

# Safety Audit – BIS 14489



## Report

For

## EISAI Pharmaceuticals India Private Limited

Plot No 96,97, 98, 124, 126, Lankelapalem Rd, Paravada,  
Visakhapatnam, Andhra Pradesh 531021

By

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Client Name	EISAI Pharmaceuticals India Private Limited
Assessment Date	15 <sup>th</sup> & 16 <sup>th</sup> December 2020
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## Acknowledgement

**TheSafetyMaster™** team is thankful to **EISAI Pharmaceuticals India Private Limited**, for providing us an opportunity to undertake the Safety Audit BIS14489 in their Vizag unit. **TSM TheSafetyMaster™ Private Limited** would like to express sincere gratitude to all HODs, Process people, Maintenance people, operators, engineers, workmen, contractors, and house-keeping for their assistance, services, coordination, and willingness to share their knowledge and experience during the visit.

We would also like to express our special thanks of gratitude to **Top Management & site team** who gave us the opportunity to do the Safety Audit.

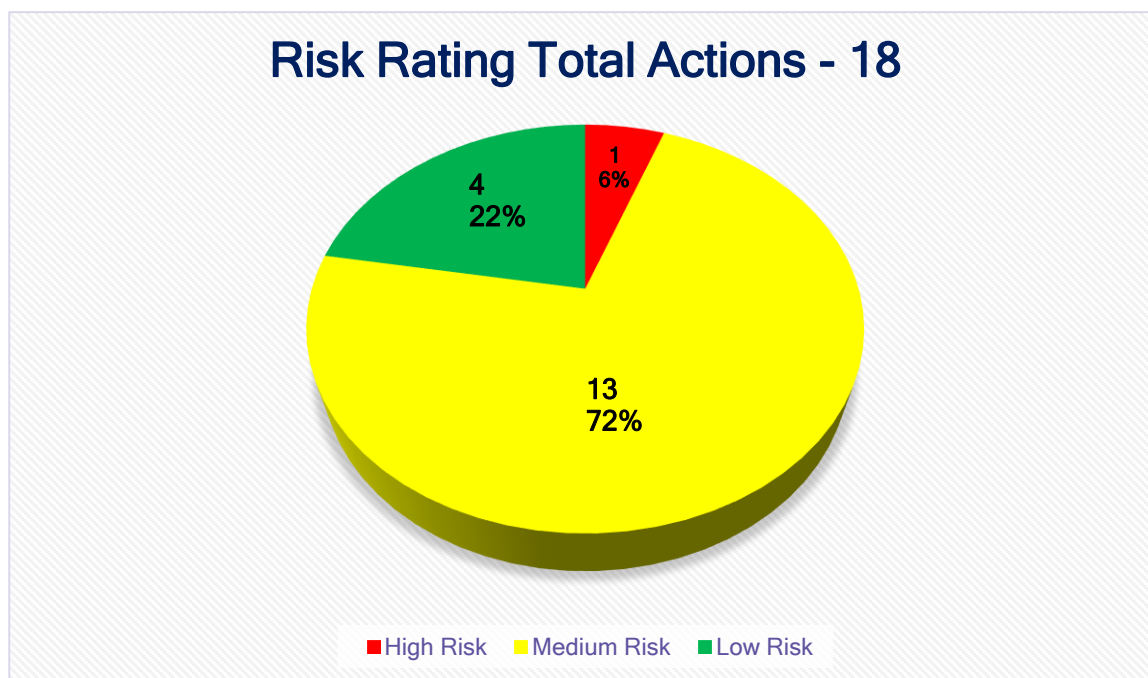
We would like to mention that without above coordination the completion of this audit would have been impossible. We are really thankful to them.

## Executive Summary

The site gives importance to safety, has workplace safety procedures of safety element and is eager to improve safety management system in the field at the earliest by taking the latest BIS 14489, Factories Act 1948, Indian Electricity Rules, Petroleum Rules, Andhra Pradesh Factory Rules, BIS1641-46, BIS3034, National Building Code, NFPA code of practice and amendments in relation to the safety, considering International/National Best Practices.

