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Particle Size and Dissolution

Practical 16 - Bench practical

Aim

To compare dissolution for preparations differing in particle-size distribution while controlling other formulation factors.

Principle

A dissolution test measures transfer of drug into a defined medium under controlled hydrodynamic conditions. A profile provides information across time and may reveal lag, burst release or incomplete release.

Temperature, apparatus, medium, speed, sampling and analytical method are selected for the product and study purpose. An in-vitro profile alone does not establish a clinical duration of action.

Materials and Requirements

- Qualified dissolution apparatus and the specified vessels
- Product-specific medium and calibrated temperature measurement
- Validated sampling and assay arrangement
- Reference standard and dosage units

Procedure

1. Record product, batch, dose, apparatus, medium composition and volume, agitation, temperature and sampling schedule.
2. Verify apparatus readiness and the method-required medium preparation and deaeration conditions.
3. Introduce units using the prescribed technique and collect individual-vessel samples at the planned times.
4. Use the validated sampling location and filtration procedure. Replace withdrawn volume where specified and document the exact scheme.
5. Measure concentrations within the established assay range using appropriate standards and blanks.
6. Correct for removed drug and dilution. Plot individual and mean cumulative release, retain variability and compare with the applicable criteria.

Observations and Record

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

Time	Measured concentration	Corrected released mass	Release percentage
Initial	Record baseline	Calculate	Calculate
Time point 1	Record	Calculate	Calculate
Time point 2	Record	Calculate	Calculate
Final planned point	Record	Calculate	Calculate

Calculations

- For equal-volume replacement: Mn = V x Cn + v x sum(Ci for earlier samples)
- Release (%) = Mn / initial drug amount x 100

Worked Example

Illustrative V = 900 mL and replacement sample volume v = 10 mL. Concentrations at three times are 0.010, 0.020 and 0.030 mg/mL.

Corrected mass at the third point = 900 x 0.030 + 10 x (0.010 + 0.020) = 27.3 mg.

For a 50.0 mg initial amount, release is 54.6%. This calculation assumes the stated replacement scheme and a stable dissolved analyte.

Controlled particle-size study

- Characterise the size fractions and keep dose, material state, excipients and test conditions consistent.
- Discuss surface area, wetting, aggregation and solid-state changes as possible explanations. Smaller nominal size does not ensure faster release when aggregation or poor wetting intervenes.

Result and Interpretation

- Report the entire profile, individual-unit variability and the actual conditions.
- Compare controlled-release products using an appropriate product-specific design and acceptance approach.
- Distinguish incomplete release from analytical loss or an unsuitable test condition.

Precautions

- Maintain method-specified temperature and hydrodynamics.
- Control sampling time, filter recovery and volume replacement.
- Avoid treating pooled samples as evidence of individual-unit uniformity.
- Investigate apparatus or assay failures before interpreting the profile.

Viva Questions and Answers

Why correct for sampling?

Withdrawn fluid removes drug that contributes to cumulative release.

Why examine individual units?

A similar mean can conceal large unit-to-unit variation.

Does faster dissolution always mean a better controlled-release product?

No; performance must match the intended release target.

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