

Quality Control of Marketed Tablets and Capsules

Practical 10 | Industrial Pharmacy I

Aim

To study Quality Control of Marketed Tablets and Capsules, and interpret the recorded observations.

Principle

- Pharmacopoeial quality control applies the relevant general chapter and product monograph to the exact dosage form. Mass uniformity, content uniformity, assay, disintegration and dissolution answer different questions.
- The property is obtained from a defined observable under controlled conditions.
- Replicate measurements, instrument checks and consistent units are needed before comparison.

Materials and Apparatus

- Marketed tablet/capsule records and the assigned applicable pharmacopoeial methods and apparatus.
- Assigned test material and calibration or comparison material.
- The apparatus specified for this property, a balance or volumetric equipment where relevant, and a record sheet.

Method

1. Record product identity, strength, dosage form and the pharmacopoeial edition used.
2. Identify the tests and limits applicable to that product rather than copying a universal limit.
3. Perform or review the assigned measurements and retain individual unit readings.
4. Calculate mass variation, assay or release on the correct product basis.
5. Compare each result with its own acceptance criterion and required stage rules.
6. Report compliance only for the tests actually completed.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Product and dosage form	_____
Test name	_____
Individual readings	_____
Calculated value	_____
Applicable limit	_____
Interpretation	_____

Calculations and Interpretation

- Mass deviation (%) = $(\text{individual mass} - \text{mean mass}) / \text{mean mass} \times 100$.
- Drug released (%) = $\text{corrected cumulative drug amount} / \text{declared dose} \times 100$.
- Apply the assigned content-uniformity calculation separately; mass variation does not automatically establish content uniformity.

Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: _____

Conclusion: _____

Precautions

- Keep temperature and test conditions consistent across comparative readings.
- Record raw readings before rounding calculated values.
- Do not compare results obtained with different methods as if they were interchangeable.

Viva Questions

1. Is disintegration the same as dissolution?

No. Disintegration is physical breakup; dissolution measures drug entering the specified medium.

2. Why control the test conditions?

A change in conditions may alter the measured property independently of the intended variable.

3. Why retain replicate readings?

They show repeatability and help identify an anomalous measurement.

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