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Quality Evaluation of Herbal Tablets and Capsules

Practical 17 - Bench formulation practical

Aim

To evaluate herbal tablets and capsules using suitable identity, content and physical-quality evidence.

Principle

Capsule quality depends on the shell, fill material and filling process. Powder flow, packing and compatibility can influence filling consistency and subsequent product performance.

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 fill formula and capsule shell specification
- Suitable capsule-filling arrangement
- Balance and required physical, assay and release 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. Calculate target fill composition and choose the shell size through the selected bulk-volume and compatibility assessment.
4. Prepare the blend and assess relevant flow and packing properties before filling.
5. Fill using the specified process and record shell identity, fill mass and process observations.
6. Evaluate mass variation, appearance, content and the disintegration or dissolution characteristics required for the product.
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
Shell and fill identity	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Fill mass	Record the adopted method	Record	Evaluate
Content / physical tests	Record the adopted method	Record	Evaluate
Release evaluation	Record the adopted method	Record	Evaluate

Calculations

• Net fill mass = filled capsule mass - corresponding empty shell mass
• Relative fill deviation (%) = (individual fill - mean fill) / mean fill x 100

Worked Example

Illustrative filled and empty shell masses are 420 and 90 mg: net fill is 330 mg.
For a mean fill of 325 mg, this unit differs by (330-325)/325 x 100 = 1.54%.
Use the relevant method and sample-size requirements when drawing a formal conclusion.

Herbal product panel

• Map tablet and capsule tests separately to the selected product specification.
• Add botanical identity, fingerprint or marker control and appropriate contaminant requirements; mass uniformity alone does not establish botanical-content consistency.

Result and Interpretation

• Distinguish shell variation from fill variation and state the complete quality evidence.
• 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 suitable shell conditioning and approved materials.
• Control segregation and fill handling.
• Avoid inferring drug-content uniformity from fill mass alone.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

Why consider shell compatibility?

Moisture and chemical interactions can affect product stability and function.

What does bulk volume help estimate?

The space required for the selected fill mass.

Does a consistent fill guarantee dissolution?

Release performance requires its own test.

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