Original Article
ISSN (Online): 2456-8651

International Journal of Engineering Science Technologies
September-October 2023 7(5), 1–16

THE RISK MANAGEMENT APPROACH BY APPLYING HAZARDOUS AREA CLASSIFICATION, WHICH HELPS IN IDENTIFYING THE CRITICAL ZONES IN A PHARMACEUTICAL INDUSTRY

A. Yudhistra kumar [1], Linga Murthy [2]

[1] Porus Labs Pvt Ltd, Unit 6, Atchutapuram, Visakhapatnam, Andhra Pradesh, India
[2] Aragen Life Science Pvt Ltd (GVK BIO), Mallapur, Hyderabad, India

Received 23 July 2023
Accepted 25 August 2023
Published 09 September 2023

Corresponding Author
A. Yudhistra kumar,
yudhistrakumar@gmail.com

DOI 10.29121/IJOEST.v7.i5.2023.533

Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

ABSTRACT

Identifying the various critical zones in the pharmaceutical industry, various protection to the electrical instruments / equipment's and the ingress protection enclosures class based on the international standards are presented. Collecting the flammability data based on the MSDS. Classifying the various location in the form of various zones by using different international standards. Application of various ATEX standards, Temperature class and ingress protection for the different equipment's. In the pharmaceutical industry the zone 1, zone 2, zone 21 and zone 22 were classified as four, two, three, and two locations. The VOC concentration were highest in the clean room was 8 ppm during the monitoring. The ATEX standard Ex d, Ex e, Ex I, Ex n and Ex p were used in various zones for different instruments or electrical equipment's. Temperature class 400 o C, T2 was highest inside the boiler. Ingress protection class of IP65, IP66 and IP67 enclosures are used for the various equipment's.

Keywords: Hazard Area Classification, Critical Zone, ATEX Standard

1. INTRODUCTION

Hazardous Area Classification (HAC), which identifies the potential risk of the hazardous explosion, which may be caused due to the ignition source from the gases, vapour, and flammable liquid, which are used in the process industry Tommasini (2013). By identifying the various zones, we can easily identify the critical zones in the occupational environment. There are different standards and guidelines, which are laid by the international body to classify the hazardous zones in the working environment, The HAC, which divides the various facility in the form of zones as per

the International electrotechnical commission (IEC) EN 60079-10-1, 2009 standard Zohdirad et al. (2016). In case of the liquid, we must check the threshold limit of the flammability aspects such as flash point (FP) and Auto ignition temperature (AIT), which helps in the assessment whether the chemical material requires hazardous zonal classification or not Eckhoff (2006). The probability of the various type of release of the flammable liquid or gases or the hazardous vapours has been classified into different grades, which are given below.

Continuous grade: The release of the flammable liquid or gases or vapour is in the form of a continuous manner or long time persistent in the environment.

Primary grade: The release of the flammable liquid or gas or vapour, which may occur periodically or during the normal operations in the occupational environment.

Secondary grade: The release of the flammable liquid or gases or vapour is not expected to release during the normal operations or may occur occasionally or during abnormal situation, which may occur rarely.

The zonal classification of the various zones is based on the presence of the duration of the persistent of the explosive gases in the atmosphere.

Zone 0: Where the explosive gases are present > 1000 hours / year.

Zone 1: Where the release of the explosive gases is in between 10 to <1000 hours / year

Zone 2: The release of gases of the explosive nature does not occur in the normal operations. Its release is < 10 hours / year.

The volatile organic compound (VOC) are the chemical compounds, which are having higher pressure and lower solubility in the water. The VOCs are emitted in the pharmaceutical industry from the various sources such as solvent dispensing area Tzanakopoulou et al. (2021) or the diesel storage area Pang et al. (2014), solvent tanker unloading area and fugitive emissions from the various mechanical equipment's Boltic et al. (2013), which are used in the process such as reactors, condensers, centrifuges, and dryers. Monitoring of the VOC help in knowing the hazardous concentration, which are present in the occupational environment.

