Dosage Form:

A dosage form is the physical form in which a medication is produced and administered to deliver the active drug effectively to the patient. It includes the drug and other non-active ingredients (excipients) that help in drug delivery.

Types of Dosage Forms:

1. Solid Dosage Forms:

- Tablets – e.g., Paracetamol tablet
- Capsules – e.g., Amoxicillin capsule
- Powders – e.g., Oral rehydration salts
- Granules – e.g., Antacid granules

2. Liquid Dosage Forms:

- Solutions – e.g., Cough syrups
- Suspensions – e.g., Antacid suspension
- Emulsions – e.g., Cod liver oil emulsion

3. Semi-Solid Dosage Forms:

- Ointments – e.g., Antibiotic ointment
- Creams – e.g., Hydrocortisone cream
- Gels – e.g., Diclofenac gel

4. Gaseous Dosage Forms:

- Inhalers – e.g., Salbutamol inhaler
- Aerosols – e.g., Nasal sprays

5. Parenteral Dosage Forms:

- Injections – e.g., Insulin injection
- Infusions – e.g., IV fluids

Each dosage form is chosen based on the route of administration, drug properties, and patient needs.

Definition of Capsules:

Capsules are solid oral dosage forms in which the drug or active ingredient is enclosed within a gelatin or non-gelatin shell. These shells can be hard or soft, depending on the formulation. Capsules are used to deliver powders, granules, semi-solids, or liquids orally.

Why Capsules?

1. Easy to Swallow – Smooth, tasteless shell improves patient compliance.

2. Taste Masking – Encloses bitter or unpleasant drugs.

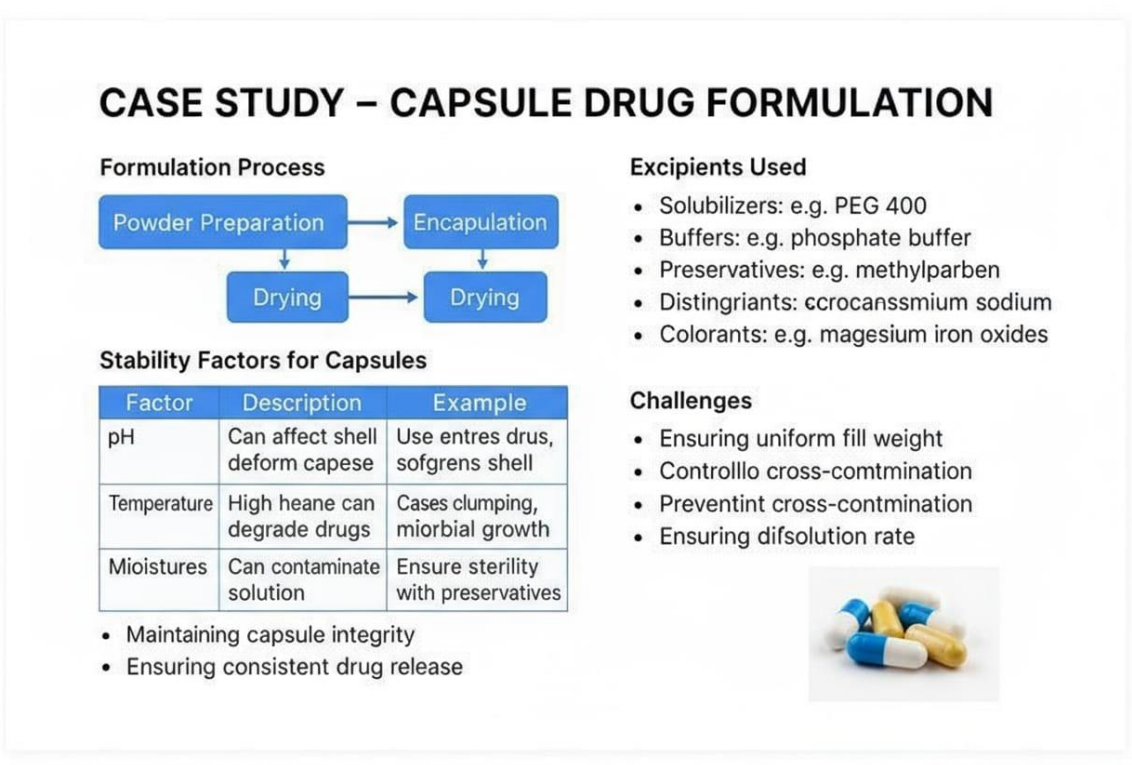
3. Accurate Dosing – Delivers a precise amount of medication.

4. Fast Dissolution – Gelatin shell dissolves quickly in the stomach.

5. Flexible Formulation – Can contain powders, beads, or even liquids (in softgels).

6. Good Stability – Protects drug from light, air, or moisture (with proper packaging).

Capsules are preferred for their convenience, effectiveness, and versatility in pharmaceutical applications



Types of Capsules with Examples:

1. Hard Gelatin Capsules

- Made of two pieces (body and cap)
- Filled with powders, granules, or pellets
- Example: Amoxicillin 500 mg capsule

2. Soft Gelatin Capsules (Softgels)

- Single-piece, flexible shell
- Contain liquids, oils, or semi-solids
- Example: Vitamin E softgel

3. Enteric-Coated Capsules

- Shell resists stomach acid; dissolves in intestine
- Used for acid-sensitive drugs
- Example: Omeprazole EC capsule

4. Modified/Controlled Release Capsules

- Designed to release the drug slowly over time
- Example: Propranolol extended-release capsule

5. Delayed-Release Capsules

- Drug is released after a specific time or in a specific part of the GI tract
- Example: Rabeprazole delayed-release capsule

These types allow for flexibility in drug delivery based on patient needs and drug properties.

