POLICY ON INTERNAL AUDIT

INTRODUCTION:

This document provides a policy for Internal audit which shall be conducted to evaluate compliance level of the organization with respect to the principles of current Good Manufacturing Practice.

SCOPE:

Applicable to all the internal audit conducted at …… and Associated unit by Audits and Compliance team from Corporate Quality Assurance.

POLICY DETAILS:

- Internal audit is an internal improvement program and findings of inspections are confidential. Internal audit findings cannot be shared with personnel who are not …….. employee.

- Internal audit programs shall be carried out in accordance with pre-defined approved procedure.

- An approved Internal audits plan / schedule shall be in place at corporate quality assurance.

- Internal audits shall be performed at least once in a year/ risk-based approach i.e., Risk and compliance rating shall be used for decision on frequency based on the "Complexity of dosage forms and compliance level for manufacturing units.

- Adhoc Internal audits may be additionally performed on special occasions but not limited to.

  a) Receipt of critical observation during regulatory inspections.
  b) Receipt of warning letter, import alert, NOC or NCR.
  c) Product recall, repeated batch failures, repeated complaints, or safety concerns in case of pharmacovigilance practices.
  d) In case of new processes/ procedures implemented.

- There shall be documented auditor certification program in place with pre-defined evaluation and certification criteria. Auditor re-certification shall be carried out at predefined frequency.

- Internal audit shall be led by experienced, qualified personnel and must be independent from the unit where internal audit is planned.
- Internal audit program at manufacturing units shall be conducted considering the "Six system approach" i.e., Quality system, Production system, Facilities and equipment system, laboratory controls system, Materials system and packaging & labeling system.

- Following areas shall be covered in internal audit of manufacturing units but not limited to:

  a. Personnel Department:
  b. Storage of raw materials, packing materials and finished products.
  c. Production and in-process control:
  d. Labelling Control:
  e. Quality Control:
  f. Quality Assurance:
  g. Documentation:

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h. Details of Personnel of Various Departments:
i. Safety, Sanitation, and hygiene:
j. Validation and revalidation program:
k. Calibration of instruments or measurement systems:
l. Complaints Management:
m. Recall Procedure:
n. New areas:
o. Maintenance of Building and Equipment:
p. Water purification System:
q. Qualification and validation of computerised systems
r. Results of previous internal audits and quality audits
s. Documents related to regulatory affairs:
t. Control on contract analysis:
u. Engineering:
v. Discarding of Residues:
w. Corporate Quality Functions:
x. Drug safety:
y. Combination Products (Medical devices):

- There shall be written categorization program in place for categorization of internal audit observations.
- Records associated with Internal audit program shall be maintained as per the defined retention period in the respective procedure.
- Internal audit program shall include a mechanism for regular reporting of observations and CAPA to site management.
- Internal audit observation shall be extrapolated to the other areas for its investigation, impact assessment and necessary corrective actions through approved procedure.
- Response to inspection including agreed upon CAPA along with responsibility and timeline shall be prepared and issued to auditors within timely manner.
- There shall be effective follow-up programs to ensure all recommendations for corrective action are implemented.
- Internal audits program shall be periodically re-assessed to focus on areas of risk identified.
- Guidance checklist shall be in place for the auditors while performing the internal audits.
- There shall be approved procedure in place to conduct the Desktop internal audit if needed. Desktop Internal Audit can be performed in case of restriction on travelling for ……. and its associated sites during emergency like situation or any unavoidable circumstances. Such emergency situations may include but are not limited to widespread outbreak of illness in humans resulting into pandemic (e.g., COVID-19) and acts of nature that result in restricted travel between …… manufacturing sites.
- For desktop internal audit, virtual review tools can be used including audio video calls wherever possible.
- There shall be structured program in place for availability of documents through electronic mode, safe and secured access to auditors and auditees.

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AMENDMENT AND WAIVER:
The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION:

Internal Audit:
A periodic, systematic and independent examination to determine whether quality related activities and their results comply with documented systems, are effectively implemented and are suitable for achieving the quality objectives of organisation.

Desktop Internal audit:
A systematic and independent examination to determine whether quality related activities and their results comply with documented systems, are effectively implemented and are suitable for achieving the quality objectives through audio-visual tools and / or physical inspection by site located auditors.

ABBREVIATIONS:

CAPA	: Corrective Action and Preventive Action
cGMP	: Current Good Manufacturing Practices
ICH	: The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
WHO	: World Health Organisation.
NOC	: Notice of concern
NCR	: Non Compliance report

REFERENCES:
WHO Good Manufacturing practices for Pharmaceutical Products: Main principles, WHO Technical Report Series No. 986, Annex 2.
WHO Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 996, Annex 4.
EudraLex - Volume 4 Good Manufacturing Practices (GMP) Guidelines, Part I – Basic Requirements for Medicinal Products, Chapter 9: Self Inspection.
ICH Q7: Good Manufacturing Practice.
Guidance for Industry April 2021 by USFDA: Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency