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Liposomes and Niosomes

Practical 4 - Bench formulation practical

Aim

To prepare a liposome or niosome model and evaluate vesicle properties and marker entrapment.

Principle

Liposomes form bilayer structures from suitable phospholipids, whereas niosomes commonly use selected nonionic surfactant systems. Hydrophilic and lipophilic materials associate differently with aqueous compartments and bilayer regions.

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 lipid or nonionic-surfactant system and marker
- Controlled film-hydration or other selected preparation arrangement
- Qualified size-characterisation and separation methods
- 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. Record component identity, ratio, marker amount and the selected preparation method.
4. Prepare and hydrate the film or use the approved alternative process, documenting hydration and size-control conditions.
5. Separate free from vesicle-associated marker using a qualified technique and verify recovery through the separation.
6. Measure size distribution, dispersity where applicable, morphology or supporting evidence, entrapment and changes during the defined storage observation.
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
Composition / method	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Size distribution	Record the adopted method	Record	Evaluate
Free and associated marker	Record the adopted method	Record	Evaluate
Storage observation	Record the adopted method	Record	Evaluate

Calculations

• Entrapment efficiency (%) = associated marker / input marker x 100
• State the separation recovery and whether the result is apparent or recovery-corrected.

Worked Example

Illustrative input marker 10.0 mg and validated free-marker amount 2.0 mg give an apparent associated amount of 8.0 mg and 80.0% entrapment.
If separation recovers only 85% of an independent marker control, investigate that loss before interpreting the entrapment result.
A size result of 150 nm alone does not establish a uniform unilamellar population.

Result and Interpretation

• Report composition, method and the full characterisation evidence. Distinguish size, dispersity, morphology and encapsulation.
• 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

• Control oxidation and storage conditions for sensitive components.
• Use the qualified separation method.
• Handle organic solvents and sonication equipment through the laboratory procedure.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

How do liposomes and niosomes differ?

Their main bilayer-forming components differ.

Why validate free-marker separation?

Separation losses or leakage can bias entrapment estimates.

Does one mean diameter describe the whole population?

No; distribution and supporting characterisation are important.

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