Risk Assessment on Asphyxiation Hazard for Pharmaceutical Industry

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Abstract— In pharmaceutical industry there are huge amount of usage of inert gases. There are many areas from technical area to clean area where inert gas is used to improve quality product as well safety point of view. But there is a chance of asphyxiation hazard in case of leakage. After evaluating the type of inert Substances and area of application it is further need to have proper estimation of release. Quantum of release needs to be evaluated mathematically. How much pressure of inert gas is being used, Up to what extent it can lead to spread into the atmosphere, calculate the amount of release whether it can easily deplete the oxygen level from safest level to dangerous level. All these aspects need to be evaluated carefully while assessing asphyxiation hazard risk assessment. The basic scope of this study is to provide adequate information about asphyxiation hazard for supervisors, line managers, direct workers and users wherever inert gases are produced, stored, used, or where oxygen depletion could otherwise occur.

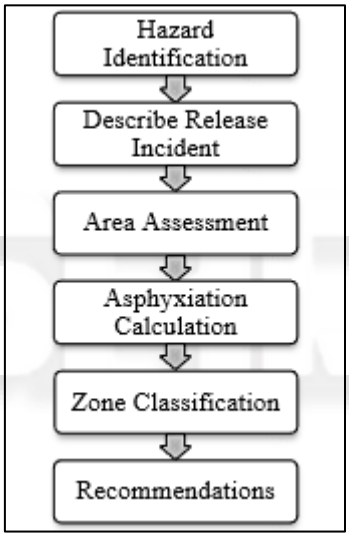
Keywords: Pharmaceutical Industry, Asphyxiation Hazard, Inert Gases& Oxygen Depletion

I. INTRODUCTION

Pharmaceutical is a very diverse industry across the world. It has multidisciplinary branches to deliver their products to end user in form of API (Active Pharmaceutical Ingredient), Medicines and other specialty chemicals which help to maintain individual health. Pharmaceutical industry is one of the sophisticated industries who deliver safest drug or product to the customers by using all the hazardous raw material or chemical. In pharmaceutical industry there are numerous highly hazardous chemical are handled and used like explosive, flammable, toxic, corrosive and radioactive substances. For that reason there are risks of fire, explosion, toxic gas release, chemical burn etc. To handle safely all these hazardous substances, a proper and systematic hazard risk assessment to be performed to cater the entire possible emergency. Risk assessment is a technique to identify the hazard and evaluate the risk in such a manner that chemical or products are handled safely without harming to anyone. Apart from the above potential risk Asphyxiation hazard is still much challenger to the pharmaceutical industry as well as automobile, chemical, storage, warehouse everywhere where there is chances of oxygen deficiency. The majority of incident occurred in the industry due to asphyxiation hazard while entering into confined space, drainage chamber, Confined equipment, Area where inert gas is used continuously. This dissertation is solely prepared to perform risk assessment on asphyxiation hazard and its control measures by which industrial accident can be reduce substantially.

II. METHODOLOGY

Nitrogen is the main component of air and is present at approximately 78% by volume, the other major components being oxygen, approximately 21% and argon, approximately 1%. Depletion of the concentration of oxygen can have an effect on life. An atmosphere containing less than 18% oxygen is potentially hazardous and entry into areas with atmospheres less than 20% oxygen is not recommended. Asphyxiation due to low oxygen concentrations is often rapid and with no prior warning. Following below methodology shall be used for Risk Assessment on Asphyxiation Hazard for Pharmaceutical Industry.



A. Step No-1 Hazard Identification:

Hazard Identification is the first step for approaching of Risk assessment. For Asphyxiation Hazard first we need to identify the source. Inert gases are main causes of asphyxiation hazard there are several inert gases are used in pharmaceutical industry which is useful in their process for quality point view and safety point view both. Below following gases are some example of Inert gases and their source of example.

Sr. No.	Name of Inert Gas	Source of Example
	Nitrogen Gas	Gas Cylinder or Fixed Pipeline
	Liquid Nitrogen	Dewar or Cryo-Can/Vessel
	Argon	Gas Cylinder

B. Step No-2 Describe Release Incident:

A second step is to describe release incident means inert gas how is being released and quantum of release into the assessment area or plant area where there are chances of asphyxiation. The maximum worst case scenario also need to be consideration while risk assessment.

Sr. No.	Name of Inert Gas	Release Incident Source	Possible quantum of Release	Worst Case Scenario
	Nitrogen Gas	Gas Cylinder	A single Nitrogen Gas cylinder contains approximately 7 m^3 of gas.	Assume release of the full quantity of substance handled on Site in a single at any time.

C. Step No-3 Area Assessment:

Area assessment needs to be verified where inert gas is utilized. Area shall be assess in for example any room where inert gas is used in form of gas cylinder.

Total Area Volume in Cubic Meter = (L × B × H)

Where

L = Length of the room in meter

B = Breadth of the room in meter

H = Height of the room in meter

D. Step No-4 Asphyxiation Calculation:

Asphyxiation calculation shall be done as per given formula.

Formula

$$O_2\ \% = 100 \times \frac{0.2095 \times (V_r - V_g)}{V_r}$$

Where

O2 = Oxygen Percentage

Vr = Volume of Room in m3

Vg = Volume of Gas in m3

E. Step No-5 Zone Classification &Marking:

Once asphyxiation calculation is determined then zone classification & Marking can be done accordingly. Area shall be classified into two zones.

1) Safe Zone – A area where oxygen percentage is observed even after leaking or releasing of any inert gas between 19.5 % to 21 % shall be considered as safe zone.
2) Alert Zone- A area where oxygen percentage is observed even after leaking or releasing of any inert gas below 19.5 % then that area shall be considered as a Alert.

