There are three routes from powder to tablet. The choice depends on the drug's dose, flow, compressibility, and heat/moisture sensitivity (decided in pre-formulation, Ch. 1).

3.6.1 Wet granulation

- **When:** Most common method; for powders that flow badly or compress poorly.
- **Process:** Dry powders are mixed, then a **binder solution** is added to form a wet mass → wet mass is screened into granules → granules are **dried** → dried granules are screened to uniform size → **lubricant** is mixed in → compression.
- **Equipment:** Planetary/rapid mixer granulator (mixing + wet massing), oscillating granulator (screening), tray dryer or fluid-bed dryer (drying), tablet press (compression).

Flowchart — wet granulation:

```
Weigh & sieve drug + diluent + disintegrant (part)
        ↓
Dry mixing (blender / rapid mixer granulator)
        ↓
Wet massing: add binder solution → dough-like mass
        ↓
Wet screening: pass through sieve → wet granules
        ↓
Drying: tray dryer / fluid-bed dryer (remove moisture)
        ↓
Dry screening: uniform granule size
        ↓
Lubrication: mix in lubricant + remaining disintegrant + glidant (brief!)
        ↓
Compression on tablet press → TABLETS
```

3.6.2 Dry granulation

- **When:** For drugs that are **moisture- or heat-sensitive** (can't tolerate wet massing/drying).
- **Process (two variants):**

1. **Slugging:** Powder is compressed into large crude tablets ("slugs") → slugs are milled into granules → lubricated → recompressed into final tablets.
2. **Roller compaction:** Powder is squeezed between two counter-rotating rollers into solid ribbons/sheets → milled into granules → compressed.

- **Simple explanation:** No water, no heat — just "press, break, press again." Like making breadcrumbs from a dry rusk instead of wet dough.

3.6.3 Direct compression

- **When:** For drugs with good flow and compressibility, or with directly-compressible excipients (MCC, spray-dried lactose).
- **Process:** Simply **mix drug + excipients → compress**. Fewest steps, cheapest, fastest.
- **Limitation:** Needs excellent powder flow and uniform mixing; high-dose drugs are difficult.

Comparison table (exam favourite):

Feature	Wet granulation	Dry granulation	Direct compression
Steps	Many (mix, wet, dry, compress)	Medium (press, mill, press)	Few (mix, compress)
Moisture/heat	Used (bad for sensitive drugs)	Not used	Not used
Flow improvement	Excellent	Good	Depends on excipients
Cost/time	Highest	Medium	Lowest
Best for	Poor-flowing powders	Moisture/heat-sensitive drugs	Free-flowing, low-dose drugs

3.6.4 The tablet press — how it works

- **Single-punch press:** One die, slow — used for R&D and small batches.
- **Rotary press:** Many dies on a rotating turret — thousands of tablets per minute; the industry workhorse.

Three stages in every compression cycle:

1. **Filling:** Powder/granules flow from the hopper through the feed frame into the die cavity (lower punch is down).
2. **Compression:** Upper punch descends; both punches squeeze the powder into a hard compact.
3. **Ejection:** Upper punch rises; lower punch pushes the tablet up and out; a scraper pushes it into the collection chute.

Diagram — draw it (three panels): Panel 1 "FILLING": die cavity full of powder, lower punch down. Panel 2 "COMPRESSION": upper punch pressing down, powder squeezed. Panel 3 "EJECTION": lower punch pushing the finished tablet up out of the die.

> **Key takeaway:** Choose the method by the drug's personality — wet granulation for bad flow, dry for water-fearers, direct for easy powders.

3.7 Infographic concept box — "Tablet birth story"

> *(For the designer: a 3-lane road diagram.)*

- **Lane 1 — WET:** "Mix → wet → dry → compress. For stubborn powders."
- **Lane 2 — DRY:** "Press → mill → press. No water. For sensitive drugs."
- **Lane 3 — DIRECT:** "Mix → compress. Fastest. For well-behaved powders."
- All three lanes end at the same finish line: a tablet press stamping out tablets.

3.8 Pharmacy relevance

Every paracetamol, antacid, or vitamin tablet a pharmacist dispenses was born in one of these three processes. When a patient complains a tablet "doesn't work fast," the pharmacist who knows disintegrants and granulation can explain why. Pharmacists in industry run these very machines and processes.

3.9 India context

India manufactures a huge share of the world's generic tablets — rotary presses running three shifts are the backbone of Indian pharma hubs (Hyderabad, Ahmedabad, Baddi, Sikkim). Direct compression is popular in India for cost-sensitive generics because it saves time, energy, and equipment cost. IP monographs for tablets are built around the quality tests in Chapter 4.

3.10 Key points

1. Tablet = compressed disc of drug + excipients; accurate, cheap, stable, convenient.
2. Excipient roles: diluent (bulk), binder (glue), disintegrant (break-up), lubricant (ejection), glidant (flow).
3. Lubricant helps the tablet *leave* the die; glidant helps powder *enter* the die.
4. Tooling = upper punch + lower punch + die; tip shapes: flat, concave, bevel-edged; sizes standardised (B/D tooling).
5. Three manufacturing routes: wet granulation (most common), dry granulation/slugging/roller compaction (moisture-sensitive), direct compression (simplest).
6. Tablet press cycle: filling → compression → ejection.

3.11 Common confusions

- **Granulation vs compression:** Granulation *prepares* the granules; compression *forms* the tablet. Wet granulation includes a compression step at the end.
- **Slugging vs roller compaction:** Both are dry granulation; slugging uses a tablet press to make crude slugs, roller compaction uses rollers to make ribbons.
- **Binder vs disintegrant:** Binder *holds together*; disintegrant *breaks apart*. They oppose each other — formulation is a balance.

