PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Incidents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for Handling of Incidents.

2.0 SCOPE:

This SOP is applicable to all the manufacturing sites.

3.0 RESPONSIBILITY:

CQA (Officer/ Executive)	**:**	Preparation, Distribution (To Plant-QA & Corporate Departments), Revision, Retrieval and Destruction of this SOP. Issuance of Incident Form and to maintain the Log for all Corporate Departments.
CQA (Operating Manager)	**:**	Review, Training and Effective implementation of this SOP. (To Plant-QA and other Corporate Departments)
Plant QA (Officer/ Executive)	**:**	Preparation of Plant SOP in accordance with this SOP and Retrieval of this SOP. Issuance of Incident Form and to maintain the Log for Plant.
Plant QA (Operating Manager)	**:**	Training and Effective Implementation of this SOP to all Concerned Department of Plant.
Initiator (Concerned department)	**:**	Initiation of the Incident.
Initiating Department (Head)	**:**	Training and Implementation of this SOP. Review of Incident. Impact / Risk Assessment, Root Cause Analysis and CAPA Implementation.

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Incidents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

4.0 ACCOUNTABILITY:

Head CQA : Approval, Authorization, ensure Training and Implementation of this SOP. Authorization of Incident (for all Major Incidents for Plant and Corporate). Approval / Rejection and Closure of Incident for all Corporate Departments.

Head QA : To ensure Training and Effective Implementation of this SOP. Approval / Rejection and Closure of Incident at Plant.

Head R & D (If Applicable) : Evaluation of Incident.

Head Operations (If Applicable) : Assessment of Incident.

Head DRA : To review the observed incident and evaluate the impact assessment. Notification to the Regulatory Agencies / QP / MAH etc.

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
CAPA	Corrective Action and Preventive Action
CHR	Corporate Human Resource
CIT	Corporate Information Technology
CQA	Corporate Quality Assurance
DRA	Drug Regulatory Affairs
EHS	Environment Health and Safety
GMP	Good Manufacturing Procedure
INC	Incident
No.	Number
PPIC	Production Planning and Inventory Control
QA	Quality Assurance
QRA	Quality Risk Analysis
R&D	Research and Development
RA	Regulatory Affairs
RCA	Root Cause Analysis
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 DEFINITION:

6.1.1 **Incident:** An event which is undesired / unexpected observed or noticed.

6.1.2 **Repetitive Incident:** An incident which has an occurrence of three times in a focus area and similar in nature within three months review period shall be considered as

Repetitive Incident.

6.1.3 **Major Incident:** The Incident which is having direct impact on Safety and Quality of the Product of which the impact to patient / personnel is highly probable, including life threatening situation.

6.1.4 **Moderate Incident:** The Incident which is having indirect impact on Safety and Quality of the Product of which the impact to patient / personnel is most probable, including life threatening situation.

6.1.5 **Minor Incident:** The Incident which is having no impact on Safety and Quality of the Product of which no impact to patient / personnel.

6.2 INITIATION OF INCIDENT:

Note: Any concerned personnel can initiate the incident.

6.2.1 Initiating department shall raise the request to CQA / QA for Incident Form in the Format **as shown in Annexure-XI "Request Form for Issuance of SOP / Format"** of **CQA SOP "SOP on SOP"**.

6.2.2 CQA / QA Officer / Executive shall assign a Incident Number in '**Incident Log Book**' as shown in **Annexure–II** and same no. shall be entered in Incident Form as shown in **Annexure-I.**

6.2.3 **Assignment of Incident Number:**

6.2.3.1 Following Numbering system shall be followed in Corporate Department(s) in which EQMS Software has not been implemented:

Incident Number shall be assigned as,

INC/X/YY/NNNN

Where,

INC	**:**	Denotes Incident
/	**:**	Denotes Separator
X	**:**	Denotes Plant Code
YY	**:**	Denotes the last two digits of the Current Year
NNNN	**:**	Denotes the Serial Number starting from 0001

Example: INC/A/24/0001→ Denotes First **Incident Form** of Plant raised in year 2024.

In case of all Corporate Incident, plant code shall not be followed and Number shall be assigned as follows **INC/X/YY/NNNN**.

Example: INC/CQA/24/0001→ Denotes First **Incident Form** of CQA raised in year 2024.

Note: For Plant code Refer CQA SOP No. CQA/001 "SOP on SOP".

6.2.3.2 In case of EQMS software is not working due to break down, server down etc. in Corporate /Plant(s) in which EQMS software has been implemented following Numbering system shall be followed manually:

Incident Numbering System for Plant:

INC/X/VV/M/YY/NNN,

Where,

INC	**:**	Denotes Incident
/	**:**	separator
X	**:**	Denotes Plant Code
VV	**:**	Denotes Plant Department Code (For e.g. QA, QC, HR etc.)
M	**:**	Denotes Identification for Manual Incident
YY	**:**	Last two digits of the Calendar Year
NNN	**:**	Serial Number of the Incident(s) raised in current Calendar Year.

