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Dissolution Improvement by Solid Dispersion

Practical 6 - Bench formulation practical

Aim

To prepare a drug-carrier dispersion and compare dissolution with the untreated drug and a physical mixture.

Principle

A solid dispersion distributes drug within a solid carrier. Dissolution may change through wetting, size reduction, altered crystallinity or other drug-carrier interactions. Improved release does not automatically establish an amorphous product.

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 slightly soluble model drug and carrier
- Selected fusion or solvent-removal arrangement
- Assay, dissolution and suitable solid-state characterisation methods
- 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. Define the drug-to-carrier ratio and prepare untreated-drug and physical-mixture controls.
4. Use the approved fusion or solvent-removal method, recording temperatures or solvent-removal conditions relevant to material stability.
5. Recover, condition and size the preparation by the specified method, documenting yield and content uniformity.
6. Compare dissolution under identical conditions and use appropriate solid-state evidence when discussing the mechanism.
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
Preparation	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Drug and carrier ratio	Record the adopted method	Record	Evaluate
Measured content	Record the adopted method	Record	Evaluate
Dissolution / solid-state evidence	Record the adopted method	Record	Evaluate

Calculations

• Theoretical loading (%) = input drug mass / total input solids x 100
• Drug recovery (%) = measured recovered drug / input drug x 100

Worked Example

Illustrative input: 1.00 g drug and 4.00 g carrier give 20.0% theoretical loading.
If the recovered material contains 0.95 g drug, drug recovery is 95.0%.
Compare the dispersion with the physical mixture as well as the untreated drug to distinguish process effects from simple carrier addition.

Result and Interpretation

• Report recovery, content, dissolution and the evidence supporting the proposed physical state.
• 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

• Choose a process within the drug and carrier stability limits.
• Evaluate residual solvent when relevant.
• Avoid equating a missing thermal peak alone with proven amorphisation.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

Why include a physical mixture?

It separates the effects of carrier addition from the preparation process.

Must every dispersion be amorphous?

No; dispersions can contain different material states.

Does faster dissolution prove better clinical exposure?

That requires additional evidence.

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