3.12 Common mistakes

1. Calling magnesium stearate a glidant — it is primarily a *lubricant*.
2. Saying direct compression suits all drugs — it needs good flow and compressibility.
3. Forgetting that over-mixed lubricant slows dissolution.
4. Mixing up which punch ejects (the *lower* punch pushes the tablet up).

3.13 Mnemonics

- **Excipient roles:** "**D**iluents bulk, **B**inders glue, **D**isintegrants break, **L**ubricants slide, **G**lidants glide" → "**D**aily **B**ig **D**oses **L**ove **G**ood tablets."
- **Press cycle:** "**F**illing → **C**ompression → **E**jection" → "**F**ill, **C**rush, **E**ject."

3.14 Exam summary (one page)

Tablets are compressed discs of drug + excipients — accurate, economical, stable, and convenient. Excipients by role: diluents (lactose, MCC — bulk), binders (starch paste, PVP — glue particles), disintegrants (starch, superdisintegrants — break tablet via swelling/wicking), lubricants (magnesium stearate — easy ejection; excess slows dissolution), glidants (colloidal silicon dioxide — flow), plus colours/flavours. Tooling = upper punch + lower punch + die; faces flat/concave/bevel-edged, embossed or scored; sizes standardised (B/D tooling). Manufacturing: (1) wet granulation — mix, wet-mass with binder, screen, dry, lubricate, compress (best for poor flow); (2) dry granulation — slugging or roller compaction, no water (for moisture/heat-sensitive drugs); (3) direct compression — mix and compress (simplest, needs good flow). Presses: single-punch (R&D) and rotary (production). Cycle: filling → compression → ejection.

3.15 One-minute revision

Tablet = squeezed powder disc. Helpers: diluent bulks, binder glues, disintegrant breaks, lubricant ejects, glidant flows. Mould = punch + die. Three roads: wet (stubborn powders), dry (water-fearers), direct (easy powders). Press rhythm: fill, crush, eject.

3.16 Exam questions

Short questions

1. Define tablet. List four advantages and two disadvantages of tablets as a dosage form.
2. Classify tablet excipients by role with two examples each.
3. Explain the mechanisms of disintegrant action.
4. Why is excess magnesium stearate harmful? Explain with the mechanism.
5. Draw a labelled diagram of tablet tooling (punches and die).
6. Compare wet granulation, dry granulation, and direct compression in a table.
7. Describe the three stages of the tablet compression cycle.

MCQs (answers at end)

1. Which excipient increases tablet bulk when the drug dose is small?

a) Binder b) Diluent c) Lubricant d) Glidant

1. Sodium starch glycolate is a:

a) Binder b) Lubricant c) Superdisintegrant d) Diluent

1. The punch that ejects the tablet is the:

a) Upper punch b) Lower punch c) Both d) Neither

1. Slugging is a type of:

a) Wet granulation b) Dry granulation c) Direct compression d) Coating

1. Which method is preferred for a moisture-sensitive drug?

a) Wet granulation b) Dry granulation c) Sugar coating d) None

1. Colloidal silicon dioxide acts mainly as a:

a) Lubricant b) Glidant c) Binder d) Disintegrant

1. In wet granulation, the binder is added during:

a) Lubrication b) Wet massing c) Drying d) Compression

1. Biconvex tablets are usually made with:

a) Flat punches b) Concave punches c) Multi-tip punches d) Scored punches

Answers: 1-b, 2-c, 3-b, 4-b, 5-b, 6-b, 7-b, 8-b

Viva questions

1. Your granules flow beautifully but tablets cap during compression. Is this an excipient problem or a process problem? How will you start troubleshooting?
2. Why is the lubricant always added last and mixed only briefly?
3. A 2 mg drug needs a 200 mg tablet — which excipient class solves this, and why?
4. When would you choose roller compaction over wet granulation?

Application-based

1. A new drug degrades in water and flows poorly. Select a manufacturing method, justify your choice, and list the equipment needed for each step.
2. Tablets from a direct-compression batch show high weight variation. List three probable causes linked to excipients/process and suggest corrective actions.

3.17 References

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Chapter 4 — Tablet Defects, Quality Control & Packaging (Unit II)

4.1 Learning objectives

After studying this chapter, you will be able to:

1. Identify common tablet defects by appearance and name their causes.
2. Suggest remedies for capping, picking/sticking, chipping, mottling, and weight variation.
3. Define IPQC and list the in-process checks done during tablet manufacturing.
4. Describe finished-product tests for tablets: weight variation, hardness, friability, disintegration, dissolution, and assay.
5. State the commonly taught pharmacopoeial expectations for friability, disintegration, and weight variation.
6. Select appropriate packaging for tablets with justification.

4.2 Definitions

- **Tablet defect:** Any visible or measurable flaw in a tablet — wrong appearance, broken, chipped, or out-of-specification property.
- **Capping/lamination:** The top (or layers) of the tablet separate like a cap — the classic compression defect.
- **IPQC (In-Process Quality Control):** Quality checks done *during* manufacturing (not after), so problems are caught and fixed immediately.
- **Finished-product tests:** Quality tests done on the *completed* batch before it is released for sale.
- **Friability:** Tendency of tablets to chip, crumble, or break on handling — measured as % weight loss after tumbling.
- **Hardness (crushing strength):** Force needed to break a tablet — measures mechanical strength.
- **Disintegration:** Break-up of the tablet into small particles in fluid under standard test conditions.
- **Dissolution:** The rate and extent to which the drug dissolves from the tablet into a standard medium — the lab test closest to predicting absorption.

Simple explanation: Making tablets is like running a bakery at high speed — some biscuits come out burnt, broken, or misshapen. **Defects** are the broken biscuits; **IPQC** is the baker tasting and checking *during* baking; **finished-product tests** are the final quality check before packing the boxes. **Packaging** is the wrapper that keeps them fresh till the customer eats them.