The dust pollution playing a vital role in the pharmaceutical industry. The accumulation of the dust particles leading to explosion, which are having the major impact Abbasi & Abbasi (2007), further the potentiality of the risk is very difficult to understand Wan Sulaiman et al. (2020). It is very much important to know the nature and kind of dust, which is present in the occupational environment. The dust particles are generated while handling the powder particles of the intermediates, which are produced during the drying process or Jet milling or the multi milling and blending activities to get the desired final product. The accumulation of the dust particles, which leads to explosion Cashdollar (2000) and Boeck et al. (2023), so its zonal classification plays a vital role. The classification of the dust pollution zones has been described in the American national standard institute (ANSI)/ISA 60079-10-2 (12.10. 05)-2013, Explosive Atmospheres — Part 10-2: C. The classification of the dust explosion, which are given below.

Zone 20: Continuous formation of the dust cloud - $\geq$ 1000 hours / year or 10 % of the operating time

Zone 21: Primary grade of release of the dust or the occasionally release of dust during normal operations - $\leq$ 1000 hours / year or 0.1 to 10 % of the operating time.

Zone 22: In this zone, there is no combustible dust particle generating during normal operations. Although minor dust particles, which may vary from < 10 hours / year or < 0.1 % of the operating time.

Rate of release: The source of release of dust, which can be divided into two different types.

1) A small quantity of release, which is ≤ 1 gram / second.
2) A substantial release rate, which is ≥ 1 and < 10 grams / second.

In case of the release of the dust particle concentration is more than 10 grams/second, then it is treated an emergency and it should be rectified immediately.

The main aim of the HAC is to reduce the ignition sources by installing the suitable equipment's with appropriate grade tools, so that we can avoid the accidents in the various critical zones Tommasini (2013), Bozek et al. (2014) and Paloma et al. (2020). The ATEX is a French word, which refers to the **At**mosphere **Ex**plosives directives, which was introduced in the year of 2003, which has increased pressure in maintaining the safety for the electrical equipment, which are used in the hazardous operational environment EPCS. (2014) and Hoffmann & Kögl (2017). Each of the ATEX code, which represents certain risk management approach, which are indicated on the various electrical instruments / equipment's in the operational zones. The potential risk of an anticipation hazard from the vapours, highly flammable chemicals, water ingress, arch flash, short circuit, thermal or due to the mechanical sources and the flammable dust particles will be restricted by using appropriate ATEX codes for the instruments / electrical equipment's. The appropriate ATEX grades, which are recommended to be used in the various critical working zones has been presented in Table 1.

Table 1

Table 1 ATEX Standards - Different Codes of Protection for the Various Electrical Equipments

Zone	Type of protection	Description
Zone 0 & Zone 20	In this zone we have not allowed the electrical equipment as it is not applicable. Intrinsically safe Electrical apparatus categories 'ia' and 'ib' with its associated circuits has been used with the protection 'i'	Intrinsic Safety (Ex i) - A circuit or part of a circuit is intrinsically safe when it exposes to the spark or thermal effect produced in the circuit. In this code 'i' refers that in case of any short circuit or earthing fault is incapable of causing ignition under prescribed conditions as there is a presence of vapour or gases in the working environment. An Intrinsically safe apparatus is one in which all electrical circuits are intrinsically safe. It is placed in one of the following categories: a) Category (Ex ia) Equipment in this category is incapable of causing ignition in normal operation or in a single fault, or with any combination of two faults applied with a specified safety factor for current and / or voltage. b) Category (Ex ib) Equipment in this category is incapable of causing ignition in normal operation or with a single fault applied, with a specified safety factor for current and/ or voltage.
	a) Type of protection Adequate for zone 0. b) Flameproof equipment Type of protection 'd'	Flameproof Enclosure (Ex d) An enclosure for electrical equipment, which is properly secured, an internal explosion of the flammable gas or vapour, which may originate inside the enclosure will not damage the equipment. We can say that the enclosures, which acts as a flame proof against the internal flammable gas or vapour for which it is designed
Zone 1 & Zone 21	c) Pressurised enclosure Type of protection 'p'	Pressurised Enclosure (Ex p) The enclosure for electrical apparatus, which prevents the entry of the flammable gas or vapour by maintaining the air or other non-flammable gas. With in the enclosure at a pressure above that of the external atmosphere. This type of protection has following categories. a) Pressurisation with air and alarm in case of loss of air pressure [Ex p (1)]

