Industrial Pharmacy - I

Experiment No. 8

Aim: Quality control test of (as per IP) marketed tablets and capsules.

1. Objective

To evaluate the quality, uniformity, and performance of marketed tablets and capsules using standard Indian Pharmacopoeia (IP) methods, ensuring compliance with pharmaceutical standards.

2. Introduction

Marketed tablets and capsules must meet stringent quality standards to ensure efficacy, safety, and stability. Quality control testing assesses:

- **Physical characteristics** (appearance, size, shape, color)
- **Mechanical properties** (hardness, friability)
- **Chemical content** (assay, uniformity)
- **Drug release profile** (dissolution, disintegration)
- **Microbial safety**

The tests also help detect counterfeit or substandard products.

3. Materials and Equipment

3.1 Materials

- Marketed tablets or capsules
- Distilled water, phosphate buffers, or other suitable dissolution media
- Solvents (methanol, ethanol, etc., depending on assay)
- Reference standard drug (for assay)
- Chemicals for titration, if applicable

3.2 Equipment

- Analytical balance

- Vernier caliper
- Tablet hardness tester
- Friabilator
- Disintegration test apparatus
- Dissolution test apparatus (USP type I or II)
- UV-Visible spectrophotometer or HPLC system
- Mortar and pestle
- Sieves
- pH meter

4. Quality Control Tests for Tablets

4.1 Physical Evaluation

1. **Appearance:** Check color, shape, size, and presence of cracks or chips.
2. **Uniformity of Weight:**
   - Weigh 20 tablets individually.
   - Calculate average weight.
   - Compare individual tablet weight with average.
   - IP limits:
     - Tablets <80 mg: ±10%
     - 80–250 mg: ±7.5%
     - 250 mg: ±5%
3. **Thickness and Diameter:**
   - Measure with Vernier caliper.
   - Record mean and standard deviation.
4. **Hardness / Crushing Strength:**
   - Measure force required to break a tablet (kg/cm²).

- IP: Tablets should withstand normal handling.

5. **Friability:**

- Use a friabilator; rotate 100 tablets at 25 rpm for 4 min.
- Acceptable loss: ≤1% w/w.

4.2 Chemical Evaluation

1. **Assay of Active Ingredient:** Perform using titrimetric, spectrophotometric, or HPLC methods as per IP monograph.
2. **Uniformity of Content:** Determine content in 10 individual tablets.

IP limit: 85–115% of label claim (RSD ≤6%).

4.3 Disintegration Test

- Apparatus: Disintegration tester with distilled water at **37 ± 2°C**.
- Tablets should disintegrate within the time specified in the IP monograph (usually 15–30 min for immediate-release tablets).

4.4 Dissolution Test

- Apparatus: USP Type I (basket) or Type II (paddle).
- Medium: As per drug monograph (e.g., 900 mL phosphate buffer pH 6.8).
- Conditions: Rotate at 50–100 rpm, 37 ± 0.5°C.
- Collect aliquots at specified intervals and measure drug release using UV or HPLC.
- Compare % drug release with IP or manufacturer specification.

5. Quality Control Tests for Capsules

5.1 Physical Evaluation

1. **Appearance:** Color, shape, size, and integrity of shell.
2. **Uniformity of Weight:** Weigh 20 capsules individually.

IP limit: ±7.5% for hard gelatin capsules.

3. **Shell Integrity:** Inspect for cracks, leaks, or deformation.

5.2 Chemical Evaluation

1. **Assay of Active Ingredient:** Dissolve capsule contents in suitable solvent and assay as per IP.
2. **Content Uniformity:** Evaluate at least 10 capsules individually.

IP specification: 85–115% of label claim, RSD ≤6%.

5.3 Disintegration Test

Capsules should disintegrate within the time specified by IP (typically 30 min for hard gelatin capsules). Use distilled water at 37 ± 2°C.

5.4 Dissolution Test

- Similar to tablets: Use appropriate USP apparatus and medium.
- Ensure drug release meets IP specifications.

6. Additional Tests

1. **Moisture Content:** Using loss on drying or Karl Fischer titration, especially for hygroscopic drugs.
2. **Microbial Limit Test:** For non-sterile tablets and capsules, ensure total aerobic microbial count, yeast, and mold counts comply with IP.
3. **Uniformity of Mass and Content:** Cross-check weight and content correlation.

7. Notes and Precautions

- Always use calibrated instruments.
- Conduct assays and dissolution tests in triplicate for accuracy.
- Perform tests under controlled temperature and humidity.
- Follow aseptic conditions if evaluating sterility-sensitive formulations.
- Compare results with IP monographs for compliance.

8. References

1. Indian Pharmacopoeia (IP), 2020, Vol. I & II, Govt. of India.

2. United States Pharmacopeia (USP 43-NF 38).