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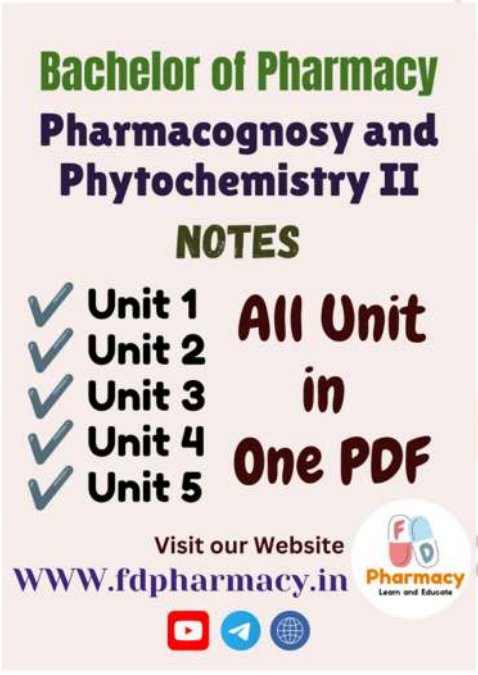
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INDUSTRIAL PHARMACY - I

UNIT 3

TOPIC :

- **Capsules :**

  a. Hard gelatin capsules : Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

  b. Soft gelatin capsules : Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

Capsules

- Capsules are solid dosage forms in which one or more medicinal and inert substances are enclosed in a small, shell-like container made from gelatin or other suitable materials.
- They are designed to mask the taste and odor of drugs and to facilitate easy swallowing.
- Capsules can deliver drugs in solid, liquid, or semi-solid form.
- The shell quickly disintegrates in the gastrointestinal tract, releasing the drug for absorption.
- Capsules are classified mainly into Hard Gelatin Capsules and Soft Gelatin Capsules.

Advantages:

- Tasteless and odorless.
- Attractive appearance.
- Easy to swallow.
- Protects drug from light, air, and moisture.
- Allows flexibility in formulation (powders, granules, pellets, liquids).

Disadvantages:

- Sensitive to humidity and temperature.
- Unsuitable for highly soluble salts (can cause gastric irritation).
- Not suitable for efflorescent or deliquescent materials.
- More expensive to produce than tablets.

Types of Capsules

Type	Description	Shell Composition
Hard Gelatin Capsules (HGC)	Two-piece shell — body and cap; filled with dry powders or pellets.	Gelatin + Water + Coloring + Opacifying agents
Soft Gelatin Capsules (SGC)	One-piece shell containing liquid or semi-solid fill.	Gelatin + Plasticizers (glycerin/sorbitol) + Preservatives

Hard Gelatin Capsules

- Capsules are solid dosage forms in which the drug substance is enclosed in a hard or soft soluble container made from gelatin.
- Hard gelatin capsules (HGCs) are primarily used for solid or powdered formulations (e.g., powders, granules, pellets, or small tablets).
- They are one of the most preferred dosage forms because:
  - They mask the unpleasant taste and odor of drugs.
  - Offer accurate dosing and are easy to swallow.
  - Provide better bioavailability than compressed tablets in some cases.
  - Allow flexibility in formulation, suitable for both clinical trials and commercial products.

Composition of capsule shell:

- Gelatin (35%) – Derived from collagen of animal bones or skin. Provides strength and elasticity.
- Water (30%) – Acts as a plasticizer.
- Colorants and opacifiers (1–2%) – Titanium dioxide is used as an opacifier.
- Preservatives (0.2%) – Methylparaben, propylparaben (optional).
- Sugar (optional) – Adds hardness and shine.

Advantages of Hard Gelatin Capsules

- Easy to formulate and swallow.
- Masks unpleasant drug taste.
- Can accommodate various dosage forms (powder, pellets, liquid).
- Rapid drug release and absorption.
- Easily identifiable by color and size.
- Tamper-evident with banding or imprinting.

Disadvantages

- Not suitable for hygroscopic or deliquescent drugs.
- Unsuitable for aqueous or highly volatile materials.
- Gelatin is animal-derived (not suitable for vegetarians/vegans).
- May soften or become brittle under improper storage.

Manufacturing Process of Hard Gelatin Capsule Shells

- The production process consists of several key steps performed in a controlled environment (Temperature: 20–25°C; Relative humidity: 40–60%).

