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HAZARD IDENTIFICATION, RISK ANALYSIS AND RECOMMENDATIONS FOR IMPROVING SAFETY IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

Pharmaceutical companies form the backbone of an effective health care service and its development is essential for the progress of any nation. With the evolution of pharmaceutical industry new processes are being used for cost effective and high productivity. The danger of an accident happening also increases with induction of new processes. As of late, particularly from 2010 to 2015, accidents in pharmaceutical industry have been significantly increased mainly because of human errors, resulting in fire, explosions and various accidents. The majority of the incidents happen because of the low familiarity with the safe working procedure.

This study concentrates the methods that are being used to assess and minimize the risks that dwell in any company thereby enhancing the wellbeing of the industry. The methods that are mainly used are Hazard identification, Task analysis, internal audit, HAZCOM using MSDS, and Failure mode and effect analysis (FMEA).The palpable proof of mechanical threats and hazardous zones are isolated effectively and sound incident circumstances are recognized which could hamper the workplace. This paper deals with the various techniques that have been implemented in reducing the risk to as low as reasonably practicable (ALARP) level and necessary recommendations are made to improve the safety inside the pharmaceutical plant premises.

KEYWORDS: Risk Assessment, Hazard Identification, Task Analysis, Internal Audit, Hazcom

INTRODUCTION

The Indian Pharmaceutical industry has been seeing incredible development as of late, controlled by increasing utilization stages of the nation and solid interest from fare markets. The pharmaceutical business in India is evaluated to be worth about US$ 10 billion, developing at a yearly rate of 9%. In world rankings, the residential business stands fourth as far as volume and thirteenth in quality terms. The positioning in worth terms might likewise be a reflection of the low costs at which medications are sold in the nation. The key features of the industry include being high on regulations, less price elasticity, limited consumer choice, research oriented and highly dependent on the health infrastructure. [1] For any industry to be effective in all terms, it ought to meet the generation necessities to achieve greater profits as well as keep up the most astounding safety norms for all concerned activities. The business needs to recognize the hazards, survey the related risks and control the risks to middle of the road level on a nonstop premise to achieve the desires results.

Generally with the rising episodes of flame mishaps in pharmaceutical manufacturing plants, the safety concerns have turned into a genuine matter of open deliberation. The major harms in the pharmaceutical industries are most generally brought about by a slip, trip or fall, release of hazardous substances or mishandling. In spite of a tremendous change in the innovation and strategies used to build and fabricate plants, there are occurrences that happen like gas

leakages, blasting of boilers or a whole process plant is leveled to the ground by flame. All the process industries and pharmaceutical plants are in no way, shape or form resistant from calamities, as the occasions at Chernobyl and Bhopal in the past and all the more as of late, in Japan have appeared.

HAZARD IDENTIFICATION AND RISK ANALYSIS IN PHARMACEUTICAL INDUSTRY

Hazard Identification Risk Assessment (HIRA) includes a basic framework for gathering data pertaining to present safety measures and use of a decision making process. It helps in identifying the cause that may result in a major accident, and the outcomes, and what alternatives are there to anticipate and alleviate the risk. It likewise helps with diminishing the event of incidents and near misses. It is a procedure of determining so as to characterize hazards their likelihood, recurrence and seriousness and assessing the risk, including wounds and potential loses. Risk assessment gives the true premise to exercises proposed in the methodology to lessen misfortunes from distinguished hazards. [2] Ultimately, the objective is to reduce the level of hazards and risk associated with them in the industry which is one of the important factors which has an irresistible impact on the betterment of the company. This paper briefly describes five methods used for hazards identification and risk analysis in a pharmaceutical industry with inspected issues and provides important suggestions that have been made to improve the safety of the same.

Process Description

The production of oral solid dosages, for example, tablets is a complex multi-stage process under which the beginning materials change their physical qualities various times before the last dose structure is created. Conventionally, tablets have been made by granulation, a procedure that confers two essential & critical qualities: liquidity and ability to be versatile & compact. Both wet granulation and dry granulation (slugging and roll compaction) are utilized. Despite whether tablets are made by direct pressure or granulation, the initial step, processing and blending, is the same; consequent steps contrast. Various unit procedures are included in making tablets, including molecule size diminishment and estimating, mixing, granulation, drying, compaction, and (as often as possible) covering. Different components connected with these procedures can truly influence content bioavailability, security & safety, or consistency.

