Discovery Labs	STANDARD OPERATING PROCEDURE			
	SOP No.:	SOP-QC-051-01	Effective Date:	
	Supersedes:	SOP-QC-051-00	Next Review Date:	
	Department:	Quality Control	Page:	1 of 4
TITLE: HANDLING OF INCIDENTS				

1.0 PURPOSE:

To lay down a procedure for Identification, Reporting, Investigation and Implementation of corrective and Preventive action for incidents.

2.0 SCOPE:

This procedure is applicable to address the incidents reported through unexpected activities/actions and failures reported for documentation having impact on quality system for all departments at Discovery Laboratories P Ltd.

3.0 RESPONSIBILITY:

3.1 All departments are responsible to identify and report any incident.

3.2 Head-QA/Designee is responsible to review the incidents and assessing the impact.

3.3 Head-QA/Designee is responsible to close the incident in consultation with department Heads.

4.0 DEFINITIONS:

4.1 **Incidents:**

An incident is undue, unexpected action, activity or event resulting to non compliance with procedures/specifications/approved documents.

5.0 PROCEDURE:

5.1 Incidents shall report the following circumstances in the quality control, but not limited to;

5.1.1 Quality Control sampling and testing

5.1.2 Working/Reference standards management

5.1.3 Stability studies

5.1.4 Volumetric solutions/reagents handling

5.1.5 documentation

5.1.6 Re-printing / Damage in print

5.2 Any potential incident occurred during any activity shall be notified by the person who observed the incident.

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5.3 Person who identified/ handle the incident in consultation with in-charge shall fill the incident report.

5.4 The incident details shall be reviewed by immediate supervisor along with the person notified the incident.

5.5 The incident report shall be submitted to the quality assurance department.

5.6 QA assign incident number as follows;

ICR-XX-YYZZZ

Where,

ICR : Represents for "Incident control report"

XX : Represents for "Department Code"

ZZZ : Represents the "serial number" from 001

YY : Represents for "year code"

(e.g.: ICR-QC-17001 is the first incident report number in the year 2017)

5.7 Upon receipt of incident, QA personnel shall enter the incident details in Incident log (QC050-FM107).

5.8 Investigation and impact assessment shall be carried out by QA co-ordination with respect department personnel.

5.9 Training shall be provided by Head or designee on requirement.

5.10 Department Head / Designee shall take necessary measures to avoid reoccurring of such incidents.

5.11 Closure comments shall be made by Head-QA or his designate after review and assessment of the incident.

5.12 Some typical examples of incidents with respect to practice are given below.

5.12.1 Wrong Analytical Report Number allocations.

5.12.2 Transcriptional errors during reports and certificate of analysis compilation.

5.12.3 Improper integration of chromatograms

5.12.4 Damage or missing of documents.

5.12.5 Damage or misprinting of labels

5.12.6 Injection sequence is not followed as per respective STP.

5.12.7 Errors in results found during review

5.12.8 Stand alone computer system crash connected to instrument.

5.12.9 Spillage during charging of materials

5.12.10 During handling of the materials

5.12.11 Preventive maintenance

5.12.12 Calibrations

5.12.13 Quality Management systems

5.13 Some typical examples of incidents where incidents report is not required.

5.13.1 Chromatograms, disregarded due to system suitability failure, retention time shifting, area variation, peak splitting, blank interference, carryover, baseline noise/drift, spikes, wrong label of peak names and bracketing standard failure.

5.13.2 Instrument failure due to missing vial, lost prime; Needle malfunctioning, Column overpressure, column leakage and communication errors.

5.13.3 Incorrect information entered in sample set (i.e. Batch Number, Column ID No., Sample name etc.)

5.13.4 Analysis repetition due to instrument break down or malfunctions.

5.13.5 Data correction in documentation due to wrong entry.

5.13.6 Re printing and issue of labels.

5.13.7 IR spectra with % transmittance less than 60% at wave number 2000

5.14 For the incidents mentioned under section 5.13, the following corrective actions shall be initiated.

5.14.1 Disregarded chromatograms/data charts shall be filled with reason for disregard on the first page of chromatograms/data charts set.

5.14.2 Corrective action shall be taken by noting down the appropriate remarks in equipment usage log register in case of analysis repetition.

5.14.3 In case of incorrect information entered in chromatograms / errors found in documentation due to wrong entry, the error shall be crossed out once, with analyst signature and date.

5.15 If any error observed in the documents before releasing the batch/document, the errors shall be corrected on the same documents with signature and date. If the any errors observed after releasing the batch/document, an Errata report shall be prepared and attached to the original report/data.

5.16 The investigation process shall include review of the pre and post batch samples which are associated with the cause of incidence where ever required.

5.17 Incident shall be closed within 5 working days from the data of initiation with necessary CAPA implementation, justification needs to be given in case of extension of the specified timeline.

6.0 FORMATS / ANNEXURE(S):

6.1 Incident Report : QC050-FM110

6.2 Incident Log Register : QC050-FM111

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref CCF No.
00		New SOP prepared.	--

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