Step 1: Dipping

- Stainless steel pins (moulds) mounted on metal bars or plates are dipped into the warm gelatin solution (45–50°C).
- The pins correspond to the shape and size of capsule body and cap.
- The gelatin film adheres to the pins due to viscosity and surface tension.
- Separate pin bars are used for caps and bodies.

Step 2: Rotation

- Immediately after dipping, the pins are rotated slowly to ensure even distribution of gelatin around the pin.
- This also prevents accumulation or dripping at the bottom of the pins.
- The thickness of the gelatin layer depends on viscosity of solution, dipping time, and withdrawal speed.

Step 3: Drying

- The coated pins are passed through a series of drying chambers where temperature, humidity, and airflow are precisely controlled.
- Warm air (25–35°C) is circulated to gradually remove moisture from the gelatin film.
- Proper drying ensures:
  - Uniform wall thickness
  - Sufficient mechanical strength
  - Prevention of brittleness
- Overdrying can make capsules brittle, while under-drying can make them soft or sticky.

Step 4: Stripping

- After drying, the gelatin film (now solidified) is stripped off the pins automatically by a stripping mechanism.
- The hollow capsules are now open-ended tubes — one for the body and one for the cap.

Step 5: Trimming

- The stripped shells are conveyed to a trimming station, where rotating knives cut each cap and body to the correct length.
- Trimming ensures uniform size and proper fit of cap and body during assembly.

Step 6: Joining

- The body and cap are aligned and fitted together using a joining machine.
- They are temporarily joined for packaging as empty capsule shells ready for filling.
- In some cases, banding or locking mechanisms (e.g., Coni-Snap® design) are used to prevent separation during handling or filling.

Sizes of Hard Gelatin Capsules

Capsule Size	Approx. Capacity (mg)	Suitable for
000	950 – 1350 mg	Very large dose; used for high-dose or veterinary preparations; difficult to swallow
00	650 – 1000 mg	Large adult dose; used for bulky powders
0	400 – 600 mg	Standard adult size; most commonly used
1	300 – 500 mg	Medium dose for adults
2	250 – 400 mg	Medium dose; easy to swallow
3	200 – 300 mg	Small dose; for potent drugs
4	150 – 200 mg	Small dose; for pediatric or elderly use
5	100 – 150 mg	Very small dose; mainly pediatric or highly potent drugs

Filling of Hard Gelatin Capsules

- ❖ Filling of Hard Gelatin Capsules involves introducing the drug substance (in powder, granule, pellet, or liquid form) into the empty capsule shells.
- ❖ Each capsule consists of two parts:
  - Body → longer part, filled with the drug material.
  - Cap → shorter part, used to close the capsule.
- ❖ The goal is to ensure accurate dosage, uniform fill weight, and smooth capsule closure without damage or leakage.

Methods of Filling Hard Gelatin Capsules

- ➢ Filling operations may be carried out manually, semi-automatically, or automatically, depending on production scale.

A. Manual (Hand Filling Method)

Used for small-scale or laboratory preparation.

Steps:

1. Arrangement of Capsule Board:
   - A manual capsule-filling tray holds a specific number of capsules (e.g., 100–300).
   - Capsules are loaded into the tray with caps facing upward.
2. Separation of Cap and Body:
   - A mechanism or plate separates caps and bodies automatically.
3. Filling:
   - The body portion remains in the lower tray and is filled with powder by spatula, hand tamping, or powder spreader.
4. Rejoining:

    - After filling, the cap tray is placed over the body tray and pressed to lock caps and bodies together.
5. Ejection:
    - The filled capsules are removed, cleaned, and polished.

Advantages:

- Simple and inexpensive.
- Suitable for small batches.

Disadvantages:

- Labor-intensive and time-consuming.
- Not suitable for industrial-scale production.

B. Semi-Automatic Capsule Filling Machine

Used for medium-scale manufacturing.

Working Steps:

1. Loading of empty capsules into the loading rings.
2. Separation of body and cap sections mechanically.
3. Filling station:
    - Powder is filled into bodies using auger, piston tamping, or vibratory systems.
4. Joining:
    - Caps are automatically placed back onto bodies and locked.
5. Ejection:
    - Filled capsules are discharged and collected.

