GMP Audit Checklist

Facility Name / Location

Date of Audit

Auditor(s)

INSTRUCTIONS:

This checklist is designed to assist in conducting a Good Manufacturing Practices (GMP) audit to assess compliance with GMP regulations. Carefully review each item and mark the corresponding checkbox to indicate compliance or note any observations and areas that require attention. Use the "Notes/Observations" section to provide additional details, necessary improvements, and any required follow-up.

PERSONNEL

Personnel hygiene and cleanliness (e.g., handwashing, protective clothing).	☐ Yes	☐ No	☐ NA
Training and documentation of personnel training records.	☐ Yes	☐ No	☐ NA
Adequate staffing levels for current operations.	☐ Yes	☐ No	☐ NA

Observations / Notes / Corrective actions, if any:

FACILITY AND EQUIPMENT

Facility cleanliness and maintenance.	☐ Yes	☐ No	☐ NA
Equipment calibration and maintenance records.	☐ Yes	☐ No	☐ NA
Adequate storage and handling of raw materials and products.	☐ Yes	☐ No	☐ NA
Adequate storage conditions (e.g., temperature and humidity control).	☐ Yes	☐ No	☐ NA
Clean and organized storage areas.	☐ Yes	☐ No	☐ NA

Observations / Notes / Corrective actions, if any:

DOCUMENTATION AND RECORDS

Written procedures for all GMP-related activities.	☐ Yes	☐ No	☐ NA
Documented procedures for product specifications and quality control.	☐ Yes	☐ No	☐ NA
Records of manufacturing and quality control activities.	☐ Yes	☐ No	☐ NA
Documentation of deviations, investigations, and corrective actions.	☐ Yes	☐ No	☐ NA
Record retention and access procedures.	☐ Yes	☐ No	☐ NA

Observations / Notes / Corrective actions, if any:

PRODUCTION AND PROCESS CONTROLS

Batch production records, including traceability.	☐ Yes	☐ No	☐ NA
Process validation records.	☐ Yes	☐ No	☐ NA
In-process controls and monitoring.	☐ Yes	☐ No	☐ NA
Labeling and packaging controls.	☐ Yes	☐ No	☐ NA
Handling of returned products and complaints.	☐ Yes	☐ No	☐ NA

Observations / Notes / Corrective actions, if any:

QUALITY CONTROL

Testing and sampling procedures.	☐ Yes	☐ No	☐ NA
Laboratory equipment calibration and maintenance.	☐ Yes	☐ No	☐ NA
Documentation of testing results.	☐ Yes	☐ No	☐ NA
Stability testing records.	☐ Yes	☐ No	☐ NA
Product release procedures.	☐ Yes	☐ No	☐ NA

Observations / Notes / Corrective actions, if any:

VENDOR AND SUPPLIER CONTROL

Vendor qualification and auditing procedures.	☐ Yes	☐ No	☐ NA
Documentation of vendor evaluations.	☐ Yes	☐ No	☐ NA
Handling of raw materials and components from approved sources.	☐ Yes	☐ No	☐ NA

Observations / Notes / Corrective actions, if any:

SANITATION AND CLEANING

Cleaning and sanitation procedures.	☐ Yes	☐ No	☐ NA
Records of cleaning and sanitation activities.	☐ Yes	☐ No	☐ NA
Cleaning validation records.	☐ Yes	☐ No	☐ NA
Pest control procedures and records.	☐ Yes	☐ No	☐ NA

Observations / Notes / Corrective actions, if any:

COMPLAINT HANDLING

Procedures for receiving, documenting, and investigating complaints.	☐ Yes	☐ No	☐ NA
Documentation of complaint investigations and resolutions.	☐ Yes	☐ No	☐ NA
Trend analysis of complaints.	☐ Yes	☐ No	☐ NA

Observations / Notes / Corrective actions, if any:

PRODUCT RECALL AND WITHDRAWAL

Procedures for initiating and conducting product recalls.	☐ Yes	☐ No	☐ NA
Records of mock recall exercises.	☐ Yes	☐ No	☐ NA
Product recall notifications and communications.	☐ Yes	☐ No	☐ NA

Observations / Notes / Corrective actions, if any:

TRAINING AND EDUCATION

Training programs and records for GMP-related topics.	☐ Yes	☐ No	☐ NA
Documentation of personnel competency assessments.	☐ Yes	☐ No	☐ NA
Training on changes to GMP regulations.	☐ Yes	☐ No	☐ NA

Observations / Notes / Corrective actions, if any:

REGULATORY COMPLIANCE

Adherence to current GMP regulations and guidelines.	☐ Yes	☐ No	☐ NA
Records of interactions with regulatory agencies.	☐ Yes	☐ No	☐ NA
Notification and reporting of adverse events.	☐ Yes	☐ No	☐ NA

Observations / Notes / Corrective actions, if any:

ADDITIONAL NOTES / OBSERVATIONS

[Insert any additional notes, observations, or details made during the GMP audit.]

STATEMENT OF INSPECTION

We, the undersigned auditors, have completed the Good Manufacturing Practices (GMP) audit of the facility/company named above. We certify that the facility/process has been assessed for compliance with GMP regulations, and any identified issues have been documented and addressed.

Inspector's Name :

Date :

Signature :

APPROVED BY

Name :

Date :

Signature :