		b) Pressurisation with air and automatic switching off from electric supply in case of loss of air pressure [Ex p (2)] c) Pressurisation with inert gas and raise of alarm in case of loss of inert gas pressure [Ex p (3)] d) Pressurisation with inert gas and automatic switching off from electric supply in case of loss of inert gas pressure [Ex p (4)] e) Dilution with air and alarm in case of loss of air supply [Ex p (5)] f) Dilution with air and automatic switching off from electric supply in case of loss of air supply [Ex p (6)]
	d) Sand filled apparatus Type of protection 'q'	Sand filled apparatus (Ex q). Electrical apparatus which has all its live parts entirely embedded in a mass of powdery material, in such a way that under the conditions of use, the designed apparatus will not get effected due to the arc occurrences within the outer explosive atmosphere either by the transmission of flame or by the overheating of the walls of the enclosure.
Zone 1 & Zone 21	e) Oil immersed apparatus type of protection 'o' f) Such other apparatus as may be specifically certified. or assessed for use in zone1 areas –Type of protection 's'	Oil immersed Apparatus (Eq. o) – Electrical apparatus in which all parts on which arc may occur in normal service are immersed in oil to a sufficient depth to prevent ignition of an explosive gas mixture that may be present above the surface of the oil and all live parts on which arcs do not occur in normal service are either immersed in oil protected by some other recognised techniques
Zone 2 & Zone 22	b) Non-sparking apparatus Type of protection 'n'	Non-sparking Apparatus (Ex n). Apparatus which in normal operation is not capable of igniting a surrounding explosive atmosphere, and a fault capable of causing ignition is not likely to occur.
	c) Increased safety apparatus Type of protection 'e'	Increased safety (Ex e) – A method of which additional protection is adopted to protect from the arc and the possibility of the exposure due to the increase in the temperature, which may result in the spark in the abnormal circumstances.
Zone 2 & Zone 22	d) Hermetically sealed apparatus – Type of protection 'S'	A Method of protection in which the equipment is designed in such a way that the external inflammable gases or vapours cannot enter the enclosure and hence prevents a source of ignition like an arc or spark coming into contact with the inflammable gas or vapour.

equipment / instruments, which are used in the different zones in the critical working environment. The IEC standard was used for the classification of the Temperature Class (T) for different types of protection, where the flammable gases / vapour can get ignited with hot surfaces of the various equipment's in presence of sufficient fuel and oxygen concentration, which are present in the occupational environment. The T class of the maximum surface temperature has been given in Table 2.

Table 2

Table 2 The Different Temperature Class and Maximum Surface Temperatures

Temperature Class	Maximum Surface Temperature (°C)
T1	>450
T2	>300
T3	>200
T4	>135
T5	>100
T6	>85

Ingress protection (IP)

The IP rating is the level of protection rating given to the electrical enclosure to strengthen the durability of an electrical device and to secure it from dust and water Ingress Bloch (2009). In an environment where dust or water could damage

electrical components, a sealed enclosure is used to avoid any such damage to the equipment. The IEC standard 60529, which defines the IP Code or Ingress Protection Code, which refers to the various classifications and the rating of the degree for the protection provided to the various mechanical casings and electrical enclosures against intrusion of water or dust due to accidental contact. The IP65 rating describes the electrical enclosure as a specification of dust Ingress Protection of 2 to 8 hours, IP66 enclosures has protection against dust and jets of water ingress up to a limited period. IP67 enclosures are dust tight and protected against the immersions.

