

**SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)**

**STANDARD OPERATING PROCEDURE**


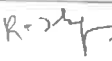
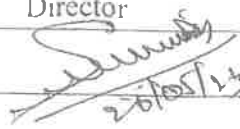
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TITLE: SAFE & AT-RISK BEHAVIORS, EHS INCIDENTS REPORTING & INVESTIGATION

including a fire, explosion, rupture, or hazardous chemical leak. Process safety incidents can pose significant risks to workers, the environment, and nearby equipment, facilities, and communities.

- 3.1.13 **Environmental Incident** - An event that may cause harm or potential harm to an environmental receptor e.g., air, water, land, wildlife, or local habitat.
- 3.1.14 **Nonconformity** - Non-fulfilment of a requirement. Nonconformity relates to requirements in this document and additional OH&S management system requirements that an organization establishes for itself.
- 3.1.15 **Corrective action** - Action to eliminate the cause(s) of a nonconformity or an incident and to prevent recurrence. The term has been modified to include reference to "incident", as incidents are a key factor in occupational health and safety, yet the activities needed for resolving them are the same as for nonconformities, through corrective action.
- 3.1.16 **Man-Hours Worked:** The total number of employee-hours worked by all employees working in the work premises. It includes all employees including contractors and visitors. Man-hours worked shall be calculated from the pay roll or time clock recorded including overtime. When this is not feasible, the same shall be estimated by multiplying the total man-days worked for the period covered by the number of hours worked per day. The total number of man-days for a period is the sum of the number of men at work on each day of the period. If the daily hours vary from department to department, separate estimates shall be made for each department and the result added together. When actual man-hours are not used, the basis on which the estimates are made shall be indicated.
- 3.1.17 **Lost Time Injury Frequency Rate (LTIFR)** – This is a safety performance indicator, which provides "the number of lost time injuries per million man-hours worked in a specific period of time. The frequency rate shall be calculated both for lost time injury and reportable lost time injury as follows:

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Name	S. Shanmukha Rao	R Elangovan	K. Sharath Reddy
Designation	Jr. Executive-EHS	DGM -EHS	Director
Sign & Date	 24/05/23	 25/05/23	 26/05/23

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**LTIFR<sub>A</sub> = (Number of lost time injuries x 10<sup>6</sup>) / Total Man-hours worked in the specified time**

**LTIFR<sub>B</sub> = (Number of reportable lost time injuries x 10<sup>6</sup>) / Total Man-hours worked in the specified time**

3.1.18 **Lost Time Injury Severity Rate (LTISR)** – This is a safety performance indicator, which provides “the number of lost days due to lost time injuries per million man-hours worked in a specific period of time. The severity rate shall be calculated both for lost time injury and reportable lost time injury as follows:

**LTISR<sub>A</sub> = (Man-days lost due to lost time injuries x 10<sup>6</sup>) / Total Man-hours worked in the specified time**

**LTISR<sub>B</sub> = (Man-days lost due to reportable lost time injuries x 10<sup>6</sup>) / Total Man-hours worked in the specified time**

3.1.19 **Incidence Rates:** It is the ratio of the number of injuries to the number of persons during the period under review. It is expressed as the number of injuries per 1000 persons employed.

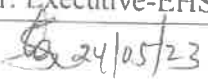

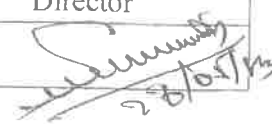
The incidence rate may be calculated both for lost-time injuries and reportable lost-time injuries as follows:

**Lost-time injury incidence rate = (Number of lost-time injuries x 1000) / Average number of persons employed during the reporting period**

**Reportable lost-time injury incidence rate = (Number of reportable lost-time injuries x 1000) / Average number of persons employed during the reporting period**

Since reportable lost-time injury incidence rate is based on the lost time injuries reportable to the statutory authorities, it should be used for official purposes only. In all other cases lost-time injury incidence rate should be used.

3.1.20 **Unsafe Behavior or At-Risk Behavior** - Any behavior that an employee engages in without regard to safety rules, standards, procedures, instructions, and specific criteria in the system. Unsafe behaviors or At-Risk Behaviors lead to unsafe practices i.e., unsafe actions and unsafe conditions.

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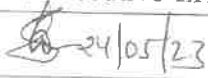

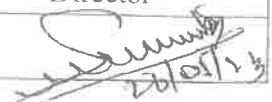
TITLE: SAFE &amp; AT-RISK BEHAVIORS, EHS INCIDENTS REPORTING &amp; INVESTIGATION

**3.2 Abbreviations:**

- SOP : Standard Operating Procedure  
 HoD : Head of Department  
 EHS : Environment Health and Safety  
 P&A : Personnel & Administration department  
 FIR : First Intimation Report  
 IICFT : Incident Investigation Cross Functional Team

**4.0 Responsibility:**

- 4.1 It is the responsibility of all employees to report unsafe behaviors (including nonconformities) and EHS incidents (include near miss, accident, ill-health, fire, explosion, process safety incident, environmental incident).
- 4.2 The responsibility of implementation and compliance with the SOP lies with all HoDs for their respective departments.
- 4.3 Block In-charge / respective engineers provide information about the incident to their manager and EHS.
- 4.4 EHS / OHC / Trained First Aiders team perform the first for injured person and inform to the Plant Head.
- 4.5 HR arrange to send the injured person to designated Hospital for further treatment, if necessary.
- 4.6 In case the injured person is hospitalized, HR communicates same to the injured person's family and arrange one person for supporting the injured person in the hospital, if necessary.
- 4.7 Site Head/Factory Manager communicates to the government authorities, whenever necessary.
- 4.8 For reportable injury, the procedure laid down in The Factories Act, 1948 and The Karnataka Factories Rules, 1969 shall be followed.

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**5.0 Accountability:**

- 5.1 The accountability of reporting work-related unsafe behaviors (includes nonconformities) and EHS incidents (include near miss, accident, ill-health, fire, explosion, process safety incident, environmental incident) and investigation based on potential risks lies with the respective HoDs.
- 5.2 The accountability of training on this SOP for awareness and competency development lies with the EHS Head.

