STANDARD OPERATING PROCEDURE				
Title: Hazard Identification and Risk Assessment				
SOP No.:		**Department:**	EHS	
		Effective Date:		
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1.0 OBJECTIVE:

To lay down a procedure for Hazard Identification and Risk Assessment to Operations, Processes, Activities and Events about the company's Safety System and performance as appropriate.

2.0 SCOPE:

This SOP is applicable to the Hazard Identification and Risk Assessment on all organization employees and on-site contractors' products, processes and services.

3.0 RESPONSIBILITY:

Officer/Executive–EHS: Drafting & Training of SOP.
Officer/Executive-QA: Distribution (To concern Departments) of SOP.

4.0 ACCOUNTABILITY:

Head-QA: For Approval of SOP.
Head- EHS: For Checking, Training & Effective implementation of SOP.
Officer/ Executive – Departments: Perform and implement the recommendation
HOD Department: Proper execution & revision as per requirement

5.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
No.	Number
Ltd.	Limited
QA	Quality Assurance
QC	Quality Control
EHS	Environmental Health and Safety
MTC	Medical Treatment Case
RWDC	Restricted Work Day Case
LWDC	Lost Work Day Case
TPD	Total Permanent Disability
TV	Television
CP	Control Plan

6.0 PROCEDURE:

Every employee of the organization shall be trained on his/ her area of operation prior to start the work.

6.1 HAZARD IDENTIFICATION:

6.1.1 Routine and non-routine activities.

6.1.2 Activities of personnel having access to the workplace including contractors and visitors.

6.1.3 Reported accidents and incidents

6.1.4 Safety inspection audits

6.1.5 Weekly and monthly safety meeting

6.2 RISK ASSESSMENT:

When Risk Assessment is conducted safety and efficacy need to be considered in addition to the quality concerns. During the assessment all the risks that may be reasonably expected to occur in the activity under evaluation should be listed as Medium, low and high risk classification.

Risk should be classified as follow:

High: Imminent and serious danger
Stop work & action immediately
Senior Management attention required

Medium: Moderate danger
Action as soon as possible
Management responsibility must be specified

Low: Minor to negligible danger
Manage by routine procedures
Look for ways for continual improvement

A through risk analysis is required to ensure an effective risk control. It should review the materials, activities equipment, storage, distribution and interned use of the product.

A list of the potential risks (biological, chemical and physical) which may be introduced.
In the risk analysis the following basic questions should be addressed:

- What is the nature of possible risks?
- What is the probability of their occurrence and how easy is it to detect them
- What are the consequences

6.3 QUANTITATIVE ASSESSMENT OF RISKS:

6.3.1 Emergency (E): The hazard and risk is addressed by applicable legal requirements such as Indian

Factory Act etc. or any hazard/ risk which results in fatal accidents/ severe damage to human being/ assets/ environment/ quality.

6.3.2 **Abnormal (A):** The hazard/ Risk having a concerned expressed by Employees, Neighbors, Local Resident, society**.**

6.3.3 N**ormal (N):** The hazard/ Risk having less concern or no Concern or does not have the ability to impact any human/ assets/ environment/ quality.

6.3.4 Any Hazard/ Risk which is associated with an **Emergency (E)** & **Abnormal (A)** are considered as significant risks by default irrespective of it subsequent **Risk Priority Number (RPN)** as per Quantitative Risk Assessment & necessary control measures shall be taken address all such concerns.

6.3.5 **Risk Priority Number**: After identifying the hazard & determination of risks, carrying out risk assessment & classify the risk based on the Risk Priority Number (RPN) Refer **Annexure I**.

