HAZARD IDENTIFICATION AND RISK ASSESSMENT IN API OF PHARMACEUTICAL INDUSTRY

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Abstract

The Hazard Identification and Risk Assessment or HIRA can serve as a risk assessment tool that will assist users in identifying the hazards and assess the risks involved in each identified hazard. This risk assessment tool will identify potential hazards involved in each task in departments. Once the hazard is identified, the risks involved will be estimated and classified. If the perceived risk falls in a category that is higher than the lower risk category, possible control measures will be recommended. At the same time, the user can add new action plans, tasks and control measures to the system to update the existing information system. Based on various study, we provided suggestions to implement the same to applicable industries..

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1. INTRODUCTION ABOUT HAZARD IDENTIFICATION AND RISK ASSESSMENT

HIRA is an analytical technique that combines the technology and experience of worker (or) supervisors in identifying potential failure modes possible for the process and its elimination. HIRA is a ''before-the-event'', action necessary for the team (safety, maintenance, production) to make changes to the production process easily and cheaply. This risk assessment method is used to manage security risks. Hazards have been identified and evaluated; Potential control measures will then be recommended for safe execution of activities. It is a continuously developing technology. It should avoid unsafe operation and provide a safe execution process.

Risk Priority Number (RPN) $=$ Severity $\times$ Probability

Hazard Identification

Hazard identification (HAZID) is the identification of studies, which form the critical stage of a risk assessment. They are two way purpose of identifying hazard.

-To find a list of hazards to be evaluated using other risk assessment techniques.

-To do a qualitative assessment has taking measures to mitigate the risks arising from the hazards. This is known as hazard assessment. When the initial hazard identification phase, the criteria used to show the risk will be established and the potential hazards and accidents will be reviewed. For this determination, the facility will be divided into different classes. In addition, to identify the threats will be classified into high, medium and low hazards. It is of great importance that the level of hazards is clearly demonstrated to reduce the level of risk.

Risk Assessment

Hazard identification is the initial process of finding, following the necessary steps, calculating risk assessment and management of environmental risk. Preliminary risk assessment and risk scoping are

-Risk assessment in detailed

-Communicated with suitable residual risk

Risk assessment with certain logical steps to carry out by

-Looking the hazard

- Decided who might to be harmed

- Evaluate the risk arising from the hazard

- Record findings

- Review your assessment

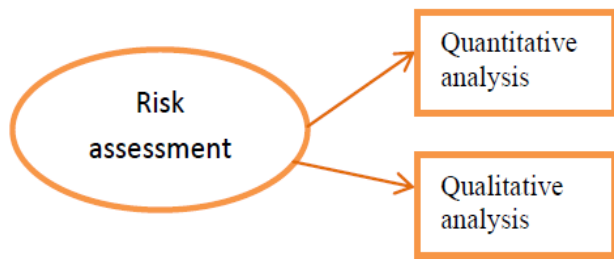There are two types of risk assessment

Figure 1.1. Types of risk assessment

Qualitative analysis is the object probability estimate based upon known risk information applied the circumstances being considered. Quantitative analysis is these type is subjective, based upon personal judgment backed by generalized data risk. Qualitative assessments are easier to make and are the once required for legal purposes. When there are types of work, whose hazards and risks are similar in different workplaces or physical areas, a generally qualitative risk assessment can be made in the pharmaceutical industry.

2. REVIEW OF LITERATURE

Hazard Identification, Risk Assessment and Risk Control in Chemical Industry – R. Panday and B. Rachmat (2020) The study found that the company XYZ identified 104 hazards in the year 2017 due to poor working environment, worker attitudes, manual work, equipment and machinery. This study showed that 57% of the total risks fall in the medium range, 38% are high, 5% low, and none of them are classified under extreme risk. To control risk, the company is taking proactive action through the elimination of risk, engineering, administration and personal protective equipment (PPE).

Determination of hazard in truck manufacturing industry using hazard identification risk assessment technique – R.Pawin vivid, N. Selvakumar, M. Ruvankumar (2020) This study aims to identify potential risks in assembling the process in industry using Risk Identification Risk Assessment (HIRA). Appropriate risk controls are providing engineering controls, administrative controls and personal protective equipment (PPE). This HIRA study can help make employers more active in ensuring the safety and health of workers. Hazards have been identified and evaluated, then possible control measures will be recommended for safe execution of activities.

