

Preparation and Evaluation of Tetracycline Capsules

Practical 05 | Industrial Pharmacy I

Aim

To study Preparation and Evaluation of Tetracycline Capsules, and interpret the recorded observations.

Principle

- Capsule filling depends on a uniform, suitable-flowing powder blend. Capsule-shell properties and tetracycline stability must be considered separately from fill mass.
- A dosage form combines an active ingredient with excipients selected for processing, stability and performance.
- Preparation and evaluation are linked: changes in composition or process can alter the product quality attributes.
- Identify the exact tetracycline form and the approved blend composition.
- Calculate the assigned fill quantity and observe uniform blending and filling.
- Record shell closure and appearance together with individual fill masses.
- Evaluate the finished capsules by the specified mass/content, disintegration and release tests.

Materials and Apparatus

- Assigned tetracycline form and excipients, capsule shells, filling demonstration and quality-test equipment.
- Assigned active ingredient, excipients and the instructor-approved master formula.
- Balance, mixing/preparation equipment, packaging materials and the assigned evaluation apparatus.

Method

1. Read the master formula and identify the purpose of each ingredient.
2. Calculate the quantities for the assigned laboratory batch and check ingredient identity.
3. Follow the specified order of addition and preparation process, recording actual quantities and process observations.
4. Measure the yield or finished quantity and package the laboratory preparation as specified.
5. Evaluate the product attributes listed for this dosage form with documented methods.
6. Compare the observations with the assigned specification and explain any difference.

Observation Record

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

Observation / parameter	Record / finding
Drug form	_____
Blend uniformity	_____
Shell size	_____
Fill mass	_____
Disintegration	_____
Assay and release	_____

Calculations and Interpretation

- Batch scale factor = desired quantity/master-formula quantity.
- Scale each ingredient by the same factor unless the approved formula specifies otherwise.
- Assay (%) = measured active amount/declared active amount × 100, on the same unit and product basis.

Result

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

Finding: _____

Conclusion: _____

Precautions

- Record changes in process or composition; do not conceal a deviation.
- Use the specification assigned to the exact product and dosage form.
- A teaching batch is for laboratory evaluation and is not released for patient use.

Viva Questions

1. Why identify excipient functions?

Each excipient can influence processing, stability, release or acceptability.

2. Why is appearance alone insufficient for evaluation?

It does not establish content, performance, stability or microbiological quality.

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