

# Pharmaceutical Out-Of-Specification (OOS) Investigation Checklist

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## 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)

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# Verification & Validation

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

## Verification Start Date

## Verification End Date

## Number of Batches Verified

## Number of Failed Batches (During Verification)

## 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**

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**Reviewer Name (Printed)**

Write something...

**Reviewer ID (Employee Number)**

Enter a number...