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Development and Evaluation of a Toothpaste Base

Practical 21 - Bench formulation practical

Aim

To prepare and evaluate a toothpaste base using a controlled laboratory formula.

Principle

A toothpaste base suspends an approved abrasive in a structured humectant and aqueous system. Abrasive properties, binder hydration, mixing and surfactant incorporation influence extrudability and uniformity.

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 abrasive, humectant, binder and aqueous-phase formula
- Controlled mixer, extrusion arrangement and evaluation methods
- 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. Hydrate the selected binder using the approved sequence and incorporate humectant and abrasive with controlled mixing.
4. Add the specified surfactant and flavour system at the qualified stage, controlling aeration and mass balance.
5. Evaluate homogeneity, pH by the prescribed dispersion method, extrusion and phase behaviour. Assess active compatibility separately where an active is included.
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
Dispersion pH	Record the adopted method	Record	Evaluate

Attribute or stage	Method / conditions	Individual readings	Calculation / comment
Extrudability	Record the adopted method	Record	Evaluate
Homogeneity and phase behaviour	Record the adopted method	Record	Evaluate
Abrasive and active compatibility record	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 allocation for 100 g base: 35 g abrasive, 30 g humectant and 1 g binder leave 34 g for the defined aqueous phase and other approved ingredients.

If an active is added, adjust the complete formula and assess its compatibility and analytical recovery.

Result and Interpretation

- Evaluate the defined laboratory base. Therapeutic and abrasivity claims require their appropriate tests and product evidence. 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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