**6.0 Procedure:**

**6.1 Safe Behaviors & At-Risk Behaviors Reporting**

- a. As the foundation to achieve “Target ZERO EHS Incident” is based at “Target ZERO Unsafe Action”, at Shilpa Pharma Lifesciences Limited, Unit-2 all employees are encouraged to report Safe Behaviors and At-Risk Behaviors in Annexure 4: Safe Attitude For Excellence in EHS Round (SAFER). The SAFER reporting is aimed at encouraging Safe Attitude for Excellence in EHS amongst SPL team members.
- b. Safe behaviors observed are the foundation of “Safe Attitude for Excellence in EHS” and shall be encouraged with “SAFER Points”. For each safe behavior observed, 10 SAFER Points shall be issued to the individual.
- c. Unsafe Behaviors (Unsafe Acts & Unsafe Conditions) observed are potential causes of EHS related incidents and necessary corrective actions shall be implemented to address them promptly.

**6.2 EHS Incidents Reporting**

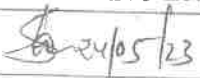

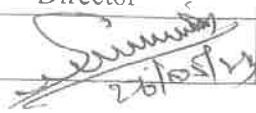
- a. If any near miss/incident happened, FIR (in Annexure 2) shall be given to EHS Dept within 1 hour. For high severity incidents, FIR can be submitted as early as possible after providing emergency support to the injured person.
- b. EHS In-Charge shall number the reported incidents in the Format IR-YYYY-MM-SN, where:

IR: Stands for “Incident Reported”

YYYY: Stands for “Year”

MM: Stands for “Month” starting with “01” for Jan till “12” for Dec.

SN: Stands for “Serial Number” starting with 01, 02 and so on.

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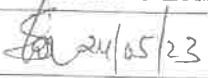

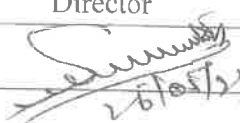
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**6.3 EHS Incident Investigation**

- a. Deploy consistent incident investigation method for all categories of EHS related incidents.
- b. Investigate all work-related incidents, no matter how small. The incident shall be investigated by trained incident investigators (IICFT – Incident Investigation Cross Functional Team) within 5 working days and reported in Annexure 2 - Incident Investigation Report.
- c. In case of damage to equipment/property, such equipment/property need to be retained till the investigation is completed by the IICFT.
- d. Investigation shall be done by the concerned supervisor, EHS Head/Designee and one Safety Committee Member.
- e. Following steps should be followed for a thorough investigation:
  - Prepare for the Investigation
  - Gather the Facts
  - Analyze the Facts to find out the root cause/most probable causes.
  - Develop Conclusions to address the root cause/most probable causes.
  - Write a Report with Recommend Corrective Actions
  - Implement Corrective Actions
  - Share the Learning
- f. **Annexure 5** is a guiding checklist for incident investigation using appropriate methodology based on potential severity to find out root cause/most probable causes of the incident and plan for necessary corrective actions to prevent recurrence of similar incident in future.
- g. Evaluate, with the participation of concerned employees, the need for corrective action to eliminate the root cause(s) or most probable cause(s) of the incident. The focus of the investigation is to find out “why the failure(s) occurred” through a “fact finding approach”.

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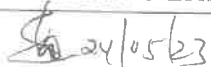

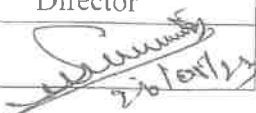
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- h. Investigate the incident in order that it does not recur or occur elsewhere by determining the cause(s) of the incident and by determining if similar incidents have occurred or if they could potentially occur.
- i. Review existing assessments of EHS impacts/risks relevant to the incident, as appropriate.
- j. Use one of “Why-Why” or “Fish Bone” or “Fault Tree Analysis” technique or any other suitable technique to explore the cause-effect relationships underlying the incident. The primary goal of the technique is to determine the “root cause” of the incident in a structured and systematic manner till we arrive at the root cause. Refer to Annexure 6 for sample “Why-Why” or “Fish Bone” or “Fault Tree Analysis” reports.
- k. The classification of potential severity of incident and identification of high severity EHS related incident i.e., “High Potential EHS Incident”, is very important in deciding the extent of investigation as well as tool for event investigation for loss prevention. **A High Potential EHS Incident will have potential severity “4-Major” & “5-Catastrophic”.**
- l. Based on potential severity assessment of the event, following broad guidelines should be followed to determine investigation team leader, members, timeline, investigation method and report approver.

IICFT	Severity 1 & 2	Severity 3	Severity 4 & 5
Leader	Concerned Supervisor	Concerned HOD	Site Head / Factory Manager
Members	Injured Person and EHS In-Charge	Injured Person, Witness, One Safety Committee Member and EHS In-Charge	Injured Person, Witnesses, Concerned HOD, One Safety Committee Member, EHS Head and Experts (if needed)

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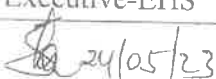

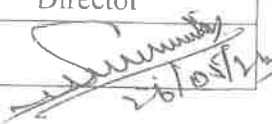
Timeline	48 hours	3 working days	7 working days
Method	Informal	Informal	Why-Why/Fish Bone/Fault Tree/Other Appropriate Method
Report Approver	Concerned HOD	Site Head / Factory Manager	Head-API Operations / Technical Director

**6.4 Recommended CAPAs, Implementation of CAPAs, Closure & Monitoring**

- a. Determine and implement corrective and preventive actions, in accordance with the hierarchy of risk controls as per **Annexure 6 – Techniques to Find Root Cause(s)** following appropriate methods like “Why-Why” or “Fish Bone” or “Fault Tree Analysis” or “Any Other Appropriate Technique”.
- b. Corrective actions shall be appropriate to the effects or potential effects of the incidents or nonconformities encountered.
- c. Review the effectiveness of any action taken, including corrective action.
- d. Assess/audit the effectiveness of corrective and preventive actions on regular basis through follow ups.
- e. Horizontal deployment, communication to employees and interested parties for preventing the occurrence to ensure sustenance.