Risk control analysis of a furniture production activities using hazard identification and risk assessment method – Sri Indrawati, Atyanti Dyah Prabaswari and M. Abdul Fitriyanto (2018) This study is to identify risks and determine risk control using risk identification and risk assessment method (HIRA). There are three main stages in identifying and analyzing hazards, classifying hazards and risk control.

The result shows that there are nine potential hazards in furniture production, out of which 22% are classified as high risk level, namely the hands and fingers cut off by the machine. Administration and engineering control and personal protective equipment, three types of risk control functions are prescribed to reduce the risk.

Analysis of the Potential Hazard Identification and Risk Assessment (HIRA) and Hazard Operability Study (HAZOP): Case Study – Bambang Suhardi, Pringgo Widyo Laksono, Andhika Ayu V.E, Jafri Mohd.Rohani, Tan Shy Ching (2018) This study aims to identify HIRA and HAZOP to identify and assess risk in the workplace. There are 17 findings of potential hazards in the production areas of batik printing, which can be classified into five types of hazards: labor attitude, work posture, work process, work center, and physical work environment. Out of the risk assessment, 34% in the extreme threat category, 24% threat in the high and medium category, and 18% in the low threat category, respectively. The proposed improvements are based on the HAZOP analysis worksheet. Practical solutions proposed include improvements in work attitude, work posture and physical work environment.

Risk Assessment in paint shop using HIRA for Automobile Industry – R. Sathishkumar, S. Kamalakannan, S. Sureshbalaji (2017) This study is to identify the hazards, then the risks can be accessed by the hazards and then the severity rating for the hazards can be analyzed. The paint shop focuses on other chemicals and mechanical operation, followed by equipment that helps users classify the hazard and assess the risk involved in each identified hazard. This risk assessment tool will identify potential hazards involved in each task in departments. Initially the hazard is identified, in which the risks involved will be estimated and classified. If the perceived risk falls in a category that is higher than the lower risk category, possible control measures will be recommended. At the same time, the manipulator can add new action plans, tasks and control measures to the system to update the existing information system.

Hazard Identification and Risk Assessment in Automotive Industry – R. Ramesh , Dr.M. Prabu, S.Magibalan, P. Senthilkumar (2017) The hazard identification and risk assessment or HIRA system can serve as a risk assessment tool that helps users identify hazards and assess the risks involved in each identified hazard. This risk assessment tool will identify potential hazards involved in each task in departments. Once the hazard is identified, the risks involved will be estimated and classified. If the perceived risk falls in a category that is higher than the lower risk category, possible control measures will be recommended. At

the same time, the user can add new action plans, tasks and control measures to the system to update the existing information system.

Hazard Identification and Risk Assessment by Qualitative and Quantitative methods – Selvanagaraj K, Prasanna S.P (2017) This study is intended to identify hazards and risks that can be assessed by a quantitative and qualitative method to determine whether the identified risks are significant or non-significant. A qualitative risk assessment can be performed by examining identified risks with legislative concern, interested party concern, business concern, and potential emergency concerns. Quantitative risk assessment can be performed using Risk Priority Number (RPN), which is derived from the frequency and duration of exposure, severity of harm and the number of people affected. A risk-based control plan should be designed according to the values of the risk priority number after the identification of hazards and the assessment of risks. Risk control measures should be followed by hierarchy of controls by elimination / substitution, engineering control, administrative control and personal protective equipment. This method is applicable to all industries in order to reduce the hazards and risks that make the workplace a safe working environment.
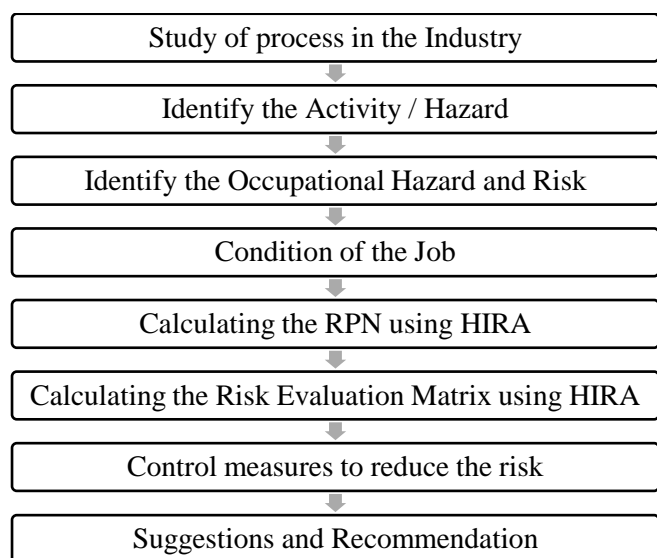
3. METHODOLOGY