During the audit our team came across a lot of tedious processes with better scope for improvement of safety implementations. Site should define Safety Management Philosophy, Top 10 Risks and Action Plan, Develop and Implement Safety Management standard on priority, develop structured training modules, assessment cum validation system of the training and conduct training on all elements of the safety management system.

The summary of total actions based on risk rating is as below:



## Acronyms

<b>ANSI</b>	American National Standard Institute
<b>ASME</b>	American Society of Mechanical Engineers
<b>CCPS</b>	Center for Chemical Process Safety
<b>HAZOP</b>	Hazard and Operability (Study)
<b>SWP</b>	Safe Work Practices
<b>LOTO</b>	Lockout/Tag out
<b>MSDS</b>	Material Safety Data Sheet
<b>NFPA</b>	National Fire Protection Association
<b>OSHA</b>	Occupational Safety and Health Administration
<b>P&amp;ID</b>	Piping and instrument diagram
<b>PSM</b>	Process Safety Management
<b>RAGAGEP</b>	Recognized and generally accepted good engineering practice
<b>RBPS</b>	Risk Based Process Safety
<b>OSHA</b>	Occupational Safety Health Administration
<b>PSSR</b>	Prestart up Safety Review
<b>MI</b>	Mechanical Integrity
<b>PSI</b>	Process Safety Information
<b>MOC</b>	Management of change
<b>PHA</b>	Process Hazards Analysis
<b>ERP</b>	Emergency Response Plan

## Glossary

**Accident:** An incident that results in significant human loss (either injury or death), significant property damage, and/or a significant environmental impact.

**Accountability:** The obligation to explain and answer for one's actions that are related to expectations, objectives, and goals. In this context, those that are accountable for PSM activities are answerable to the one person who has the ultimate responsibility for the program. There may be multiple persons accountable for an activity but only one person with the ultimate responsibility. Accordingly, it is a powerful element of an effective process safety management system.

**Asset integrity:** A PSM program element involving work activities that help ensure that equipment is properly designed, installed in accordance with specifications, and remains fit for purpose over its life cycle.

**Checklist** A list of items requiring verification of completion; typically, a procedure format in which each critical step is marked off (or otherwise acknowledged/verified) as it is performed. Checklists are often appended to procedures that provide a more detailed description of each step, including information regarding hazards, and a more complete description of the controls associated with the hazards. Checklists are also used in conjunction with formal hazard evaluation techniques to ensure thoroughness.

**Consequence:** The direct, undesirable result of an incident sequence usually involving a fire, explosion, or release of toxic material. Consequence descriptions may be qualitative or quantitative estimates of the effects of an accident in terms of factors such as health impacts, economic loss, and environmental damage.

**Controls:** Engineered mechanisms and administrative policies/procedures implemented to prevent or mitigate incidents.

**Competency:** A PSM program element associated with efforts to maintain, improve, and broaden knowledge and expertise.

**Determine:** To conclude; to reach an opinion consequent to the observation of the fit of sample data within the limit, range, or area associated with substantial conformance, accuracy, or other predetermined standard; to obtain firsthand knowledge of.

**Effectiveness:** The combination of process safety management performance and process safety management efficiency. An effective process safety management program produces the required work products of sufficient quality while consuming the minimum amount of resources.

**Hazard:** Chemical or physical conditions that have the potential of causing harm to people, property, or the environment. In these *Guidelines*, hazard refers to the first risk attribute: What can go wrong.

**Hazardous chemical:** A material that is toxic, reactive, or flammable and is capable of causing a process safety incident, if released.

**Hazard identification and risk assessment (HIRA):** A collective term that encompasses all activities involved in identifying hazards and evaluating risk at facilities, throughout their life cycle, to make certain that risks to employees, the public, or the environment are consistently controlled within the organization's risk tolerance.

