ChecklistGuro

Pharmaceutical Out-Of-Specification (OOS) Investigation Checklist

Show only Checklist

Display Style
Default

Initial Assessment & Containment

Actions taken immediately upon identification of an OOS result, including quarantine and notification.

Date of OOS Result

Enter date...

Time of OOS Result

Enter time...

Batch Number Affected

Test Parameter OOS

Actual Result Value

Enter a number...

Specification Limit (Upper)

Enter a number...

Specification Limit (Lower)

Enter a number...

Brief Description of OOS Result

Write something...

Material Status (Quarantine)

- [ ] Quarantined
- [ ] Not Quarantined

Root Cause Investigation

Detailed examination of all potential factors contributing to the OOS result, including raw materials, equipment, processes, and personnel.

Description of OOS Result & Associated Data

Write something...

Batch Record Review Status

- [ ] Completed
- [ ] In Progress
- [ ] Not Applicable

Potential Contributing Factors (Select All That Apply)

- [ ] Raw Material Variation
- [ ] Equipment Malfunction
- [ ] Process Deviation
- [ ] Personnel Error
- [ ] Analytical Method Issue
- [ ] Environmental Factor

Raw Material Lot Number

Enter a number...

Date of Raw Material Receipt

Enter date...

Details of Equipment Maintenance Records Review

Write something...

Analytical Method Validation Status

- [ ] Valid
- [ ] Expired
- [ ] Needs Revalidation

Corrective Action Plan (CAP)

Specific steps to address the root cause and prevent recurrence of the OOS result.

Detailed Description of Corrective Action

Write something...

Estimated Cost of Corrective Action

Enter a number...

Planned Completion Date

Enter date...

Responsible Department

- [ ] Manufacturing
- [ ] Quality Assurance
- [ ] Engineering
- [ ] Procurement

Action Priority

- [ ] High
- [ ] Medium
- [ ] Low

Affected Areas/Equipment

- [ ] Raw Material A
- [ ] Equipment X
- [ ] Process Step Y

Prepared By (CAP Initiator)

Verification & Validation

Confirmation that the implemented CAP effectively resolved the issue and the process is back in control.

Verification Start Date

Enter date...

Verification End Date

Enter date...

Number of Batches Verified

Enter a number...

Number of Failed Batches (During Verification)

Enter a number...

Verification Outcome

- [ ] Successful
- [ ] Partial Success
- [ ] Unsuccessful

Detailed Verification Results & Observations

Write something...

Verification Lead Signature

Documentation & Records

Ensuring complete and accurate documentation of all investigation activities, findings, and actions taken.

Investigation Protocol Number

Write something...

Date of OOS Result

Enter date...

Time of OOS Result

Enter time...

Batch Number

Enter a number...

Raw Data/Analytical Records

Write something...

Supporting Documentation (e.g., Certificates of Analysis)

Upload File

Investigator Signature

Document Review Status

- [ ] Not Reviewed
- [ ] Reviewed
- [ ] Approved

Trend Analysis & Preventative Actions

Reviewing historical data and identifying opportunities to prevent future OOS occurrences.

Number of OOS results in last 12 months

Enter a number...

Identified trends from OOS data?

- [ ] Yes
- [ ] No
- [ ] Unclear

Description of identified trends and potential root causes.

Write something...

Potential preventative actions considered (select all that apply)

- [ ] Process Improvement
- [ ] Equipment Maintenance
- [ ] Training Enhancement
- [ ] Supplier Qualification
- [ ] Raw Material Specification Review

Estimated cost of implementing preventative actions

Enter a number...

Target completion date for preventative actions

Enter date...

Justification for selected preventative actions and their expected impact

Write something...

Preventative actions deemed sufficient?

- [ ] Yes
- [ ] No
- [ ] Further investigation needed

Closure & Sign-off

Formal review and approval of the OOS investigation by designated personnel, ensuring all requirements are met.

Date of Final Review

Enter date...

Time of Final Review

Enter time...

Overall Assessment (Satisfactory/Unsatisfactory)

- [ ] Satisfactory
- [ ] Unsatisfactory

Summary of Review Findings & Justification (if applicable)

Write something...

Reviewer Signature

Reviewer Name (Printed)

Write something...

Reviewer ID (Employee Number)

Enter a number...