STANDARD OPERATING PROCEDURE	
Department: Pharmacovigilance	**URS No.:**
Title: Pharmacovigilance Audit & Inspection Readiness	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1. OBJECTIVE:

This Standard Operating Procedure (SOP) describes the procedure for Pharmacovigilance Audit and Inspection Readiness.

2. SCOPE:

This SOP is applicable to…….

3. RESPONSIBILITY:

3.1. Pharmacovigilance Department:

Preparation of this SOP, prepare the applicable documents and logs. Distribution, Retrieval and Destruction of this SOP.

3.2. Quality Assurance (QA)Department:

Responsible for communication and management of all the external auditors and inspectors for this cause.

3.3. Pharmacovigilance Officer In-charge(PvOI):

Review, Approval, Training and effective implementation of this SOP.

4. ACCOUNTABILITY:

PvOI and QA

5.1. PROCEDURE:

5.1.1. Audit:

A systematic and independent examination of data, statements, records, operations and performances of an enterprise for a stated purpose. An audit provides reassurance, identifies areas for improvements and investigates actual or suspected problems. Audits are also conducted to ensure that the company staff is compliant with relevant national and international regulations and company specific standard operating procedures (SOP's) for the conduct of activities.

5.1.2. Auditee:

It is an organization (or part of an organization) that is being audited.

5.1.3. Auditor:

An auditor is someone who is responsible for evaluating the validity and reliability of a company or organization's data, records or operations.

5.1.4. Audit Plan:

An audit plan is a document that outlines description of activities and arrangement for an individual audit.

5.1.5. Critical finding:

Fundamental weakness in the PV systems or practices that adversely deviate from the PV regulations and/or affect the rights and safety of patients or poses a potential risk to public health and/or represents a serious violation of applicable regulatory requirements.

5.1.6. Major finding:

It's a significant weakness in one or more PV processes or practices, or a fundamental weakness in part of one or more PV processes or practices that is detrimental to the whole process and/or could potentially adversely affect the rights, safety or well-being of patients and/or could potentially pose a risk to public health and/or represents a violation of applicable regulatory requirements which is however not considered serious.

5.1.7. Minor finding:

It's a weakness in the part of one or more PV processes or practices that is not expected to adversely affect the whole PV system or process and/or rights, safety or well-being of patients.

5.2. Objective of PV audits and inspections

5.2.1. The appropriateness and effectiveness of the implementation and operation of the PV system, including its quality system for PV activities and records shall be verified.

5.2.2. To determine the extent to which the audit criteria are fulfilled and contributing to the improvement, control and governance of PV processes.

5.2.3. To assess and establish that the MAH has qualified personnel, robust system and facilities to conduct PV activities.

5.2.4. To identify, record and address non - compliance which may pose a risk to public health.

5.2.5. To take action wherever considered necessary based on the result of the inspections.

5.3. A planned audit as per "Audit Plan" shall be communicated to the PvOI/Head PV in advance and the dates of the audit shall be agreed mutually within reasonable time limits. The procedure should be handled as mention in SOP "Self Inspection (Internal Quality Audit)"

5.4. At the conclusion of the audit, an"Audit Report" including recommendations from the auditor on identified findings shall be received by PvOI/Head PV.

5.5. In case any non - compliance are observed and agreed during an internal Pharmacovigilance audit, the same shall be handled as per SOP "Self Inspection (Internal Quality Audit)"

5.6. A date shall be agreed between auditor and auditee depending on the severity of non – compliance and time needed to complete the Corrective and Preventive actions.

5.7. PvOI/Head PV shall track the completion of CAPA "Corrective and Preventive Actions" plan as per timelines provided by auditee.

5.8. A re-audit shall be organized to ensure if the Corrective and Preventive actions have been made effective need based.

5.9. In case the Corrective and Preventive actions not made implemented, then further effectiveness of CAPA shall be ensured by PvOI/Head PV.

6. DISTRIBUTION:

Not Applicable

7. REFERENCES:

Not Applicable

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8. ABBREVIATIONS:

CAPA	Corrective and Preventive Actions
QA	Quality Assurance
MAH	Marketing Authorization Holder
NA	Not Applicable
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
PvOI	Pharmacovigilance Officer Incharge

9. ANNEXURE:

Not Applicable

10. REVISION HISTORY:

Revision No.	Effective Date	Reason for change	CC No.
00		New SOP	Nil