**6.5 Training and Information**

- a. EHS Head shall capture the EHS related unsafe behaviors and incidents in the Weekly EHS Dashboard (Annexure 7) and share with the Site Head/Factory Manager, Technical Director, and Head API Operations.
- b. EHS Head shall retain information of the nature of the incidents and subsequent actions taken in Annexure 8 – Summary of Work-Related Injury & Illness.
- c. EHS Head shall display the safety statistics of the unit as under as per Annexure 9 - EHS Performance Display Board.

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## SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)

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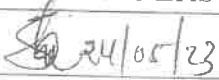

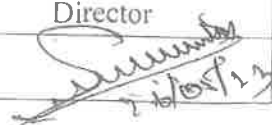
- d. EHS Head shall communicate the achievement of each million man-hours without RLTI to all employees and Site Head/Factory Manager, Technical Director, and Head API Operations.
- e. The Leadership Team shall encourage the unit team to achieve and celebrate each million man-hours without RLTI and the same should be rewarded in appropriate manner.
- f. EHS team shall communicate relevant learning's from these reporting to concerned employees through training and displays.

7.0 **Related Documents :**

- 7.1 EHS Incident - First Information Report : Annexure 1
- 7.2 EHS Incident - Investigation Report : Annexure 2
- 7.3 Appreciation letter for safe behavior/  
Warning letter for at-risk behavior : Annexure 3
- 7.1 Safe Attitude For Excellence in EHS Round (SAFER) : Annexure 4
- 7.2 Guiding Checklist for Incident Investigation : Annexure 5
- 7.3 Sample Root Cause Finding Techniques : Annexure 6
- 7.4 EHS Incident Dashboard : Annexure 7
- 7.5 Summary of SAFER and EHS Incidents : Annexure 8
- 7.6 EHS Performance Display Board : Annexure 9
- 7.7 Learning from Past EHS Incidents (Internal / External) : Annexure 10

8.0 **Distribution record:**

S. No	Department/Block	No. of Copies	Remarks
1	Environment, Health & Safety	01	----
2	Quality Assurance	01	----
3	Quality Control	01	----
4	AO	01	----
5	AM	01	----
6	C	01	----
7	D	01	----

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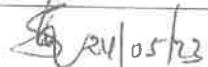

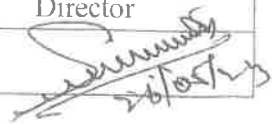
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14	Engineering	01	----
15	Warehouse	01	----
16	IT	01	----
17	P&A	01	----
18	R&D	01	----

9.0 Revision record:

S.No	Revision Status	Details of Revision	Effective date	Remarks
1.	00	<ul style="list-style-type: none"> <li>First issue (SOP/U-EHS/GEN/015/00)</li> </ul>	07.11.15	---
2.	01	<ul style="list-style-type: none"> <li>Periodical review.</li> <li>Section-5 Accountability is incorporated as per (QASOP (SOP/QA/GEN/001)</li> </ul>	13.11.17	---
3.	02	<ul style="list-style-type: none"> <li>Periodical review (SOP/U-2/EHS/GEN/015/02)</li> </ul>	01.11.19	---
4.	03	<ul style="list-style-type: none"> <li>Periodical review (SOP/U-2/EHS/GEN/015/03)</li> <li>Annexure – 1 Near miss/Incident/Accident first information report added in the SOP.</li> <li>FM-EIIS-018-00 changed/Near miss included in Annexure-2</li> <li>FM-EHS-025-00 changed/details included in</li> </ul>	12.12.21	---

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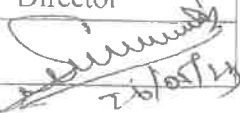
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S.No	Revision Status	Details of Revision	Effective date	Remarks
		Annexure-3		
5.	04	<ul style="list-style-type: none"> <li>SOP Revised as per the Change Control: (Ref. CRAF No. CRAF/EHS/081/22/U-2).</li> <li>In the Header Company name changed from Shilpa Medicare Limited to Shilpa Pharma Lifesciences Limited</li> <li>Shilpa Medicare limited Logo removed.</li> <li>Distribution list updated as per current practices</li> </ul>	13.09.22	---
6.	05	<ul style="list-style-type: none"> <li>SOP Tiles changed to "Safe &amp; at-risk behaviors, EHS incidents reporting &amp; investigation", thoroughly revised and added new Annexures 4 to 10 for improving the existing process.</li> <li>Annexure-1 title changed as 'EHS Incident - First Information Report'.</li> <li>Annexure-2 title changed as 'EHS incident - investigation report'</li> <li>Annexure-3 title changed as 'appreciation letter for safe behavior/ warning letter for at-risk behavior'</li> </ul>	05/06/23	---

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**SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)**

**ANNEXURE-I**

**EHS INCIDENT - FIRST INFORMATION REPORT**

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**EHS INCIDENT - FIRST INFORMATION REPORT**

**Definition of EHS Incident:** Occurrence arising out of, or in the course of, work that could or does result in injury and ill health. An incident where injury and ill health occurs is sometimes referred to as an "accident". An incident where no injury and ill health occurs but has the potential to do so may be referred to as a "near-miss".

To be filled by the person responsible for the location of the incident and submitted to in-charge safety.