Key takeaway: Quality is *built in* during manufacturing (IPQC) and *verified* at the end (finished-product tests). Testing alone cannot fix a bad process.

4.3 Terminology (word bank)

Term	Meaning in one line
Picking	Small bits of tablet surface sticking to punch faces (logo/punch marks pull off)
Sticking	Granules sticking to die walls/punch faces, roughening the tablet
Mottling	Uneven colour distribution on the tablet surface
Double impression	A second, fainter punch mark from the punch hitting twice
Weight variation	Individual tablets differing too much from the average weight
Content uniformity	Each tablet containing the specified drug amount within limits
Roche friabilator	The standard tumbling instrument for the friability test
Disintegration apparatus	Basket-rack assembly moving tablets up-down in fluid at 37 °C
Dissolution apparatus	Basket (Type I) or paddle (Type II) stirred vessel for dissolution testing

4.4 Tablet defects — causes and remedies (the troubleshooting table)

Technical concept: Every defect has a *formulation cause* (wrong excipient/amount) or a *process cause* (wrong machine setting). Troubleshooting = match the defect to its cause, then fix the cause.

Defect (what you see)	Main causes	Remedies
Capping/lamination — top separates like a lid; tablet splits into layers	Air trapped in granules; over-dried granules; too much fines; deep concave punches; high compression speed	Pre-compression step; reduce fines; optimum moisture; use flat/bevel punches; slow the press
Picking — surface bits pulled off, punch logo damaged	Over-wet granules; worn/damaged punch faces; insufficient lubricant	Dry granules properly; polish/replace punches; add lubricant; use anti-adherent
Sticking — rough surface, material on die wall	Too little lubricant; over-wet granules	Increase lubricant; dry granules; clean tooling
Chipping — broken edges	High ejection force; weak edge design; misaligned tooling	Reduce ejection force; use bevel-edged punches; check alignment
Mottling — patchy, uneven colour	Colour migration during drying; poor colour mixing	Use lake colours; improve mixing; control drying
Weight variation — tablets differ in weight	Poor powder flow; uneven die filling; poor mixing; punch length variation	Improve flow (glidant/granulation); check feed frame; uniform mixing
Double impression — faint second punch mark	Free rotation of lower punch during ejection	Check anti-turning devices; control ejection

Simple explanation for the big two:

- **Capping** is like a badly glued envelope flap that pops open — air trapped inside or over-dried glue (binder) is usually the culprit.
- **Picking/sticking** is like dosa sticking to a dry tawa — the tawa (punch) needs proper seasoning (lubricant) and the batter (granules) must not be too wet.

Diagram — draw it: Six small tablet sketches in a row, each labelled: (1) cap lifting off the top — "capping"; (2) pitted surface with bits missing — "picking"; (3) broken edge — "chipping"; (4) patchy colour — "mottling"; (5) two overlapping punch marks — "double impression"; (6) layered split — "lamination."

Common confusion: Picking vs sticking — picking = bits stick to the *punch face* (surface pits); sticking = material sticks to the *die wall* (rough sides, hard ejection). Both are fixed with lubricant and proper drying.

Key takeaway: Don't memorise defects blindly — link each to *air, moisture, lubricant, or machine setting*, and the remedy follows logically.

4.5 In-process quality control (IPQC)

Technical concept: IPQC checks are done *while the batch is being made*, at set intervals (e.g., every 30 minutes), so drift is corrected before thousands of bad tablets are produced.

Standard IPQC checks for tablets:

1. **Appearance** — colour, shape, embossing, no visible defects (checked continuously).
2. **Weight of 20 tablets** — weighed together and individually at intervals; catches weight variation early.
3. **Thickness** — measured with vernier callipers; thickness drift signals die-fill or compression problems. (Pharmacopoeias don't fix universal thickness limits — each product sets its own; IPQC watches for *consistency*.)
4. **Hardness** — checked with a hardness tester (e.g., Monsanto/Pfizer type); too soft = friable, too hard = won't disintegrate.
5. **Friability (in-process)** — quick check that tablets survive handling.
6. **Disintegration (in-process)** — confirms the batch will break up properly.
7. **Granule checks before compression** — moisture content, particle size, flow (angle of repose).

Simple explanation: IPQC is the CCTV of tablet manufacturing — it watches the process live. Finished-product testing is the post-mortem. Smart factories rely on the CCTV, not the post-mortem.

Key takeaway: IPQC = check *during* production, fix *immediately*. It saves batches.

4.6 Finished-product tests for tablets

Technical concept: After manufacture, a sample of the finished batch is tested against the pharmacopoeial/product specification. Only batches passing *all* tests are released.

4.6.1 Description and identification

- **Description:** Colour, shape, size, markings — must match the product specification.
- **Identification:** Chemical test confirming the drug's identity (e.g., IR, chemical reaction).

4.6.2 Weight variation test

- **Method:** Weigh 20 tablets individually; compare each to the average weight.
- **Commonly taught IP limits:** Average weight ≤ 80 mg → ±10%; 80–250 mg → ±7.5%; > 250 mg → ±5%. Not more than 2 tablets outside the limit, none outside twice the limit.
- *(As widely taught from IP; confirm against the current edition for exact wording.)*

4.6.3 Uniformity of dosage units / content uniformity

- For low-dose tablets where weight variation alone can't guarantee dose accuracy, the *drug content* of individual tablets is assayed; IP/BP/USP specify acceptance limits.

4.6.4 Hardness (crushing strength)

- **Method:** Hardness tester measures the force (in kg or Newtons) needed to break a tablet.
- **Interpretation:** Minimum ~3–4 kg is a common working target for handling; too hard delays disintegration. (Product-specific; pharmacopoeias describe the test, and working ranges come from product development.)