Risk Priority Number (RPN) is obtained by multiplying the following factors:

Where, **RPN= F * S**

F - Frequency: Likelihood of the occurrence on incident
S - The risk from the hazard is determined by estimating the potential severity of the harm**.**

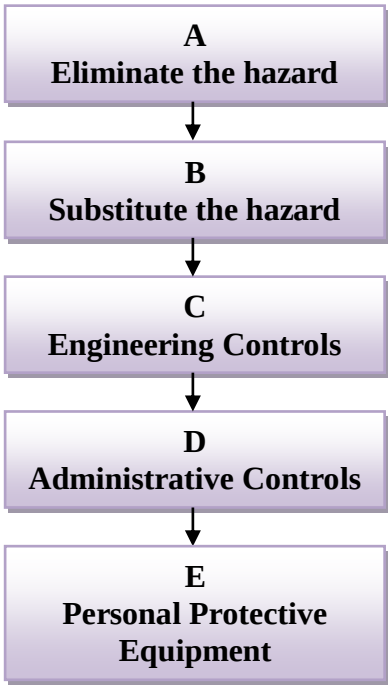
The allocating values for frequency (F) & Severity (S) is as per **Annexure II.**

6.3.6 While assigning Frequency (F) & Severity (S) rating after applying hierarchical control measure additional Control measures shall be recommendation to reduce the risks as per risk control plan mentioned in **Annexure III.**

6.4 HIERARCHY OF CONTROL:

6.4.1 The recognized hierarchy of control is as follows. Basically, the higher the risk, the higher the control measure should be up the hierarchy as per **Annexure III.**

6.4.2 The aim should always be to eliminate all high risks, then eliminate or minimize as far as reasonably practicable moderate risks by either one or a combination of control measures.



6.4.3 Where a more involved and detailed risk assessment is undertaken, the assignment of risk rating may be taken into consideration.

6.5 HIRA should be used for recording hazard identification & Risk Assessment (HIRA) as per **Annexure VI.**

6.5.1 Hazard Identification & Risk Assessment (HIRA) shall be approved by EHS Head.

6.6 HAZARDS RE-EVALUATION:

6.6.1 The hazard identification and risk assessment shall be reviewed at least once in two years or if there is change in the process and equipments.

6.6.2 To ensure proper identification of hazards, the safety officer shall review all activities.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure I	Risk Priority Number (RPN) Matrix	
Annexure II	Table for Frequency	
Annexure III	Table for Severity	
Annexure IV	Risk Based control Plan	
Annexure V	Types of controls and their effectiveness	
Annexure VI	Hazard Identification And Risk Assessment	

ENCLOSURE: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Environment, Health & Safety
- Controlled Copy No. 03 Engineering
- Controlled Copy No. 09 Quality Control
- Controlled Copy No. 10 Warehouse
- Controlled Copy No. 11 Human Resource
- Master Copy Quality Assurance

9.0 REFERENCES:

- Relevant Operational Control Procedures
- Emergency Preparedness and Response Procedures
- IS 15656:2006

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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

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ANNEXURE – I
RISK PRIORITY NUMBER (RPN) MATRIX

Frequency	**5** **(Very High –** Has happened more than once per year in the divisions)	**5** **(Low)**	**10** **(High)**	**15** **(High)**	**20** **(Very High)**	**25** **(Very High)**
	4 **(High –** Has happened in the division and more than once per year in company)	**4** **(Low)**	**8** **(Medium)**	**12** **(High)**	**16** **(Very High)**	**20** **(Very High)**
	3 **(Medium –** Has happened in the company)	**3** **(Low)**	**6** **(Medium)**	**9** **(Medium)**	**12** **(High)**	**15** **(High)**
	2 **(Low –** Happened in the Pharma industries globally last 20 years)	**2** **(Very Low)**	**4** **(Low)**	**6** **(Medium)**	**8** **(Medium)**	**10** **(High)**
	1 **(Very Low –** Happened in the industries globally last 10 years)	**1** **(Very Low)**	**2** **(Very Low)**	**3** **(Low)**	**4** **(Low)**	**5** **(Low)**
		1 **(Very Low)**	**2** **(Low)**	**3** **(Medium)**	**4** **(High)**	**5** **(Very High)**
		Severity				

ANNEXURE – II
TABLE FOR FREQUENCY

Rating	Level	Description
5	**Very High**	Has happened once during last one year in the division
4	**High**	Has happened in the division or once during last one year in the company
3	**Medium**	Has happened in the Company
2	**Low**	Happened in the Pharmaceutical industries globally during last 20 years
1	**Very Low**	Happened in the industries globally during last 10 years

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ANNEXURE – III
TABLE FOR SEVERITY