METHODOLOGY

The methodology mainly corresponds to study and analyze the causes of potentially dangerous phases of a pharmaceutical company by Identification of hazards, Assessment of risks using the FMEA technique (failure modes and effects analysis) for the mechanical equipment like pumps, Task analysis of the hazards related to human behavior, Compliance audit through Checklists for the boilers (check lists analysis), HAZCOM through the analysis of Material Safety Data Sheet analysis and communication of hazards to the workers and hazard analysis and risk assessment.

Hazard Identification

Hazard Identification technique requires the employer, in discussion with the workers ought to recognize all apparently noticeable hazards which can possibly bring about an incident / accident in association with Likelihood, Severity and Consequences of the accident/incident. The Hazard Identification procedure is used to distinguish dangers that could achieve a potential major accident for the full extent of operational modes, including normal operations, start-up, and shutdown, moreover potential, basic or unpredictable conditions. Reassessment of Hazards has to be done at a point where huge change in operations has happened or manufacture of any new substance has been added in the plant facility.

[3]Hazards are identified in the pharmaceutical plant for its inventories, layout of the plant and the process involved in the manufacturing process, storage condition etc. Walk through surveys were carried out in discussion with plant operator, manager under their supervision and assistance. The HAZID study generally outlines all the possible hazards involved in the plant and gives the possible scenarios for leaks, fires, explosion and other possible hazards. (Selvan et.al). All the hazards that are identified are tabulated along with the prevailing control measures. Necessary recommendations are made on further analysis if the prevailing control measures and the further suggestions that were made are taken to the top level management's knowledge.

FMEA

The second methodology that has been implemented for the analysis of risks is Failure mode and effect analysis. Failure mode effect analysis was initially created by NASA to enhance and check the reliability of space program equipment. FMEA is a standout amongst the most critical and generally utilized methods for risk assessment. It is deliberate to be a proactive activity process completed ahead of time actualizing new or changes in items or process in a perfect world. FMEA is mostly conducted in the configuration or procedure improvement stages and it distinguishes corrective actions required to decrease failures to guarantee the most noteworthy conceivable yield safety and reliability. [4]

According to this method, risk assessment was conducted for the pumps by a review team who seriously investigate the potential failure modes, potential failure effects, potential causes and controls that are already in place are analyzed. Based on the analysis of past failure data and the expert assistance, severity rating is given to the particular failure mode and similarly occurrence and detects ability.

Severity

Severity generally denotes the seriousness of the effect that is being caused by the failure mode. If the rating of severity is higher, it means that the seriousness that will be caused by the risk will also be higher.

Table 1: Table for severity Level

Ranking	Event /Failure	Level of Effect
10	Highly dangerous event without any warning	
		Unacceptably high
9	Highly dangerous Events that happen with	
	warning	Unacceptably high
8	Destructive failure without safety	Very high
7	System inoperable equipment damage	High
6	System inoperable minor damage	Moderate
5	System inoperable without damage	Low
4	Performance degradation	Very low
3	Performance degradation without system failure	
		Minor
2	System operation with minimal interference	Very minor
1	None	None

Occurrence

The occurrence of the event mainly depends upon the data of the past accidents and failures from which the likelihood of the particular failure can be isolated.

Table 2: Table for Occurrence Level

Rating	Classification	Example
10		
9	Very high	Inevitable failures
8		
7	High	Repeated failures
6		
5	Moderate	Occasional failures
4		
3	Low remote	Few failures
2		
1	Remote	Failures unlikely

Detect Ability

It is the assessment of the likelihood that the prevailing control measure will detect the failure even and its cause.

