ChecklistGuro

Pharmaceutical Batch Record Review Checklist

Batch Header Verification

Confirm accuracy and completeness of batch header information (batch number, manufacturing date, expiry date, etc.).

Batch Number

Enter a number...

Manufacturing Date

Enter date...

Expiry Date

Enter date...

Batch Size (Units)

Enter a number...

Manufacturing Site

- [ ] Site A
- [ ] Site B
- [ ] Site C

Batch Record Notes (if applicable)

Write something...

Raw Material Traceability

Verify raw material lot numbers, supplier details, and certificate of analysis (CoA) alignment.

Raw Material Name

Write something...

Lot Number

Enter a number...

Receipt Date

Enter date...

Supplier

- [ ] Supplier A
- [ ] Supplier B
- [ ] Supplier C

Certificate of Analysis (CoA)

Upload File

Supplier Reference Number

Write something...

Quantity Received

Enter a number...

Equipment Log Review

Assess equipment usage, cleaning records, and calibration status for each step.

Equipment ID

Enter a number...

Calibration Date

Enter date...

Calibration Result

Enter a number...

Calibration Status

- [ ] Pass
- [ ] Fail
- [ ] NA

Calibration Notes

Write something...

Last Maintenance Date

Enter date...

Technician Signature

In-Process Control (IPC) Data Validation

Confirm IPC results are within specifications and documented correctly.

Temperature (deg C)

Enter a number...

pH Value

Enter a number...

Viscosity (cP)

Enter a number...

Appearance

- [ ] Clear
- [ ] Turbid
- [ ] Milky
- [ ] Other

Appearance Notes (if applicable)

Write something...

IPC Test Date

Enter date...

IPC Tester Signature

Manufacturing Process Adherence

Validate adherence to established manufacturing procedures and instructions.

Step Number Verified

Enter a number...

Step Procedure Followed?

- [ ] Yes
- [ ] No
- [ ] N/A

Detailed Observations/Comments on Process Adherence

Write something...

Date of Procedure Execution

Enter date...

Time of Procedure Execution

Critical Process Parameters Monitored

- [ ] Temperature
- [ ] Pressure
- [ ] pH
- [ ] Humidity
- [ ] Agitation Speed

Operator Signature

Deviation & Change Control Review

Check for any deviations from the approved process and associated change controls.

Deviation Report Number

Enter a number...

Deviation Occurrence Date

Enter date...

Summary of Deviation

Write something...

Root Cause Identified?

- [ ] Yes
- [ ] No

Root Cause Investigation Details

Write something...

Corrective Action Plan Approved?

- [ ] Yes
- [ ] No

Corrective Action Plan Description

Write something...

Corrective Action Completion Date

Enter date...

Quality Control (QC) Testing Verification

Confirm QC testing has been performed and results are within specifications.

Sample Size (n)

Enter a number...

Result - Assay

Enter a number...

Result - Impurity 1

Enter a number...

Result - Impurity 2

Enter a number...

Pass/Fail Status

- [ ] Pass
- [ ] Fail
- [ ] Pending

Failure Investigation (if applicable)

Write something...

QC Release Date

Enter date...

QC Analyst Signature

Documentation Completeness & Accuracy

Ensure all process steps, observations, and signatures are documented completely and accurately.

Reviewer Signature

Review Date

Enter date...

Comments/Observations (if any)

Write something...

Document Legibility

- [ ] Excellent
- [ ] Good
- [ ] Fair
- [ ] Poor

Number of Pages Reviewed

Enter a number...

Required Signatures Present

- [ ] Manufacturing Lead
- [ ] Quality Assurance
- [ ] Packaging Lead

Batch Release Approval

Verify proper review and authorization for batch release based on completed record.

Quality Assurance Reviewer Signature

Review Date

Enter date...

Batch Number (Confirmation)

Enter a number...

Release Status

- [ ] Approved
- [ ] Rejected
- [ ] Conditional Approval

Release Notes/Comments (if applicable)

Write something...

Release Authorizer Signature