

Preparation and Evaluation of Film Coating of Tablets or Granules

Practical 04 | Industrial Pharmacy I

Aim

To study Preparation and Evaluation of Film Coating of Tablets or Granules, and interpret the recorded observations.

Principle

- Film coating deposits a polymer-based layer. Polymer, plasticizer and process conditions influence film continuity, adhesion and the effect on release.
- 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 role of the polymer, plasticizer and vehicle.
- Review the coating-feed and drying balance demonstrated by the instructor.
- Observe coating distribution, sticking, picking or roughness during the assigned run.
- Measure dry mass gain and assess the film and relevant release behaviour.

Materials and Apparatus

- Assigned cores, film former, plasticizer and coating vehicle; supervised coating 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
Core mass	_____
Coating composition	_____
Process observations	_____
Dry coated mass	_____
Film appearance	_____
Release effect	_____

Calculations and Interpretation

- Dry coating gain (%) = (coated dry mass - initial core mass)/initial core mass × 100.

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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