Example: INC/C/QA/M/24/001: Denotes first Manual Incident QA raised in year 2024.

Note:
For Plant Specific Department Code refer Plant specific "SOP on SOP".

Incident Numbering System for Corporate:

INC/X/VVV/M/YY/NNN

Where,

INC	**:**	Denotes Incident
/	**:**	separator
X	**:**	Denotes Corporate i.e. 'COPR'
VVV	**:**	Denotes Corporate Department Code (For e.g. CQA, CIT, CHR etc.)
M	**:**	Denotes Identification for Manual Incident
YY	**:**	Last two digits of the Calendar Year
NNN	**:**	Serial Number of the Incident(s) raised in current Calendar Year.

Example: INC/COPR/CIT/M/24/001: Denotes first Manual Incident of CIT dept. raised in year 2024.

Note:
For Corporate Department Code refer CQA SOP "SOP on SOP".

6.2.4 Any Incident occurred or noticed in Facility / Process / Equipment / Instrument / Document / Utility / Software / System /any other, the concerned personnel shall immediately inform to his/her Concerned Department Head or his designee and the concerned QA/CQA Personnel who shall decide in consultation with Head CQA/QA, whether to continue the Process or Stop the Process / Activity.

6.2.5 Incidents shall be classified as Major, Moderate and Minor.

6.2.6 In case of Major and Moderate Incident, the Concerned Department Head or his / her Designee in consultation with QA shall assess decision taken by him or her based on impact assessment and risk involved in the process for holding the operation (using '**HOLD**' label) until the Incident is investigated or disposed off or to continue the production and / or any activity.

6.2.7 Initiator of Concerned Department shall initiate the **'Incident Form'** in format as shown in **Annexure-I** after identification of Incident immediately or within 24 hrs. (if having justified reason).

6.2.8 The concerned Person / Department Head along with Head CQA/QA shall arrange to investigate Incident as per **CQA SOP "Root Cause Analysis".**

6.2.9 Incase of minor Incident is repeated for a significant three times, it shall be considered as moderate Incident. Further, investigation shall be followed by an Impact assessment and finally followed by CAPA.

6.2.10 In case of Moderate Incident which has potential to alter the quality of product, shall be implemented only after proper evaluation, impact and Risk assessment by Concerned Department Head or his / her Designee in consultation with Head CQA/QA who shall assess for its adequacy, accuracy, correctness and completeness of decision taken by Concerned Department Head.

6.2.11 In case Major Incident which has potential to alter the quality of product shall be implemented only after proper evaluation, impact and Risk assessment by Concerned Department Head or his / her Designee in consultation with Senior Management, Head CQA, Head QA and Head DRA (If applicable).

6.2.12 Incidents can be categorized as per following Table but not limited to:

S.No.	Incident Category	Description
1.	Spillage	Fall, Drop or leakage of chemicals, Starting Material or Drug Products (Other than process loss)
2.	Breakage	Breakage of glassware or any machine part during manufacturing
3.	Document	Damage of document, Fall, Drop or leakage of chemicals on document
4.	Person	Garment torned during Entry/Exit
5.	Measurement/ Calculation	Calculation Errors
6.	Handling of Material	Wrong material taken, mix-up of containers of two Batches/Products/Packaging Materials
7.	Breakdown	Any breakdown or malfunctioning

6.2.13 The initiator of Concerned Department shall write the Incident details (Incident noticed for, product details) specifying the area like compression, coating, packing, filling etc.

6.2.14 The initiator of Concerned Department in consultation with Concerned Department Head shall mention the Observed Incident along with Status of Operation (Stopped / Continue/ Hold) in Incident form.

6.2.15 Head of Initiating Department shall identify the Repetitive Incident (If any) in consultation with CQA/QA and same shall be recorded in the Incident Log book. e.g. in case first, second, third time repeated incident, shall be written as I, II, III and so on.

6.2.16 Initiating Department Head in consultation with Head CQA/QA shall take immediate remedial action and record the same in Incident Form.

6.2.17 In case, if there is any impact on the other batches / products shall be evaluated by Concerned Department Head.

6.2.18 Initiating department Head shall perform the investigation for incident through Root Cause Analysis as per **CQA SOP "Root Cause Analysis"** and **RCA No.** shall be recorded in Incident form.

6.2.19 Impact assessment and Risk assessment shall be performed as per **CQA SOP "Quality Risk Management"** and **QRA No.** shall be recorded in Incident form.

