DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Incident	**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 for handling of Incidents related to all Department of ……..

3.0 RESPONSIBILITY:

3.1 QA (Officer/Executive): Preparation, Distribution, Revision, Retrieval and Destruction of this SOP. Issuance of Incident Form and to maintain the Incident Log.

3.2 Manager QA: Review, Training and effective implementation of this SOP to all concerned Departments.

3.3 Initiator(Concerned Department): Initiation of the Incident.

3.4 Initiating Department (Head): Training and Implementation of this SOP. Review of Incident. Impact /Risk Assessment, Root Cause Analysis and CAPA Implementation.

4.0 ACCOUNTABILITY:

4.1 Head QA: Approval, ensure Training and Implementation of this SOP. Approval / Rejection and Closure of Incident(s) of the Plant.

5.0 DEFINITIONS:

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

5.2 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.

5.3 Critical 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.

5.4 Major 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.

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

6.0 PROCEDURE:

6.1 INITIATION OF INCIDENT:

Note: Any concerned personnel can initiate the incident.

6.1.1 Initiating department shall raise the request to QA for Incident Form in the Format **"Request Form for Issuance of Documents"** as per Format No. **F02** of SOP, Titled **"Procedure for Documentation & Data Control"**.

6.1.2 Initiator of Concerned Department shall initiate the 'Incident Form' in format as shown in Annexure-I immediately after identification of Incident.

6.1.3 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**.

6.1.4 **Assignment of Incident Number:**

INC/YY/NNN

Where,

INC **:** Denotes Incident

/ **:** separator

YY **:** Last two digits of the Calendar Year

/ **:** separator

NNN **:** Serial Number of the Incident(s) raised in current Calendar Year.

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 Personnel who shall decide in consultation with Head QA, whether to continue the Process or Stop the Process / Activity.

6.1.5 The initiator of Concerned Department shall write the Incident details (Incident noticed for, product details) specifying whether occurred during Manufacturing or packing etc.

6.1.6 The initiator of Concerned Department in consultation with Concerned Department Head shall mention the description of Incident occurred.

6.1.7 Head of Initiating Department shall identify the Immediate Remedial action taken (If any) and record the same in Incident Form.

6.1.8 **NOTIFICATION TO CUSTOMER/REGULATORY AGENCY:**

6.1.8.1 Concerned Customer/Regulatory Agency shall be notified if any Incident is applicable, which may have impact on the product quality to seek their acceptance. It is necessary to first get comments from the Concerned Customer or Regulatory Agency through scan copy / hard copy of Incident Form. Signed scan copy shall be attached with Incident Form than only Incident shall be proceeding for Approval by Head QA.

6.2 INVESTIGATION & IMPACT ASSESSMENT:

6.2.1 Initiating department Head shall perform the investigation for incident through Root Cause Analysis (If Applicable) as per SOP, Titled **"Root Cause Analysis"** and **RCA No.** shall be recorded in Incident form.

6.2.2 Impact assessment and Risk assessment (If Applicable) shall be performed as per SOP**,** Titled **"Quality Risk Management"** if there is direct impact on safety and Quality of the Product and **QRA No.** shall be recorded in Incident form.

6.3 CATEGORIZATION OF INCIDENT:

6.3.1 Based on the outcome of investigation, Categorization of Incident shall be done by Quality Assurance as Critical, Major or Minor.

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

6.3.3 In case of Major and Critical 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.

6.3.4 In case Minor Incident is repeated for a significant three times, it shall be considered as Major Incident. Further, investigation shall be followed by an Impact assessment and finally

followed by CAPA.

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

6.3.6 Types of Incidents can be summarized as per following Table but not limited to:

S.No.	Incident Type	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

6.4 REVIEW OF INCIDENT BY IMPACTED DEPARTMENTS

6.4.1 Manager QA shall evaluate the Incident Form and same shall be forwarded to other impacted departments including production, Engineering, Quality control, Warehouse etc. for their Impact assessment, evaluation and review comments, where applicable.

6.4.2 Head of Concerned Department shall initiate Corrective and Preventive action(s) (CAPA) on the basis of investigation and root cause analysis performed.

6.4.3 CAPA shall be evaluated as per SOP, Titled **"Corrective Action and Preventive Action (CAPA)"** and CAPA Reference No. shall be recorded in the Incident form and Incident Log Book.

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

6.5 APPROVAL OR REJECTION OF INCIDENT:

6.5.1 After receiving the review comments from all the Concerned Departments, final assessment of the Incident shall be done by Head QA for approval or rejection with Name, sign and date.

