

Preparation and Evaluation of Sustained-Release Matrix Tablets

Practical 14 | Instrumental Methods of Analysis and Novel Drug Delivery Systems

Aim

To study Preparation and Evaluation of Sustained-Release Matrix Tablets, and interpret the recorded observations.

Principle

- A matrix can control release through diffusion, swelling, erosion or combined processes. Tablet mechanical properties, drug content and release profile are evaluated separately.
- 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 matrix polymer and the proposed release mechanism.
- Observe blend/granulation and compression in the approved laboratory process.
- Assay extracted drug by UV against a suitable calibration.
- Measure the assigned dissolution profile and relate it to the matrix design.

Materials and Apparatus

- Assigned drug, matrix polymer and excipients; laboratory tablet preparation and UV-assay 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
Polymer/formula	_____
Tablet dimensions	_____
Mechanical observations	_____
Drug content	_____
Time-release profile	_____

Calculations and Interpretation

- Assay (%) = $\text{measured active amount} / \text{declared active amount} \times 100$.
- For release measurements, apply the actual sampling and dilution corrections before calculating percentage released.

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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