4.6.5 Friability

- **Method:** Roche friabilator — tablets are tumbled (commonly 100 revolutions) and weighed before/after.
- **Commonly taught limit:** Weight loss **not more than 1.0%**.
- **Simple explanation:** Tablets are tumbled like clothes in a washing machine — if they come out chipped and lighter, they won't survive transport.

4.6.6 Disintegration

- **Method:** Basket-rack assembly in fluid at 37 ± 2 °C; tablets must break into particles passing the mesh.
- **Commonly taught IP expectations:** Uncoated tablets — within **15 minutes**; plain coated tablets — within **30 minutes** (enteric-coated have special acid/buffer stages — see Ch. 5).
- *(Standard teaching values; the monograph is the final authority.)*

4.6.7 Dissolution

- **Method:** USP Type I (basket) or Type II (paddle) apparatus; tablet in 900 mL medium at 37 °C; samples withdrawn over time and drug measured.
- **Interpretation:** Monographs specify how much drug must dissolve by a given time (the "Q" value, e.g., not less than 80% in 45 minutes — varies by product). Dissolution is the in-vitro test most closely linked to bioavailability.

4.6.8 Assay and impurities

- **Assay:** Total drug content per tablet (commonly 90–110% of label claim for many products — per monograph).
- **Impurities/degradation products:** Must stay within monograph limits.

Master table — finished-product tests at a glance:

Test	What it checks	Commonly taught expectation
Description/identification	Right product, right drug	Matches specification
Weight variation (20 tablets)	Uniform die filling	±10% / ±7.5% / ±5% by weight band
Content uniformity	Uniform drug per tablet	Within pharmacopoeial limits
Hardness	Mechanical strength	Enough to handle, not so hard it won't disintegrate
Friability	Chipping resistance	NMT 1.0% weight loss
Disintegration	Break-up in fluid	15 min (uncoated), 30 min (coated)
Dissolution	Drug release rate	Meets monograph Q value
Assay	Drug content	Within monograph limits

Common confusion: Disintegration vs dissolution — disintegration = tablet *breaks into pieces* (physical); dissolution = drug *dissolves into solution* (chemical). A tablet can disintegrate yet dissolve slowly (poorly soluble drug). Dissolution is the more meaningful test.

> **Key takeaway:** Each test answers one question — the right product? the right amount? strong enough? breaks up? releases drug? All must pass.

4.7 Packaging of tablets

Technical concept: Tablets are packed to protect from moisture, light, and breakage, and to give unit-dose convenience.

- **Strip packs:** Tablet sealed between two aluminium foils — cheap, common in India, good moisture barrier.
- **Blister packs:** Plastic cavity (PVC/PVDC) sealed with aluminium foil — one tablet per cavity; **alu-alu** (aluminium both sides) for highly moisture-sensitive drugs.
- **HDPE bottles:** Bulk packs (30/100/500 tablets) with desiccant sachets and induction-sealed caps — common for chronic-therapy medicines.
- **Glass bottles:** Older style; still used for some products.
- Labels must carry name, strength, batch, mfg/expiry dates, storage, and manufacturer details per regulatory rules.

Simple explanation: Strip = the sachet of tablets; blister = the push-through card; bottle = the family pack. Moisture-fearing tablets get alu-alu; ordinary ones manage with strip/PVC blister.

> **Key takeaway:** Packaging is the last guardian of all the quality built in Chapters 3–4.

4.8 Infographic concept box — "Tablet quality journey"

> *(For the designer: a left-to-right pipeline with checkpoints.)*

- **DEFECTS** (magnifier on chipped tablet): "Cap, pick, chip, mottle — each has a cause and a cure."
- **IPQC** (CCTV icon): "Checked during making: weight, thickness, hardness, friability, disintegration."
- **FINAL TESTS** (tick-mark clipboard): "Weight variation, hardness, friability ≤1%, disintegration, dissolution, assay."
- **PACK** (blister icon): "Strip, blister, alu-alu, HDPE bottle — matched to the tablet's fears."

4.9 Pharmacy relevance

Pharmacists reject defective stock (chipped, mottled, soft tablets) and counsel patients never to use tablets past expiry or from damaged packs. In industry, pharmacists run IPQC and release testing — this chapter is literally their job description.

4.10 India context

Indian pharmacies commonly stock strip packs — pharmacists must check strip integrity (torn strips = moisture entry). During monsoon, pharmacists advise patients to keep bottles tightly closed with desiccants inside. CDSCO and IP requirements make the tests in this chapter legally binding for Indian manufacturers.

4.11 Key points

1. Main defects: capping/lamination, picking, sticking, chipping, mottling, weight variation, double impression — each has formulation and process causes with logical remedies.
2. IPQC = during-manufacture checks (appearance, weight, thickness, hardness, friability, disintegration) for immediate correction.
3. Finished-product tests: description, identification, weight variation, content uniformity, hardness, friability (NMT 1%), disintegration (15/30 min), dissolution (Q value), assay.
4. Disintegration = breaking up; dissolution = drug dissolving — dissolution predicts absorption better.
5. Tablet packs: strip, blister (PVC or alu-alu), HDPE bottles with desiccant.

4.12 Common confusions

- **Picking vs sticking:** Picking = punch face pulls bits off (surface pits); sticking = die wall grabs material (rough sides).
- **IPQC vs finished-product tests:** IPQC = *during* production to *correct*; finished tests = *after* production to *release/reject*.
- **Hardness vs friability:** Hardness = force to *break* one tablet; friability = *chipping* of many tablets on tumbling. A very hard tablet can still be friable at edges.