**Incident:** An unplanned sequence of events with the potential for undesirable consequences.

**Incident investigation:** A systematic approach for determining the causes of an incident and developing recommendations that address the causes to help prevent or mitigate future incidents. See also Root cause analysis and apparent cause analysis.

**ITPM program:** A program that develops, maintains, monitors, and manages inspection, testing, and preventive maintenance activities.

**Life cycle:** The stages that a physical process or a management system goes through as it proceeds from birth to death. These stages include conception, design, deployment, acquisition, operation, maintenance, decommissioning, and disposal.

**Operator:** An individual responsible for monitoring, controlling, and performing tasks as necessary to accomplish the productive activities of a system. Operator is also used in a generic sense to include people who perform a wide range of tasks (e.g., readings, calibration, incidental maintenance, manage loading/unloading and storage of hazardous materials).

**Procedures:** Written step-by-step instructions and associated information (cautions, notes, warnings) that describe how to safely perform a task.

**Recognized and generally accepted good engineering practice (RAGAGEP):** Legal, consensus, or recommended practices with respect to design, construction, operations, and maintenance of equipment. RAGAGEPs can take the form of labor regulation; consensus codes and standards, recommended practices, and other guidance published and maintained by industry trade and professional organizations; manufacturer's recommendations for design, installation, operations, and maintenance; or guidance derived from the operating history of the equipment within a given facility or the industry as a whole. RAGAGEPs used in the chemical/processing industry are consensus industry codes, standards, and recommended practices. These codes and standards define the level of acceptable practice within the industry for various technical and administrative issues.



**Risk:** The combination of three attributes: what can go wrong, how bad could it be, and how often might it happen.

**Training:** Practical instruction in job and task requirements and methods. Training may be provided in a classroom or at the workplace, and its objective is to enable workers to meet some minimum initial performance standards, to maintain their proficiency, or to qualify them for promotion to a more demanding position.

**Written program:** A description of a management system that defines important aspects such as purpose and scope, roles and responsibilities, tasks and procedures, necessary input information, anticipated results and work products, personnel qualifications and training, activity triggers, desired schedule and deadlines, necessary resources and tools, continuous improvement, management review, and auditing.

## Objective

Risk Based Safety Assessment as per the BIS 14489 is the first step in understanding the level of safety management system of a facility in which assessment objective is to find key strength and opportunities for improvement in infrastructure, people and standard documents. A systematic and thorough approach carries out the gap assessment to test the company's safety standards & score them, identify potential areas for improvement, identify best course of action to achieve desired Safety Standards.

The following are the objective of this Safety Audit:

- ✚ To study and evaluate the current state and effectiveness of existing Safety management systems at EISAI Pharmaceuticals India Private Limited – Vizag and find the gaps and give recommendations with respect to BIS 14489, Indian Electricity Rules, Petroleum Rule, Factories Act & Rule, IS1646 standards and best international practices in safety management.
  
- ✚ Conducting Gap Analysis and preparing pathfinder report with scoring of each element of Risk Based Safety Management System
  
- ✚ Prepare an action item plan through a systematic approach to overcome the gaps as observed in gap analysis.

## Background

### TSM TheSafetyMaster™ Private Limited

TheSafetyMaster™ is a young organization with a dedicated team of young, innovative, research driven & experienced professionals, who want to create value for their customers by providing ingenious services in the field of Safety.

Our Vision is to see TheSafetyMaster™ as a globally recognized Organization, delivering its Services & Products through talented people and use of latest technologies with Safety, Efficiency, and Quality & Values for its Customers, Partners & Society at large with the aim of **“SAFER INDIA, BETTER WORLD”**.

Our Mission is to deliver Safety Services to our Customers with High Customer Satisfaction & priority and making safety a priority for everyone.