1) Marking of Alert Zone-

F. Step-6 Recommendations:

Recommendations shall be made for alert area where there are chances of asphyxiation hazard. These recommendations shall be adopted from hierarchy of controls includes.

1) Elimination
2) Substitution
3) Engineering Control
4) Administrative Controls
5) Personal Protective Equipment

III. PLANT DESCRIPTION

Pharmaceutical Plant especially API manufacturing plant generally planned as per GMP guideline where quality and safety are kept on first priority. For any pharmaceutical industry either local or external FDA approval need to be taken on periodic interval to ensure their quality and product safety. Pharmaceutical industry has to maintain good culture and ethics to maintain their quality standard and safety standard which can meet to international standard. If there is any small deviation or incident is observed immediately corrective action is taken as well as preventive action is taken to avoid recurrence and its logged also.

Inert gas not only helps to maintain the quality standard of the product it is very important where moisture sensitive and Air sensitive product or RM is handled or processing. In pharmaceutical industry plant is designed in such a manner that raw material is charged from one end and output is taken out from another end and back to back this process can be cycled respectively.

A. Manufacturing Technical Area–

A manufacturing technical area where raw material and intermediate are handled and charged or processed where crude product is obtained from this facility. There are many equipment like reactor, ANFD (Agitated Neustch Filter Dryer), Centrifuge, Pressure Filter, Glove Box, PTS (Powder Transfer System) and Dryer are used to get the crude. Manufacturing technical area has potential source for usage of Inert gases. Generally two types of inert gases are used in technical area first one is Nitrogen and second one is Argon. This technical area has potential for asphyxiation hazard during charging of inert gas into the equipment and below following reason could be the source of leakage. Liquid nitrogen is also used in this facility to get temperature at lower side where cryo liquid such as liquid nitrogen is used.

The risk of asphyxiation can arise, even outdoors, in the vicinity of:

- Gas leaks from the pipeline joints/ flange/ Holes on pipe
- Vent/ exhausts of the equipment where inert gas is purged
- Outlet of safety valves and rupture disks of equipment.
- Openings of machines in which liquid nitrogen is used for freezing
- Blind flanges of pipeline

IV. ASPHYXIATION HAZARD ASSESSMENT

Asphyxiation Hazard assessment has been performed for one of the room of manufacturing technical area of one of pharmaceutical industry. Technical area where all raw materials are charged into the equipment like reactor centrifuge and dryer to get the crude material during this process area inert gas is used to remove oxygen from the equipment for example nitrogen gas is charged into the reactor for blanketing the reactor or inerting purpose this helps to improve quality of product as well as prevention from the fire or explosion.

Example: - A area or room where nitrogen gas is being charged into the process reactor for inerting purposes. This nitrogen gas is being charged through the gas cylinder capacity of 7 cubic meters and operator was monitoring the activity in the room.

A. Step No-1 Hazard Identification:

As described above Hazardous material is Nitrogen Gas which can caused for Asphyxiation Hazard. This Nitrogen Gas is used through the Gas cylinder. The volume of Nitrogen gas in gas cylinder is 7 m3 of gas.

B. Step No-2 Describe Release Incident:

Release incident Model have been described below.

Name of Inert Gas	Release Incident Source	Possible quantum of Release	Worst Case Scenario
Nitrogen Gas	Gas Cylinder	A Nitrogen Gas cylinder contains approximately 7 m3 of gas.	Assume release of the full quantity of substance handled on Site in a single at any time.

Worst case scenario for release incident shall be taken into account is the full quantity of substance

C. Step No-3 Area Assessment:

Area for manufacturing technical area is
Total Area Volume in Cubic Meter = (L × B × H)
Where
L = Length of the room in meter = 5 meter.
B = Breadth of the room in meter = 4 meter.
H = Height of the room in meter = 3 meter.
Total Area Volume in Cubic Meter = (5 × 4 × 3)
Total Area Volume in Cubic Meter = 60 m3
No window is available in technical area of manufacturing facility.

D. Step No-04 Asphyxiation Calculation:

Asphyxiation calculation shall be done as per given formula.
Formula

$$O_2\ \% = 100 \times \frac{0.2095 \times (V_r - V_g)}{V_r}$$

Where

O2 = Oxygen Percentage	=	?
Vr = Volume of Room in m3	=	60 m3
Vg = Volume of Gas in m3	=	7 m3

Formula

$$O_2\ \% = 100 \times \frac{0.2095 \times (60 - 7)}{60}$$

$$O_2\ \% = 18.5$$

Hence Result is 18.5 % of oxygen will be available during the process operation if nitrogen gas is releases in this area.

E. Step-5 – Zone Classification & Marking:

Oxygen % in technical area of manufacturing facility is 18.5 % which is below from 19.5 % it shows clearly that asphyxiation hazard so this area will be considered as Alert Area. Hence the operator might be got unconscious due to inhalation of nitrogen gas.

1) Marking of Alert Zone-

F. Step-6 Recommendations:

- Information, training
- Proper installation and operation
- Ventilation and atmospheric monitoring for inert gases and oxygen deficiency
- Ventilation/ monitoring prior to entry into confined spaces or enclosures
- Ventilation/monitoring for entry into other spaces where inert gases may be present
- SOP on Work permit.

V. CONCLUSION

This dissertation will help us to predict the risk assessment on asphyxiation hazard in pharmaceutical industry which will not only prevent to accident, human injury, illness etc. It is also beneficial to unnecessarily loss of inert gases while using in production area. This dissertation is complete information pack to classify the all the plant where inert gas is used or utilized. This information includes the hazard identification, quantum of release, asphyxiation calculation and control measures. All the inert gas are silence killer any these gases are used worldwide in all the pharmaceutical industry and chemical industry, This report will be utilized in pharmaceutical, chemical and other industries where inert gas generator and gases are used.

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