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Hazardous Area Classification in Pharmaceutical Industry

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***Abstract*: The pharmaceutical industry discovers, develops, produces, and markets drugs or pharmaceutical drugs for use as medications to be administered (or self-administered) to patients to cure them. Pharmaceutical drugs and ingredients are manufactured from raw materials through both chemical and physical means. During this process various unit of operations are performed like separation, crystallization, evaporation, filtration, distillation and reaction by using diverse chemicals flammable liquid, flammable solid, flammable gas and other hazardous chemicals. In pharmaceutical industry there is huge risk of fire due to handling of variety of flammable liquid, flammable solid, flammable gas and other hazardous chemicals. Hazardous Area Classification in pharmaceutical is the evaluation and classification of hazardous (classified) locations using scientific and engineering principles, within facilities where chemicals are manufactured, processed or utilized. Hazardous areas are classified solely for the purpose of ensuring the safe and proper specification and installation of electrical/ electronic equipment located within them.**

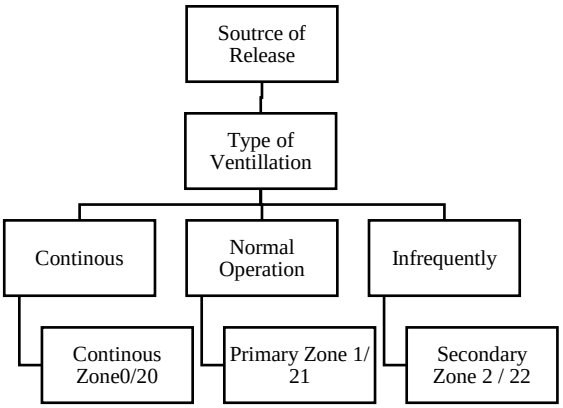
Keywords: - Hazardous Area Classification, Risk Assessment, Electrical Installation in Hazardous area.

1. INTRODUCTION

In present scenario pharmaceutical industry is rapidly growing with adopting advance engineering techniques to improve its production delivery capacity as well as to achieve optimum result without compromising safety. Pharmaceutical industry has greater risk of Fire and explosion due to handling of various hazardous chemicals. In pharmaceutical
industrial there are several multiple causes of fire and explosion but inadequate electrical equipment, in appropriate electrical fixtures, improper electrical component design, substandard electrical installation is a major causes among them. The hazardous area classification presented in this report is based on the experience and guidance provided in various standards. This report provides guidance about appropriate selection of electrical installation in hazardous area.

2. METHODOLOGY

Hazardous area classification A three dimensional space in which a flammable atmosphere or may be expected to be present in such frequencies as to require special precautions for the construction, and use of electrical apparatus. All other areas are referred to as non-hazardous in this context. A mixture with air, under normal atmospheric conditions, of flammable materials in the form of gas, Vapor, or mist, in which after ignition, condition spreads throughout the unconsumed mixture.
Following flow charts and below steps shall be followed for classification of hazardous zones



2.1 Step No-1

Source of Release:
A source of release is a point or location from which a gas, Vapour, mists or liquid may be released into the atmosphere so that a hazardous atmosphere could be formed from equipment, tank or other with location wise and details floor wise. Source of release it depends on the properties of the chemicals. For HAC the following data is required

For Gas and Vapour
Flash point, Flammability Limit LFL, UFL, AIT Auto ignition temperature, Vapour pressure

For Dust
A/B Classification, Minimum explosive Concentration, particle size, Minimum ignition temperature, Electrical resistivity.

2.2 Step No-2

Grades of release:
Which type of release is being leaked out or getting exposure into the atmosphere. There are three grades of release, as listed below in order of decreasing frequency and likelihood of the explosive gas atmosphere being present.

International Journal of Engineering Research & Technology (IJERT)
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Vol. 8 Issue 03, March-2019

- Continuous grade
- Primary grade
- Secondary grade

A source of release may give rise to any one of these grades of release or to a combination of than one.

Continuous grade of release: Release which is expected to occur continuously, or for long periods, or frequently.

Primary grade of release: periodically or occasionally during normal operation.

Secondary grade of release: Release which is not expected to occur in normal operation and, if it does occur, is likely to do so only infrequently and for short periods.