### TheSafetyMaster™ Values



## Project Details

**EISAI Pharmaceuticals India Private Limited – Vizag Unit** has trusted **TSM TheSafetyMaster Private Limited** through a work order for Safety Audit as per BIS14489 that involves the review and evaluation of Safety systems at the facility with respect to best practices. Safety System evaluation entails the systematic review of safety programs to verify the suitability of the system and its effectiveness and consistency in implementation.

Safety Audit refers to a set of interrelated approaches to manage hazards associated with the industries and intended to reduce the frequency and severity of incidents and improve the behavior of the people. TheSafetyMaster™ team assessed all the Safety elements during their visit on 15<sup>th</sup> & 16<sup>th</sup> December 2020.

## Assessment Methodology

### Preparation-

- Selected Team members of TheSafetyMaster™
- Communicate needed facilities and engagement requirements
- Establish and agree schedule with EISAI Pharmaceuticals India team
- Collect background information from plant team
- Develop Assessment plan and submit to EISAI Pharmaceuticals India team

### Conducting Assessment-

- Opening meeting
- Develop understanding of a facility
- Develop understanding of Safety Management program
- Collecting information
- Evaluating safety inside the infrastructure through field visits
- Evaluating safety standards through document verification
- Evaluating people capability in safety systems through discussions
- Developing findings & provide risk rating and recommendations
- Closing presentation

### Final Report Submission-

- Detailed report

## Assessment Procedure

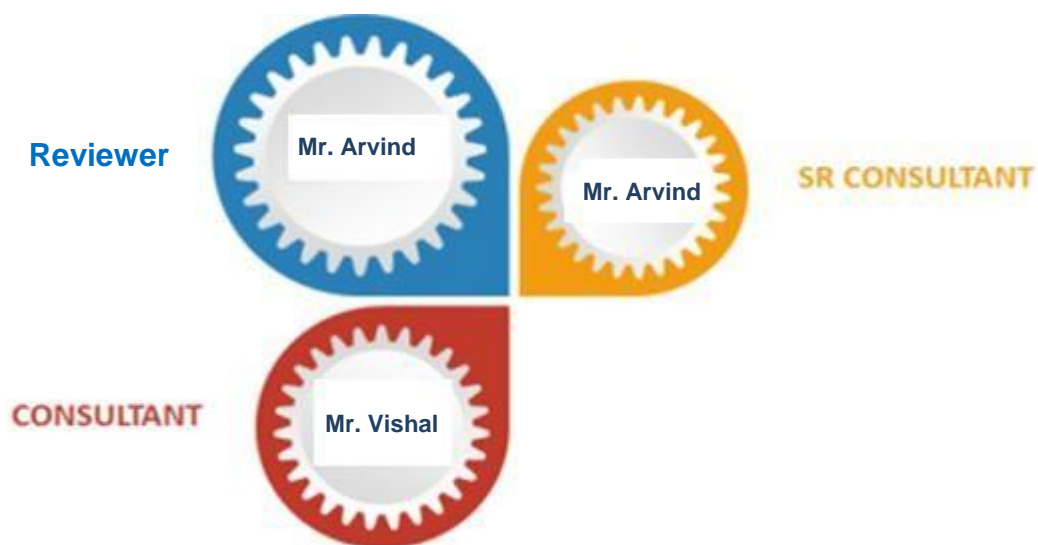
- Discussion with qualified site Team about the detail planning, prior to the Audit.
- During assessment we met various employees, leaders and various team members of EISAI Pharmaceuticals India Private Limited - Vizag
- Obtaining authorization and assessing all the areas of the plant site. Got overview of **do's and don'ts** at site and PPE requirements.
- Two days of visit with duration of 16 hours of Safety Audit BIS14489 conducted to find out gap in the field and verify the documentations.
- Observing Gap and Recommend as per National/International best practices.
- Recording date and the location of area where safety issue involves.
- Element Scoring according to TheSafetyMaster™ criteria.
- Conducting clog meeting to give an overview of gap observed during the assessment.
- Submitting detailed action item based report

