



Pharmaceutical Compound Record Review Checklist

Raw Material Verification

Ensuring correct raw materials are used, including lot number and expiry date verification.

Raw Material Status

- ☐ Approved
- ☐ Quarantine
- ☐ Rejected

Raw Material Name

Lot Number

Expiry Date

Quantity Received

Enter a number...

Quantity Used

Enter a number...

Supplier Name

- ☐ Supplier A
- ☐ Supplier B
- ☐ Supplier C

Received By (Signature)

Equipment Setup and Calibration

Confirmation of correct equipment setup, calibration status, and functionality.

Equipment ID

Enter a number...

Calibration Due Date

Enter date...

Calibration Status

- ☐ Current
- ☐ Overdue
- ☐ Pending

Calibration Reading (Before)

Enter a number...

Calibration Reading (After)

Enter a number...

Calibration Method

Write something...

Calibrator Signature

Calibration Notes/Comments

Write something...

Weighing and Measurement Accuracy

Verification of accurate weighing of raw materials and in-process components.

Raw Material Weight (Actual)

Enter a number...

Raw Material Weight (Target)

Enter a number...

Weight Variance (Actual vs. Target)

Enter a number...

Within Tolerance?

☐ Yes

☐ No

Discrepancy Notes (if applicable)

Write something...

Weighing Date

Enter date...

Weighing Time

Weigher Signature

Mixing and Processing Parameters

Review of mixing times, temperatures, speeds, and other critical process parameters.

Mixing Speed (RPM)

Mixing Time (Minutes)

Temperature (°C)

pH

Start Time

Date of Mixing

Mixing Mode (e.g., Continuous, Intermittent)

- ☐ Continuous
- ☐ Intermittent

In-Process Controls (IPC)

Checking of all in-process controls and adherence to specifications.

pH Value

Temperature (°C)

Particle Size (µm)

Appearance

- ☐ Clear
- ☐ Cloudy
- ☐ Milky
- ☐ Particulate Matter

Reaction Completion Time

Viscosity Characteristics

☐ Low

☐ Medium

☐ High

Additional IPC Observations

Write something...

Documentation Completeness

Ensuring all steps are documented legibly and completely in the compound record.

Description of any deviations from standard procedure

Write something...

Operator's initials

Write something...

Date of compounding

Enter date...

Start time of compounding

Reviewer Signature

Procedure Version Used

☐ Version 5.0

☐ Version 3.2

☐ Version 2.1

Number of revisions

Batch Number and Record Integrity

Verification of correct batch number assignment and overall record integrity.

Assigned Batch Number

Record Creation Date (System Generated)

Record Review Date

Reviewer Signature

Unique Record Identifier (if applicable)

Write something...

Record Alteration Log (if any)

Write something...

Record Status

- ☐ Active
- ☐ Inactive
- ☐ Archived

Deviation Handling & Resolution

Documentation of any deviations from standard procedures and their resolutions.

Detailed Description of Deviation

Write something...

Deviation Category (e.g., Equipment, Material, Process)

- ☐ Equipment
- ☐ Material
- ☐ Process
- ☐ Personnel
- ☐ Other

Estimated Impact on Product Quality (Scale of 1-5)

Enter a number...

Date Deviation Occurred

Enter date...

Root Cause Analysis

Write something...

Corrective Actions Taken

Write something...

Date Corrective Actions Implemented

Enter date...

Signature of Person Implementing Corrective Action

Final Product Appearance & Testing

Assessment of final product appearance and pending/completed testing results.

Detailed Description of Final Product Appearance

Write something...

Visual Defects Observed (select all that apply)

- ☐ Discoloration
- ☐ Foreign Particles
- ☐ Crystallization
- ☐ Clumping
- ☐ None Observed

Particle Size (Microns)

Enter a number...

Appearance Assessment - Pass/Fail

- ☐ Pass
- ☐ Fail

Testing Completion Date

Photo Documentation of Product Appearance (if applicable)

 Upload File

Record Review & Approval

Review and approval of the complete compound record by designated personnel.

Record Review Date

Reviewer Signature

Reviewer Name

Reviewer Employee ID

Record Status (Approved/Rejected)

- ☐ Approved
- ☐ Rejected

Review Comments (if rejected)

Write something...

Approval Signature (if approved)