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Oral Matrix and Reservoir Delivery Systems

Practical 13 - Bench formulation practical

Aim

To prepare a hydrophilic matrix tablet and relate composition and compaction to drug-release behaviour.

Principle

A hydrophilic matrix hydrates on contact with the dissolution medium. Drug movement may involve diffusion through the hydrated layer, polymer swelling and matrix erosion. Polymer grade, concentration, drug solubility and tablet porosity influence the profile.

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

- Model drug or approved marker, identified HPMC grade, diluent and lubricant
- Tablet press operated by trained staff
- Tablet physical-test equipment and dissolution apparatus
- 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. For a direct-compression teaching blend, screen compatible powders, mix the drug with the diluent and matrix polymer, and add lubricant by the specified final-blending step.
4. Have the trained operator compress at the planned settings. Record tooling, tablet mass, thickness and compression setting for each batch.
5. Assess mass variation, dimensions, mechanical properties and the complete release profile rather than disintegration alone.
6. 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.
7. Calculate the specified response, variability and material balance. Compare with predefined teaching or product criteria and discuss sources of variation.
8. 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
Blend composition	Record the adopted method	Record	Evaluate
Tablet mass and dimensions	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Mechanical properties	Record the adopted method	Record	Evaluate
Dissolution at planned times	Record the adopted method	Record	Evaluate

Calculations

• Component mass = target batch mass x component fraction
• Drug released (%) = corrected released drug mass / labelled or measured initial content x 100

Worked Example

Illustrative 400 mg teaching tablet: marker 20 mg, HPMC 80 mg, microcrystalline cellulose 294 mg, colloidal silica 2 mg and magnesium stearate 4 mg.

For 100 tablets, the theoretical batch mass is 40.0 g; the matrix polymer requirement is 8.00 g. This is a model formula for a controlled comparison, not a validated marketed product.

If corrected released mass at a time point is 12.0 mg from a measured initial content of 20.0 mg, release is 60.0%.

Result and Interpretation

• Describe how the release curve changes with polymer grade, level and compaction. Compare batches under the same dissolution conditions.
• 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

• Use machine guards and trained compression operators.
• Control lubricant blending and moisture, which can alter compaction and release.
• Select dissolution conditions suitable for the model and formulation.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

Why can HPMC slow release?

Hydration creates a polymer-rich layer that changes diffusion and erosion.

Why record polymer grade?

Different viscosity and substitution grades may produce different matrix behaviour.

Is low disintegration the same as controlled release?

No; the full drug-release profile is required.

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