1.0 PURPOSE:

To lay down the procedure for establishing a comprehensive system of documented Audit system in order to determine the effectiveness of the Quality Management System and recommend Correction, Corrective and Preventive action.

2.0 SCOPE:

This procedure is applicable for departments to conduct the Internal Audits at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 QA is responsible to prepare the Internal audit schedule.

3.2 QA-Head is responsible to ensure that Internal Audits are conducted as per the Schedule and Non-conformities are closed out at appropriate time.

3.3 Auditees/ Respective functional heads are responsible to close the non-conformance within the predefined time period.

4.0 DEFINITIONS:

Internal Audit : A planned & systematic verification of a system, procedure or operation by internal auditor in order to determine or monitor compliance, effectiveness of Quality Management System. Un-announced walk-through audits shall be conducted as part of the Internal Audit system to detect the operational deviations.

Auditor(s): An individual or group of persons, those who are responsible for conducting Internal audit.

Auditee: A representative from respective area/section of the department being audited.

Correction: Repair, rework, or adjustment and relates to the disposition of an existing discrepancy.

Corrective Action: Action taken to eliminate the causes of an existing non- conformity, defect or other undesirable situation to prevent recurrence.

Preventive Action: Action taken to eliminate the causes of a potential non-conformity, defect, or other undesirable situation to prevent occurrence.

5.0 PROCEDURE:

5.1 Internal audits shall be conducted to monitor the implementation and compliance of Good Manufacturing Practices in the facility and to improve the quality systems.

5.2 Quality Assurance Department shall prepare the annual audit schedule current version of Annual Audit Schedule' formatQA020-FM056 in the month of December for the forthcoming year by marking 'X' for the Scheduled months and circulate controlled copy to concerned departments.

5.3 The audit shall cover Production, Engineering, Warehouse, Quality control, Quality Assurance, Human resources, EHS

5.4 The frequency for the audit of plant manufacturing and its supporting functions shall be **Once in three months.**

5.5 The dates for the audits shall be agreed and QA shall inform concerned departments and auditors in advance i.e. one week by way of an internal communication.

5.6 Audits shall be carried out as per schedule and deviations, if any shall be recorded with suitable justifications.

5.7 QA Head or his authorized nominee shall lead the internal audit team from cross-functional areas comprising Production, QC, Engineering, HR, SHE and Warehouse to carry out the audits. The auditors shall be suitably trained and be independent of the area being audited.

5.8 The Head of the department or authorized nominee of the respective department shall be the auditee for respective department.

5.9 An opening meeting shall be carried out by the lead auditor with respective department before carrying out the audit.

5.10 Auditor shall then execute the audit to check the compliance to lay down procedures/ guideline. The auditor shall use the checklist for conducting the audit and / or the auditor may be considered the single / multiple Quality systems, manufacturing& testing activities.

5.11 Auditor shall make a note of all the observations or Non-Conformity observed during the audit in the Non-compliance report and takes the concurrence from the auditee. Each observation or Non-Conformity shall be listed in separate NC form.

5.12 **Qualification criteria for internal auditors:**

5.12.1 Internal auditors shall be chosen based on their qualification, experience and training.

5.12.2 A minimum of 1 or 2 members having minimum 5Years experience in their respective area by covering all departments i.e. Warehouse, Production, Quality Control, Engineering, Quality Assurance and Human Resources at site.

5.12.3 Head-QA shall train internal Auditors on cGMP modules.

5.12.4 Head- QA shall qualify auditors for conducting internal audits and issues a certificate as per current version QA020-FM130 and list of Qualified Trainers as per current version QA020-FM134.

5.13 **Internal audit procedure:**

5.13.1 The internal audit team shall audit the department based on the internal audit checklist given as per the respective formats.

5.13.2 In addition in the given checklist any non-conformance observed during audit shall be noted in the given checklist.

5.13.3 As per annual audit schedule, audit dates for respective department in the respective month shall be finalized along with auditor name as per the current version QA020-FM128 and copies shall be circulated to concerned Departments.

5.13.4 All the observations found during the audit, which do not comply to the Quality system and are against the cGMP shall be raised as Non- Compliances.

5.13.5 Non- Compliances shall be categorized as follows:

5.13.5.1 **Critical:** Having significant impact on product quality or safety, likely to have a serious or harmful affect on the patient.

5.13.5.2 **Major:** Having significant impact on product quality and safety may affect the patient safety

5.13.5.3 **Minor:** Having no significant impact on product quality and safety.