Date	Time	Area/Block	Location	Incident No (to be filled by EHS)

**INJURED PERSON**

(If more than one person involved, use back side of this paper with below particulars)

Name:	Employee Type: Company / Contractor
Gender: Male / Female	Contractor Name:
Age:	Name of the immediate supervisor :
Identity No:	Name of the shift in charge:
Designation:	Name of the block in charge:
Names of the Witnesses: 1. 2.	
<b>Nature of Injury if any:</b>	<b>Damaged Property if any</b>
<b>Treatment</b>	
First Aid at Occupational Health Centre	
Hospitalization	

**DETAILS OF INCIDENT:**

Description of the Incident :

Immediate Measures taken to control the incident:

<b>Signature of Incharge</b>	<b>Signature of HOD/Designee</b>

<b>SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)</b>	
ANNEXURE - II	
EHS INCIDENT - INVESTIGATION REPORT	
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**EHS INCIDENT - INVESTIGATION REPORT**

**Date & Time of the Incident:** \_\_\_\_\_ **Shift:** \_\_\_\_\_

**Incident No:** \_\_\_\_\_

**Description of the Event:** \_\_\_\_\_

**Immediate Action:** \_\_\_\_\_

Incident Title						
Classification	FATAL / HCI / LWC / RWC / MTC / FAC / NM / PSI / FIRE / TOXIC RELEASE / ENVIRONMENTAL INCIDENT (Refer Section 3 for definitions of these terms)					
Incident Potential	Worst Case Severity		Likelihood		Worst Case Risk	
Details of the Person						

**IICFT Members (Investigation Team):**

- i)
- ii)

**Chronological Actions:**

- i)
- ii)

**Root Cause Analysis:** Attach root cause analysis report along with this report.

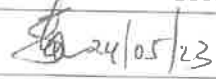

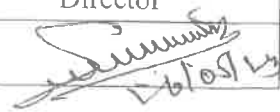
**Root Causes:**

- i)
- ii)

**Corrective and Preventive action:**

- i)
- ii)

**IICFT Leader comment:**

	Prepared by	Reviewed by	Approved by
Name	S. Shanmukha Rao	R Elangovan	K. Sharath Reddy
Designation	Jr. Executive-EHS	DGM -EHS	Director
Sign & Date	 24/05/23	 25/05/23	 26/05/23

<b>SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)</b>	
ANNEXURE – II	
EHS INCIDENT - INVESTIGATION REPORT	
Document Reference No.: SOP/U-2/EHS/GEN/015/05	Page 2 of 2



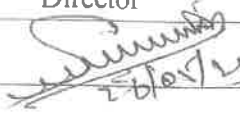
**Approver comment:**

**CAPA implementation evidence:** Attach relevant evidence for review and closure of CAPAs.

**CAPA closure status:** Open/Close

**Learning from past EHS Incidents shared with concerned.** Yes/No

Investigation Team	Department	Signature	Date
IICFT-Members			
IICFT-Leader			
EHS Head			
IICFT-Approver			

	Prepared by	Reviewed by	Approved by
Name	S. Shanmukha Rao	R Elangovan	K. Sharath Reddy
Designation	Jr. Executive-EHS	DGM -EHS	Director
Sign & Date	 24/05/23	 25/05/23	 25/05/23

<b>SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)</b>	
ANNEXURE-III	
APPRECIATION LETTER FOR SAFE BEHAVIOR/ WARNING LETTER FOR AT-RISK BEHAVIOR	
Document Reference No.: SOP/U-2/EHS/GEN/015/05	Effective Date: 05/06/23
Page 1 of 1	

Appreciation/Warning Letter Number:	
Name of Employee / Contract Worker:	
Identity No:	
Name of Contractor	
Safe Behavior Demonstrated:	
At-Risk Behavior Performed:	
Block/Dept :	Shift/area in-charge :
Description of Safe Behavior / At-Risk Behavior:	
Accepted by Name:	
Sign & Date:	
Area Incharge, Mgr. / Engineer Name:	
Sign & Date:	
Issued by Name:	
Sign & Date:	
Engineering Manager/HOD Name:	
Sign & Date:	
EHS Manager/HOD Name:	
Sign & Date:	

Name	Prepared by	Reviewed by	Approved by
	S. Shanmukha Rao	R Elangovan	K. Sharath Reddy
	Jr. Executive-EHS	DGM -EHS	Director
Sign & Date	24/05/23	25/05/23	26/05/23

## SHILPA PHARMA LIFESCIENCES LIMITED, Unit 2

### Annexure-IV

#### Safe Attitude For Excellence in EHS Round (SAFER)

Document Reference No.: SOP/U-2/EHS/GEN/015/05		Effective Date: 05/06/20
Date:	SAFER No:	Dept Code/Sr No
Time:	Location/Area:	
Observee(s):	Department:	
Emp ID(s)/Contractor(s):	Activity observed:	
1-Assert Integrity	9-Mechanical Hazard	13-Personal Protective Equipment
2-Competency	6-Emergency Management	14-EHS Procedures
3-Permit to Work	7-Incident Management	15-Static Hazard
4-Contractor Safety	8-Management of Change	16-Any Other

Safe Act(s) Observed:

SAFER Points:

Words of Appreciation:

At-Risk Behaviour(s) Observed:

Action Taken:

1. I agree with the safety recommendation and I will follow the safety recommendation always.

2. I request more clarification on the observation/recommendation.

Signatures of Observee(s)

Signature of Observer 1

Signature of Observer 2

Name of Observee(s)