4.13 Common mistakes

1. Writing "friability limit is 1%" without "not more than" — the limit is NMT 1.0% weight loss.
2. Giving disintegration limits without saying uncoated vs coated.
3. Suggesting "increase compression force" for capping — high force often *worsens* capping (trapped air); reduce fines and control moisture instead.
4. Forgetting dissolution when asked "which test best predicts bioavailability."

4.14 Mnemonics

- **Defects:** "**C**apping, **P**icking, **S**ticking, **C**hipping, **M**ottling" → "**C**areful **P**harma **S**tudents **C**heck **M**edicines."
- **Final tests:** "**W**eight, **H**ardness, **F**riability, **D**isintegration, **D**issolution, **A**ssay" → "**W**e **H**ave **F**ull **D**ata **D**aily, **A**ssured."

4.15 Exam summary (one page)

Tablet defects and their cures: capping/lamination (trapped air, over-drying → pre-compression, moisture control), picking/sticking (wet granules, worn punches, low lubricant → dry, polish, lubricate), chipping (ejection force → bevel punches), mottling (colour migration → better mixing), weight variation (poor flow → glidant/granulation), double impression (punch rotation → fix tooling). IPQC checks during manufacture — appearance, weight of 20, thickness, hardness, friability, disintegration, granule moisture/flow — allow immediate correction. Finished-product tests: description/identification, weight variation (±10%/±7.5%/±5% bands), content uniformity, hardness, friability (NMT 1.0% after tumbling), disintegration (15 min uncoated/30 min coated), dissolution (basket/paddle, monograph Q value), assay and impurities. Disintegration is physical break-up; dissolution is drug going into solution and best predicts absorption. Packaging: strip packs, PVC or alu-alu blisters, HDPE bottles with desiccant — chosen by moisture sensitivity and cost.

4.16 One-minute revision

Defects tell you what went wrong — read them like symptoms: cap = air/moisture, pick = wet/lube, chip = force/edge, mottle = colour, weight = flow. IPQC watches during making; final tests judge after. Remember: friability ≤1%, disintegration 15/30 min, dissolution predicts blood levels. Pack to protect.

4.17 Exam questions

Short questions

1. Define capping and lamination. Give three causes and three remedies.
2. Distinguish picking from sticking with causes and remedies for each.
3. What is IPQC? List five IPQC checks for tablets and what each detects.
4. Describe the friability test (apparatus, procedure, limit).
5. Distinguish disintegration from dissolution. Which better predicts bioavailability? Why?
6. Write the weight-variation limits for tablets as commonly taught from the IP.
7. Name three types of tablet packaging and state which product each suits.

MCQs (answers at end)

1. Separation of the tablet top as a cap is called:

a) Mottling b) Capping c) Picking d) Chipping

1. The standard friability limit is:

a) NMT 0.5% b) NMT 1.0% c) NMT 2.0% d) NMT 5.0%

1. IPQC is carried out:

a) After marketing b) During manufacturing c) On raw materials only d) By the patient

1. Uncoated tablets should disintegrate within (commonly taught):

a) 5 min b) 15 min c) 30 min d) 60 min

1. The dissolution apparatus with a paddle is USP Type:

a) I b) II c) III d) IV

1. Double impression is caused by:

a) Wet granules b) Free rotation of the lower punch c) Excess lubricant d) Deep concave punches

1. Alu-alu blisters are preferred for:

a) Cheap vitamins b) Highly moisture-sensitive drugs c) Syrups d) Injections

1. Which test measures resistance to chipping during handling?

a) Hardness b) Friability c) Disintegration d) Assay

Answers: 1-b, 2-b, 3-b, 4-b, 5-b, 6-b, 7-b, 8-b

Viva questions

1. Your batch shows capping. Walk me through your troubleshooting in order.
2. Why is dissolution considered more meaningful than disintegration?
3. A tablet is very hard but still fails friability — how is that possible?
4. When is content uniformity tested instead of weight variation?

Application-based

1. A direct-compression batch shows progressive weight variation through the run. Diagnose using IPQC data (weight, thickness trends) and propose three corrective actions.
2. Design a QC plan (IPQC + finished-product tests) for a new 500 mg uncoated tablet, stating the purpose of each test.

4.18 References

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Chapter 5 — Tablet Coating: Types, Polymers, Defects & Quality Control (Unit II)

5.1 Learning objectives

After studying this chapter, you will be able to:

1. Define tablet coating and explain why tablets are coated (need).
2. List advantages and limitations of coating.
3. Describe the four coating types — sugar, film, compression, enteric — with their processes.
4. Name coating polymers for film coating and enteric coating with examples.
5. Explain the stages of sugar coating and film coating.
6. Describe coating equipment: conventional pan, perforated pan, fluidised bed.
7. Identify coating defects and suggest remedies.
8. List quality-control tests for coated tablets.

5.2 Definitions

- **Tablet coating:** Applying a thin outer layer (sugar, polymer film, or compressed coat) around a tablet core for protection, taste-masking, identification, or controlled drug release.
- **Tablet core:** The uncoated compressed tablet that receives the coating.
- **Sugar coating:** The traditional multi-stage process of building up thick sucrose layers around the core.
- **Film coating:** Spraying a thin polymer film (a few micrometres) onto tablets in a rotating pan.
- **Compression (press) coating:** Pressing a dry coating powder around a tablet core using a tablet press — a "tablet within a tablet."
- **Enteric coating:** A special coating that stays intact in stomach acid but dissolves in intestinal fluid, protecting the drug from acid or the stomach from the drug.
- **Polymer:** A large molecule made of repeating units — the film-forming backbone of coatings (e.g., HPMC, cellulose acetate phthalate).

