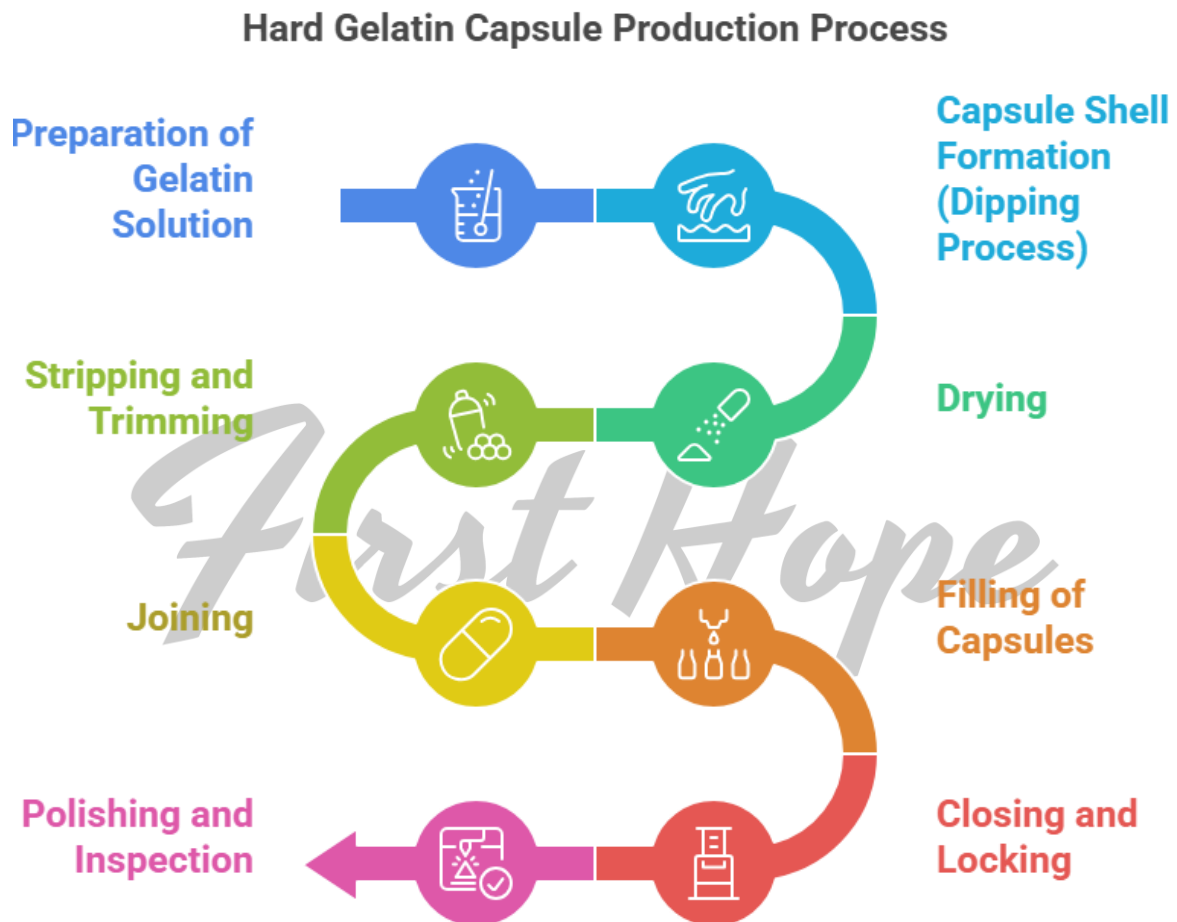


Capsule Production

Capsule Production Process

- Capsules are solid dosage forms in which drug substances are enclosed in a shell, usually made of gelatin.
- The production process differs slightly for **hard gelatin capsules** and **soft gelatin capsules**, but the general steps are systematic and controlled.

Hard Gelatin Capsule Production Process



1. Preparation of Gelatin Solution

- Gelatin is mixed with water, colorants, and preservatives.
- Heated to form a viscous solution.
- Air bubbles are removed to ensure uniform capsule shells.