Output: 20,000–50,000 capsules/hour.

Advantages:

- Higher accuracy and uniformity.
- Requires less operator skill.
- Consistent fill weight.

C. Automatic Capsule Filling Machine

Used for large-scale production in the pharmaceutical industry.

Working Principle:

- All operations (separation, filling, joining, ejection) occur continuously and automatically.

Filling Mechanisms Used:

1. Auger fill principle: Powder delivered via rotating screw.
2. Dosator piston: Compresses and transfers a plug of powder into capsule body.
3. Tamping pin method: Powder compacted in layers before being pushed into capsule.

Steps in Automatic Filling:

1. Rectification: Aligns capsules with body and cap oriented correctly.
2. Separation: Vacuum separates caps and bodies.
3. Dosing: Powder, pellets, or granules filled into the body.
4. Tamping / Compaction: Ensures uniform plug formation and accurate weight.
5. Joining: Cap placed back on body and locked.
6. Ejection: Filled capsules are discharged and sent for polishing.

Output: Up to 150,000–200,000 capsules/hour.

Finishing and Polishing of Hard Gelatin Capsules

- After the filling and joining of hard gelatin capsules, they undergo a finishing and polishing process to improve their appearance, remove dust, and ensure cleanliness before packaging.
- Proper finishing is important for aesthetic appeal, patient acceptability, and quality assurance.
- Capsules coming directly from filling machines often have powder adhering to their external surface, which can cause dull appearance, cross-contamination, and inaccurate weight if not removed.

Methods of Finishing and Polishing

A. Manual Cleaning

- Used for small-scale or laboratory production.
- Capsules are cleaned by:
  - Wiping with a clean, lint-free cloth or tissue paper.
  - Rolling the capsules gently on a soft absorbent paper.
  - Using a soft brush to remove powder adhering to the surface.
- Suitable for small batches but not practical for large-scale production.

B. Pan Polishing

- Used in medium to large-scale manufacturing.
- Polishing pan (similar to tablet coating pan) is employed.
- Capsules are tumbled in a rotating pan lined with a soft cloth or polishing material.
- A small amount of polishing medium such as naphtha, mineral oil, or light liquid paraffin may be used to impart gloss.
- After tumbling, capsules appear clean, smooth, and shiny.

C. Cloth-Dust Polishing

- In this method, capsules are passed through a series of cloth-lined chambers or rotating brushes.
- The soft cloths wipe off excess powder from capsule surfaces.
- The process also helps in removing static charges that cause powder adherence.

D. Brushing and Vacuum Cleaning (Automatic Capsule Polishers)

- Used in industrial-scale capsule production.
- Capsules pass through a rotating brush system where soft nylon brushes remove any adhering powder.
- A vacuum suction system simultaneously removes the loosened dust and particles.
- This method provides high-speed, continuous cleaning and ensures capsules are uniformly polished.
- Example: *Capsule Polisher Machine* or *Automated Capsule Cleaning System.*

Special Techniques of Formulation of Hard Gelatin Capsules

A. Coating of Drug Particles

- Used for moisture-sensitive, light-sensitive, or taste-masking purposes.
- The drug particles are coated with materials like:
  - Ethyl cellulose
  - Hydroxypropyl methylcellulose (HPMC)
  - Gelatin
- Protects the drug from the environment and reduces interaction with the capsule shell.
- Example: Coating of ferrous salts to prevent interaction with gelatin.

B. Microencapsulation

- The drug is enclosed within microscopic polymer coatings to form microcapsules.
- Carried out using techniques like coacervation, spray drying, or interfacial polymerization.
- Advantages:
  - Protects unstable drugs.
  - Masks unpleasant taste or odor.
  - Provides controlled or sustained release.
- Example: Microencapsulated aspirin or chloramphenicol.

C. Pelletization / Spheroidization

- The drug is converted into small spherical pellets using extrusion–spheronization.
- These pellets are then filled into capsules.
- Benefits:
  - Ensures uniform distribution of the drug.
  - Allows combination of multiple release rates in one capsule.
  - Reduces dose dumping and improves bioavailability.
- Example: Omeprazole pellets in hard gelatin capsules.