6.2.20 Based on the outcome of investigation, Categorization of Incident shall be done by Initiating Department Head as Major, Moderate or Minor.

6.2.21 The categorization of Incident shall be based upon the impact and risk involved in the process, product and patient(s) Health and Safety.

6.2.22 Initiating department Head if required shall provide the details of additional testing / activity to the applicable other Concerned Departments Head or his designee.

6.2.23 Target completion date and person responsible to perform additional testing / activity shall be provided by the other Concerned Departments Head or his designee and shall sign the Incident form.

6.3 SELECTION OF INCIDENT COMMITTEE:

6.3.1 Operating Manager CQA/QA shall evaluate the Incident Form and same shall be forwarded to the Incident Committee for their Impact assessment, evaluation and review comments.

6.3.2 Incident shall be forwarded to other Department(s)) based on impact assessment including production, Engineering, Quality control, Warehouse, PPIC, HR, Information Technology and EHS Department etc. for their review comments, where applicable.

6.3.3 Operating Manager CQA/QA shall review the comments received from the committee and shall enter the final tentative completion Date of Incident Closure considering review comments and TCD provided by the Incident committee.

6.3.4 Head Operations shall also review the review comment(s) of the committee, except for Incident related to QMS system of QA, QC and CQA department.

6.3.5 Operating Manager CQA/QA shall evaluate the Incident for its adequacy and correctness, and submit to Head CQA for Approval / Rejection.

6.3.6 If required, Head QA shall further provide notification to Drug Regulatory Affairs (Marketing Authorization Holder / QP) / Customer / R&D / CQA and others (if applicable) for review comments.

6.4 APPROVAL OR REJECTION OF INCIDENT:

6.4.1 After receiving the review comments from all the Concerned Departments and response of notification if required, re-categorization of Incident shall be done by Head CQA/QA with proper justification.

6.4.2 The need of CAPA shall be evaluated by Head CQA/QA as per **CQA SOP "Corrective Action and Preventive Action (CAPA)"** and CAPA Reference No. shall be recorded in the Incident form and Incident Log Book.

6.4.3 Final assessment of Incident shall be performed by Head CQA/QA for approval or rejection with sign and date.

6.4.4 The intimation for the approval / rejection of Incident with justification shall be given to initiating department Head by Head CQA/QA.

6.4.5 In case of Approval / Rejection, Incident Form shall be submitted to QA and same shall be logged by QA with sign & date in "Incident Log Book" as shown in **Annexure-II.**

6.4.6 In case of Approval / Rejection of Corporate Incident, Incident Form shall be submitted to CQA department and same shall be logged by CQA with sign & date in "Incident Log Book" as shown in **Annexure-II.**

6.4.7 In case of Major Incident, the final assessment of Incident shall be authorized by Head CQA.

6.5 POST IMPLEMENTATION REVIEW AND CLOSING OF INCIDENT:

6.5.1 After receiving the approved Incident Form, the Concerned Department shall execute the proposed CAPA**.**

6.5.2 Operating Manager CQA/QA shall monitor and review the compliance of CAPA.

6.5.3 In case occurrence of Major Incidents, a Change control procedure shall be followed to fix the problem as per the current version of **CQA SOP "Change Management".**

6.5.4 In case occurrence of three Moderate repetitive Incidents, a Change control procedure shall be followed to fix the problem as per the current version of **CQA SOP "Change Management".**

6.5.5 In case occurrence of Minor repetitive Incidents, a trend shall be considered for further impact evaluation. If required, change control procedure shall be followed need based.

6.5.6 After completion of CAPA, Head Operations (if applicable) shall provide the closure comments.

6.5.7 Operating Manager CQA/QA shall review the completeness of Incident and shall provide closure comments.

6.5.8 Head CQA/QA shall further review the post implementation for its correctness and completeness with closure comments.

6.5.9 Incident Form shall be closed within 30 working days from the final TCD provided by Operating Manager CQA/QA, if required extension shall be planned based on **"Delay Justification Report for Closure of Incident"** as shown in **Annexure-III.**

6.5.10 Only three extensions shall be applicable based on proper justification as per **Annexure-III "Delay Justification Report for Closure of Incident"**.

6.5.11 In case of 1st, 2nd and 3rd extension, Head Operations (if applicable) shall give their review comments on delay justification.

6.5.12 In case of Major Incident, the authorization notification shall be required by Head CQA for their review comments for extension of Major Incident.

6.5.13 The Delay Justification shall be approved / rejected by Head CQA/QA based on justification and revised Target Completion Date.

6.5.14 Timeline for 1st and 2nd extension shall be acceptable based on delay justification and Impact Assessment as per **Annexure-III "Delay Justification Report for Closure of Incident"** with revised Target completion date.

