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Preparation and Evaluation of Spherules

Practical 5 - Bench formulation practical

Aim

To prepare pellets by a selected spheronisation process and assess their shape, size and recovery.

Principle

A suitably plastic wet mass is formed and rounded through controlled processing. Material composition, wetness, extrusion conditions and spheronisation energy affect pellet shape and size distribution.

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 pellet-forming powder blend and binder liquid
- Extrusion-spheronisation equipment operated by trained staff
- Drying arrangement, sieves and image-analysis method
- 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. Prepare the specified powder blend and add the selected liquid through the documented wet-massing process.
4. Record wet-mass condition and have the trained operator perform extrusion and spheronisation at the planned settings.
5. Dry through the prescribed method and determine the chosen size fractions.
6. Measure pellet shape using a defined image-analysis approach and assess mechanical behaviour and marker distribution where required.
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
Wet-mass and process condition	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Sieve fractions	Record the adopted method	Record	Evaluate
Shape measurements	Record the adopted method	Record	Evaluate
Recovery / marker content	Record the adopted method	Record	Evaluate

Calculations

• Usable yield (%) = recovered mass in target fraction / total input solids x 100
• Aspect ratio = major dimension / minor dimension; define the measurement method.

Worked Example

Illustrative input solids 100 g and recovered target-size fraction 72 g give 72% usable yield.
A pellet with measured major and minor dimensions 1.10 and 1.00 mm has aspect ratio 1.10.
Interpret the distribution of shape measurements rather than one selected pellet.

Result and Interpretation

• Discuss size, shape and usable yield together. Explain any effect of wet-mass condition and processing on the result.
• 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 guarded equipment through the trained operator.
• Record liquid addition and drying losses.
• Use representative images rather than selecting only the most spherical units.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

Why does wetness matter?

It influences plasticity, extrusion and rounding.

What does an aspect ratio near one suggest?

A more equidimensional outline under the stated measurement method.

Why report usable yield?

Total recovery may include material outside the desired size range.

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