2.3 Step No-3

Adequate Ventilation:

Adequate ventilation is that which is sufficient to prevent accumulations of significant quantities of gas-air mixtures in concentration over one-fourth of the lower flammable limit. Adequately ventilated area could be naturally ventilated or artificially ventilated.

2.4 Step No-4

Degree of Ventilation:

The effectiveness of the ventilation in controlling and persistence of the explosive gas atmosphere will depend upon the degree and availability of ventilation and design of the system. For example, ventilation may not be sufficient to prevent the formation of an explosive gas atmosphere but may be sufficient to avoid its persistence.

High Ventilation: Can reduce the concentration at the source of release virtually instantaneously, resulting in a concentration below the lower explosive limit. A zone of negligible extent results. However, where the availability of ventilation is not good, another type of zone may surround the zone of negligible extent.

Medium Ventilation: Can control the concentration. Resulting in a stable zone boundary, whilst the release is in progress, and where the explosive gas atmosphere does not persist unduly after the release has stopped.

Low Ventilation: Cannot control the concentration whilst release is in progress and/or cannot prevent undue persistence of a flammable atmosphere.

2.5 Step No-5

Availability of Ventilation:

The availability of ventilation has an influence on the presence or formation of an explosive gas atmosphere. Thus the availability (as well as the degree) of ventilation needs to be taken into consideration when determining the type of zone.

Three levels of availability of the ventilation should be considered.

Good: ventilation is present virtually continuously

Fair: ventilation is expected to be present during normal operation. Discontinuities are permitted provided they occur infrequently and for short periods.

Poor: ventilation which does not meet the standard of fair or good, but discontinuities are not expected to occur for long periods.

2.6 Step-6

Zone Classification

For Vapour/Gases:

Zone 0: That part of a hazardous area in which a flammable atmosphere is continuously present or present for long periods.

Zone 1: That part if a hazardous area in which a flammable atmosphere is likely to occur in normal operations.

Zone 2: That part of a hazardous area in which a flammable atmosphere is not likely to occur in normal operation and, if it occurs, will only for short period.

For Dust:

Zone 20: That part of a hazardous area in which an explosive dust atmosphere is present continuously or is present for long periods.

Zone 21: That part if a hazardous area in which an explosive dust atmosphere is likely to occur in normal operations.

Zone 22: That part of a hazardous area in which an explosive dust atmosphere is not likely to occur in normal operation and if it does occur it will exist for a short period only.

Grade of release	Degree						
	High			Medium			Low
	Availability						
	Good	Fair	Poor	Good	Fair	Poor	Good, Fair or Poor
Continuous	(Zone 0 NE) Non Hazardous	(Zone 0 NE) Zone 2[a]	(Zone 0 NE) Zone 1[a]	Zone 0	Zone 0 +Zone 2	Zone 0 +Zone 1	Zone 0
Primary	(Zone 1 NE) Non Hazardous	(Zone 1 NE) Zone 2[a]	(Zone 0 NE) Zone 1[a]	Zone 1	Zone 1 +Zone 2	Zone 1 +Zone 2	Zone 1 or Zone 0[C]
Secondary	(Zone 2 NE) Non Hazardous	(Zone 2 NE) Non Hazardous	Zone 2	Zone 2	Zone 2	Zone 2	Zone 1 or even Zone 0[c]

Table-1

2.7 Step-7

Extent of Zone: distance in any direction from the source of release to the point where the gas/air mixture has been diluted by air to a value below the lower explosive limit.

In the Vapour concentration modelling, the zone 1 boundary is determined by the 100% LEL. The zone 1 to zone 2 boundaries is determined by the 25% LEL using the class D Pasqual stability class level of ventilation

2.8 Step-8

Hazard Radius

The largest horizontal extent of the hazardous area, independent of ground effects, that is generated by the source when situated in the open area under unrestricted

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Vol. 8 Issue 03, March-2019

natural ventilation. This is the distance at which the concentration of flammable Vapour in air has fallen to the lower flammability limit.

2.9 Step-9

Zone Marking

Zone marking will enable us to classified zone where appropriate electrical installation can be made and this marking to be shown on plant layout to easy access of zoning of hazardous area and hazardous sign board shall also be displayed at prominent place to aware the plant community.