Table 3: Table for Detect Ability Level

Rating	Detection by Control	Detection Level
10	Failure mode not detected by design control	Absolute uncertainty
9	Very remote chances of detection by the design control	Very remote
8	Remote chances of detection by design control	Remote
7	Very low chances of detection of failure mode by design control	Very low
6	low chances of detection of failure mode by design control	Low
5	Moderate chances of detection of failure mode by design control	Moderate
4	Moderately high chances of detection of failure mode by design control	Moderately high
3	High chances of detection of failure mode by design control	High
2	Very high chances of detection of failure mode by design control	Very high
1	Failure mode detected by design control	Almost certain

RPN number is then calculated by the formula RPN = S*O*D

After the evaluation of RPN number, necessary recommendations are done so as to reduce the RPN number of the analyzed activity /product /service and similar procedure is followed for the other flow related equipments and necessary actions recommended are tabulated. A graph is plotted with activity/event that is leading to the failure is taken along the X-axis and RPN values are taken along Y-axis to form a RPN chart. From that graph the event/activity that has higher RPN is shown immediate attention and necessary actions are taken to reduce the same. Same procedure is followed to other activities (Suresh etal, 2014)

Compliance Audit (Checklist Analysis):

This is a most viable method for catching and going on the experience of others, also, along these lines is a significant hazard identification method. These methods are generally utilized towards the end as a last check with the goal that nothing has been dismissed by different strategies and this strategy don't cover a wide range of danger, especially facility-specific hazards, and they don't encourage lateral thinking .They can be viably utilized for agreeing to a

engineering standard or a lawful compliance. [5]

According to the Indian boilers act 1923, a checklist was prepared to audit the compliance of the boilers present inside the industry premises with the assistance of the safety supervisor and necessary corrective actions are recommended in order to remove the non-conformities.

Task Analysis

This method is implemented in commercial ventures fundamentally to distinguish dangers connected with human variables, procedural blunders and the 'man-machine interface'. This procedure can most broadly be connected to workplaces, for example, control rooms, or to particular occupations, for example, start-up or shut-down operations. All the categories of dangers that are distinguished by the technique incorporate or may incorporate procedural failures, HR issues, risky human mistakes and inaccurate reactions to alerts.[5]

Some of the operations that are capable of causing danger to the workers in the event of not following the safe operating procedures and hoarse play of the workers are shortlisted along with their corresponding hazards .Then necessary hazard control methods that are to be followed are also tabulated and communicated to the workers.

HAZCOM using MSDS

MSDS is a helpful document of data to acknowledge the existence of the risks associated with the chemicals and treatment of perilous or harmful materials. It is additionally great to allude the specialized points of interest given by the supplier of materials on their items. [3] Analysis of all the chemicals that are used in the production process of the company are collected and based on the analysis of their properties from the MSDS (Material Safety Data Sheet) of the chemicals, the chemicals are isolated based on their hazardous nature. The highly dangerous chemicals are checked whether the workers carefully follow the handling procedures and know the nature of hazardous chemical they are working with and the measures to be taken in case of an emergency . If it is not known, it has been effectively communicated to the workers by explaining the hazards involved in the handling of hazardous chemicals in the regional language.

RESULTS AND DISCUSSIONS

Hazard Identification

Hazard identification is carried out in the whole plant and necessary recommendations are made to reduce the vulnerability by establishing proper control measures to the hazards associated with the plant. The table below lists the hazards that were prevailing in various zones of the company and necessary recommendations that are suggested to reduce its occurrence and severity.

Table 4: Table for Hazard Identification

LOCATION/ PROCESS/ ACITIVITY/ UNIT	ZONE	HAZARD PRESENT	CAUSES	CONTROL MEASURE	RECOMMENDATIONS
HSD Storage	Zone 1	Fire &	Spillage of	Secondary containment is	
Tank		explosion,	HSD	provided	
		Air	Hot work	Hot work permit is in	
		pollution,	operation	place	
		Loss of	Electrical	Fire hydrant is provided in	
		man &	spark from	the area	

