Dissolution Profile of a Marketed Controlled-Release Formulation

Practical 13 | Instrumental Methods of Analysis and Novel Drug Delivery Systems

Aim

To study Dissolution Profile of a Marketed Controlled-Release Formulation, and interpret the recorded observations.

Principle

- A controlled- or sustained-release dissolution profile measures drug entering the specified medium with time. It is method-dependent and does not by itself establish in-vivo equivalence.
- The property is obtained from a defined observable under controlled conditions.
- Replicate measurements, instrument checks and consistent units are needed before comparison.

Materials and Apparatus

- Assigned marketed CR/SR product, dissolution apparatus and validated concentration assay.
- Assigned test material and calibration or comparison material.
- The apparatus specified for this property, a balance or volumetric equipment where relevant, and a record sheet.

Method

1. Record product identity, declared dose and the assigned dissolution method.
2. Check the medium, apparatus, agitation and temperature specified for that product.
3. Obtain timed aliquots in the supervised demonstration and document replacement volumes.
4. Determine concentrations using the validated analytical calibration.
5. Correct cumulative amount for drug removed in earlier aliquots when the sampling design requires it.
6. Plot percentage released against time and compare with the product-specific criterion supplied.

Observation Record

Complete this record using actual laboratory findings or the provided teaching data.

Observation / parameter	Record / finding
Time	_____
Medium volume	_____
Aliquot volume	_____
Assay concentration	_____
Cumulative amount	_____
Percent released	_____

Calculations and Interpretation

- With constant vessel volume V and equal withdrawn/replaced aliquot volume v: cumulative amount at time n = V Cn + v × sum(Ci for earlier samples).
- Released (%) = corrected cumulative amount/declared dose × 100.
- Concentrations must represent the vessel medium after any analytical dilution correction.

Worked Illustration

Illustration: V = 900 mL, v = 5 mL, C1 = 0.020 mg/mL and C2 = 0.040 mg/mL give cumulative amount at time 2 = 900 × 0.040 + 5 × 0.020 = 36.1 mg, for equal replacement and the stated constant-volume design.

The values in this illustration are for calculation practice.

Result

Record the actual finding, calculated value with units where relevant, and a conclusion supported by the observations.

Finding: _____

Conclusion: _____

Precautions

- Keep temperature and test conditions consistent across comparative readings.
- Record raw readings before rounding calculated values.
- Do not compare results obtained with different methods as if they were interchangeable.

Viva Questions

1. Why correct for withdrawn drug?

Earlier aliquots remove drug that would otherwise be omitted from the cumulative released amount.

2. Why control the test conditions?

A change in conditions may alter the measured property independently of the intended variable.

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