Study of process in the Industry
↓
Identify the Activity / Hazard
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Identify the Occupational Hazard and Risk
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Condition of the Job
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Calculating the RPN using HIRA
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Calculating the Risk Evaluation Matrix using HIRA
↓
Control measures to reduce the risk
↓
Suggestions and Recommendation

Figure 3.1 Methodology

By the conduct of safety inspection in everyday at the work area to identify hazards and to make HIRA. Major hazards present in the work area are charging of solid chemicals / powders into the reactor / vessel and rotocone vacuum drier leads to skin burns and respiratory problems due to dust exposure. For the determination of hazards, process, involved skilled

worker and their activities are studied. Condition of job is obtained by their work depend on various conditions regular, irregular, normal, abnormal and emergency conditions. Risk calculated by the combination of probability and severity.

3.1 Risk evaluation matrix

The risk matrix is a matrix used during risk assessment to define the level of risk by considering the probability or the category of probability against the category of severity of the outcome**.**
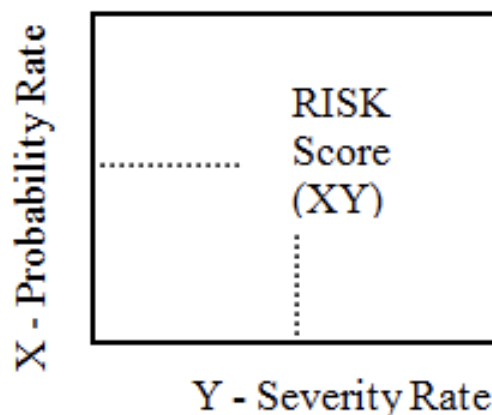

Figure 3.2 Risk Evaluation Matrix

The combined score is calculated for each hazard. If the score is 4 or less, it is considered a low risk. If the score is 6 to 12, it is considered a moderate risk. If the score is 15 or higher, it is considered a high risk. In addition, emergencies are considered high risk. Apart from this, any risk rating / probability rating of 4 or 5 will be considered as medium / high risk. All legal issues associated with the work are identified, listed and all are considered to maintain the necessary controls.

3.2 Probability Rate

The probability of occurrence is an estimate of how often a dangerous event occurs. It is the ratio of total results to favorable outcomes. Regarding the probability if they are indifferent or the ratio seen in a sample. A review of historical events that assists with this determination. Each threat of concern is evaluated according to numerical ratings and definitions.

Rating	Description	Examples of Description
5	Almost certain	Very high probability of damage.
4	Likely	High probability of damage.
3	Possible	Moderate probability of damage.

| 2 | Unlikely | Low probability of damage. |
| 1 | Rare | Very low probability of damage. |

Table 3.1 Probability Rate

3.3 SEVERITY RATE

Severity rates of injury indicate injuries and illnesses. An employee who takes time to return to work after an injury has had a serious problem that may return immediately.

