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Online GMP Training

GMP7 | Production Controls

This module looks at the controls for starting materials, dispensing and processing, then it addresses what actions to take when confronted with a deviation and how to calculate yield and reconciliation.

OBJECTIVES

- Identify controls required for receiving, storing and dispensing starting materials
- Identify process controls in room and line clearance, formulation, in-process checks and batch records
- State GMP requirements for handling deviations
- Recognise how yield and reconciliation are calculated

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CONTENT

Introduction

- Objectives
- Reviews and assessment
- Overview

Starting material control

- What do you think?
- What do the GMP rules state?
- Overview
- Introducing starting materials to production
- 1. Receiving
- 2. Sampling and testing
- 3. Status labelling
- 4. Storing
- 5. Issuing
- Order these steps of starting material control
- When does direct control over product quality begin?
- Why are storage conditions critical to product quality?

Dispensing control

- What do you think?
- What do the GMP rules state?
- Overview
- Dispensing process
- 1. Room clearance
- 2. Setup
- 3. Weighing
- 4. Clean-up
- When does room clearance occur?
- Select true or false for each statement.

Processing control

- What do you think?
- What do the GMP rules state?
- Overview
- Room and line clearance
- Introducing materials
- Formulation controls
- In-processing checks
- Monitoring processes
- Testing line samples
- Batch records
- Cleaning-up
- Examples of GMP regulatory citations
- Match the terms and activities
- Select true or false for each statement

Deviations

- What do you think?
- What do the GMP rules state?
- Overview
- Handling deviations and CAPA
- Describe the deviation

Yield and reconciliation

- Overview
- Theoretical yield and expected yield
- Actual yield
- Reconciliation
- GMP for yield and reconciliation
- Match the terms
- True or false?

Conclusion

- Summary