6.5.15 In case of 3rd extension, the recommendation from Head Operations (if applicable), Head QA and authorization from Head CQA in consultation with senior management shall be required.

6.5.16 In case the Incident(s) is not closed within proposed target completion date of 3rd extension, then upon consultation by Head initiating department, Plant Head, Plant QA Head and Head CQA, the top management shall decide for further line of action based on impact assessment and risk assessment or discontinuation of proposal.

6.5.17 After closure comments by Head CQA/QA, Incident Form shall be submitted to CQA/QA and same shall be documented by CQA/QA in the Incident Logbook.

6.5.18 Review and Trending of Incident shall be performed on monthly basis (except EQMS Software) for Major, Moderate and Minor Incidents as per format shown in **Annexure-IV "Trend Chart for Incidents".**

6.5.19 Trends shall be prepared graphically (bar charts) and further shall be reviewed by the Operating Manager CQA/QA and Approved by Head CQA/QA for any reoccurrence of "Repetitive Incident".

6.5.20 The Original Copy of the Incident Form shall be submitted to CQA / QA and the Photocopy (stamped as "Reference Copy") of the same shall be attached to respective product BPCR in which Incident has occurred.

6.5.21 In case more than one document affected, reference Incident No. with asterisk mark (*) shall be mentioned in the respective document with sign & date.

6.5.22 Incident Procedure shall be followed as per format shown in **Annexure-V "Flow Chart for Handling of Incident".**

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Incident Form	
Annexure-II	Incident Log Book	
Annexure-III	Delay Justification Report for Closure of Incident	
Annexure-IV	Trend Chart for Incidents	
Annexure-V	Flow Chart for Handling of Incident	

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Corporate Quality Assurance
- Controlled Copy No. 02 Corporate Information & Technology
- Controlled Copy No. 03 Corporate Accounts
- Controlled Copy No. 04 Corporate Purchase
- Controlled Copy No. 05 Corporate Human Resource
- Controlled Copy No. 06 Corporate Health & Medical Services
- Controlled Copy No. 07 Corporate Pharmacovigilance
- Controlled Copy No. 08 Corporate Environment, Health & Safety
- Controlled Copy No. 09 Corporate PPIC
- Controlled Copy No. 10 Corporate DRA
- Master Copy Corporate Quality Assurance

9.0 REFERENCES:

- ICH Q7 Good Manufacturing Practice Guide For Active Pharmaceutical Ingredients.
- Draft Guidance WHO Deviation Handling and Quality Risk Management, July 2013.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Incidents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-I (Specimen Copy)

LOGO	***X-----** **LOCATION **QUALITY ASSURANCE**#
INCIDENT FORM	
Incident No.:	

Note: If space is insufficient for recording the information, the same shall be recorded in additional attachment sheet duly signed.

Part A: Initiation of Incident	
Initiating Department: **Incident Observed on (Date & Time):** **Incident Initiation (Date & Time):** **Incident Initiated By (Name):**	
Incident Noticed for (Mark Tick √): **(Facility / Process / Software / Equipment / Instrument / Documents / System / Utility / Any others) etc.**	Specify Area : Document No. / Title:
Product Details: Product Name :	**Batch No. :**
Mfg. Date :	**Exp. Date :**
Market :	**Pack Size :**
Observed Incident:	
Status of Operation : (Mark Tick √) Stopped : ☐ Continue : ☐ Hold ☐ **Initiated By:**	
Name: **Sign:** **Date:**	
Incident No.:	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Incidents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Repetitive Incident if any:

1. Incident No. _____ 2. Incident No. _____ 3. Incident No. _____

Immediate Remedial Action Taken (If Any):

Impact on other Batch(es) / Product(s) if any:

Evaluation and review comments:

Detailed Investigation for Incident:

RCA: Applicable ☐ **Not Applicable:** ☐

If Applicable, RCA No.:
If Not Applicable, then mention Justification / Comments:

Impact Assessment/Risk Assessment of Incident Product Quality / Area / System / Document / Patient Health & Safety :

QRA: Applicable ☐ **Not Applicable:** ☐

If Applicable, QRA No.:
If Not Applicable, then mention Justification / Comments:

Reviewed by Initiating Department Head:

Name: Sign: Date:

Incident No.:

Classification of Incident : (Mark Tick √) Major : ☐ **Moderate:** ☐ **Minor:** ☐

Any Additional testing / Activity Requirements, If any:

Responsible Person: TCD:

Initiating Department Head (Sign & Date)

Other Department (Sign & Date)

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Handling of Incidents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Part B: Selection of Incident Committee (By Operating Manager QA):

Impact Assessment, Evaluation and Review Comments by Incident Committee: Tick (✓/X) mark where applicable by Operating Manager QA.