Rating	Description
1	Injury / Ergonomics
2	First aid cases
3	Crush / Severe Injury
4	Permanent disorder
5	Fatal or death

Table 3.2 Severity Rate

4 RESULTS AND DISCUSSION

S.NO	Equipment/ Location	Hazards	OHS Risk	Condition of the job	Assessing RPN with Existing controls		
					P	S	R
1	Stainless steel reactor	Dust exposure, vapors, fumes	Respiratory problems and burns	R	4	3	12
2	Stainless steel vessel	Dust exposure, vapors, fumes	Respiratory problems and burns	R	4	3	12
3	Rotocone vacuum drier	Dust exposure	Respiratory problems and burns	R	3	3	9
4	Basket centrifuge	Dust exposure, vapors, fumes	Respiratory problems, Eye irritation and burns	R	4	3	12

Figure 4.1 Assessing RPN with existing controls

Existing controls			Additional Controls	Assessing RPN with additional controls			Risk level
Engg.	Admin.	PPE		P	S	R	
Scrubber & Ventilation system	SOP	Organic vapor mask	Powdered air purifying respirator	2	1	2	Low
Scrubber & Ventilation system	SOP	Organic vapor mask	Powdered air purifying respirator	2	1	2	Low
Scrubber & Ventilation system	SOP	Organic vapor mask	Powdered air purifying respirator	2	1	2	Low
Scrubber, Blower & Ventilation system	SOP	Organic vapor mask	Powdered air purifying respirator	2	2	4	Low

Figure 4.2 Assessing RPN with additional controls and its risk level
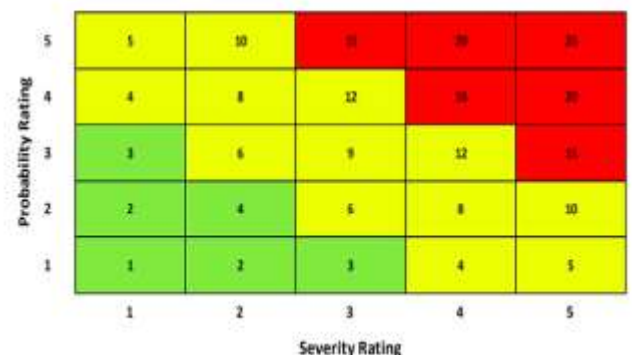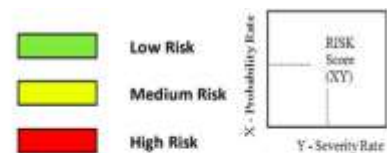

Figure 4.3 Risk Evaluation Matrix

By assessing the HIRA method, the above table shows the findings of hazard and risk assessment in API of pharmaceutical industry. From these able to identify the potential hazard in API, the findings of the potential hazard of a risk by assessing the RPN value with existing controls value ranges from 9 to 12, it is considered that the level of risk is medium. By chance of implementation of additional control measures of Powdered Air Purifying Respirator that the additional controls value ranges from 2 to 4, it is considered that the level of risk is low.

4.1 Control measures

Figure 4.4 Hierarchy of Controls

A) Elimination

The elimination of the equipment is not suitable for the process. Without this equipment the process cannot able to proceed furtherly.

B) Substitution

The substitution of alternative equipment (or) process procedure are also not suitable for that process.

C) Engineering controls

Engineering controls are to eliminate (or) minimize the hazards. By the way of isolating the hazard by means of implemented the scrubber, ventilation and blower system and all other possible control measures.

D) Administrative Controls

Document of Standard Operating Procedures (SOP), Work permit and safe work practices are all available to reduce the potential hazards, noise, stress and ergonomic hazards.

E) Personal Protective Equipment (PPE)

It creates a barrier against workplace hazards. PPE is acceptable as a control method in following when engineering controls are don't eliminate the hazards. By the way of PPE, implementing the Powdered Air Purifying Respirator (PAPR) the hazard is eliminated. Powdered Air Purifying Respirator (PAPR) can be used to protect against gases, vapours and particles. It is a type of respirator used to safeguard workers against the contaminated air.

5. CONCLUSION

This report discussed the impacts due to handling of flammable, explosive and toxic chemicals and their various hazards. The initially steps for emergency preparedness and maintaining a safe work place for all employee and to outlining and studying the hazard. So hazard identification and risk assessment technique to

assess all hazards and will establish priorities to employee, so that the most dangerous situations will be addressed first and those least likely to occur. HIRA study were made various hazards of different equipment's and process were found and addressed. Recommendations and suggestions are provided Environmental Health and Safety (EHS) team to avoid the occurrence of such hazards. All other hazards are easily within control limits and away from habitation area.

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