## Site Details

### EISAI Pharmaceuticals India Private Limited

Plot No 96,97, 98, 124, 126, Lankelapalem Rd, Paravada,  
Visakhapatnam, Andhra Pradesh 531021

## Assessment Team Details



## Risk Matrix

Risk Level	Risk Rating	Risk Rating Description
High	1	Definitely could occur during the process
	2	Most probably could occur
Medium	2.5	Possibly could occur during the process
	3	
Low	3.5	Very less Possibility to occur
	4	Unlikely to occur
	5	

# SECTION – 1

## SAFETY SYSTEM REVIEW

### **Action Plan Target:**

High Risk – Less than 15 Days  
Medium Risk – Less than 30 Days  
Low Risk – Less than 45 Days



S.No.	Good Practices Observed during the Audit
1.	Organization has established structure Safety Management system
2.	Commitment of Top Management on safety is evident.
3.	Organization has established process for reporting, recording and investigating the incidents.
4.	Organization has established process for Emergency Management and prepared an emergency management plan. The Emergency Management Plan is practiced through Mock Drills.
5.	Organization has established Mutual Aid assistance with neighboring industries
6.	There is checklist to check before processing a new batch after the reactors are cleaned
7.	There are 60 trained firefighters and 30 trained first aiders available in the plant and distributed shift wise
8.	The safety shower and eye washer are provided in the different areas of the plant and maintained in good condition
9.	There is insulation mat in front of the all electrical panels and maintained in good condition
10.	Charging of raw materials in API 3 is being done under nitrogen pressure.
11.	Anti-skid tapes are provided on the stair steps to prevent slip and trip hazard
12.	There is a fixed emergency glass door to evacuate in case of emergency by breaking the glass.
13.	Medical checkup of employees is being done once in a year and some specific tests like audio metery, color blindness etc are being done for the employees as per their work area exposure.
14.	Occupational exposure limits study has been conducted by 3 <sup>rd</sup> party.

15.	There is safety instruction board at the entry of the solvent yard to restrict mobile, smoking etc.,
16.	There is compatibility chart of chemicals in the store
17.	Modular type DCP fire extinguishers fire detection and alarm system are installed inside the warehouse
18.	There is a dedicated phone numbers for effective communication in case of any emergency at the gate,
19.	The safety induction for visitors is available at the gate.
20.	Powder safety study has been conducted by 3 <sup>rd</sup> party to ensure the safe running of the plant
21.	Powered air purifying respirator is provided in R&D area to handle any emergency situation
22.	Process hazards are identified in process engineering research lab and precautions has been taken accordingly
23.	Multi gas detectors are provided and alarm panel is in security and hooter is in R&D
24.	Calibration of instruments are being done annually by 3 <sup>rd</sup> Party.
25.	In 10L glass reactor rupture disc is provided and alarm for high temperature is also there
26.	In OHC distribution record of medicines & other items for first aid boxes is available
27.	Dedicated fire water storage for firefighting is sufficient as per the pump capacity
28.	There is preventive maintenance schedule for electrical panels
29.	There is work permit system/ LOTO system is in place and being implemented in its true spirit.

S. No.	Observations	Element / Evidence	Standard	Recommendation	Risk Level	Rating
	<b>It was observed</b>			<b>It is recommended</b>		
1.	Safety Committee is in place having equal number of management & worker representative but the worker representatives are selected and not elected	Safety Culture & System	Factories Act 1948 Section 41G	The worker representative of the safety committee shall be elected as per the provisions of the Factories Act 1948	Low	3.5
2.	There is no Dead Man Switch and there is no checklist for operating the forklifts used inside the premises.	Safety Culture & System	Best Practices	It is necessary to install standard safety features like dead man pedal and daily checklist shall be developed for safe operation of forklifts	Medium	3
3.	In API pilot plant, safety valve and rupture disc is provided in reactor R7 and its connected to the scrubber but there is no high temperature or pressure alarm	Safety Culture & System	Best Practices	It shall be ensured that high temperature or pressure alarm shall be provided so that before blowing of safety valve or rupture disc system temperature or pressure can be controlled.	Medium	2.5
4.	SCBA sets are available in different areas of the plant but workers in warehouse are not fully aware of its use.	Safety Culture & System	Best Practices	Workers shall be trained on about the use of SCBAs.	Medium	3
5.	In CCOE storage area, identification tags are not available on the	Safety Culture & System	Best Practices	Identification tags shall be provided on all equipment and proper earthing shall be maintained	Medium	3