Sign

Figure- 1

2.10 Step-10

Type of Electrical Equipment in Hazardous Area

Type of Protection	Marking
Zone 0	
Intrinsic Safety	
Zone 1	
Equipments suitable for Zone 0	
Flameproof enclosure	"d"
Pressurized Apparatus	"p"
Powder Filling	"q"
Oil emersion	"o"
Intrinsic Safety	"i"
Encapsulation	"m"
Zone 2	
Equipments suitable for Zone 0 or 1	
Non Sparking	"n"
Increased Safety	"e"
Zone 20/21/22	
Ingress Protection Rating along with Temperature class	

Table-2

3. PLANT DESCRIPTION

In pharmaceutical industry generally plant area segregated in which manner the product flow process easily can be obtained. The process starts from the hazardous raw material to finished Product.

3.1 Warehouse - A major pharmaceutical warehousing challenge involves these "appropriate storage conditions." Different chemicals can have vastly different requirements in terms of temperature, and inert system. Storage of flammable and hazardous chemical ii is very challenging part. If proper design is not considered at initial stage can form at disaster or catastrophic event even after small deviation of mistake. Generally large quantity of flammable solvent are stored underground storage tank and above ground storage tank where high level of safety is considered to avoid any mis happening.

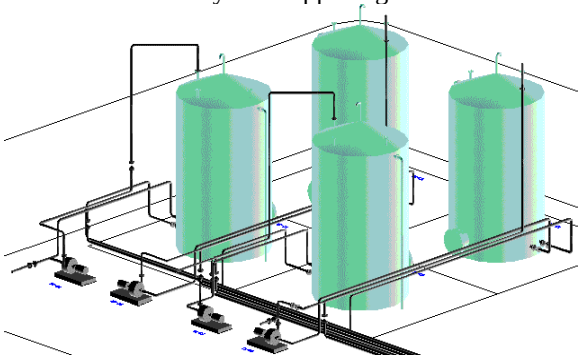

Figure- 2

3.2 Processing Unit- Process unit is the heart of any pharmaceutical industry where are unit of operation area performed in specified manner to get desired specified result. In processing unit there are numerous unit of operations area carried out to perform the process like reaction by the process reactor , filteration by the centrifuge, neustch filter, Agitated neustch filter, Pressure filter unit, Distillation process by distillation fraction column and other many process like drying by dryer or crystallization etc.,

3.3 Utility Section- Utility section is a back bone of pharmaceutical industry. Utility involves various type of utility resources like water again there area various variety of utility water like soft water, DM water, Brine, Chilled Water, RO water Steam etc. and apart from this various gases like nitrogen, compressed air, are used to actuation of miscellaneous process equipment.

3.4 Hazardous Waste Storage Area- After processing of chemicals and intermediate whenever waste is generated in terms of Water, Solid, and Residue that is also hazardous in nature and same probability of accident during handling. Hazardous waste storage area is also important area where hazardous area classification study is performed.

4. CLASSIFICATION OF HAZARDOUS AREA

Classification of hazardous area has been performed based on above methodology for storage tank having flammable liquid Acetone of Warehouse section and rest of others area shall be assessed accordingly to above methodology.

4.1 Step No-1

Source of Release:

As per the table given below Example Taken Acetone Solvent is filled in Above ground storage tank which

International Journal of Engineering Research & Technology (IJERT)
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having nitrogen blanketing system the vent is situated on the tank where Vapour of flammable chemical acetone is vented through the vent. The property of Acetone is showing below.

S. No.	Chemical	Flash point ° c	Boiling point (°C)	LEL %	UEL %	AIT
1	Acetone	< -2.0	56.2	2.6	12.8	465

Table- 2

4.2 Step No-2

Grades of release:

Continuous grade of release: Inside the storage tanks flammable Vapour and atmosphere is present continuously during normal operation

Primary grade of release: periodically or occasionally during normal operation.

Secondary grade of release: Around the storage tank flammable Vapour and atmosphere is likely to do so only infrequently and for short periods.

4.3 Step No-3

Adequate Ventilation:

As per sown pic Acetone is stored in above ground storage tank which is in open atmosphere hence ventilation will be natural

4.4 Step No-04

Degree of Ventilation:

If ventilation is under natural atmosphere then degree of ventilation will be medium.