☐ **Manager Production**	**Review Comments:** **TCD:** **Responsible Person:** **Name:** **Sign:** **Date:**
☐ **Manager Engineering**	**Review Comments:** **TCD:** **Responsible Person:** **Name:** **Sign:** **Date:**
☐ **Manager QC**	**Review Comments:** **TCD:** **Responsible Person:** **Name:** **Sign:** **Date:**
☐ **Manager Warehouse**	**Review Comments:** **TCD:** **Responsible Person:** **Name:** **Sign:** **Date:**
☐ **Manager PPIC**	**Review Comments:** **TCD:** **Responsible Person:** **Name:** **Sign:** **Date:**
☐ **Manager HR**	**Review Comments:** **TCD:** **Responsible Person:** **Name:** **Sign:** **Date:**
Incident No.:	
☐ **Manager IT**	**Review Comments:** **TCD:** **Responsible Person:** **Name:** **Sign:** **Date:**
☐ **Manager Safety (EHS)**	**Review Comments:** **TCD:** **Responsible Person:** **Name:** **Sign:** **Date:**
☐ **Others, If any**	**Review Comments:** **TCD:** **Responsible Person:** **Name:** **Sign:** **Date:**

Review Comments by Operating Manager QA:

Tentative Completion Date:

Name: _____ **Sign:** _____ **Date:** _____

Review Comments By Head Operations (If applicable):

Name: _____ **Sign:** _____ **Date:** _____

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Incidents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Review Comments by Operating Manager QA for adequacy and correctness:

Name: _____ **Sign:** _____ **Date:** _____

Part C: Notification of Incident by Head QA:

Notification to Regulatory Affairs (Marketing Authorization Holder / QP):
Review Comments:

Name: _____ **Sign:** _____ **Date:** _____

Notification to Customer:
Review Comments:

Name: _____ **Sign:** _____ **Date:** _____

Notification to R & D, if applicable:
Review Comments:

Name: _____ **Sign:** _____ **Date:** _____

Incident No.:

Notification to CQA (if applicable):
Review Comments:

Name: _____ **Sign:** _____ **Date:** _____

Notification to Others, if applicable: (Specify:_____)
Review Comments:

Name: _____ **Sign:** _____ **Date:** _____

Part D: Approval or Rejection of Incident by Head QA:

Re-categorization of Incident (if required): (Mark Tick √) Major: ☐ **Moderate:** ☐ **Minor:** ☐
Justification for Re-categorization:

Corrective and Preventive Action : (Put '√'Mark) **Required** ☐ **Not Required** ☐
If required, Reference CAPA No.: **Responsible Person:**
If not required mention justification:

Final Assessment: Tick mark (✓/x): Approved ☐ **Rejected** ☐

Review Comments:

Name: _____ **Sign:** _____ **Date:** _____

Intimation to Initiating Department:
Review Comments:

Initiating Department Head

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Incidents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

(Sign & Date)

Authorization By Head CQA: (In case of Major Incident only)
Review Comments:

Name: **Sign:** **Date:**

Incident No.:

Part E: Post Implementation Review:

Review Comments By Operating Manager QA:

Name: _____ Sign: _____ Date: _____

Part F: Closure of Incident:

Closure Comments by Head Operations (If Applicable):

Name: _____ Sign: _____ Date: _____

Closure Comments by Operating Manager QA:

Name: _____ Sign: _____ Date: _____

Closure Comments by Head QA:

Name: **Sign:** **Date:**

Incident Closure by QA:

Incident closed on :

Name: **Sign:** **Date:**

Note: #In case of CQA documents Word QA (Quality Assurance) shall be replaced with CQA (Corporate Quality Assurance) in format.
**Location: It is the location of the plant and place.
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PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Incidents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-II

LOGO

***X-----**

**LOCATION

CORPORATE QUALITY ASSURANCE #

INCIDENT LOG BOOK

Year:

S.No.	Date of Issuance	Incident No.	Concerned Department	Issued By CQA (Sign & Date)	(Facility/ Software / Equipment / Instrument / System/Document/Utility/Any others) etc.	Description of Incident	Repeated Incident Status	Initial Categorization (Major/ Moderate Minor)	Approved / Rejected	Logged By CQA (Sign & Date)	Re-Categorization (Major/ Moderate/ Minor)	Reference CAPA No.	Incident Closed By (Sign & Date)	Remarks

Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.

