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.

Water-for-Injection System Audit Checklist

Practical 22 - Audit case-study practical

Aim

To create and apply an evidence-based audit checklist for the specified facility or supplier.

Principle

An audit evaluates objective evidence against defined criteria and scope. A checklist supports consistent coverage but does not replace risk-based sampling, interviews and corroboration of actual practice.

Materials and Requirements

- Fictional site profile, applicable current requirements and SOPs
- Audit plan, checklist and finding templates
- Selected records and interview notes
- 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 purpose, scope, products, jurisdictions, auditor roles and sampling rationale.
3. For each question specify the requirement, objective evidence and record to inspect; trace one selected batch or transaction end to end.
4. Classify each observation using the approved system and describe the evidence, requirement and gap without speculation.
5. Prepare an exit summary and proposed action follow-up with responsibility, due dates and effectiveness evidence.
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.

Audit question / criterion	Evidence sampled	Finding / risk	Action / verification
Governance / scope	Identify records	Assess	Assign
Selected process	Trace evidence	Assess	Assign
Follow-up	Review closure	Assess	Verify

Calculations

- Closure completion (%) = verified closed actions / actions due for closure x 100

Worked Example

Illustrative 8 actions are due and 6 have verified closure: completion = 75%.
The two remaining actions must be evaluated by risk; the percentage does not itself establish site compliance.

Audit scope: Water-for-injection system

• System design and materials; generation and distribution qualification; sanitisation; sampling representativeness; microbial and endotoxin trends; alarms, maintenance and excursion response.
• For each listed area record the criterion, selected evidence, actual observation, risk and follow-up.

Result and Interpretation

• Deliver a traceable checklist, factual finding statements and a risk-based follow-up plan.

Precautions

• Avoid patient or commercial identifiers in teaching records.
• Do not confuse absence of evidence with proof of conformity.
• Do not claim an audit is a regulatory certification.

Viva Questions and Answers

What makes a finding defensible?

A clear criterion, objective evidence and a described gap.

Why sample records?

A reasoned sample examines actual implementation within the audit scope.

Is an action closed when promised?

Closure requires verified implementation and, where relevant, effectiveness.

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.