

# 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.

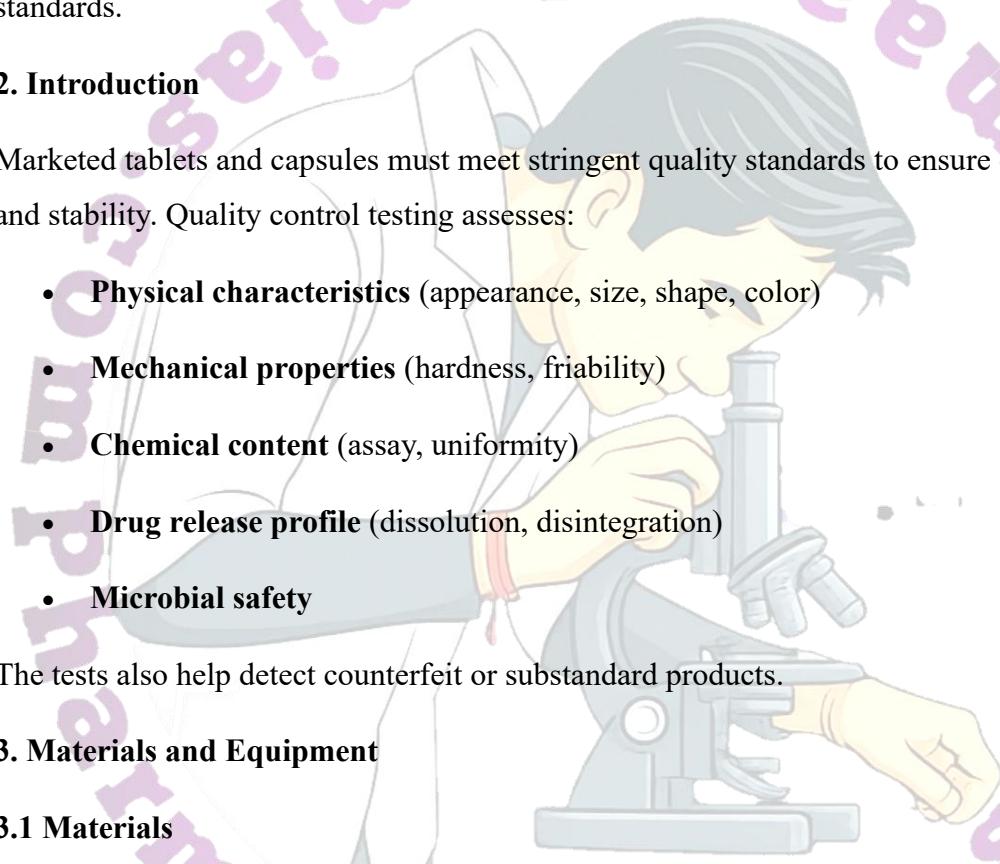
### 3. Materials and Equipment

#### 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:**

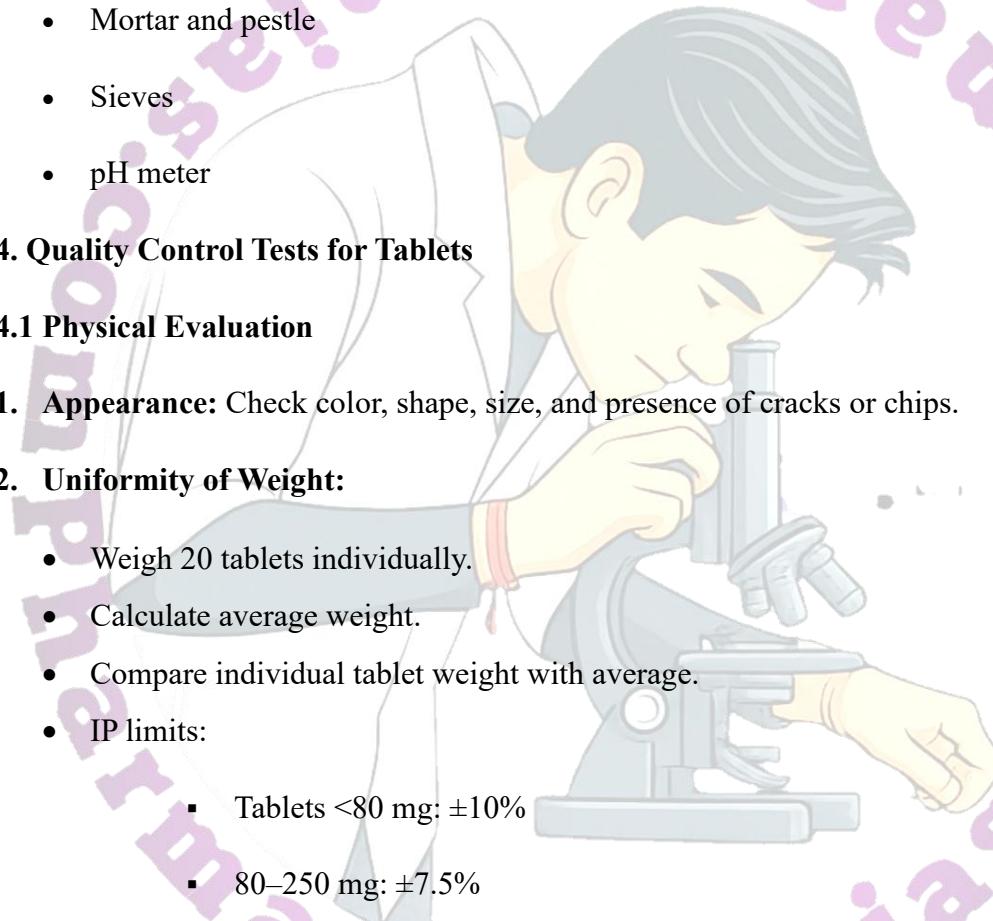
- Weigh 20 tablets individually.
- Calculate average weight.
- Compare individual tablet weight with average.
- IP limits:
  - Tablets <80 mg:  $\pm 10\%$
  - 80–250 mg:  $\pm 7.5\%$
  - 250 mg:  $\pm 5\%$

**3. Thickness and Diameter:**

- Measure with Vernier caliper.
- Record mean and standard deviation.

**4. Hardness / Crushing Strength:**

- Measure force required to break a tablet ( $\text{kg}/\text{cm}^2$ ).



- IP: Tablets should withstand normal handling.

## 5. Friability:

- Use a friability; rotate 100 tablets at 25 rpm for 4 min.
- Acceptable loss:  $\leq 1\%$  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  $\leq 6\%$ ).

## 4.3 Disintegration Test

- Apparatus: Disintegration tester with distilled water at  $37 \pm 2^\circ\text{C}$ .
- 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,  $37 \pm 0.5^\circ\text{C}$ .
- 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:  $\pm 7.5\%$  for hard gelatin capsules.

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

## 5.2 Chemical Evaluation

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

IP specification: 85–115% of label claim, RSD  $\leq$  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  $37 \pm 2^\circ\text{C}$ .

## 5.4 Dissolution Test

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

## 6. Additional Tests

- Moisture Content:** Using loss on drying or Karl Fischer titration, especially for hygroscopic drugs.
- Microbial Limit Test:** For non-sterile tablets and capsules, ensure total aerobic microbial count, yeast, and mold counts comply with IP.
- 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

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

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