Table 4: Contd.,					
		material,	open circuit		
		Fuel	Spark from	HSD is received in closed	Spark arrestor should
		Losses	running	drums	be used in vehicles.
			vehicles		
			Unsafe Act	Smoking is not allowed	No smoking board
				inside the factory	should be present in
				premises	the storage area
Diesel	Zone 1	Fire &	Excessive	Ear muffs are given to	Proper engineering
Generator		explosion,	noise	workers	control should be in
		Air			place to reduce the
		pollution,			noise level
		Noise	Toxic fumes	Silencer is attached with	Exhaust should to
		pollution	from	chimney	monitored once ina
			exhaust		year to prevent air
					pollution.
			Hot work	Hot work permit is in	
			operation	place	
			Electrical	Fire hydrant is provided in	
			Spark	the area	
Gas Bank I	Zone 8	Fire &	Leakage of	Manual gas detection	Automatic gas
		explosion,	gas	system is present,	detection system
		Air			should be installed
		pollution,	Welding	Hot work permit is in	
		Loss of	Operation	place	
		man &	Electrical	CO2 fire extinguisher is	
		material,	spark	available and earthing is	
		Fuel		provided.	
		Losses	Unsafe acts	Smoking is not allowed	No smoking board
				inside the factory	should be present in
				premises	the storage area
			Spark from	Gas is received in closed	Spark arrestor should
			running	cylinders	be used in vehicles.
			vehicles		
Boiler	Zone 2	Fire &	Excess	Pressure gauge is in place,	
		explosion,	Pressure	Calibration of instrument	
		Air	inside the	is done every year	
		pollution,	boiler		
		Noise	Gas leakage	Manual gas detection	Automatic gas
		pollution,	due to	system is present,	detection system
		Loss of	damaged		should be installed
		man &	pipeline		
		material	Hot work	Hot work permit is in	
			operation	place	
			Excessive	Ear muffs are given to	Proper engineering
			noise	workers	control should be in
					place to reduce the
					noise level
			Electrical	Fire hydrant is provided in	
			spark from	the area	
			open circuit		
Solvent	Zone 3	Fire &	Spillage of	SOP is available and	
Storage Area		explosion,	solvent	containers are closed	
		Air		properly.	
		pollution,	Hot work	Hot work permit is in	
		Loss of	operation	place	

Table 4: Contd.,					
		man &	Developme	DCP fire extinguisher is	Workers should be
		material	nt of static	available.	trained about static
			charge		charge.
			Spark from	Flame proof electrical	
			open	fittings are present.	
			electric		
			circuit		
Electrical	Zone 2	Fire &	Spark from	CO2 fire extinguisher is	
Control Panel		explosion,	open	available and earthing is	
		Air	electric	provided.	
		pollution,	circuit		
		Loss of	Hot work	Hot work permit is in	
		man &	operation	place	
		material			
Warehouse	Zone 4	Fire &	Leakage	Careful handling of the	Spill kit should be in
		explosion,	from	containers	place and emergency
		Air	Containers		eye washer should be
		pollution,			present.
		Injury to	Hot work	Hot work permit is in	
		workers,	Operation	place	
		Property	Electrical	CO2 fire extinguisher is	
		damage,	Spark	available and earthing is	
		Fuel		provided.	
		Losses	Unsafe Acts	Workers are trained to	Warning signs on near
				follow SOP	miss should be
					provided.
			Charging of	DCP fire extinguisher is	Workers should be
			Stacker	available.	trained about static
			batteries		charge.
			Falling of	PPE is provided to	
			container	workers.	
			from the		
			stacker		
			Overload in	Maximum load capacity is	Stacker load test
			the stackers	displayed on the stacker	should be done every
				and racks.	1 year.
Chemical	Zone 7	Fire &	Leakage	Spill control kit is	
storage (QC)		explosion,	from	available.	
		Air	Container		
		pollution,	Chemical	Body shower is present.	
		Injury to	splashes		
		workers,	Fumes	The muffle furnace and	
		Property	During	drying oven is kept near	
		damage,	heating/	fume hood.	
		Fuel	drying of		
		Losses	materials		
			Fumes from	Nose mask is provided to	
			open	workers.	
			containers		
Air	Zone 5	Damage	Generation	Dust extraction system is	
Compressor		to workers	of dust	used to collect the dust.	
		health	particles		
			Excessive	Ear muffs are provided.	Proper engineering
			noise		control should be in
					place to reduce the