Name of Observer 1

Name of Observer 2

**SHILPA PHARMA LIFE SCIENCES LIMITED UNIT-2**  
**Annexure-V**

**Guiding Checklist for Incident Investigation**

Document Reference No.: SOP/U-2/EHS/GEN/015/05

Effective Date: 05/06/23

Page 1 of 4

<b>GUIDING CHECKLIST FOR INCIDENT INVESTIGATION (use for "Potential Severity 4 &amp; 5" incidents)</b>			
<input type="checkbox"/> In plant Incident: <input type="checkbox"/> Health related <input type="checkbox"/> Contractor / Client Incident		<input type="checkbox"/> Work Related: <input type="checkbox"/> Environment related <input type="checkbox"/> Safety related :	
<b>Section 1.0</b>		<b>General Information</b>	
Incident Date,	Time:	<b>Type(s) of Incident</b>	
Department	Area:	Fatality: <input type="checkbox"/>	Restricted work: <input type="checkbox"/>
Incident Location:		Lost Time <input type="checkbox"/>	Medical Aid (Medical treatment first aid): <input type="checkbox"/>
		First Aid <input type="checkbox"/>	Occupational illness <input type="checkbox"/>
		(Non-medical first aid):	
Name of injured person	<b>Non Injury Types</b>		<b>Consequences</b>
Hours in to duty:	Fire / explosion <input type="checkbox"/>		Days Lost Time .....
Occupation	Code No	Equipment Damage <input type="checkbox"/>	
Immediate Supervisor:	Business Interruption <input type="checkbox"/>		Act Cost .....
Installation Supervisor	Near Miss <input type="checkbox"/>		Est Cost .....
Reported by:	Signed:	<b>Injury Types</b>	
Name of Witness: 1.	Signed:	Pre medical first aid <input type="checkbox"/>	
2.	Signed:	Medical treatment related <input type="checkbox"/>	
3.	Signed:	Lost time accident <input type="checkbox"/>	
		<b>Environment</b>	
Contract Company Name:		Major solvent spill/leak <input type="checkbox"/>	
Job:		Contaminated fire water <input type="checkbox"/>	
Other:		Major Effluent Water spills/leaks <input type="checkbox"/>	
		Non conformance <input type="checkbox"/>	
		<b>Addition Significant Implications / impact</b>	
		Environment <input type="checkbox"/>	
		Health <input type="checkbox"/>	
		Safety <input type="checkbox"/>	
		Production <input type="checkbox"/>	
<b>Section 2.0</b>			
<b>Event leading up to and description of Incident</b>			
(What, When, Where, Why, How? (explain in full including date, cause and action, use adnl page if required))			
<b>TYPE OF CONTACT</b>			
<input type="checkbox"/> Struck Against (Running or Bumping Into) <input type="checkbox"/> Struck by (Hit By Moving Object) <input type="checkbox"/> Fall from Elevation to Lower Level <input type="checkbox"/> Fall on Same Level (Slip and Fall, Trip Over) <input type="checkbox"/> Caught in (Pinch and Nip Points)		<input type="checkbox"/> Caught on (Snagged, Hung) <input type="checkbox"/> Caught Between or Under <input type="checkbox"/> Contact With (Electricity, Heat, Cold, Toxics Radiation, Caustics, Biological, Noise) <input type="checkbox"/> Overstress. (Overload, Overexertion, Overexposure, Ergonomic)	
<b>Section 3.0</b>			
<b>INJURY / ILLNESS DETAIL</b>			
Name of Patient:			
Occupation:			
Injury/Illness Description			



**SHILPA PHARMA LIFE SCIENCES LIMITED UNIT-2**

**Annexure-V**

**Guiding Checklist for Incident Investigation**

Document Reference No.: SOP/U-2/EHS/GEN/015/05

Page 2 of 4

**Section 4.1 Immediate cause (s): Substandard Acts (Unsafe Acts ) and Substandard Condition (Unsafe Condition)**

**UNSAFE/SUBSTANDARD ACT**

- Operating Equipment Without Authority
- Failure to Warn
- Failure to Secure
- Operating at Improper Speed
- Making Safety Devices Inoperative
- Using Defective Equipment
- Failing to use PPE Properly
- Improper Loading
- Improper Placement
- Improper Lifting
- Improper Position for Task
- Servicing Equipment in Operation
- Under Influence of Alcohol and/or Other Drugs
- Horseplay
- Using Equipment Improperly

**UNSAFE/SUBSTANDARD CONDITION**

- Inadequate Guards or Barriers
- Inadequate or Improper Protective Equipment
- Defective Tools, Equipment or Materials
- Congestion or Restricted Action
- Inadequate Warning System
- Fire & Explosion Hazards
- Poor Housekeeping /Disorder
- Noise Exposure
- Radiation Exposure
- Temperature Extremes
- Inadequate or Excess Illumination
- Inadequate Ventilation
- Hazardous Environmental Conditions

Describe in detail about the unsafe act/condition

**Section 4.2 Basic (Root) Causes(s): Personal factor and job factors (The reason for the existence of the immediate cause)**

Personal factors (use check list in page 1, sec 7)

- Inadequate Physical/Physiological Capability
- Inadequate Mental/Physiological Capability
- Physical or Physiological Stress
- Mental or Psychological
- Lack of Knowledge
- Lack of Skill
- Improper Motivation

Job Factors (use check list in page 1, sec 7)

- Inadequate Leadership and/or Supervision
- Inadequate Engineering
- Inadequate Purchasing
- Inadequate Maintenance
- Inadequate Tools and Equipment
- Inadequate Work Standards
- Excessive Wear and Tear
- Abuse or Misuse

Describe about the selected root causes

**INCIDENT INVESTIGATION REPORT**

Part No.:

**Section 4.3 Lack of Control: Inadequate program, Inadequate Program standards, Inadequate Compliance to Standards (Relate to Safety program)**

Describe

- |   |   |
|---|---|
| <input type="checkbox"/> Planned inspection                   | <input type="checkbox"/> Inadequate Leadership and/or supervision |
| <input type="checkbox"/> Critical task procedure/analysis     | <input type="checkbox"/> Training                                 |
| <input type="checkbox"/> Task observation                     | <input type="checkbox"/> Health and hygiene control               |
| <input type="checkbox"/> Accident /Incident analysis          | <input type="checkbox"/> Communication                            |
| <input type="checkbox"/> Emergency preparedness               | <input type="checkbox"/> Purchasing materials                     |
| <input type="checkbox"/> Implementation of rules/work permits | <input type="checkbox"/> Engineering and change management        |
| <input type="checkbox"/> Use of PPE                           | <input type="checkbox"/> Housekeeping and workplace maintenance   |