D. Sealing of Capsules

- Capsules can be sealed to prevent leakage or tampering.
- Common sealing methods:
  - Banding – A colored gelatin band is applied at the junction of cap and body.
  - Thermal welding – Heat is used to fuse cap and body.
  - Liquid sealing – Alcohol-water solution used to partially dissolve and rejoin edges.
- Helps in maintaining integrity, safety, and stability.

E. Combination Filling (Powder + Pellet / Granule + Liquid)

- Used when drug requires different release rates or drug-drug separation.
- Example: Capsule containing immediate-release granules and sustained-release pellets.
- Also used for liquid-in-solid systems, where the liquid is absorbed onto an inert carrier (e.g., microcrystalline cellulose) before filling.

F. Plug Formulation (Tamping Technique)

- Used in automated capsule-filling machines.
- The powder is compressed into plugs which are then inserted into the capsule body.
- Provides uniform fill weight and accurate dosing for fine powders with poor flow.

G. Capsule-in-Capsule Technique

- A smaller capsule is placed inside a larger capsule.
- Used when two drugs are chemically incompatible or require different release times.
- Example: One capsule containing a buffer and another containing a drug, both packed together.

Common Manufacturing Defects in Hard Gelatin Capsules

A. Dented or Deformed Capsules

➢ Capsules appear misshapen, flattened, or have dents on the surface.

Causes:

- Excessive vacuum during capsule separation.
- Improper storage (low humidity makes capsules brittle).
- Rough handling during filling or packaging.
- Over-drying of capsule shells.

Prevention:

- Control humidity at 35–45% RH.
- Use correct vacuum settings.
- Handle capsules gently.
- Avoid over-drying during drying or polishing.

B. Cap and Body Separation (Loose or Unlocked Capsules)

➢ The cap and body of the capsule do not lock properly, causing separation during handling.

Causes:

- Incorrect locking during filling.
- Damaged or worn-out capsule joining mechanism.
- Overfilled capsules preventing closure.
- Capsule shells swollen due to excess moisture.

Prevention:

- Maintain proper capsule moisture (13–16%).
- Adjust capsule-filling machine to ensure proper locking.
- Avoid overfilling.
- Store capsules in dry conditions.

C. Broken or Cracked Capsules

➢ Capsules show cracks or splits on the shell surface.

Causes:

- Low humidity (capsule becomes brittle).
- High compression force in tamping method.
- Defective capsule shells from supplier.
- Rough handling during polishing or packaging.

Prevention:

- Maintain controlled environment (temperature 20–25°C, RH 40–50%).
- Avoid excessive compression pressure.
- Inspect incoming shells for defects.

D. Color Variation

➢ Capsules show uneven color or mottled appearance.

Causes:

- Improper mixing of colorants or dyes.
- Overheating during drying or polishing.
- Light or moisture exposure.
- Use of different batches of shells.

Prevention:

- Ensure uniform mixing of colorants during shell preparation.
- Avoid direct light exposure.
- Maintain consistent drying temperature.
- Use capsules from the same batch.

E. Shell Softening or Stickiness

➢ Capsules become sticky, soft, or adhere to each other.

Causes:

- High humidity or high temperature in the storage area.
- Hygroscopic or oily material migrating to shell.
- Inadequate drying after filling.

Prevention:

- Maintain storage at 20–25°C and 35–45% RH.
- Use protective coatings or seal shells.
- Add moisture barrier agents if required.

In-Process and Final Product Quality Control Tests for Capsules

In-Process Tests

1. Weight variation test
    - Random capsules are weighed before and after removing contents.
    - The difference indicates the net fill weight.
    - Acceptance limits as per IP/BP.
2. Locking efficiency
    - Ensures proper joining of cap and body to prevent separation.
3. Visual inspection
    - Checks for cracks, dents, color uniformity, and cleanliness.

Final Product Quality Control Tests

Test	Purpose	Method
Disintegration test	Ensure capsule breaks down within specified time	6 capsules tested in water at 37°C; should disintegrate within 30 minutes (IP).
Dissolution test	Ensure drug release profile	Use USP apparatus I (basket) or II (paddle).
Uniformity of weight	Ensure dose uniformity	20 capsules weighed individually; limits ±10%.
Content uniformity	Ensures consistent drug content	10 capsules analyzed individually; 85–115% of label claim.
Moisture content	Prevent brittleness or microbial growth	Karl Fischer method or IR moisture analyzer.
Microbial test	Ensure product is free from pathogens	Tests for total viable count and specific microorganisms.
Shell integrity	Ensure no leakage or cracks	Visual and mechanical tests.