Table 4: Contd.,					
					noise level
Granulation	Zone 5	Worker	Developme	DCP fire extinguisher is	Workers should be
Machine		injury	nt of static	available and equipments	trained about static
			charge	are earthed.	charge and conductive
					shoes should be
					provided.
			Generation	Nose mask is provided	
			of dust	and dust extraction system	
			particles	is used to collect the dust.	
			Excessive	Ear muffs are provided.	Proper engineering
			noise		control should be in
					place to reduce the
					noise level
LPG storage	Zone 6	Fire &	Leakage of	Manual gas detection	Automatic gas
Area		explosion,	gas	system is present,	detection system
		Air			should be installed
.	.	pollution,	Welding	Hot work permit	
		Loss of	Operation		
		man &	Electrical	CO2 fire extinguisher is	
		material,	spark	available and earthling is	
		Fuel		Provided.	
		Losses	Unsafe acts	Smoking is not allowed	No smoking board
				inside the factory	should be present in
				premises, Danger sign is	the storage area
				present	

FMEA

Failure mode effect analysis that has been carried out for the pump area and necessary recommendations are done to reduce the RPN so as to reduce the effects caused due to failure of equipment.

Table 5: Failure Mode and Effect Analysis for Pumps

Activity/ Product/ Service	Potential failure Modes	Potential failure effects	Severity (S)	Potential Causes	Occurrence (O)	Current control	Detection (D)	RPN	Actions Recommended	Resp.
Pumps	Main Bearing Failure	Damage to the pump	6	Pump cannot spin	3	Inspection	6	108		
	Leakage in water control valve	Insufficient water discharge	5	Rupture during operation	4	Inspection	5	100	Discharge test	Mr. Kishan Aswal
	Water control valve is inappropriately closed	No water discharge	5	Human error	4	Inspection	4	80	Verification should be done by the safety supervisor	Mr. Kishan Aswal

Table 5: Contd.,

	Short Circuit in the electrical panel	Damage to the property environment, Loss of man	6	Breaker fails to open	2	Inspection	3	36		
	Drive Shaft Fracture	Reduction in flow rate	6	Less Pressure	2	Inspection	3	36		
	No signal in the pressure/ flow transmitter	No water discharge	3	Device failure	2	Inspection	5	30		Mr. Kishan Aswal
	Manual test valve is prematurely opens/ is left open after test	Damage to the pump	6	Diversion of firewater overboard	1	Redundant valve in discharge line & Low pressure switch is present	3	18	Independent check of valve position after testing & periodically thereafter Indicate pressure switch status in control room should be maintained	Mr. Kishan Aswal
	Manual test valve prematurely closes/ is left closed during test	Damage to the pump	6	Blocked discharge from firewater pump	1	Pressure control valve is present	3	18		
	Isolation valve is prematurely closes/ is left closed after test	Damage to the pump	6	Loss of water	1	Inspection	3	18	Independent check of valve position after testing should be done	Mr. Kishan Aswal