Describe the above selected lack of control

**Section 5.1 Immediate Action Taken (Control, contain, treat) (Corrective action)**

**Section 5.2 Preventive actions taken/Proposed**

**SHILPA PHARMA LIFE SCIENCES LIMITED UNIT-2**

**Annexure-V**

**Guiding Checklist for Incident Investigation**

Document Reference No.: SOP/U-2/EHS/GEN/015/05

Page 3 of 4

Preventive actions taken:		
Preventive actions proposed:		
<b>Section 6.0</b> <span style="float: right;"><b>Risk Assessment Review &amp; carry out the risk assessment after the occurrence of incident</b></span>		
Has the Risk been included in Risk Register ?	Yes	No
Re-evaluate the Risk on the basis of the actions taken now	Yes	No
<b>Space for additional comments from other sections, sketch etc</b>		
<b>Section 7</b> <b>Basic Cause(s):</b> <i>(the reason for the existence of the immediate cause)</i>		
Personal factors ( check list)	Job Factors ( Check list)	

SHILPA PHARMA LIFE SCIENCES LIMITED UNIT-2

Annexure-V

Guiding Checklist for Incident Investigation

Document Reference No.: SOP/U-2/EHS/GEN/015/05

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<p><input type="checkbox"/> <b>Inadequate Physical/Physiological Capability</b></p> <ul style="list-style-type: none"> <li>1.1 Inappropriate height, weight, size, strength, reach,</li> <li>1.2 Restricted range of body movement</li> <li>1.3 Limited ability to sustain body positions</li> <li>1.4 Substance sensitives or allergies</li> <li>1.5 Sensitives to sensor extremes (temperature, sound,</li> <li>1.6 Vision deficiency</li> <li>1.7 Hearing deficiency</li> <li>1.8 Other sensor deficiency (touch, taste, smell, balance)</li> <li>1.9 Respiratory incapacity</li> <li>1.10 Other permanent physical capabilities</li> <li>1.11 Temporary disabilities</li> </ul> <p><input type="checkbox"/> <b>Inadequate Mental/Psychological Capability</b></p> <ul style="list-style-type: none"> <li>2.1 Fears and phobias</li> <li>2.2 Emotional disturbance</li> <li>2.3 Mental illness</li> <li>2.4 Intelligence level</li> <li>2.5 Inability to comprehend</li> <li>2.6 Poor judgment</li> <li>2.7 Poor coordination</li> <li>2.8 Slow reaction time</li> <li>2.9 Low mechanical aptitude</li> <li>2.10 Low learning aptitude</li> <li>2.11 Memory failure</li> </ul> <p><input type="checkbox"/> <b>Physical or Physiological Stress</b></p> <ul style="list-style-type: none"> <li>3.1 Injury or illness</li> <li>3.2 Fatigue due to task load or duration</li> <li>3.3 Fatigue due to lack of rest</li> <li>3.4 Fatigue due to sensory overload</li> <li>3.5 Exposure to health hazards</li> <li>3.6 Exposure to temperature extremes</li> <li>3.7 Oxygen deficiency</li> <li>3.8 Atmospheric pressure variation</li> <li>3.9 Constrained movement</li> <li>3.10 Blood sugar insufficiency</li> <li>3.11 Drugs</li> </ul> <p><input type="checkbox"/> <b>Mental or Physiological</b></p> <ul style="list-style-type: none"> <li>4.1 Emotional over load</li> <li>4.2 Fatigue due to mental task load or speed</li> <li>4.3 Extreme judgment/decision demands</li> <li>4.4 Routine, monotony, demand for uneventful vigilance</li> <li>4.5 Extreme concentration/perception demands</li> <li>4.6 "Meaningless" or "degrading" activities</li> <li>4.7 Confusing directions/demands</li> <li>4.8 Conflicting demands/directions</li> <li>4.9 Preoccupation with problems (frustration)</li> <li>4.10 Mental illness</li> </ul> <p><input type="checkbox"/> <b>Lack of knowledge</b></p> <ul style="list-style-type: none"> <li>5.1 Lack of experience</li> <li>5.2 Inadequate orientation</li> <li>5.3 Inadequate initial training</li> <li>5.4 Inadequate update training</li> <li>5.5 Misunderstood directions</li> </ul> <p><input type="checkbox"/> <b>Lack of Skill</b></p> <ul style="list-style-type: none"> <li>6.1 Inadequate initial instructions</li> <li>6.2 Inadequate practices</li> <li>6.3 Infrequent performance</li> <li>6.4 Lack of coaching</li> <li>6.5 Inadequate review instruction</li> </ul> <p><input type="checkbox"/> <b>Improper Motivation</b></p> <ul style="list-style-type: none"> <li>7.1 Improper performance is rewarded</li> <li>7.2 Proper performance is punished</li> <li>7.3 Lack of incentives</li> <li>7.4 Excessive frustration</li> <li>7.5 Inappropriate aggression</li> <li>7.6 Improper attempt to save time or effort</li> <li>7.7 Improper attempt to avoid discomfort</li> <li>7.8 Improper attempt to gain attention</li> <li>7.9 Inadequate discipline</li> <li>7.10 Inappropriate peer pressure</li> <li>7.11 Improper supervisory example</li> <li>7.12 inadequate performance feedback</li> <li>7.13 Inadequate reinforcement of proper behaviour</li> <li>7.14 Improper production incentives</li> </ul>	<p><input type="checkbox"/> <b>Inadequate Leadership and/or Supervision</b></p> <ul style="list-style-type: none"> <li>1.1 Unclear or conflicting reporting relationships</li> <li>1.2 Unclear or conflicting assignment of responsibility</li> <li>1.3 Improper or insufficient delegation</li> <li>1.4 Giving inadequate policy, Procedure, Practices