**Location: It is the location of the plant and place.

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Incidents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-III (Specimen Copy)

LOGO	***X-----** **LOCATION **QUALITY ASSURANCE#**
DELAY JUSTIFICATION REPORT FOR CLOSURE OF INCIDENT	

DETAILS OF INCIDENT	
Department:	Date:
Reference Incident No.	
Description of Incident	
Previous Due date for Incident closure	

DELAY JUSTIFICATION DETAILS			
(Mark Tick √): ☐ 1st Extension	☐ 2nd Extension	☐ 3rd Extension	
Current status of Incident:			
Justification:			
Impact of delay:			
Open identified actions for closure:			
Revised Target Completion date for Closure::			

Initiated By:
(Sign & Date)

Reviewed By: Head Initiating Department
(Sign & Date)

Review Comments by Head Operations (If Applicable):

Name **Sign:** **Date:**

Approval / Rejection by Head QA: (Mark Tick √/x on applicable) ☐ **Approved** ☐ **Rejected**
Review Comments:
Name: **Sign:** **Date:**

Authorized By Head CQA: In case of Major Incident or 3rd Extension only:
Review Comments:
Name: **Sign:** **Date:**

Note: #In case of CQA documents Word QA (Quality Assurance) shall be replaced with CQA (Corporate Quality Assurance) in format.
**Location: It is the location of the plant and place.

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Incidents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

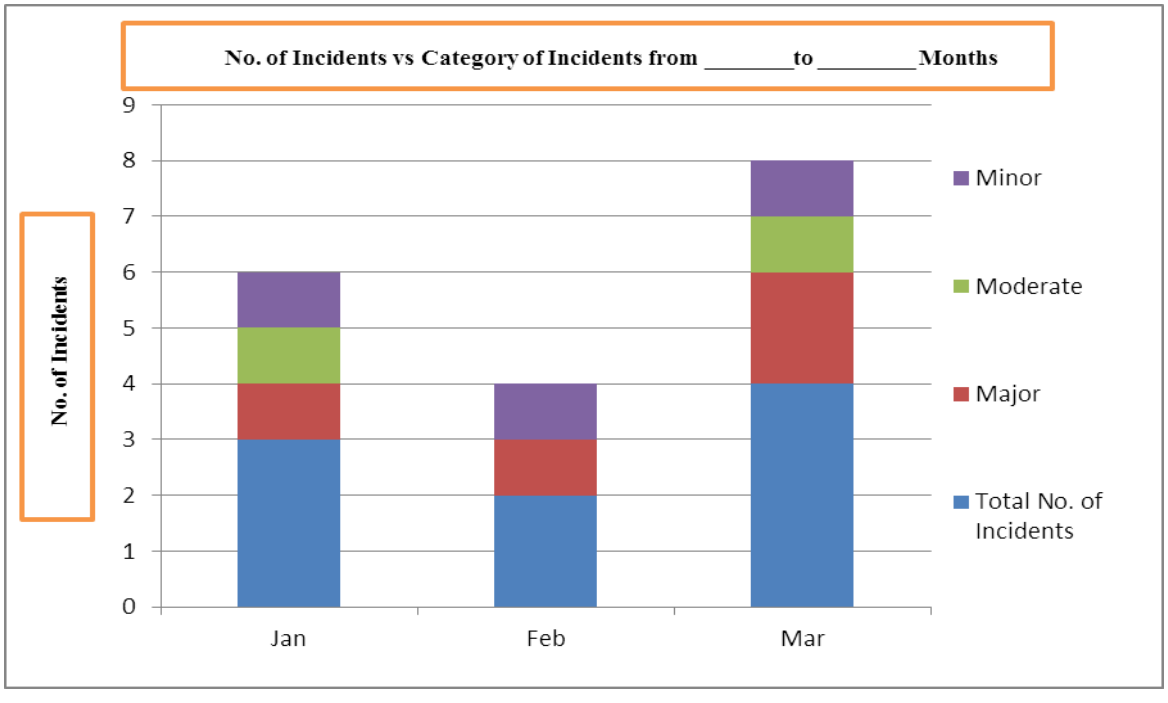
ANNEXURE-IV (Specimen Copy)

LOGO	***X------** **LOCATION **CORPORATE QUALITY ASSURANCE#**
TREND CHART FOR INCIDENTS	

1. Trend between No. of Incident(s) & Category of Incident (s):

Year: _____ **Month:_____**

S.No.	Month	Total No. of Incidents	Category of Incident		
			Major	Moderate	Minor
1.	Jan				
2.	Feb				
3.	Mar				