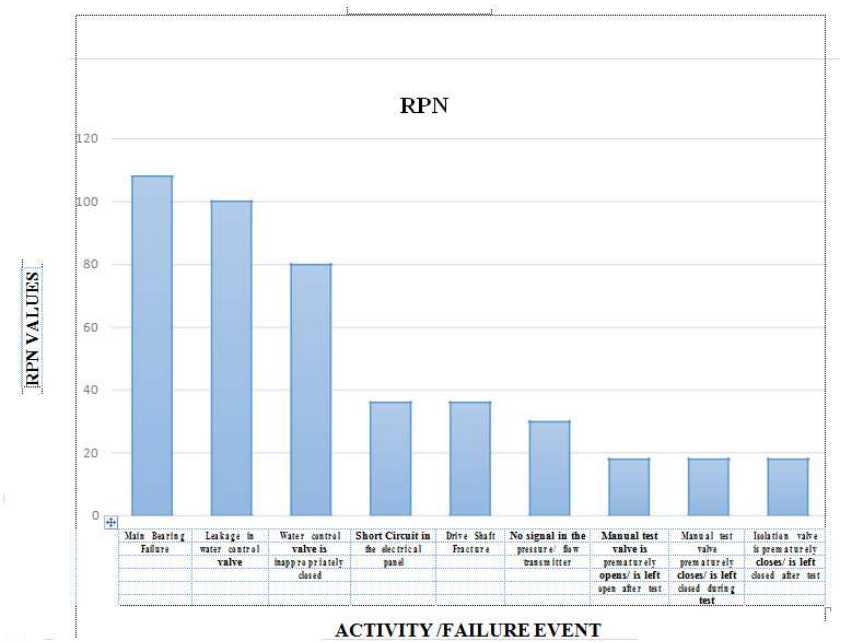

Figure 1: RPN Graph

From the above graph, it is evident that the main activity /failure event is main bearing failure and its corresponding RPN is 108. So necessary actions are taken initially to reduce the RPN value of this activity followed by the others according to their RPN values.

Compliance Audit

A checklist was prepared in accordance with the boilers act 1923, and audit has been conducted for the battery of boilers in the plant premises with the help of plant operator and non-compliances with the legal compliances are noted down and actions are recommended to the top management for further perusal.

Table 6: Checklist for Compliance Audit

Sl. No.	Description	Conformance (Yes/ No/ NA)	Recommended Corrective Action
1.	Boiler has been enlisted as per the	Yes	
	procurements of the Indian Boilers Act 1923		
2.	Boiler limit is more than 25 liters	Yes	
3.	Boiler has more than one kilogram for each	Yes	
	centimeter square outline gauge pressure and		
	working gauge pressure		
4.	Water is warmed above one hundred degrees	Yes	
	centigrade in the boiler		
5.	Pressure at which steam goes through steam	Yes	
	funnel surpasses 3.5 kilogram for every		
	square centimeters above atmospheric		
	pressure		
6.	Stem pipe surpasses 254 millimeters in	Yes	
	internal diameter and the pressure of steam		
	surpasses 1 kilogram for each square		
	centimeters above the atmospheric pressure		

Table 6: Contd.,			
7.	Worker who proposes to undertake any welding work associated with or related to a boiler, or a boiler segment or both has a Welders authentication from Competent Authority	Yes (PTW Certificate)	
8.	Annual inspection by boiler inspector is done	No	I have insisted in doing the inspection by the factory inspector as it a legal requirement.
9.	A working certificate showing validity period, maximum allowable pressure is displayed	Yes	
10.	A qualified person is present to take charge of the boiler	Yes	
11.	Any mishap that occurs to a boiler or boiler component is reported in written by the proprietor or individual in charge within 24 hrs.	Yes	
12.	Hydraulic test is performed once in 12 months	Yes	
13.	Inspection of battery of boilers is done	Yes	
14.	Examination of the water gauges, pressure gauge and safety valves	Yes (Calibration Certificate Available)	
15.	Manholes with door, hand hole and sight holes, and cleaning plugs and all caps in the header are available	Yes	
16.	There is adequate water in the boiler and that the gauge cocks are working freely while working	Yes	
17.	Cock on top of is opened to permit air to escape while working	Yes	
18.	Blow off cock and Scum cock are available	Yes	
19.	Blow off cock is completely shut and tight while working	Yes	
20.	safety valves and feed check valve are working properly	Yes	
21.	Water is spilling from any part of the boiler	Yes	I have insisted to seal the leakage in the pipe as soon as possible.
22.	Feed pump is in working order	Yes	
23.	Pressure gauge has a plain mark on it demonstrating the most elevated pressure allowed for the boiler and the mark is kept clean	Yes	

Table 6: Contd.,			
24.	Low water safety valve is present	Yes	
25.	Proper PPE is worn by the workers working	Yes	
	in the boiler area		
26.	No structural change, expansion or	Yes	
	recharging in or to a boiler without earlier		
	sanction of Chief Inspector		
27.	A person is allowed to go inside the boiler	Yes	
	with proper disconnection		
28.	SOP is present in the area	Yes	
29.	Proper PPE is present for visitors	No	Additional Ear muffs
			should be kept

Task Analysis

Task analysis is carried out for all activities that are capable of posing threat to the employees mainly because of their behavior by continuous monitoring of their work behavior and past accident data, the activities are isolated and hazards that are caused by them are tabulated. Then necessary control methods are established to minimize the hazards and they are effectively communicated to the workers by PEP talks.