or guidelines</li> <li>1.5 Giving objectives, goals or standards that conflict</li> <li>1.6 Inadequate work planning or programming</li> <li>1.7 Inadequate instructions, orientation and/or training</li> <li>1.8 Providing inadequate reference documents, directives and guidance publications</li> <li>1.9 Inadequate identification and evaluation of loss exposures</li> <li>1.10 Lack of supervisory/management job knowledge</li> <li>1.11 Inadequate performance measurement and evaluation</li> <li>1.12 Inadequate or incorrect performance measurement and evaluation</li> <li>1.13 Inadequate or incorrect performance feedback</li> </ul> <p><input type="checkbox"/> <b>Inadequate Maintenance</b></p> <ul style="list-style-type: none"> <li>4.1 Inadequate preventive             <ul style="list-style-type: none"> <li>4.1.1 Assessment of needs</li> <li>4.1.2 Lubrication and servicing</li> <li>4.1.3 Adjustment/assembly</li> <li>4.1.4 Cleaning or resurfacing</li> </ul> </li> <li>4.2 Inadequate repairs             <ul style="list-style-type: none"> <li>4.2.1 Communication of needs</li> <li>4.2.2 Schedule of work</li> <li>4.2.3 Examination of units</li> <li>4.2.4 Part substitution</li> </ul> </li> </ul> <p><input type="checkbox"/> <b>Inadequate Work standards</b></p> <ul style="list-style-type: none"> <li>6.1 Inadequate development of standards for :             <ul style="list-style-type: none"> <li>6.1.1 Inventory and evaluation of exposures and needs</li> <li>6.1.2 Coordination with process design</li> <li>6.1.3 Employee involvement</li> <li>6.1.4 Procedures/practices/rules</li> </ul> </li> <li>6.2 Inadequate communication of standards for             <ul style="list-style-type: none"> <li>6.2.1 Publication</li> <li>6.2.2 Distribution</li> <li>6.2.3 Translation of appropriate languages</li> <li>6.2.4 Training</li> <li>6.2.5 Reinforcing with sign,color codes and job aids</li> </ul> </li> <li>6.3 Inadequate maintenance of standards for             <ul style="list-style-type: none"> <li>6.3.1 Tracking of work flow</li> <li>6.3.2 Updating</li> <li>6.3.3 Monitoring use of procedures/practices/rules</li> <li>6.3.4 Inadequate monitoring of compliance</li> </ul> </li> </ul>	<p><input type="checkbox"/> <b>Inadequate Engineering</b></p> <ul style="list-style-type: none"> <li>2.1 Inadequate assessment of loss exposures</li> <li>2.2 Inadequate consideration of human factors/ergonomics</li> <li>2.3 Inadequate standards, specifications and/or design criteria</li> <li>2.4 Inadequate monitoring or construction</li> <li>2.5 Inadequate assessment of operation readiness</li> <li>2.6 Inadequate or improper controls</li> <li>2.7 Inadequate monitoring or initial operation readiness</li> <li>2.8 Inadequate evaluation of changes</li> </ul> <p><input type="checkbox"/> <b>Inadequate Purchasing</b></p> <ul style="list-style-type: none"> <li>3.1 Inadequate specifications on requisitions</li> <li>3.2 Inadequate research on materials/equipment</li> <li>3.3 Inadequate specifications to vendors</li> <li>3.4 Inadequate mode or route of shipment</li> <li>3.5 Inadequate receiving inspection and acceptance</li> <li>3.6 Inadequate communication of safety and health data</li> <li>3.7 Improper handling of materials</li> <li>3.8 Improper storage of materials</li> <li>3.9 Improper transporting of materials</li> <li>3.10 Inadequate identification of hazardous materials</li> <li>3.11 Improper salvages and/or waste disposal</li> <li>3.12 Inadequate contractor selection</li> </ul> <p><input type="checkbox"/> <b>Inadequate Tools and Equipment</b></p> <ul style="list-style-type: none"> <li>5.1 Inadequate assessment of needs and risks</li> <li>5.2 Inadequate assessment of needs and risks</li> <li>5.3 Inadequate human factors/ergonomics considerations</li> <li>5.4 Inadequate standards or specifications</li> <li>5.5 Inadequate availability</li> <li>5.6 Inadequate adjustment/repair/maintenance</li> <li>5.7 Inadequate salvage and reclamation</li> <li>5.8 Inadequate removal and replacement of unsuitable items</li> </ul> <p><input type="checkbox"/> <b>Excessive Wear and Tear</b></p> <ul style="list-style-type: none"> <li>7.1 Inadequate planning of use</li> <li>7.2 Improper extension of service life</li> <li>7.3 Inadequate inspection and/or monitoring</li> <li>7.4 Improper loading or rate of use</li> <li>7.5 Inadequate maintenance</li> <li>7.6 Use by unqualified or untrained people</li> <li>7.7 Use for wrong purposes</li> </ul> <p><input type="checkbox"/> <b>Abuse or Misuse</b></p> <ul style="list-style-type: none"> <li>8.1 Improper conduct that is condoned             <ul style="list-style-type: none"> <li>8.1.1 Intentional</li> <li>8.1.2 Unintentional</li> </ul> </li> <li>8.2 Improper conduct that is not condoned             <ul style="list-style-type: none"> <li>8.2.1 Intentional</li> <li>8.2.2 Unintentional</li> </ul> </li> </ul>
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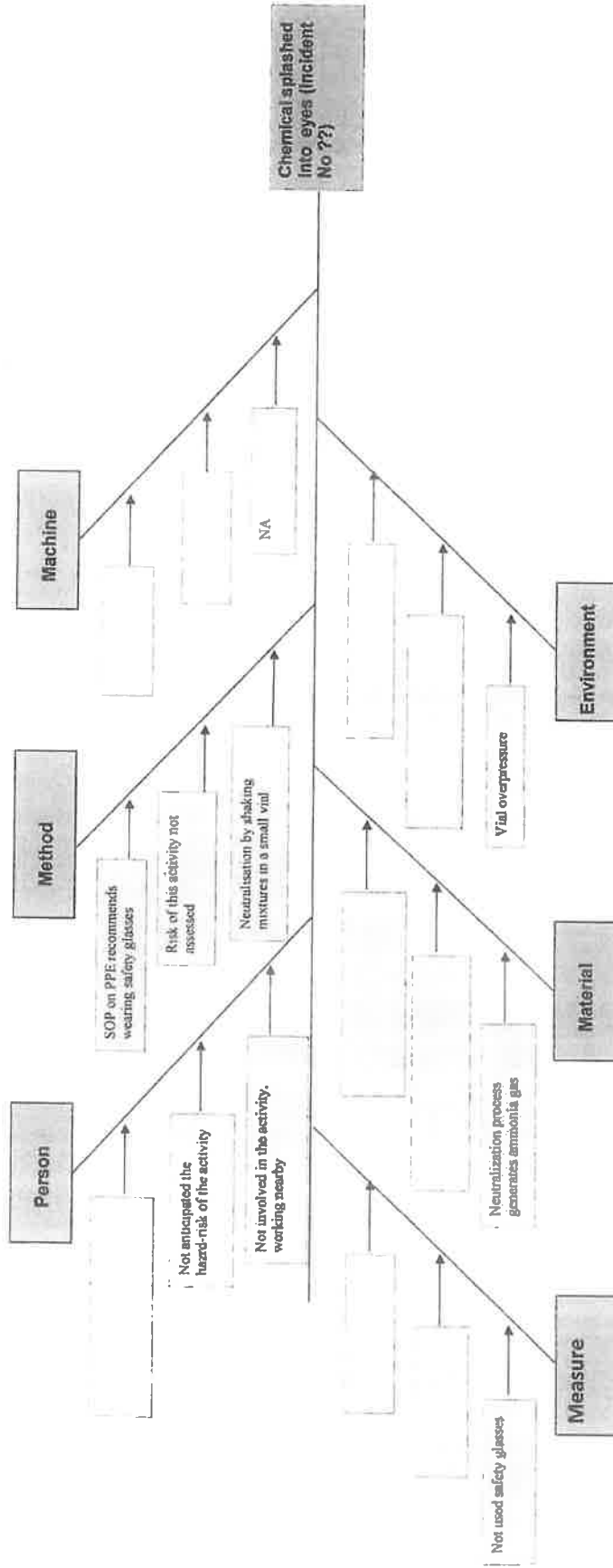
SHILPA PHARMA LIFESCIENCES LIMITED UNIT-2