5.13.6 At the end of the audit, auditor shall raise the Non-compliances, if any, as per the Current Version QA020-FM057, separate sheet shall be used for each Non-Compliance.

5.13.7 Lead auditor shall conduct an audit review meeting at the end of the audit.

5.13.8 Auditors shall review the Non-compliances along with QA. The Non compliances shall be categorized as critical / major / minor.

5.13.9 Once the audit is completed in the respective department, the audit completion details shall be captured in the internal audit schedule format; current version QA020-FM128.

5.13.10 The Head of the auditee department is responsible to carryout the investigation by taking the support of cross functional teams and shall propose the corrective action and preventive actions along with target timeline and shall ensure the closure of NC.

5.13.11 If the Non-compliance is categorized as critical, further activity shall be stopped immediately and investigation shall carried out to identify the root cause and CAPA shall be implemented. Activities shall be continued only after taking corrective action and verification.

5.13.12 An impact assessment shall be carried as part of investigation to assess the impact of critical observation on previous batches and quality systems.

5.13.13 If the Non-compliance is categorized as major, investigation and implementation of corrective action plan to be completed within three months.

5.13.14 If the Non-compliance is categorized as minor, investigation and implementation of corrective action plan to be completed within one month

5.13.15 Upon receipt of internal audit report, department shall initiate a time bound corrective actions and submit the report within 15 working days of receipts of the audit report.

5.13.16 In case the corrective action has not taken place during the scheduled time, Head of the auditee department shall discuss the concern with Head QA and get time extension.

5.13.17 QA shall verify the implementation of corrective action and preventive actions (Follow up Audit) as per the proposal.

5.13.18 After QA verification and satisfaction, the NC shall be closed and Head QA shall approve the document.

5.13.19 Continuity of the corrective actions shall be verified in the subsequent internal audits.

5.14 **Annual Review of Audit Programme:** At the beginning of the year, a detailed review of the previous year's audits shall be conducted and record audit completion and its closures dates in Annual audit schedule and conclude the closure of audits.

5.15 **NON-COMPLIANCE REPORT NUMBERING SYSTEM**:

NC-AA/YYXXX,

Whereas,

NC indicates the Non-compliance Report,
AA indicates the Name of the Department Code,

YY indicates the Year,

XXX indicates the Serial number.

6.0 FORMATS / ANNEXURE(S):

6.1 Internal audit checklist-QA : QA020-FM019
6.2 Internal audit checklist- QC : QA020-FM020
6.3 Internal audit checklist-Warehouse : QA020-FM021
6.4 Internal audit checklist-Production : QA020-FM022
6.5 Internal audit checklist-Engineering : QA020-FM023
6.6 Annual audit schedule : QA020-FM056
6.7 Non-compliance report : QA020-FM057
6.8 Internal audits checklist-EHS : QA020-FM127
6.9 Internal audit schedule : QA020-FM128
6.10 Internal audit checklist-HR : QA020-FM129
6.11 Certification of qualified auditor : QA020-FM130
6.12 List of qualified auditor : QA020-FM134

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	R.Pallavi	T. Ramya	K.V. Nagendra kumar
Department	Quality Assurance	Quality Assurance	Quality Assurance

6.13 Non-Compliance Status Record for Internal Audit : QA020-FM171

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01.07.2009	New SOP is introduced	---
01	24.08.2010	SOP Procedure is updated and formats also included.	---
02	05.01.2012	SOP Procedure is updated and formats also included.	---
03	15.06.2014	1. Department Checklists was included. 2. Procedure explained with more clarity. 3. Audit Schedule frequency from 3 to 6 months. 4. Formats explained with more clarity.	---
04	01.01.2018	1. SOP format changed make to inline with SOP-QA-001-05. 2. Definitions are included. 3. NC numbering system modified. 4. Non-Compliance status record for Internal Audit format is introduced newly.	CCF/GEN/ 17037
05	15.06.2019	1. Procedure is included for review of the previous year's audit completion and its closures dates. 2. NC Report and Internal audit schedule format has been revised. 3. Department checklists modified.	CCF/GEN/ 19009
06	11.09.2021	SOP has been revised by including the section 5.13.2.	CCF/GEN/ 21012
07		SOP has been revised by including timelines for Audit response.	CCF/GEN/ 22003

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	R.Pallavi	T. Ramya	K.V. Nagendra kumar
Department	Quality Assurance	Quality Assurance	Quality Assurance