4.5 Step No-5

Availability of Ventilation:

If degree of ventilation is medium then availability of ventilation is fair as per the below

4.6 Step-5 – Zone Marking

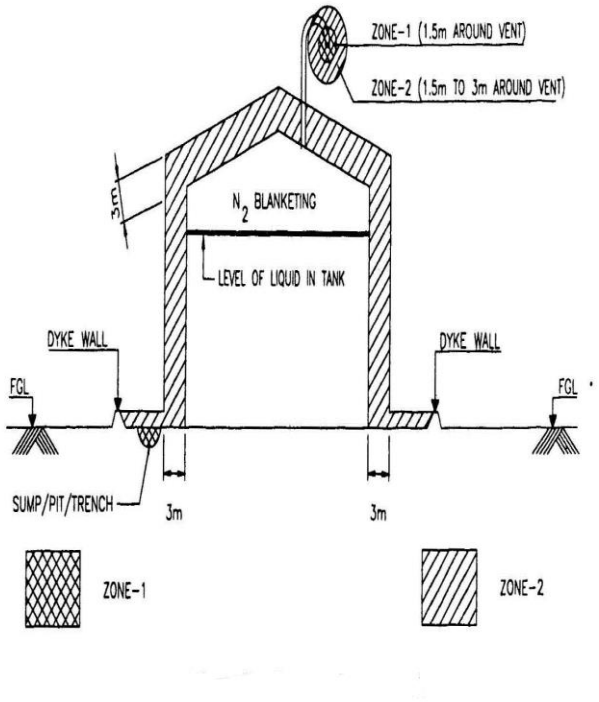

Figure-3

4.7 Step-6

Hazardous area classification table for storage tank

Sr. No	Source o release			ventilation		
	Description	**Location**	**Grad of release (1)**	**Type (2)**	**Degree (3)**	**Availability (4)**
1	Inside storage tanks-Acetone	Acetone Storage Tank	C	-	-	-
2.	Around hand hole/Vent of storage tanks	Acetone Storage Tank	P	N	VM	F
3	Around hand hole/Vent of storage tanks	Acetone Storage Tank	P	N	VM	F
4	Around storage tanks and Dyke Area	Acetone Storage Tank	S	N	VM	F
5	Sump/ Pit of Storage tank	Acetone Storage Tank	P	N	VM	F

Table-3

International Journal of Engineering Research & Technology (IJERT)
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Hazardous area classification				
Zone type (0/1/2/ 20/21/ 22)	Zone extent		Comments	Recommendations
	Horizontal	Vertical		
0	Entire Vapour space of storage tank	Entire Vapour space of storage tank	Flammable atmosphere expected to be present inside the storage tank continuously, hence it has been classified as zone 0	No Electrical Equipment is allowed
1	1.5 m from the hand hole/Vent of storage tanks	1.5 m from the hand hole/Vent of storage tanks	Around hand hole/Vent of storage tanks Zone has been classified as Zone 1	Only Flameproof enclosure Type electrical fitting allowed
2 (Extent of Zone 1)	1.5 m to 3 m from the hand hole/Vent of storage tanks	1.5 m to 3 m from the hand hole/Vent of storage tanks	Around (Extent of Zone1) hand hole/Vent of storage tanks Zone has been classified as Zone 2	Only Flameproof enclosure Type electrical fitting allowed
2	3 m from the storage tanks	3 m from the storage tanks	Flammable vapors are expected to be present in case of accidental spillage or leakage hence Zone -2	Only Flameproof enclosure Type electrical fitting allowed
1	Entire Area of Sump/pit	Entire Area of Sump/pit	Flammable vapors is likely to be present if pit is filled with the liquid	Only Flameproof enclosure Type electrical fitting allowed

5. CONCLUSION

The hazardous area classification is a one type of Proactive approach for designing and installation of appropriate electrical installation in any hazardous location/building and facility. This qualitative and scientific methodology not only evaluates the type of electrical installation but explains the degree of risk and as well as selection of equipment, accessories and many other things for example using of non-antistatic vessel, pipeline , poly bag can be pr-determined before carrying out the operation. Accordingly potential risk can bring down it to acceptable range. Zoning of Hazardous area classification deals with the environment where surrounding people also aware what to do or not even using of mobile phone in hazardous area can lead to an unacceptable fire. There are so many causes for fire in pharmacy industry it might be primary or secondary (Direct or indirect) , but the hazardous area classification assessment is one of the solution who can contributes a significant roles in Fire prevention techniques.

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