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Master Formula Record

Practical 16 - Manufacturing-document practical

Aim

To draft a controlled master formula and manufacturing instruction for a model batch.

Principle

A master formula defines approved materials, quantities, equipment, process instructions, controls and yields before batch execution. It is a controlled instruction, not a retrospective record of actual values.

Materials and Requirements

- Approved model tablet formulation and batch-size basis
- Material specifications and equipment list
- Document-control and process-control templates
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Define product, strength, dosage form, theoretical batch size and document revision.
3. Scale every ingredient with units, potency corrections where justified and a complete mass balance.
4. Write the manufacturing sequence, critical parameters, sampling, in-process controls and hold conditions.
5. Include theoretical yields, reconciliation, packaging instructions, approvals and spaces linking to executed batch records.
6. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Material / stage	Quantity or instruction	Control / criterion	Authorised role
Active / placebo marker	Calculate	Identity / potency	Assign
Excipients	Calculate	Specification	Assign
Process stages	Specify	Parameters / checks	Assign

Calculations

- Required material = master-formula quantity x new batch size / master batch size
- Potency-adjusted active mass = required active mass / potency fraction

Worked Example

Illustrative 10,000 tablets of 400 mg require 4.000 kg theoretical blend. At 50 mg active per tablet, active requirement is 0.500 kg.

At a justified potency fraction of 0.98, supplied active mass is 0.5102 kg, with the remainder of the formula reconciled according to the approved instruction.

Result and Interpretation

• Deliver a revision-controlled instruction with reconciled quantities and clear controls.

Precautions

• Do not apply an unapproved overage.
• Keep instruction values distinct from actual results.
• Require change control for revisions.

Viva Questions and Answers

What is the MFR?

The controlled master instruction and formula.

Why reconcile total mass?

Corrections and scaling must preserve the approved composition and batch basis.

Is an overage automatically acceptable?

It requires scientific and regulatory justification.

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