6.5.2 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**.

6.6 POST IMPLEMENTATION REVIEW AND CLOSURE OF INCIDENT:

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

6.6.2 Manager QA shall monitor and review the Incident, post implementation and give his/her comments.

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

6.6.4 Manager QA shall review the Incident for completeness.

6.6.5 Head QA (if applicable) shall provide the closure comments for the Incident.

6.6.6 Incident Form shall be closed within 30 calendar days from the date of approval, if required extension shall be planned based on **"Delay Justification Report for Closure of Incident"** as shown in **Annexure-III**.

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

6.6.8 Review and Trending of Incident shall be performed on Quarterly basis for Critical, Major and Minor Incidents as per **SOP.**

6.6.9 The Original Copy of the Incident Form shall be submitted to QA and the Photocopy (stamped as **"Reference Copy"**) of the same shall be attached to respective product BMR & BPR in which Incident has occurred.

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

6.6.11 Incident Procedure shall be followed as per format shown in **Annexure-IV**, Titled **"Flow Chart for Handling of Incident"**.

7.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
BPR	Batch Packing Record
CAPA	Corrective Action and Preventive Action
No.	Number
QA	Quality Assurance
RCA	Root Cause Analysis
SOP	Standard Operating Procedure
TCD	Target Completion Date

8.0 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	Flow Chart for Handling of Incident	

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No. 01 Quality Assurance Department.
- Controlled Copy No. 02 Quality Control Department.
- Controlled Copy No. 03 Production Department.

- Controlled Copy No. 04 Human Resource Department (HR).
- Controlled Copy No. 05 Engineering Department.
- Controlled Copy No. 06 Warehouse Department (Store).
- Controlled Copy No. 07 Information Technology Department

10.0 REFERENCES:

- ICH Q7 Good Manufacturing Practice Guide For Active Pharmaceutical Ingredients.

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

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STANDARD OPERATING PROCEDURE	
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Title: Handling of Incident	**Effective Date:**
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Issue Date:	**Page No.:**

ANNEXURE-I

INCIDENT FORM

Incident No.:	**Date:**
Part A: Initiation of Incident	
Initiating Department: **Incident Observed On& time:** **Incident Initiated On& time:**	**Initiated By(Name):** **Sign and Date:**
Incident Noticed for (Tick mark ✓): **Man/Equipment/Procedure/System/Facility/ Process/Utility/Documents/Any Others**	**Incident Occurred During Manufacturing/packing of Product :** **……..** **B. No. …….**

Batch Size:	**Mfg. Date:**	**Exp. Date:**
Market:	**Pack size:**	

Description of Incident:

Status of Operation : (Mark Tick √) Stopped : ☐ **Continue :** ☐ **Hold** ☐

Immediate Remedial Action Taken (If Any):

Initiator Department
Sign and Date:

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

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

Comments from Concerned Customer/Regulatory Agency (if applicable):

Name: **Sign and Date:**

Part B: Investigation& Impact Assessment

Investigation and Impact Assessment:

RCA: Applicable ☐ **Not Applicable** ☐ **If Applicable RCA No.:**

Risk Assessment: Required ☐ **Not Required** ☐ **If Required QRA No.:**

Reviewed by Initiating Department Head:
Sign and Date:

Part C: Categorization

Classification of Incident: (Tick Mark ✓): Critical: ☐ **Major:** ☐ **Minor:** ☐

Review and comments by Manager Quality Assurance:

Name: **Sign and Date:** **TCD:**

Review and comments by Manager Production:

Name: **Sign and Date:**

Review and comments by Manager Quality Control:

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

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

Name: **Sign and Date:**

Review and comments by Manager Engineering:

Name: **Sign and Date:**

Review and comments by Manager Warehouse:

Name: **Sign and Date:**

Any other Department(s), if Applicable:

Name: **Sign and Date:**

Corrective and Preventive Actions (CAPA):

Reference CAPA No.:

Reviewed by Department Head

Name: **Sign and Date:**

Part D: Approval or Rejection of Incident by Head QA

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

Review and comments:

Name: **Sign and Date:**

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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

Part E: Post Implementation Review	
Review and Comments by Manager QA:	
Name:	**Sign and Date:**
Part F: Closure of Incident	
Closure Comments by Head QA:	
Name:	**Sign and Date:**
Incident Closure by QA: **Incident closed On:**	
Name:	**Sign and Date:**

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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

ANNEXURE –II

INCIDENT LOG BOOK

Year:

S. No.	Date of Issuance	Incident No.	Concerned Department	Issued By QA (Sign & Date)	Description of Incident	Categorization (Critical/Major/Minor)	Approved / Rejected	Reference CAPA No.	Target Completion Date	Incident Closed By QA (Sign & Date)	Remarks

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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

ANNEXURE –III

DELAY JUSTIFICATION REPORT FOR CLOSURE OF INCIDENT

DELAY JUSTIFICATION DETAILS	
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)**

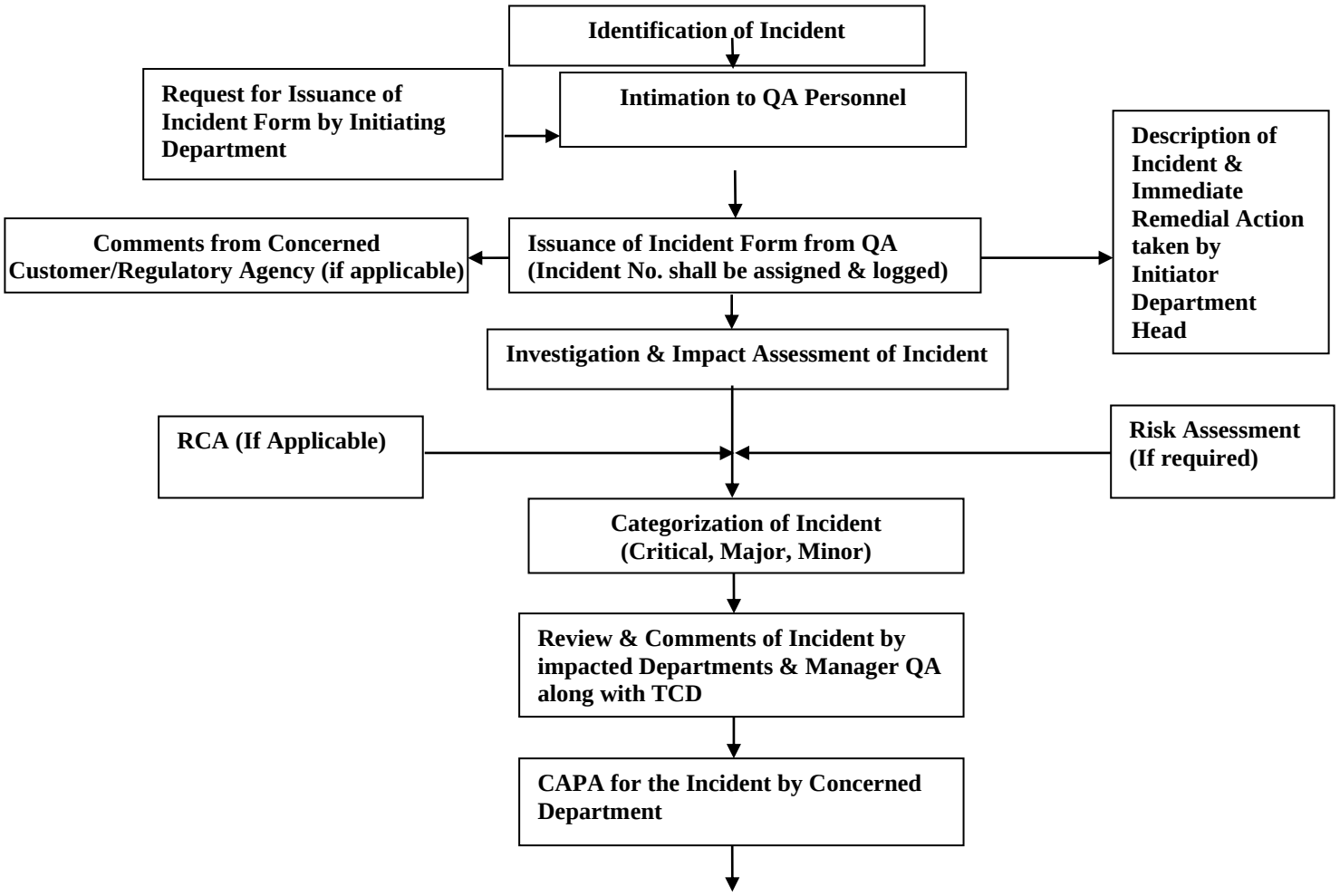
Approval / Rejection by Head QA: (Mark Tick √/x on applicable) ☐ **Approved** ☐ **Rejected**
Review Comments:

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

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

ANNEXURE-IV

FLOW CHART



DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
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