Quality-control Tests for Tablets Capsules and Injections

Experiment 4 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To record and assess the assigned dosage-form quality tests.

Principle

Quality tests examine defined attributes of a dosage form. Identity, content, physical uniformity, performance and microbiological quality are related but distinct.

Requirements

- Assigned dosage forms, prescribed test methods and limits, suitable calibrated equipment and supplied sterile-product test records.

Procedure

1. Map the tests

List the method and specification for each product before recording results.

2. Tablets

Measure the assigned mass variation, dimensions/mechanical strength, friability, disintegration, dissolution and content-related tests as required by the product.

3. Capsules

Record net fill and the prescribed disintegration/dissolution and content-related tests.

4. Injections

Interpret assigned assay, pH, particle, sterility, applicable endotoxin and integrity records; no infectious challenge test is performed.

5. Decide

Separate a valid failure from an invalid measurement and record the authorised quality-review decision.

Observations and Record

Product / test	Observed value	Assigned requirement / outcome
Tablet	_____	_____
Capsule	_____	_____
Injection	_____	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- Friability mass loss (%) = (initial mass − final mass) / initial mass × 100, using the specified cleaned/dedusted test basis.
- Example: 6.50 g to 6.47 g gives 0.462%. Apply the actual product-specific acceptance criterion.

Result

Record the completed observations, calculations and conclusion with units. State any limitation of the observation.

Precautions

- Do not apply one numerical limit to all dosage forms or product types.
- A passing physical test does not replace an assay or sterility requirement.

Viva Questions and Answers

1. Are disintegration and dissolution identical?

No. Break-up and release of dissolved drug are different endpoints.

2. What accompanies a pass/fail statement?

The product, method, result, units and assigned acceptance requirement.

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