Soft Gelatin Capsules

- Soft gelatin capsules (SGCs) are single-piece, hermetically sealed capsules made from gelatin with plasticizers and filled with liquid, semi-solid, or suspension forms of drugs.
- Unlike hard gelatin capsules, SGCs are flexible, soft, and one-piece.
- They are mainly used to encapsulate oils, suspensions, or drugs in non-aqueous solutions, improving bioavailability and masking unpleasant tastes or odors.

Nature of Shell and Capsule Content

a. Shell Composition

- Gelatin (30–40%) – Provides elasticity and film-forming properties.
- Plasticizers (15–30%) – e.g., Glycerol, sorbitol, PEG; provide flexibility.
- Water (10–20%) – Acts as a solvent for gelatin and plasticizer.
- Colorants and opacifiers (0.5–2%) – Titanium dioxide for opacity; FD&C colors for identification.
- Preservatives (optional) – Methylparaben, propylparaben.

Characteristics of Shell:

- Soft, flexible, elastic, and transparent or colored.
- Moisture content is ~6–8% for stability.
- Must be compatible with the fill material.

b. Capsule Content

- Typically liquid, semi-solid, suspension, or pasty material.
- Non-aqueous systems are preferred to prevent gelatin hydrolysis.
- Common vehicles: Vegetable oils (soybean, sesame), PEG, or non-aqueous solvents.
- Can include solubilized drugs, emulsions, suspensions, or vitamins.

Advantages

- High bioavailability due to liquid fill.
- Mask unpleasant taste/odor.
- Easy to swallow.
- Flexible dose adjustment by fill volume.
- Hermetically sealed, reducing oxidation or degradation.

Disadvantages

- Sensitive to moisture (softening) or low humidity (brittleness).
- Not suitable for aqueous solutions due to gelatin hydrolysis.
- More expensive than tablets or HGCs.
- Not suitable for high melting solids.

Size of Capsules

Capsule Size	Approx. Fill Volume (mL)	Approx. Weight of Fill (mg)	Common Use
000	1.37 mL	~1350 mg	Large doses; veterinary or high-dose human drugs
00	1.00 mL	~1000 mg	Large adult dose
0	0.68 mL	~700 mg	Standard adult dose; common for oils & vitamins
1	0.50 mL	~500 mg	Medium dose; suitable for oily formulations
2	0.37 mL	~370 mg	Medium dose; pediatric and adult
3	0.30 mL	~300 mg	Small dose; liquid vitamins, potent drugs
4	0.21 mL	~210 mg	Pediatric or low-dose formulations
5	0.13 mL	~130 mg	Very small dose; microdoses or potent APIs
6	0.10 mL	~100 mg	Low-dose specialized formulations
7	0.08 mL	~80 mg	Microdoses or highly potent drugs
8	0.06 mL	~60 mg	Smallest human softgel; highly potent drugs
9	0.05 mL	~50 mg	Specialized low-volume fills
10	0.03 mL	~30 mg	Rarely used; very potent microdoses

Importance of Base Adsorption and Minimum/Gram Factor

1. Base Adsorption

- Base adsorption is the process of adsorbing a liquid or semi-solid drug onto a dry inert base (diluent) to form a free-flowing powder suitable for capsule filling.

Importance:

1. Improves Flow Properties – Makes powders easy to fill in capsules uniformly.
2. Prevents Leakage or Sticking – Ensures capsules remain intact and do not stick to equipment.
3. Ensures Accurate Dosage – Uniform adsorption allows consistent drug content in each capsule.
4. Enhances Stability – Protects hygroscopic or moisture-sensitive drugs from degradation.

Example:

- Chloral hydrate (semi-solid) adsorbed on starch or lactose to make it fillable into capsules.

2. Minimum / Gram Factor

- The minimum/gram factor is the minimum amount of base required to adsorb 1 gram of drug to produce a free-flowing mixture for capsule filling.

Importance:

1. Prevents Over-Dilution – Ensures capsules are not unnecessarily bulky.
2. Maintains Uniformity – Guarantees consistent fill weight and drug distribution.
3. Optimizes Flow – Ensures powder mixture is free-flowing.
4. Ensures Stability – Avoids caking or moisture absorption.