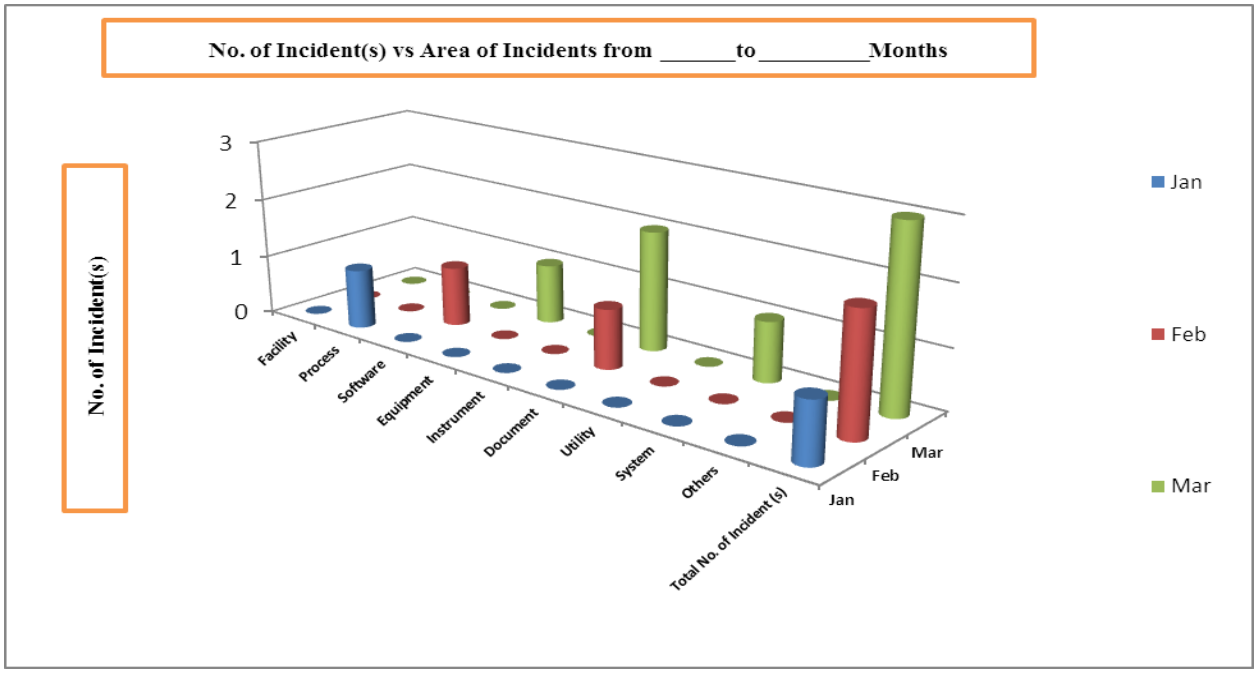
STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Incidents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

2. Trend between Total No. of Incidents & Area of Incident(s):

Area of Incident(s) like (Facility / Process / Equipment / Instrument / Documents / Utility / System / Software / Any others) etc.

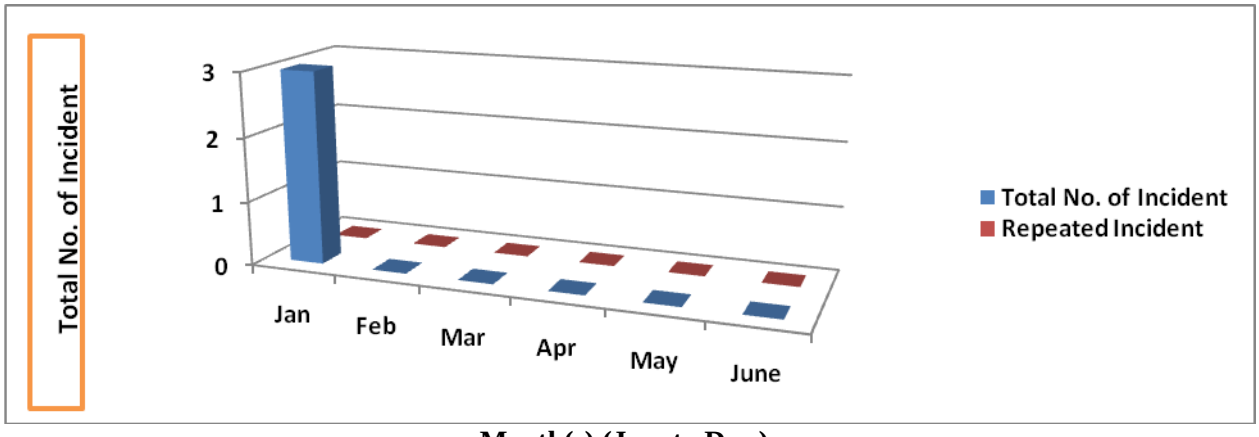
Year: _____ **Month:_____**

S.No.	Month	Area of Incident(s)									Total No. of Incident(s)
		Facility	Process	Equipment	Instrument	Document	Utility	System	Software	Others	
1.	Jan										
2.	Feb										
3.	Mar										



STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Incidents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

3. Trend between No. of Incident(s) & Name of Month:



Month(s) (Jan. to Dec.)

