First Hope

COMPLETE NOTES

Click here to visit our website

PHARMACY PRACTICAL NOTES

Complete subject and semesters are available on FirstHope app only.

Scan or click here

Click here to get the app >

Available on Google Play

JOIN THE FIRSTHOPE COMMUNITY

Join our Telegram channel

Click here to join Telegram >

Scan or click here

@FirstHopeNotes

Instagram

@firsthope.official

Click here to follow >

YouTube channel

FirstHope-Pharmacy / Live streams

Click here to watch >

WhatsApp channel

Follow FirstHope on WhatsApp

Click here to join >

FirstHope website

firsthope.co.in

Click here to visit >

B.Pharm / D.Pharm / M.Pharm / Pharm.D

Complete subjects and semesters are available in the FirstHope app.

Change-Control and Deviation Case Studies

Practical 1 - Quality case-study practical

Aim

To investigate a defined pharmaceutical-quality case and prepare a defensible decision record.

Principle

A quality-system decision connects evidence, patient or product risk, cause assessment, authorised action and effectiveness. A suspected cause is a hypothesis until supported by evidence.

Materials and Requirements

- Fictional case pack, batch history and applicable SOP
- Investigation, risk and action templates
- Trend data and a documented approval pathway
- 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. Construct a factual timeline and distinguish facts from assumptions.
3. Identify affected batches, containment and immediate product-risk questions.
4. Gather relevant laboratory, equipment, personnel and manufacturing evidence and test plausible causes.
5. Propose justified actions with owners, dates and effectiveness measures; record disposition and closure through authorised roles.
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.

Finding / evidence	Risk / impact	Action / owner	Effectiveness evidence
Observed problem	Assess	Assign	Define
Cause hypothesis	Test	Assign	Verify
Product disposition	Justify	Approve	Record

Calculations

- Recurrence rate = repeated events / defined opportunities x 100
- State the observation period and denominator when comparing rates.

Worked Example

Illustrative 6 documentation omissions in 200 records give 3.0%. After an intervention, 1 in 200 gives 0.5%. Review comparable workload and surveillance before attributing improvement to the action.

Case assignment

- Planned mixer change versus an unplanned mixing departure

• Create separate change-control and deviation records; connect their risk assessment, approvals and validation evidence.
• A retrospective change request cannot replace an honest deviation record.

Result and Interpretation

• Produce a signed-role investigation summary with evidence, unresolved questions and justified closure criteria.

Precautions

• Do not invent a root cause or delete contrary evidence.
• Distinguish containment from permanent correction.
• Do not use repeated testing to obtain a passing result.

Viva Questions and Answers

What distinguishes correction from corrective action?

Correction addresses the immediate problem; corrective action addresses its cause.

What closes an action effectively?

Evidence that it was implemented and achieved the intended sustained result.

Why assess product impact early?

Containment and disposition may be needed before the investigation is complete.

First Hope

COMPLETE NOTES

Click here to visit our website

PHARMACY PRACTICAL NOTES

Complete subject and semesters are available on FirstHope app only.

Scan or click here

Click here to get the app >

Available on Google Play

JOIN THE FIRSTHOPE COMMUNITY

Join our Telegram channel

Click here to join Telegram >

Scan or click here

@FirstHopeNotes

Instagram

@firsthope.official

Click here to follow >

YouTube channel

FirstHope-Pharmacy / Live streams

Click here to watch >

WhatsApp channel

Follow FirstHope on WhatsApp

Click here to join >

FirstHope website

firsthope.co.in

Click here to visit >

B.Pharm / D.Pharm / M.Pharm / Pharm.D

Complete subjects and semesters are available in the FirstHope app.