PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Incident Reporting in Quality Control Laboratory	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for Incident reporting in Quality Control Laboratory.

2.0 SCOPE:

This SOP is applicable for incident reporting of any Malfunctioning of Instrument, Manual error or any other incident occurring in Quality Control laboratory.

3.0 RESPONSIBILITY:

Officer, Sr. Officer, Executive – Quality control

Head – Quality Control

4.0 PROCEDURE:

4.1 Malfunctioning of Instrument

4.1.1 During analysis on instruments like HPLC, GC, TOC, UV etc. minor malfunctioning may occur due to some reasons because of which the software may show some errors.

4.1.2 The different types of malfunctioning are pump leakage, column leakage, injector problem, etc.

4.1.3 Due to these errors / malfunctioning, testing may be delayed & there may be loss in injections.

4.1.4 As soon as these errors are encountered or any malfunctioning occurs in the instrument, the same shall be immediately reported to Section head or his designee for necessary action. In the absence of Section head or his designee, report to QC Head.

4.1.5 Section head or his designee shall immediately appear at the site and shall look into the problem and investigate it.

4.1.6 Section head or his designee shall report to the QC Head for the incident and QC personal shall initiate the “Incident Report” form (Annexure-I).

4.2 Manual Error

4.2.1 Manual error is caused due to Analyst error.

4.2.2 The types of errors that are caused by Analysts are as follows (but not limited):

4.2.2.1 Preparation of wrong dilutions of solutions.

4.2.2.2 Preparation of incorrect reagent solutions, volumetric solutions, buffer solutions, media etc.

4.2.2.3 Wrong data entry of samples in instruments.

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4.2.2.4 Errors occurring during weighing.

4.2.2.5 Errors occurring due to mishandling of instruments/equipments.

4.2.2.6 Use of short cuts in method of analysis during testing.

4.2.2.7 Use of improper grade of reagents during preparation of mobile phase, reagent solution, volumetric solutions etc.

4.2.3 In exceptions to these, there may be other errors that are accountable and shall be documented.

4.3 Section head or his designee shall fill 'Incident Report' form (Annexure-I) giving details of the Incident and probable reason for the incident.

4.4 The Incident report shall be numbered as

IR/001/21

Where, IR = Incident Report

/ = Slash

001 = Serial No.

21 = Year

4.5 QC Head shall do the primary investigation and write the comments. This shall be then forwarded to QA Head.

4.6 The incident report shall be signed and closed by QC and QA Head after taking corrective action.

4.7 All the incidents shall be recorded in 'Incident Report' register and reviewed six monthly.

4.8 In case of any OOS observation, the incident shall be further investigated as per SOP.

5.0 ANNEXURE (S):

Annexure-I : Incident Report Form

Annexure-II : Incident Report Register

6.0 REFERENCE (S):

SOP: Handling of Out of Specification Results.

SOP: Preparation, approval, distribution, control, revision and destruction of Standard Operating Procedure (SOP).

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7.0 ABBREVIATION (S)/DEFINITION (S):

SOP – Standard Operating Procedure

HPLC – High Performance Liquid Chromatography

GC – Gas Chromatography

TOC – Total Organic Carbon

QC – Quality Control

QA – Quality Assurance

REVISION CARD

S. No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No
1	00	---	---	New SOP	---

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ANNEXURE – I

RESTRICTED CIRCULATION

INCIDENT REPORT FORM

Initiated By:		**QC Department**		**Date:**		
Incident Report No.:	**IR/**					
Incident Related To	☐	Equipment / Instrument	☐	Analyst	☐	Other
Name of Product / Material:						
Batch No. / A. R. No.:						
Name of Analyst:		**Stage:**				

Details of Incident

Sign:	**Date:**

Primary Investigation and Comment (QC-Head)

Sign:	**Date:**

Review and Corrective actions (as suggested) by QA-Head

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Sign :	**Date:**

Implementation status of Corrective action taken (QC Head)

Sign :	**Date:**

Closure

Affected documents closed: Yes / No.	
Head-QC	
Sign :	Date :
Approved by Head-QA	
Sign :	Date :

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INCIDENT REPORT REGISTER

Reference SOP No.:

S.No.	Date	Incident No.	Incident details	Type of Incident	Corrective Actions	Incident closure date	Remarks