2. Capsule Shell Formation (Dipping Process)

- Stainless steel pins (molds) are dipped into gelatin solution.
- A thin film of gelatin coats the pins.
- Thickness depends on viscosity and dipping time.

3. Drying

- Coated pins are passed through drying chambers.
- Controlled temperature and humidity are maintained.
- Gelatin solidifies to form capsule shells.

4. Stripping and Trimming

- Dried shells are removed from pins.
- Trimmed to proper length.
- **Two parts formed:**
 - Cap
 - Body

5. Joining

- Cap and body are joined loosely.
- Capsules are ready for filling.

6. Filling of Capsules

- Drug powder, granules, or pellets are filled into capsule body.
- **Filling methods:**
 - Dosator method
 - Tamping method

7. Closing and Locking

- Capsule cap is placed over body.
- Locked to prevent leakage.

8. Polishing and Inspection

- Capsules are cleaned to remove powder.
- Inspected for defects.

Soft Gelatin Capsule Production Process

1. Preparation of Gel Mass

- Gelatin mixed with plasticizers (glycerin, sorbitol).
- Makes shell flexible and soft.

2. Preparation of Fill Material

- Drug dissolved or suspended in oil or suitable solvent.

3. Encapsulation (Rotary Die Process)

- Two gelatin ribbons are formed.

- Fill material injected between ribbons.
- Capsules are sealed and shaped simultaneously.

4. Drying

- Capsules dried in controlled conditions.
- Removes excess moisture.

5. Inspection and Sorting

- Capsules checked for leakage, size, and shape.

Improved Capsule Manufacturing

- Modern capsule manufacturing has improved significantly to increase efficiency, quality, and automation.

Key Improvements

1. Automation

- Fully automatic machines reduce human involvement.
- Improves consistency and reduces contamination.

2. Precision Control Systems

- Control of temperature, humidity, and viscosity.
- Ensures uniform shell thickness and quality.

3. High-Speed Production

- Machines can produce thousands of capsules per minute.
- Suitable for large-scale production.

4. Use of Non-Gelatin Capsules

- HPMC (Hydroxypropyl methylcellulose) capsules developed.
- Suitable for vegetarian and moisture-sensitive drugs.

5. Advanced Drying Systems

- Controlled drying chambers improve product stability.
- Prevent brittleness or stickiness.

6. Improved Filling Accuracy

- Modern filling machines ensure precise dosing.
- Reduces weight variation.

7. Capsule Sealing Techniques

- Banding or sealing to prevent tampering.
- Improves product safety.

8. In-line Quality Control

- Sensors detect defects during production.
- Reject defective capsules automatically.

Benefits of Improvements:

- Increased production efficiency
- Better product quality
- Reduced wastage
- Compliance with GMP standards

Capsule Filling Machines (Hard Gelatin Capsules)

- Capsule filling machines are used to fill powder, granules, or pellets into hard gelatin capsules.



Types of Capsule Filling Machines:

1. Manual Capsule Filling Machine

- Used for small-scale production.
- Capsules are filled manually.

2. Semi-Automatic Capsule Filling Machine

- Combines manual and automatic operations.
- Moderate production capacity.

3. Automatic Capsule Filling Machine

- **Working Principle:**
 - Fully automated process involving multiple steps.

Main Steps in Automatic Machine:

1. Capsule loading
2. Orientation (placing capsules in correct position)
3. Separation of cap and body
4. Filling of powder
5. Capsule closing
6. Ejection of filled capsules

Filling Methods:

1. Tamping Method

- Powder is compressed into plugs before filling.

2. Dosator Method

- Powder is filled using a tube (dosator).

3. Auger Filling

- Screw mechanism delivers powder.

Advantages:

- High speed
- Accurate dosing
- Uniform filling

Soft Gelatin Capsule Filling Machines

- Soft gelatin capsules are produced using specialized machines that perform multiple operations simultaneously.

Rotary Die Machine (Most Common)

1. Gelatin Melting Tank



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