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Incorporation of Herbal and Chemical Actives

Practical 22 - Bench formulation practical

Aim

To incorporate a specified herbal or chemical active into a compatible formulation base and evaluate distribution and quality.

Principle

An oil-in-water cream contains dispersed oil droplets in a structured continuous aqueous phase. Emulsifier identity, phase ratio, cooling and rheology influence consistency and physical stability.

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 self-emulsifying wax, oil phase, humectant and purified water
- Balance, controlled heating and mixing arrangement
- Suitable mixing, temperature and measurement equipment
- 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 specified oil and water phases and heat each only within the material-specific process range.
4. Combine in the approved order with controlled mixing, then cool as specified. Add heat-sensitive ingredients only at their qualified process stage.
5. Measure the pH through the selected method and compare consistency, homogeneity and phase behaviour after the defined conditioning period.
6. 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.
7. Calculate the specified response, variability and material balance. Compare with predefined teaching or product criteria and discuss sources of variation.
8. 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
Appearance and homogeneity	Record the adopted method	Record	Evaluate
pH and measurement method	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Consistency or viscosity	Record the adopted method	Record	Evaluate
Phase behaviour and mass recovery	Record the adopted method	Record	Evaluate

Calculations

• Component mass = total target batch mass x percentage / 100
• Batch recovery (%) = recovered mass / theoretical batch mass x 100

Worked Example

Illustrative same-session 100 g bench base: self-emulsifying wax 6 g, liquid paraffin 10 g, glycerol 5 g and purified water to 100 g.

The theoretical water quantity before process adjustment is 79 g. Any process-loss adjustment and additional ingredient must be documented.

This simple teaching composition requires formulation-specific development and preservation evidence for storage or use.

Active-incorporation study

• Record identity, potency or marker specification, solubility and stability of the active. Establish the justified incorporation stage and concentration.
• For a target 0.50 g active from material with 80.0% active content, supplied amount is 0.625 g; revise the full formula mass accordingly.
• Evaluate content uniformity, compatibility, pH and relevant performance. Ingredient inclusion alone does not establish a therapeutic claim.

Result and Interpretation

• Explain the emulsion type and the effect of preparation conditions. Use product-specific targets rather than a universal pH or viscosity limit. Record appearance, homogeneity, relevant physical measurements and the defined observation period.
• 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

• Prepare only the authorised teaching batch and identify it for laboratory evaluation.
• Follow ingredient-specific handling and disposal requirements.
• Record the need for a validated preservation system before any stored or distributed product is considered.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

Why calculate all quantities first?

It identifies inconsistencies in the formula and establishes the material balance.

Why use a controlled method?

Mixing, temperature and ingredient order can change the resulting structure.

Does a visually acceptable batch establish stability?

No; stability and microbiological quality need appropriate evidence.

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