Simple explanation: Coating is the tablet's "jacket." Just as we wear a raincoat in monsoon (protection), a blazer for a wedding (looks), and a wetsuit for swimming (special function), tablets get different coats for different jobs — hide bitter taste, protect from moisture, look identifiable, or survive stomach acid to release in the intestine.

Need for coating (why coat at all — exam favourite):

1. **Taste/odour masking** — bitter drugs become swallowable.
2. **Protection** — from moisture, light, and air.
3. **Identification** — colour/shape coding avoids mix-ups.
4. **Controlled release** — enteric or sustained-release coats decide *where/when* the drug releases.
5. **Elegance** — smooth, glossy tablets improve patient acceptance.
6. **Mechanical strength** — coating reduces chipping during handling.

Advantages vs limitations:

Advantages	Limitations
Masks bitter taste/odour	Extra cost, time, and equipment
Protects from moisture/light	Needs skilled operators; process is sensitive
Product identification (colour/logos)	Coating defects possible (chipping, cracking)
Enables enteric/controlled release	Adds weight and size to the tablet
Elegant appearance, patient acceptance	Batch-to-batch colour matching can be tricky

> **Key takeaway:** Coating is a jacket with a job — every coat type exists to solve a specific problem.

5.3 Terminology (word bank)

Term	Meaning in one line
Subcoating	Early sealing layers in sugar coating that round the tablet edges
Syruping	Building up the sugar coat with coloured syrup layers
Plasticiser	Additive that makes polymer films flexible instead of brittle (e.g., PEG, glycerin)
Opacifier	Pigment (e.g., titanium dioxide) that makes the film opaque and protects from light
Enteric polymer	Polymer insoluble in acid but soluble at intestinal pH (e.g., cellulose acetate phthalate)
Perforated pan	Coating pan with holes for efficient drying airflow (e.g., Accela-Cota type)
Wurster (fluidised bed)	Bottom-spray fluid-bed coater — excellent for pellets and mini-tablets
Orange-peel effect	Rough, dimpled coating surface resembling orange skin
Weight gain	% increase in tablet weight due to coating — the main in-process control

5.4 Types of coating

5.4.1 Sugar coating

- **Process (five classic stages):**

1. **Sealing** — waterproof seal coat (e.g., shellac) protects the core from water in later syrups.
2. **Subcoating** — several sticky syrup + powder layers round off the tablet edges.
3. **Syruping (smoothing)** — many thin coloured syrup layers build a smooth coat.
4. **Finishing** — final coloured syrup for the exact shade.
5. **Polishing** — wax polishing gives the glossy shine.

- **Features:** Thick, elegant, sweet-tasting coat; but time-consuming (days), adds 30–50% weight, and needs skilled workers.
- **Simple explanation:** Like icing a wedding cake — seal, crumb-coat, many smooth layers, final colour, polish. Beautiful but slow.

5.4.2 Film coating

- **Process:** A polymer solution/suspension is **sprayed** onto tumbling tablets in a rotating pan while warm air dries it — a thin film (typically only ~2–3% weight gain) forms in hours, not days.
- **Polymers (film formers):** Hydroxypropyl methylcellulose (**HPMC** — most common), hydroxypropyl cellulose (HPC), methylcellulose, polyvinyl alcohol (PVA), ethylcellulose (for sustained release).
- **Other ingredients:** Plasticiser (flexibility), opacifier/colour (titanium dioxide, iron oxides), solvent (water or organic — water preferred for safety).
- **Features:** Fast, thin, elegant; logos/embossing stay visible; the modern standard.
- **Simple explanation:** Like spray-painting a wall — thin, quick, even. Sugar coating is like hand-plastering it.

5.4.3 Compression (press) coating

- **Process:** A tablet core is placed inside a larger die, coating powder is filled around it, and the whole is compressed — a dry "tablet within a tablet." No water, no heat.
- **Uses:** Separating incompatible drugs (one in core, one in coat), or giving a fast-release coat over a slow-release core.
- **Limitation:** Needs special tablet presses; coat uniformity is harder to control than sprayed film.

5.4.4 Enteric coating

- **Concept:** The coat **resists stomach acid (pH ~1–3) but dissolves in intestinal fluid (pH ~6–7)** — a pH-triggered jacket.
- **Why needed:** (a) Drug is destroyed by stomach acid; (b) drug irritates the stomach lining (e.g., NSAIDs); (c) drug must release in the intestine for local action.
- **Enteric polymers:** Cellulose acetate phthalate (**CAP**), hydroxypropyl methylcellulose phthalate (**HPMCP**), methacrylic acid copolymers (**Eudragit L and S** types — dissolve above specific pH values).
- **How it works (mechanism):** These polymers have acidic groups that stay unionised (insoluble) in stomach acid but ionise (dissolve) at higher intestinal pH — the same pKa logic from Chapter 1, now used as a tool!
- **Testing:** Enteric tablets must show **no disintegration in acid for 2 hours**, then disintegrate in intestinal buffer (commonly taught pharmacopoeial expectation).

Comparison table — the four coats:

Feature	Sugar	Film	Compression	Enteric
Thickness/weight gain	Thick (30–50%)	Thin (~2–3%)	Thick (dry)	Thin film
Time	Days	Hours	Fast (press)	Hours
Water used	Yes (syrups)	Yes (spray)	No	Yes (spray)
Main purpose	Taste, elegance	Taste, protection, ID	Separation, dual release	Acid protection / stomach protection
Key materials	Sucrose, shellac, wax	HPMC, plasticiser, TiO_2	Dry coating powders	CAP, HPMCP, Eudragit L/S

Common confusion: Film coating vs enteric coating — enteric coating *is* a type of film coating (thin sprayed polymer film), but with a *special pH-sensitive polymer*. All enteric coats are film coats; not all film coats are enteric.

> **Key takeaway:** Sugar = classic and sweet but slow; film = modern standard; compression = dry tablet-in-tablet; enteric = acid-proof jacket that opens in the intestine.

