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Formulation and Standardisation of Herbal Cough Syrup

Practical 19 - Bench formulation practical

Aim

To prepare and standardise an approved herbal oral-syrup model for laboratory evaluation.

Principle

A syrup is a concentrated aqueous oral-liquid vehicle containing dissolved sugars or another justified sweetening system. Botanical extracts may contribute insoluble matter, colour and variable marker content; clarity, uniformity, preservation and dose-volume consistency need separate controls.

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

- Authenticated, specified herbal extract and approved syrup formula
- Purified water and suitable vehicle ingredients
- Qualified balance, volume, pH, viscosity and marker-assay 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 extract identity, marker content, solvent residue specification and the approved formulation with all quantities and final-volume basis.
4. Prepare the syrup vehicle through the authorised process; dissolve or disperse each compatible ingredient in the prescribed sequence, avoiding unjustified heat exposure of the extract.
5. Incorporate the extract at its defined stage, adjust to final volume at the specified temperature and fill labelled laboratory containers.
6. Assess appearance, pH, viscosity under stated conditions, delivered volume, marker content and physical uniformity; specify microbial-quality and preservative-effectiveness evidence where applicable.
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
Preparation / interval	Record the adopted method	Record	Evaluate
Appearance / pH	Record the adopted method	Record	Evaluate
Viscosity / delivered volume	Record the adopted method	Record	Evaluate
Marker and microbial controls	Record the adopted method	Record	Evaluate

Calculations

• Marker per dose volume = assayed marker concentration x stated dose volume
• Vehicle solids (% w/v) = dissolved solids mass (g) / final volume (mL) x 100

Worked Example

Illustrative 60 g specified dissolved solids in a final volume of 100 mL is 60% w/v. This does not establish microbial preservation.

Illustrative marker assay 0.40 mg/mL corresponds to 2.0 mg in a 5.0 mL analytical portion; this arithmetic is not a recommended patient dose.

Result and Interpretation

• Report formula, botanical identity, marker assay, physical quality and the evidence still needed for shelf life and any proposed claim.
• 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

• Keep the preparation labelled for laboratory evaluation only.
• Use final volume rather than added-water volume for % w/v.
• Do not assume that sweetness, herbal origin or high solids proves safety or preservation.
• Use the laboratory-approved formulation and equipment procedure. Teaching batches are identified for laboratory evaluation.

Viva Questions and Answers

Why assay a marker?

It supports consistency of the specified extract and finished preparation.

Why control final volume?

It determines ingredient and marker concentrations.

Does a bench syrup test establish cough treatment?

Clinical claims require suitable product evidence and the applicable regulatory basis.

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