Review Comments:

……..

……..

Prepared By:	Reviewed By:	Approved By:
Officer/ Executive CQA	Operating Manager CQA	Head CQA
(Sign & Date)	(Sign & Date)	(Sign & Date)

(Note: Existing graphs are only for representation)

Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
**Location: It is the location of the plant and place.

PHARMA DEVILS

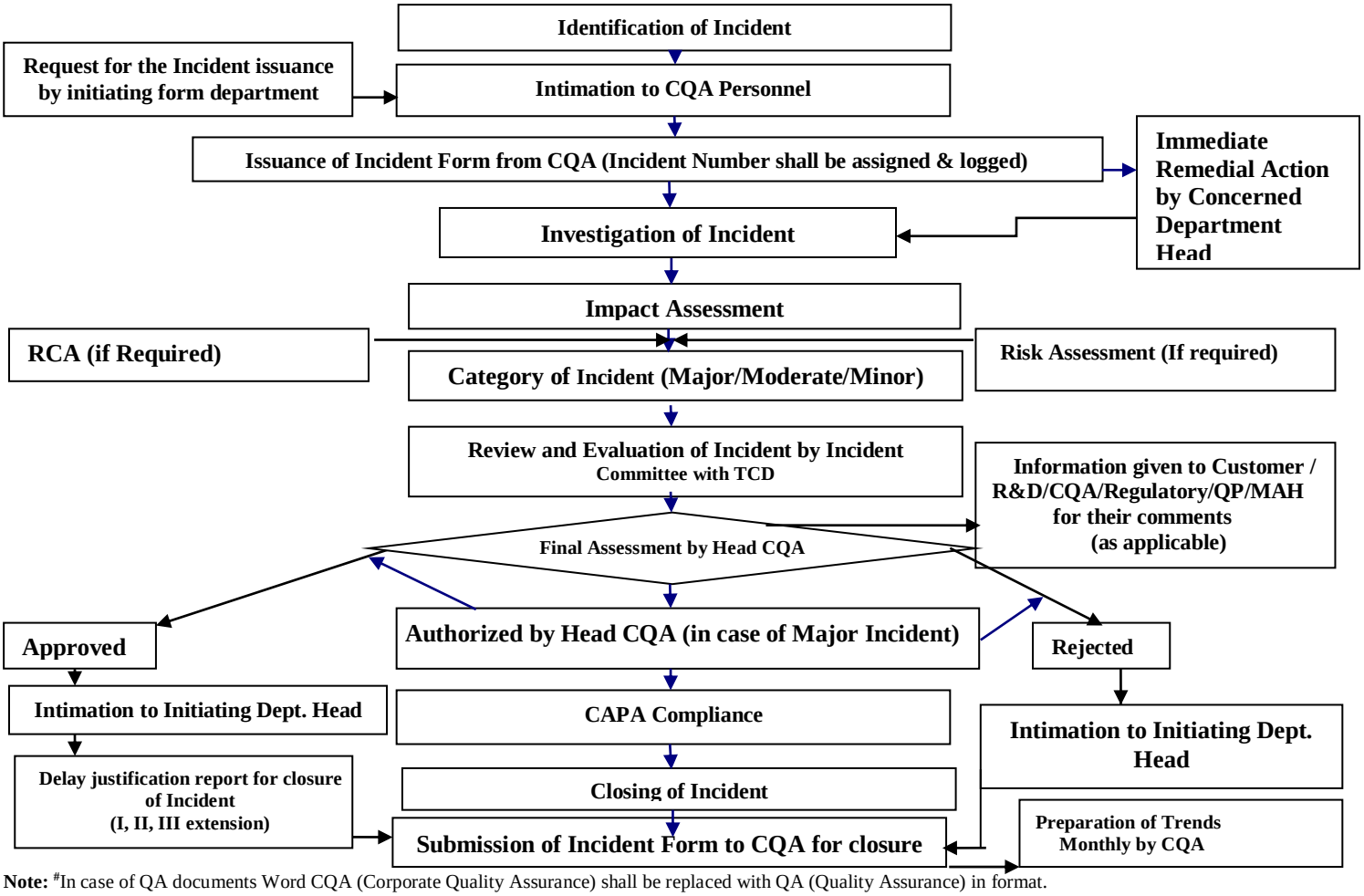
QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Incidents	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-V

LOGO	***X------** **LOCATION **CORPORATE QUALITY ASSURANCE#**

FLOW CHART FOR HANDLING OF INCIDENT



Note: #In case of QA documents Word CQA (Corporate Quality Assurance) shall be replaced with QA (Quality Assurance) in format.
**Location: It is the location of the plant and place.