5.5 Process specifications and equipment

Technical concept: Coating quality depends on balancing **spray rate, drying air (temperature and volume), pan speed, and tablet movement**. Too much spray + too little drying = sticky, defective coats; too much drying = spray dries before reaching tablets ("spray drying" defect).

Key process parameters:

1. **Pan speed** — tablets must tumble smoothly without excessive friction.
2. **Inlet air temperature/volume** — dries each sprayed layer; too hot damages heat-sensitive drugs.
3. **Spray rate and atomisation** — fine, even droplets; gun-to-bed distance matters.
4. **Coating weight gain** — monitored during the run (e.g., target ~2–3% for film coats); the main IPQC check.
5. **Drying between stages** — each layer must dry before the next lands.

Equipment:

1. **Conventional coating pan** — rotating tilted pan; drying air blows over the tablet bed; simple but slower drying.
2. **Perforated pan (e.g., Accela-Cota type)** — pan wall has holes; drying air passes *through* the tablet bed — faster, more uniform drying; the industry standard for film coating.
3. **Fluidised-bed (Wurster) coater** — air suspends pellets/tablets while coating sprays from below; superb uniformity; ideal for pellets, mini-tablets, and sustained-release coating.

Diagram — draw it: Three sketches: (1) tilted rotating pan with spray gun at the top and air inlet — label "conventional pan"; (2) cylindrical pan with dotted (perforated) wall and air arrows passing through the bed — "perforated pan: air through the bed"; (3) vertical chamber with tablets dancing on air jets and a spray nozzle at the bottom centre — "Wurster: bottom spray, air-suspended."

> **Key takeaway:** Coating is controlled drying + controlled spraying. Equipment decides how efficiently you can do both.

5.6 Coating defects — causes and remedies

Defect (what you see)	Cause	Remedy
Picking/sticking — tablets stick together or to the pan	Over-wetting (spray too fast, drying too slow)	Reduce spray rate; increase drying air; warm the pan
Blistering/peeling — film bubbles and lifts	Entrapped moisture/air; hot core with cold spray	Control drying; let cores cool; reduce spray rate
Chipping — coat breaks at edges	High pan speed, excessive friction; brittle film	Reduce pan speed; add plasticiser for flexibility
Cracking — film cracks on storage	Too little plasticiser; film too thick	Optimise plasticiser; control weight gain
Orange-peel effect — rough, dimpled surface	Spray droplets too large; poor atomisation; viscous solution	Improve atomisation; reduce solution viscosity
Colour variation/mottling — uneven colour	Poor mixing of coating suspension; uneven spraying	Keep suspension stirred; uniform spray pattern
Bridging — coating fills in embossed logos	Too much coating; poor drying	Control weight gain; improve drying
Craters — small pits in film	Air bubbles in spray; fast drying skinning over wet layer	De-aerate solution; balance spray and drying

Simple explanation: Nearly every coating defect is a **spray-vs-drying imbalance** — too wet = sticking/blistering; too dry = orange peel/craters; too rough = chipping; too brittle = cracking. Learn that one sentence and you can reason out most remedies.

> **Key takeaway:** Balance spray and drying, keep the film flexible with plasticiser, and most coating defects disappear.

5.7 Quality control of coated tablets

1. **Appearance** — uniform colour, no defects (visual inspection; the first and most used test).
2. **Weight gain uniformity** — sample tablets weighed; coating weight gain within the specified range.
3. **Thickness** — consistent coat thickness (vernier callipers; coat adds measurably).
4. **Hardness and friability** — coat should not chip on handling.
5. **Disintegration** — plain film/sugar-coated tablets: commonly taught expectation **within 30 minutes**; **enteric-coated: no disintegration in acid (2 h), then disintegration in buffer** (commonly taught pharmacopoeial expectations).
6. **Dissolution** — drug release from coated tablets must meet the monograph (coating must not trap the drug).
7. **Assay** — drug content per tablet within monograph limits.
8. **Coating uniformity** — cross-section or weight checks confirm even coating.

> **Key takeaway:** Coated-tablet QC = uncoated-tablet QC **plus** coating-specific checks (appearance, weight gain, and the special disintegration rules for enteric coats).

5.8 Infographic concept box — "Coats and their jobs"

> *(For the designer: four jacket icons in a row.)*

- **SUGAR COAT** (cake icon): "Thick, sweet, glossy. Slow — days."
- **FILM COAT** (spray-paint icon): "Thin polymer skin. Fast — hours. The modern standard."
- **PRESS COAT** (nested tablets icon): "Tablet inside a tablet. Dry process."
- **ENTERIC COAT** (shield icon): "Acid-proof in stomach, opens in intestine. CAP, HPMCP, Eudragit L/S."

5.9 Pharmacy relevance

Pharmacists must know never to crush or split **enteric-coated** or **sustained-release-coated** tablets — destroying the coat destroys the whole design (stomach irritation, dose dumping). Counselling "swallow whole, do not chew" comes straight from this chapter. Spotting defective coats (cracked, mottled) is part of receiving stock.

5.10 India context

Film coating dominates Indian tablet plants (fast, economical); sugar coating survives mainly for traditional/ayurvedic-style products. Enteric-coated NSAIDs and proton-pump-inhibitor products are everyday Indian pharmacy items. In our humid climate, moisture-barrier film coats plus alu-alu blisters are a common Indian combination for sensitive drugs.

