Preparation and Evaluation of Liposomes

Practical 16 | Instrumental Methods of Analysis and Novel Drug Delivery Systems

Aim

To study Preparation and Evaluation of Liposomes, and interpret the recorded observations.

Principle

- Liposomes are phospholipid-bilayer vesicles. Drug association, vesicle size, dispersion properties and leakage/stability require distinct measurements.
- A dosage form combines an active ingredient with excipients selected for processing, stability and performance.
- Preparation and evaluation are linked: changes in composition or process can alter the product quality attributes.
- Identify the lipid and aqueous components in the approved formulation.
- Observe the vesicle-preparation demonstration and record the composition/process variables.
- Review the method used to distinguish unentrapped from vesicle-associated drug.
- Evaluate size and drug association separately and discuss the limitations of the measurements.

Materials and Apparatus

- Prepared lipid-vesicle teaching formulations, separation records and assigned drug/size assays.
- Assigned active ingredient, excipients and the instructor-approved master formula.
- Balance, mixing/preparation equipment, packaging materials and the assigned evaluation apparatus.

Method

1. Read the master formula and identify the purpose of each ingredient.
2. Calculate the quantities for the assigned laboratory batch and check ingredient identity.
3. Follow the specified order of addition and preparation process, recording actual quantities and process observations.
4. Measure the yield or finished quantity and package the laboratory preparation as specified.
5. Evaluate the product attributes listed for this dosage form with documented methods.
6. Compare the observations with the assigned specification and explain any difference.

Observation Record

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

Observation / parameter	Record / finding
Lipid composition	_____
Vesicle-size method	_____
Total drug	_____
Unentrapped drug	_____
Entrapment	_____
Stability observations	_____

Calculations and Interpretation

- Entrapped amount = measured total drug - measured unentrapped drug, after valid separation/recovery corrections.
- Entrapment efficiency (%) = entrapped amount/total drug amount × 100.

Worked Illustration

Illustration: total drug 10.0 mg and verified unentrapped drug 2.0 mg give entrapped drug 8.0 mg and entrapment efficiency 80.0%.

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

- Record changes in process or composition; do not conceal a deviation.
- Use the specification assigned to the exact product and dosage form.
- A teaching batch is for laboratory evaluation and is not released for patient use.

Viva Questions

1. Why identify excipient functions?

Each excipient can influence processing, stability, release or acceptability.

2. Why is appearance alone insufficient for evaluation?

It does not establish content, performance, stability or microbiological quality.

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