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Transdermal Drug Delivery Systems

Practical 15 - Bench formulation practical

Aim

To prepare a polymeric patch model and evaluate its physical attributes, content uniformity and release.

Principle

A matrix patch distributes material within a polymer film. Polymer composition, plasticiser, thickness, drug state and residual solvent affect film properties and release. Release through a test membrane and permeation through skin are different measurements.

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 film-forming polymer, plasticiser, marker and solvent
- Casting surface of known area and controlled drying arrangement
- Thickness gauge, assay method and release or permeation test system
- 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 approved casting solution or dispersion, documenting solids, plasticiser fraction and mixing conditions.
4. Cast onto the measured area and dry under the specified conditions. Record film mass and check for bubbles, cracks and nonuniform regions.
5. Cut units of defined area from identified positions. Measure thickness, mass, flexibility and drug content at different positions.
6. Evaluate release using the selected membrane and receptor medium, maintaining the specified sampling and replacement scheme.
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
Position / unit area	Record the adopted method	Record	Evaluate
Thickness and mass	Record the adopted method	Record	Evaluate
Marker content	Record the adopted method	Record	Evaluate
Release / physical observations	Record the adopted method	Record	Evaluate

Calculations

• Drug per unit area = measured drug in film / film area

• For replacement sampling, cumulative released mass at time n = V x Cn + v x sum of earlier concentrations, when equal sample volumes v are replaced and receptor volume V stays constant.

Worked Example

Illustrative film contains 100 mg marker across 100 cm^2; theoretical loading is 1.00 mg/cm^2.

A 5.0 cm^2 unit therefore contains a theoretical 5.0 mg before testing content uniformity.

For V = 10 mL, v = 1 mL, and measured receptor concentrations 0.10, 0.20 and 0.30 mg/mL, corrected mass at the third point is 10 x 0.30 + 1 x (0.10 + 0.20) = 3.30 mg.

Result and Interpretation

• Report variation across the film and distinguish measured content from theoretical loading. State the membrane and receptor conditions when interpreting release.

• 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

• Use suitable ventilation and the approved drying process.

• Use validated synthetic membranes or approved prepared tissue systems.

• Keep receptor-volume accounting consistent and assess marker stability.

• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

Why evaluate different film positions?

Casting and drying can produce spatial variation.

Why correct for withdrawn receptor fluid?

Earlier samples remove material that must be included in cumulative release.

Does synthetic-membrane release establish skin delivery?

No; skin permeation needs its own appropriate evidence.

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