5.11 Key points

1. Coating needs: taste masking, protection, identification, controlled release, elegance, strength.
2. Four types: sugar (5 stages: seal, subcoat, syrup, finish, polish), film (sprayed polymer, thin), compression (dry tablet-in-tablet), enteric (acid-resistant, intestine-soluble).
3. Film polymers: HPMC (most common), HPC, PVA; plasticiser for flexibility; titanium dioxide as opacifier.
4. Enteric polymers: CAP, HPMCP, Eudragit L/S — insoluble in acid, soluble at intestinal pH.
5. Equipment: conventional pan, perforated pan (air through bed), Wurster fluidised bed (best uniformity).
6. Most coating defects = spray-vs-drying imbalance; plasticiser prevents cracking.
7. QC: appearance, weight gain, thickness, hardness/friability, disintegration (30 min plain; acid/buffer stages for enteric), dissolution, assay.

5.12 Common confusions

- **Sugar vs film coating:** Sugar = thick, slow, sweet layers; film = thin, fast, sprayed polymer. Different processes, different purposes.
- **Enteric vs sustained release:** Enteric = *where* it releases (intestine, pH-triggered); sustained = *how long* it releases (time-controlled). Different jobs.
- **Plasticiser purpose:** Makes the film *flexible*, not harder. Without it, films crack.

5.13 Common mistakes

1. Saying enteric coating "dissolves in the stomach" — it *resists* stomach acid and dissolves in the *intestine*.
2. Advising patients to crush enteric-coated tablets — never crush; the coat is the design.
3. Listing coating defects without linking them to spray/drying balance.
4. Forgetting the two-stage (acid then buffer) disintegration test for enteric tablets.

5.14 Mnemonics

- **Sugar-coating stages:** "**S**eal, **S**ubcoat, **S**yrup, **F**inish, **P**olish" → "**S**weet **S**ugar **S**hells **F**inish **P**retty."
- **Coating types:** "**S**ugar, **F**ilm, **C**ompression, **E**nteric" → "**S**ome **F**ilms **C**over **E**verything."

5.15 Exam summary (one page)

Tablets are coated to mask taste, protect from moisture/light, aid identification, enable controlled release, and improve elegance — at the cost of extra time, equipment, and possible defects. **Sugar coating** builds thick sucrose layers in five stages (sealing, subcoating, syruping, finishing, polishing) — elegant but slow. **Film coating** sprays a thin polymer solution (HPMC most common, plus plasticiser, opacifier, colour) onto tumbling tablets with warm-air drying — fast, thin (~2–3% weight gain), the modern standard. **Compression coating** presses dry coat powder around a core (tablet-in-tablet, no water). **Enteric coating** uses pH-sensitive polymers (CAP, HPMCP, Eudragit L/S) that resist stomach acid but dissolve in intestinal pH — protecting acid-labile drugs or the stomach. Equipment: conventional pan, perforated pan (air through the bed), Wurster fluidised bed (best uniformity). Process balance: spray rate vs drying air; pan speed; weight-gain monitoring. Defects (picking, blistering, chipping, cracking, orange peel, colour variation, bridging) mostly trace to spray/drying imbalance or brittle film (fix with plasticiser). QC: appearance, weight gain, thickness, hardness/friability, disintegration (30 min plain-coated; acid 2 h then buffer for enteric), dissolution, assay.

5.16 One-minute revision

Coat = jacket with a job. Sugar: sweet, slow, 5 stages. Film: thin spray, HPMC, modern standard. Press: dry tablet-in-tablet. Enteric: acid-proof, opens in intestine (CAP/HPMCP/Eudragit). Equipment: pan → perforated pan → Wurster. Defects = spray vs drying out of balance. Never crush an enteric tablet!

5.17 Exam questions

Short questions

1. Define tablet coating. List four needs for coating tablets.
2. Give four advantages and three limitations of tablet coating.
3. Describe the five stages of sugar coating.
4. Name three film-coating polymers and the role of a plasticiser.
5. What is enteric coating? Name two enteric polymers and explain how the coat works using pH.
6. Compare conventional, perforated-pan, and fluidised-bed coating equipment.
7. Explain the orange-peel effect and blistering with remedies.
8. List the QC tests for coated tablets, including the special disintegration test for enteric tablets.

MCQs (answers at end)

1. The most commonly used film-coating polymer is:

a) Sucrose b) HPMC c) Shellac d) Gelatin

1. Enteric coating resists:

a) Intestinal fluid b) Stomach acid c) Water d) Light

1. Which is an enteric polymer?

a) Lactose b) Cellulose acetate phthalate c) Starch d) Talc

1. The final glossy stage of sugar coating is:

a) Sealing b) Subcoating c) Polishing d) Syruping

1. The Wurster process is a type of:

a) Sugar coating b) Fluidised-bed coating c) Compression coating d) Dip coating

1. Orange-peel effect is mainly due to:

a) Excess plasticiser b) Poor atomisation/large droplets c) Low pan speed d) Thin film

1. A plasticiser is added to coating formulations to:

a) Add colour b) Make the film flexible c) Speed drying d) Increase thickness

1. Enteric tablets in the disintegration test must first:

a) Disintegrate in acid within 15 min b) Show no disintegration in acid for 2 h c) Dissolve fully in acid d) Be crushed before testing

Answers: 1-b, 2-b, 3-b, 4-c, 5-b, 6-b, 7-b, 8-b

Viva questions

1. A patient asks if they can crush their enteric-coated tablet because it is too big. What do you advise, and why?
2. Your film-coated batch shows blistering. What is the first process parameter you check?
3. Why does the embossed logo disappear on some coated tablets, and how do you prevent it?
4. When would you choose compression coating over film coating?

Application-based

1. You must develop a tablet for a drug that (a) is destroyed by stomach acid and (b) tastes intensely bitter. Choose the coating type, name the polymer(s), select the equipment, and justify each choice.
2. A sugar-coating run is taking too long and tablets are sticking during syruping. Diagnose the likely process faults and propose a revised approach (consider switching coating type).

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