	pumps and earthing strip is broken.					
6.	During document review, safety valves are being tested once in a year by competent person but set pressure and lifting pressure is mentioned in the certificate but reset pressure is not mentioned which is necessary	Machine Safety	Factories Act 1948 Section 41	Reset pressure shall also be written on the certificate and it shall be ensured at the time testing religiously	Medium	3
7.	Medical checkup for food handlers is being done but not for communicable / contagious diseases.	Safety culture and System	Best Practices	It shall be ensured that the food handlers are free from any contagious diseases.	Medium	3
8.	Gas cylinders are kept without proper chaining in the fabrication area	Fire Safety	Indian Electricity Rule 1956 – Rule 61	It shall be ensured that all gas cylinders shall be stored with proper marking and chaining.	Medium	3
9.	In the gas cutter set, pressure gauge was found broken and only two flashback arrestors are provided instead of four which is not safe.	Fire Safety	Gas cylinder rule 2004	It shall be ensured that 4 Nos of flashback arrestors are provided two at the cylinder and two at the torch. Also workers shall be trained to ensure it before starting the cutting operation.	High	2
10.	Toe guards are not provided at the ETP platforms	Safety Culture & System	Factories Act 1948 & Rules made thereunder	It shall be ensured that toe guards are provided at all landings and platforms	Medium	3
<b>SOLVENT STORAGE YARD</b>						

11.	The flame arrestors are installed at the vent of the solvent tanks and the periodic maintenance record records is not available	Safety culture & System	Best Practices	It shall be ensured that the flame arrestors are periodically checked and serviced and records shall be maintained.	Medium	3
<b>SOLVENT WAREHOUSE</b>						
12.	The safety awareness level of the employees working in this area found less effective.	Training	Factories act 1948 & Rules made thereunder	It shall be ensured that all employees are aware of their role as per emergency response plan	Medium	3
<b>QC &amp; R&amp;D</b>						
13.	Persons are not fully aware of their role as per Emergency Response Plan in QC area	Emergency Response	Factories Act 1948 – Sec 38	It shall be ensured that all person area trained about their role in case of emergency,	Medium	3
<b>OCCUPATIONAL HEALTH CENTER</b>						
14.	The oxygen cylinder is available and maintained in good condition but there is no standby filled oxygen cylinder	Safety Culture & System	Factories Act 1948 Section 45	A filled standby oxygen cylinder shall be available all the time for the replacement of the existing cylinder whenever required.	Medium	3
15.	Oxygen cylinders in the ambulance was found in laying condition though the pressure in the cylinder was ok (150 bar). At present	Safety culture & System	Factories Act 1948 Section 45	Cylinders shall be kept upright always and clamped properly.	Low	3.5

	Ambulance is outsourced.					
<b>FIRE PUMP HOUSE</b>						
16.	The HSD day tank in the fire pump house is having earthing from single point only which is not safe	Electrical Safety	Best practice	It shall be ensured that all equipment shall be earthed from two distinct points.	Medium	3
<b>ELECTRICAL SYSTEM</b>						
17.	The thermography of the electrical panels is not being done	Electrical Safety	Best Practices	To move towards best safety practices thermography shall be done periodically	Low	3.5
18.	Cable trenches are not being checked for any water or some unwanted material in it	Electrical Safety	Indian Electricity Rule 1956 – Rule 64	A program shall be made to check the cable trenches for unwanted material in water to ensure the safe operation.	Low	3.5

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