Typical Values:

- Semi-solid oily drugs: 2–6 g base per g of drug
- Sticky/hygroscopic drugs: 3–8 g base per g of drug

Methods of Softgel Production

A. Rotary Die Process (Most Common)

1. Principle:
    - Two gelatin ribbons are brought together on rotating dies, forming capsules around a liquid fill.
2. Steps:
    1. Gelatin ribbons are prepared (gelatin + plasticizer + water).
    2. Ribbons are fed into the rotary die assembly.
    3. Liquid fill is deposited between the ribbons.
    4. Ribbons are sealed and cut by the die rollers, forming softgels.
    5. Capsules are dried to remove excess moisture.
3. Applications:
    - Oily solutions, vitamins, hormones, fish oil capsules.

B. Plate Process (Less Common)

- Gelatin sheet is cut into pockets.
- Fill is added, and another sheet is placed on top.
- Sealing and cutting are done manually or semi-automatically.
- Mainly used for small-scale production or special shapes.

C. Other Specialized Methods

1. Reciprocating die process – For high-speed automated production.
2. Softgel encapsulation of powders – Drug powders are suspended in oil before encapsulation.
3. Liquid-in-solid technology – Oily or volatile liquids absorbed on solid carriers, then encapsulated.

In-Process Quality Control Tests

A. Gelatin Ribbon Inspection

- Check color, clarity, thickness, and viscosity of gelatin ribbon.
- Prevents defective capsule shells.

B. Fill Weight Monitoring

- During filling, sample capsules are weighed to ensure uniform fill volume.
- Adjust dosing system if variations are observed.

C. Capsule Sealing Check

- Examine capsules for proper sealing of cap and body.
- Ensures no leakage occurs during drying or handling.

D. Environmental Conditions

- Temperature: 20–25°C
- Relative Humidity (RH): 35–45%
- Prevents shell softening or brittleness.

E. Capsule Shape and Appearance

- Random samples checked for deformation, sticking, or color variation.

Final Product Quality Control Tests

A. Appearance

- Capsules should be uniform in size, shape, and color, smooth, and free from cracks or deformation.

B. Weight Variation

- Ensures capsules have consistent fill weight.
- Weigh 20 capsules individually, compare with average.
- IP Limit: ±5–10% depending on size.

C. Content Uniformity

- Ensures drug is uniformly distributed in each capsule.
- Analyze 10 capsules individually.
- Each capsule should contain 85–115% of label claim, RSD ≤ 6%.

D. Disintegration Test

- Softgels should disintegrate completely within 60 min (unless otherwise specified).
- Use disintegration apparatus with water or suitable medium at 37 ± 2°C.

E. Dissolution Test

- Determines rate and extent of drug release.
- Apparatus: USP I (basket) or II (paddle).
- Medium: 900 mL water or simulated gastric/intestinal fluid.
- Acceptance: ≥70–85% drug release within specified time.

F. Moisture Content

- Shell moisture: 12–16%.
- Measured by Loss on Drying (LOD) or Karl Fischer titration.
- Ensures shell flexibility and stability.

Packing, Storage, and Stability Testing

Packing

- Blister packs, strip packs, or HDPE bottles with desiccants to prevent moisture uptake.
- Packaging must protect from light, air, and moisture.

Storage

- Temperature: 15–25°C
- Humidity: <50% RH
- Avoid high temperature (softening) and low humidity (brittleness).

Stability Testing

- Accelerated conditions: 40°C ± 2°C / 75% RH ± 5% for 6 months.
- Long-term conditions: 25°C ± 2°C / 60% RH ± 5% for 12 months.
- Monitors appearance, fill uniformity, dissolution, moisture content, and microbial stability.

Applications of Soft Gelatin Capsules

1. Oily drugs: Vitamins A, D, E, K; cod liver oil; fish oil.
2. Liquids and suspensions: Parenteral oil solutions, essential oils.
3. Self-emulsifying drug delivery systems (SEDDS): Enhances solubility of poorly water-soluble drugs.
4. Pediatric formulations: Small-size capsules for children.
5. Veterinary use: For animal dosing of oils or liquid medications.
6. Clinical trial formulations: Rapid development with precise dosing.