Table 7: Table for Task Analysis

S. NO.	TASK	POTENTIAL HAZARDS	HAZARD CONTROL METHODS
1.	Welding /	Eye Damage	1.Welding/cutting operations shall be performed
	Cutting	Electric Shock	by trained & certified workers.
	Operation	Cuts & Burns	2.Special metal fire extinguisher (or proportional)
			must be quickly accessible in the work region and
			must be kept up in a condition of availability for
			moment use.
			3. Garbage should not be permitted to aggregate
			on the premises, as it might be lighted by the
			flashes.
			4. When welding is being performed on a higher
			level where there is an exposure to workers
			below, the area directly below the welding shall
			be cleared and marked as a "Do Not Enter Zone",
			to protect any workers passing underneath from
			being hit by sparks.
			5. All electrical lines & small apparatuses should
			be assessed and in good working condition prior
			to use.
			6. During welding operations, legitimate welding
			gloves and a full-confront, UV-beam defensive
			shield should be worn to prevent wounds to the
			Administrator.
			7. A fire watch must be kept up no less than 30
			Minutes after the hot work is finished.
2.	Welding /	Eye Damage	1.Welding/cutting operations shall be performed
	Cutting	Electric Shock	by trained & certified workers.
	Operation	Cuts & Burns	2.Special metal fire extinguisher (or proportional)
			must be quickly accessible in the work region and
			must be kept up in a condition of availability for
			moment use.
			3. Garbage should not be permitted to aggregate

Table 7: Contd.,				
				on the premises, as it might be lighted by the flashes. 4. When welding is being performed on a higher level where there is an exposure to workers below, the area directly below the welding shall be cleared and marked as a "Do Not Enter Zone", to protect any workers passing underneath from being hit by sparks. 5. All electrical lines & small apparatuses should be assessed and in good working condition prior to use. 6. During welding operations, legitimate welding gloves and a full-confront, UV-beam defensive shield should be worn to prevent wounds to the Administrator. 7. A fire watch must be kept up no less than 30 Minutes after the hot work is finished.
		Electrical		
		Shock		
		Electrical Burn		
		Arc Flash		
		Bodily injury		
3.	Working in a confined space	Unsafe oxygen level Flammable and explosive atmosphere Engulfment Electrical hazards Physical hazards Thermal hazards Slip & trip Manual handling hazards Psychological hazards	1. 2. 3. 4. 5. 6.	Work permit must be taken by the worker. The worker must a trained in working in a Confined space. Initial gas testing should be done. Worker should wear clear safety glasses, gloves, and safety helmet &safety shoes. Gas detector with the entrant should be present for constant monitoring of atmosphere at all times. Worker should take care at all times and think about the task at hand
4.	Battery repair/ maintenance work	Foot Injury due to dropping of object on foot Burns & eye injury due to Battery acid spillage/splash es Electrical	1. 2. 3. 4. 5.	Worker should wear safety shoes, goggles, apron, gloves Worker should follow proper battery handling procedures Lockout/ tag-out & manufacturer's instructions should be strictly followed by the worker Fire extinguisher should be placed in appropriate locations All combustibles and flame perils from machine territory ought to be uprooted

