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Freeze-Dried Formulations

Practical 13 - Bench formulation practical

Aim

To prepare or evaluate a freeze-dried model and relate the cycle record to product attributes.

Principle

Freeze-drying removes ice by sublimation during primary drying and removes additional water during secondary drying. Freezing behaviour and product temperature relative to critical formulation limits affect structure and recovery.

A formulation comparison is meaningful when the raw-material grades, batch size and evaluation conditions are recorded. Change one planned factor at a time or use a documented experimental design, and compare independently prepared batches rather than only repeated readings from one batch.

Materials and Requirements

- Approved model formulation and containers
- Qualified lyophiliser operated by trained staff
- Temperature and pressure records and relevant moisture and reconstitution tests
- Calibrated balance, suitable containers and identified evaluation equipment
- Controlled batch sheet and raw-data forms

Procedure

1. Define the purpose, formula, batch size, material grades and comparison conditions. Calculate all quantities before weighing.
2. Check equipment readiness and record material identities and actual quantities. Reconcile theoretical and actual batch mass.
3. Characterise the model formulation and document the basis for the selected cycle and fill conditions.
4. Have the trained operator execute the approved freezing and drying cycle while retaining product, shelf and pressure data.
5. Assess cake appearance, container integrity, residual moisture by the selected method and reconstitution behaviour.
6. Compare results with the intended attribute targets and explain relevant cycle deviations.
7. Evaluate the stated quality attributes on representative portions using the same method for all comparison batches. Record individual readings and any excluded observations with reasons.
8. Calculate the specified response, variability and material balance. Compare with predefined teaching or product criteria and discuss sources of variation.
9. Label retained preparations and dispose of remaining material through the laboratory procedure. Keep the complete preparation and evaluation record together.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Formulation and fill	Record the adopted method	Record	Evaluate
Cycle conditions	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Cake / moisture	Record the adopted method	Record	Evaluate
Reconstitution and recovery	Record the adopted method	Record	Evaluate

Calculations

• Solids recovery (%) = measured recovered dry solids / theoretical input solids x 100

Worked Example

Illustrative theoretical solids per unit 100 mg and recovered solids 98 mg give 98% solids recovery.
A good-looking cake still requires the specified moisture, content, integrity and stability evidence.

Result and Interpretation

• Relate the product evidence to the recorded cycle and critical formulation properties.
• State the preparation conditions and the evidence supporting the result. A satisfactory physical observation alone does not establish long-term stability, clinical performance or suitability for administration.

Precautions

• Operate vacuum and refrigeration equipment through trained staff.
• Use a cycle justified for the model rather than a universal temperature schedule.
• Control handling after drying to avoid moisture uptake.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

What is primary drying?

Removal of frozen solvent mainly by sublimation.

Why monitor product temperature?

It relates the cycle to product structural and thermal limits.

Does cake appearance prove stability?

Other chemical and physical evidence is required.

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