Formulation Process of Capsules:

1. Drug Selection and Evaluation:

- Choose the active pharmaceutical ingredient (API) based on therapeutic need, stability, and compatibility.

2. Pre-Formulation Studies:

- Assess physical and chemical properties of the drug (solubility, particle size, flowability).

3. Preparation of Fill Material:

- For powders: mix the drug with suitable excipients like fillers, lubricants, and glidants to ensure uniformity and good flow.

- For liquids or semi-solids (in soft gels): prepare a homogenous mixture.

4. Capsule Shell Preparation:

- Usually gelatin or hydroxypropyl methylcellulose (HPMC) shells are prepared by dipping metal molds in gelatin solution, drying, and trimming.

5. Filling Process:

- Hard capsules: fill the powder or granules into two-piece shells using capsule filling machines.

- Soft gels: fill liquid or semi-solid fill into soft gelatin shells using rotary die or plate machines.

6. Sealing:

- Hard capsules may be sealed by locking the cap and body or banding.

- Soft gels are hermetically sealed during manufacturing.

7. Quality Control:

- Check weight uniformity, disintegration, dissolution, moisture content, and microbial limits.

Excipients Used in Capsules with Examples:

1. Fillers (Diluents):

- Add bulk to the capsule when the drug dose is small.

- Example: Lactose, Microcrystalline cellulose

2. Glidants:

- Improve flow properties of the powder mix.

- Example: Colloidal silicon dioxide

3. Lubricants:

- Prevent powder sticking to machinery and ease capsule filling.

- Example: Magnesium stearate, Stearic acid

4. Disintegrants:

- Help the capsule content to break apart and dissolve faster after ingestion.
- Example: Starch, Sodium starch glycolate

5. Binders:

- Help powders stick together for uniform filling.
- Example: Povidone (PVP)

6. Preservatives:

- Prevent microbial growth in the capsule contents.
- Example: Methylparaben

7. Colorants:

- Used to identify capsules or improve appearance.
- Example: Titanium dioxide, FD&C dyes

These excipients ensure the capsule's stability, flowability, and effective drug release.

Stability Factors in Capsules:

1. Moisture Content:

- Excess moisture can cause capsules (especially gelatin) to become sticky or brittle.
- Proper humidity control (usually 40-50%) is essential.

2. Temperature:

- High temperatures can degrade both the capsule shell and drug content.
- Capsules should be stored in cool, dry conditions.

3. Light Exposure:

- Some drugs and capsule materials are sensitive to light, causing degradation.
- Use light-resistant packaging if necessary.

4. Oxygen Exposure:

- Oxygen can oxidize the drug or capsule shell, reducing effectiveness.
- Use airtight packaging or include antioxidants.

5. pH:

- Capsule shell integrity can be affected by acidic or alkaline environments.
- Formulation should consider the pH stability of both drug and shell.

6. Microbial Contamination:

- Moisture and warmth encourage microbial growth, affecting stability and safety.
- Proper preservatives and aseptic manufacturing help prevent this.

7. Compatibility:

- Interaction between drug and excipients or shell materials can affect stability.
- Compatibility testing is crucial.

Maintaining these factors ensures the capsule remains safe, effective, and stable throughout its shelf life.

Challenges in Capsules:

1. Moisture Sensitivity:

- Gelatin capsules are sensitive to moisture, which can cause them to become brittle or sticky.

2. Stability Issues:

- Some drugs may degrade inside capsules due to interaction with shell material or excipients.

3. Manufacturing Complexity:

- Filling capsules with powders, liquids, or pellets requires precise equipment and process control.

4. Limited Dose Capacity:

- Capsules have size limits, restricting the amount of drug that can be delivered in one unit.

5. Cross-linking of Gelatin:

- Over time, gelatin capsules can harden due to chemical changes, affecting drug release.

6. Storage Requirements:

- Capsules often need specific temperature and humidity conditions for proper storage.

7. Patient Acceptance:

- Large capsules can be difficult to swallow for some patients.

8. Cost:

- Capsule manufacturing can be more expensive than tablets due to materials and equipment.

Addressing these challenges is important for ensuring capsule quality and patient compliance.

Conclusion:

Capsules are a versatile and widely used dosage form offering ease of administration, accurate dosing, and improved patient compliance. Their stability depends on controlling factors such as moisture, temperature, light, and oxygen exposure. Proper selection of excipients and packaging materials is crucial to maintain the integrity and effectiveness of both the capsule shell and the drug inside. Understanding these stability factors helps in designing high-quality capsule formulations that ensure safety, efficacy, and shelf-life, making capsules an important choice in pharmaceutical drug delivery.