Table 7: Contd.,

		Shock due to	6.	Adequate ventilation should be there in the
		improper		location.
		operation and	7.	No smoking board should be present near the
		maintenance,		battery.
		battery		
		condition		
		Fire &		
		Explosion due		
		to Sparks,		
		improper		
		storage of		
		flammable		
		substance, poor		
		ventilation,		
		smoking,		
		improper		
		procedures		
5.	Handling	Eye injury	1.	Workers should wear proper PPE like aprons,
	Chemicals	Burn		gloves, safety shoes, safety helmet, goggles,
		Irritation		respirator (if needed) & face shield (if
				needed)
			2.	Workers should use the eye washer if
				chemicals fall on the eyes
6.	Lifting	Lower Back	1.	Workers should follow correct lifting
	Objects	pain		techniques
		Foot injury	2.	Workers should wear proper PPE like gloves
				& safety shoes
7.	Forklift	Trauma due to	1.	Worker should be trained to use a forklift
	operation	vibration	2.	Workers should wear proper PPE like safety
		Foot Injury		shoes, safety helmet, goggles and hearing
		Noise due to		protection
		the Engine		
8.	Using Drill	Eye damage	1.	Worker ought to use safety glasses with side
	Bit Sharpener	due to flying		shield
		chips	2.	Grounding ought to be done properly
		Injury to the		preceding the work
		hands	3.	Worker should strictly follow manufacturer’s
		Electrical		instructions
		Shock		
9.	Cleaning	Trauma due to	1.	Workers should wear proper PPE like aprons,
		chemical		gloves, safety shoes, safety helmet, goggles,
		contact		respirator or dust mask (if needed) & face
		Inhalation		shield (if needed)
		Foot injury		
		Head injury		
10.	Repair/	Electric Shock	1.	Workers ought to unplug electrical string and
	Routine	Noise		hold control of fitting amid repair/support
	maintenance	Trauma due to	2.	Workers should strictly follow
	of the Air	uncontrolled		Manufacturer’s instructions
	Compressor	release of	3.	Lock-out/tag out should be properly done and
		compressed air		verified prior to work
		Eye Injury due	4.	Workers should wear proper PPE like safety
		to flying debris		shoes, gloves, safety helmet, safety glasses
				with side shields and hearing protection
		Hand Injury		

Table 7: Contd.,				
11.	Handling of gas cylinder	Leakage or departure of combustible gasses can deliver a genuine explosive hazard Gases can be reactive Inert gases such as nitrogen, carbon dioxide and argon can bring about suffocation if discharged in amount Containers which are not appraised to acknowledge pressure can blast while receiving gasses	1. 2. 3. 4. 5. 6. 7.	Gas barrels, control valves, pressure controllers and gauges ought to be utilized carefully Broken or harmed hardware ought not be utilized and should be replaced as quickly as time permits There ought to be a standard regular check for leaks particularly in joints weight Prior to bringing a combustible gas into a response vessel, the vessel must be cleansed with oxygen or by flushing with inert gas Naked flames or different paths of ignition must be thoroughly barred from the region. Exhaust lines must be appropriately vented Gas receiving compartments must be fit for tolerating the required working pressure
12.	Working at height	Fall from Height can result in multiple fractures, neck injury, fatality Head injury due to falling objects	1. 2. 3. 4. 5. 6. 7. 8. 9.	Do as much work as possible from the ground First ensure workers can get safely to and from where they work at height Equipments should be maintained and checked regularly and only suitable ones should be used by the workers Precautionary measures should be taken by workers when working on or near fragile surfaces Proper PPE must be worn by the workers like safety helmet, full body harness, safety belt, etc Emergency evacuation and rescue procedures must be taken into consideration Ladders should not be overloaded and before working at height workers must check the equipment or materials weight they are Carrying. For information workers should check the label on the ladder Ladders should not be rested against weak upper surfaces Ladders should not be used for heavy works,

Table 7: Contd.,				
				they should use them only for light work
				For maximum of 30 minutes at a time

HAZCOM using MSDS

MSDS of all the chemicals that are used in the industry have been analyzed and checked and all the necessary handling techniques of the highly hazardous chemicals are conveyed by PEP talks and it is recommended to the management in worst cases to individually train them.

CONCLUSIONS

Hazard Identification was conducted for the pharmaceutical manufacturing plant and risk assessment was performed on the equipment& machines to identify various hazards using FMEA technique. The nonconformities are mitigated by implementing necessary corrective actions for the results that have been obtained by the above mentioned techniques to improve the safety. All the applicable legal regulation is referred and suitable measures are taken to comply with the regulation wherever the deviation occurs. Task analysis is carried to analyze the behavior of the workers and necessary suggestions were made to change the working habit of the workers by positive reinforcement. Safety and mitigation methods are properly communicated to the workers (HAZCOM), based on Material Safety Data Sheet (MSDS), so as to minimize injury from accidental exposure to hazardous chemicals. Further analysis and review of the Health, Safety & Environment Policy was done and suggestions were given for necessary improvements.

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