	Very Low	**Low**	**Medium**	**High**	**Very High**
	1	2	3	4	5
	Consequences Severity Increases				
People (Health & Safety)	Physical discomfort	Noticeable and requiring First Aid or slight health problem	Temporary disability (MTC/ RWDC) or health problem causing MTC/RWDC	Partial permanent Disability/ Lost work day case (LWDC) or major health problem causing LWDC	Fatal /Total Permanent Disability (TPD) or severe health problem causing Fatal/ TPD
Environmental	Negligible effect confined to within plant grounds/ environment	Minor effects neighbors adjacent to plant complain	Localize release makes local TV coverage/ newspaper	Major release make national TV coverage/ news paper	Massive damage makes international TV coverage/ new paper
Product or Service Quality	Some product or service fails to meet standards	Several costumer complains verbally	Several customer complain in within	Important/ major customer cancelled orders	Loss of substantial marked share due problem
Asset or financial loss	Slight damage is upto Rs. 10,000/-	Noticeable damage between Rs. 10,000 to 1 Lakhs	Large damage 1 Lakh to 10 Lakhs	Major damage 10 lakhs to 1 Crore	Severe damage more than 1 crore
Reputation	Slight to moderate impact	Loss of reputation at community level	Loss of reputation at state level	Loss of reputation at National Level	Loss of reputation at International Level

ANNEXURE – IV
RISK BASED CONTROL PLAN

RPN	Risk Category	(Risk Based Control Plan) Decision/ what needs to be done
<3	**Very Low Risk** (Non – Significant)	**Control Plan - 1 (CP -1)** • Activities having RPN < 3, Considered as acceptable risk. • No additional controls are necessary other than to ensure that existing controls are maintained & implemented
3 – 5	**Low Risk** (Non – Significant)	**Control Plan - 2 (CP -2)** • Activities having RPN between 3-5, considered as acceptable risk. • No additional controls are required unless they can be implemented at very low costs i.e., improved supervision, enhanced monitoring.
6 – 9	**Medium Risk** (Significant)	**Control Plan - 3 (CP -3)** • Additional control measures shall be put in place to reduce the RPN to acceptable level (less than 6) • The risk reduction measures shall be implemented within a defined period. • Arrangements shall be made to ensure that the controls are maintained.
10 – 15	**High Risk** (Significant & Unacceptable)	**Control Plan - 4 (CP -4)** • Engineering control/ Work instructions (WI) shall be followed to reduce risk to acceptable level (Less than 6) • In case of absence of work instruction (WI), job/ activity specific operational control plan (OCP) shall be developed and followed. • The work activity should be halted until risk controls are implemented. If it is not possible to reduce the risk, the work should remain prohibited. • Arrangements shall be made to ensure that the controls are maintained.
16 – 25	**Very High Risk** (Significant & Unacceptable)	**Control Plan - 5 (CP -5)** • It shall include all the requirements of control plan (CP – 4) & necessary changes by engineering controls to reduce risk to acceptable level. (Less than 6). • The work activity shall be halted until risk controls are implemented as control Plan – 5. If it is not possible to reduce the risk, the work shall remain prohibited. • Arrangements shall be made to ensure that the controls are maintained.

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ANNEXURE – V
TYPES OF CONTROLS AND THEIR EFFECTIVENESS

S.No.	Types of Controls	Effectiveness
1.	Eliminate the hazard Completely	100 %
2.	Engineering Controls: Create a barrier between the person and the hazards	40 – 99 %
3.	Administration Controls: by use &implementation of regulation, law, SOP/SWP/WI/OCP, safety procedures, etc.	20 -40 %
4.	Provide personal protective equipment	1 -20 %

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ANNEXURE – VI
HAZARD IDENTIFICATION AND RISK ASSESSMENT

Department:	**Date:**
HIRA Team: 1. **2.** **3.** **4.**	**Location:**

S.No.	Activity	Sub-Activity	Hazard	N/A/E	Risk	Existing control Measure	Risk Considering existing control measure			Addition control measures to bring risk to (ALARP level)	Residual risk after applying additional control measures			Remarks (if Any)
							Frequency	Severity	RPN (F*S)	1. Elimination 2. Substitution 3. Engg. Control 4. Administration Control 5. PPE's	Frequency	Severity	RPN (F*S)	