Annexure-VI  
Sample Root Cause Finding Techniques

Document Reference No.: SOP/U-2/EHS/GEN/015/05

Incident: Mr Yuva Teja was neutralising 0.1 ml of a reaction mass with ammonium chloride (saturated) solution in a 2 ml plastic vial by shaking in hand. Due to overpressure, the vial cap opened and the neutralised solution splashed into the eyes of Mr Vijay Kumar, who was working nearby.

Effective Date: 05/06/23



**SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)**

**ANNEXURE-VII**

**EHS INCIDENT DASHBOARD**

Document Reference No.: SOP/U-2/EHS/GEN/015/05

Effective Date: 05/06/23

Page 1 of 1

- 1. Number of Safe Behaviors Observed : \*\*
- 2. Number of At-Risk Behaviors Observed : \*\*
- 3. Number of Near Misses : \*\*
- 4. Number of Reportable Lost Time Injuries (RLTI) : \*\*
- 5. High Consequence Injury or Ill-health (HCI) : \*\*
- 6. Number of Restricted Work Cases : \*\*
- 7. Number of Medical Treatment Cases : \*\*
- 8. Number of First Aid Cases : \*\*
- 9. Number of Work-Related Ill-Health Cases : \*\*
- 10. Number of Process Safety Incidents : \*\*
- 11. Number of Fire Incidents : \*\*
- 12. Number of Environmental Incidents : \*\*
- 13. Number of High Potential EHS Incidents : \*\*
- 14. Number of EHS Incidents Investigated : \*\*
- 15. Number of EHS Training Conducted : \*\*
- 16. Number of EHS Suggestions Received : \*\*

	Prepared by	Reviewed by	Approved by
Name	S. Shanmukha Rao	R Elangovan	K. Sharath Reddy
Designation	Jr. Executive-EHS	DGM -EHS	Director
Sign & Date	<i>[Signature]</i> 24/05/23	<i>[Signature]</i> 25/05/23	<i>[Signature]</i> 26/05/23





**SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)**

**Annexure-IX**




**EHS Incident Statistics for (Month)**

Document Reference No.: SOP/U-2/EHS/GEN/015/05

Effective Date: 05/06/23

Page 1 of 1

- 1. Number of Reportable Lost Time Injuries (RLTI) : \*\*
- 2. Number of Total Recordable Cases : \*\*
- 3. Number of Process Safety Incidents : \*\*
- 4. Cumulative Man-hours Worked without RLTI : \*\*
- 5. Reportable Lost Time Injury Frequency Rate : \*\*
- 6. Reportable Lost Time Injury Severity Rate : \*\*
- 7. Reportable Lost Time Injury Incidence Rate : \*\*

	Prepared by	Reviewed by	Approved by
Name	S. Shanmukha Rao	R Elangovan	K. Sharath Reddy
Designation	Jr. Executive-EHS	DGM -EHS	Director
Sign & Date	 24/05/23	 25/05/23	 26/05/23



# SHILPA PHARMA LIFESCIENCES LIMITED (UNIT-2)

## ANNEXURE-X

Learning from Past EHS Incidents (Internal / External)

Document Reference No.: SOP/U-2/EHS/GEN/015/05

Page 1 of 1

### Incident Details

What Happened?	**
Where?	**
When?	**
Immediate Action	**

### CAPAS

#### Corrective Actions:

1. \*\*
2. \*\*

#### Preventive Actions:

1. \*\*
2. \*\*
3. \*\*
4. \*\*
5. \*\*
6. \*\*
7. \*\*

### Root Cause(s) and Contributing Factors

1. \*\*
2. \*\*
3. \*\*
4. \*\*
5. \*\*
6. \*\*
7. \*\*
8. \*\*

### Documents to attach, if any

\*\*

### Photographs

\*\*