Many of the researchers have conducted dust explosion studies such as use of modelling for the aluminium dust venting Song et al. (2019), the thermal characteristics of nano-polyethylene dust explosion studies Sun et al. (2019), effects of the sodium bicarbonate suppression on the dust explosion of the polyethylene have been studied Wang et al. (2020), testing aspects of the flammable powder dust before and after drying process Wei et al. (2020) and various prediction models resulting in the dust explosion due to the usage of the organic powder Pietraccini et al. (2021). There is very less published information on the hazardous area classification of the pharmaceutical industry. The study of the HAC has been carried out in the different locations of the pharmaceutical industry, which include solvent storage area, warehouse, unloading of the solvents bay, empty solvent drum storage yard and its adjacent effluent treatment plant (ETP), hazardous spent carbon storage area, production blocks and boiler area. The type of release, rate of release, zone classification, ATEX standards for electrical equipment's, temperature class (T) and IP protection have been presented in this article.

2. MATERIAL AND METHODS

The case study has been conducted in the year of 2021 in a pharmaceutical industry located at Hyderabad, India. The methodology of the hazardous area classification includes the following steps.

1) Collecting the data on the flammable materials such as FP and AIT by using MSDS.
2) Determine and study if the individual chemicals require zonal classification or not based on the FP and the AIT.
3) IEC guidelines have been used to classify the Zone 0, 1 and 2. Similarly IEC standard were used for identifying the surface temperature class for the various equipment, which are used in the different process. ANSI guidelines has been used to classify the dust exposure zone, which are in the form of zone 20, 21 and 22. Further the IEC guidelines for the ingress protection for the enclosures of the various electrical equipment's/ instruments have been presented. ATEX 137 standards / codes for the electrical equipment's protection have been used in the different zones.
4) The online VOC meter have been installed and monitored in the different locations such as solvent storage yard, unloading of the solvents, empty solvent drum storage area, production block – 1 ground floor (raw material storage area), production block -1 first floor (Intermediate process area) and production block -3 ground floor (clean room I, II).

3. RESULTS AND DISCUSSION

The various chemicals, which are used in the process has been assessed based on the FP and AIT and it is determined whether they require zonal classification or not (Table 3). Many of these chemicals are very corrosive, toxic, flammable, oxidizer, environmental pollutant, and explosive in nature Kuseva et al. (2022). Only trained people are allowed to handle these chemicals by using the proper personal protective equipment (PPE). Chemicals such as chloroform, sulphuric acid, hydrogen chloride and hydrochloride acid, which does not require zonal classification, as these chemicals do not have the FP or the AIT, as they are non-flammable in nature (Table 3).

Table 3

Table 3 List of Chemicals Used in the Process, Which Comes Under Zonal Classification or Not

S. No	Chemical Name	Flash point (Degree centigrade)	Auto ignition temperature (Degree centigrade)	Zonal classification required or not required
1	Diethyl malonate	90	424	Zonal classification required
2	Toluene	4	552	Zonal classification required
3	Dimethyl formamide	57.7	445	Zonal classification required
4	Cyclo-hexane	-17.99	245	Zonal classification required
5	Isopropyl alcohol	12.0	399	Zonal classification required
6	n-hexane	-22	233,8	Zonal classification required
7	Acetic anhydride	49	316	Zonal classification required
8	Disel	55 - 75	210	Zonal classification required
9	Acetone	-20	465	Zonal classification required
10	Methanol	12	454	Zonal classification required
11	Ethyl Acetate	-4	426.67	Zonal classification required
12	Ethylene dichloride	13	440	Zonal classification required
13	Acetic acid	Not Applicable	485	Zonal classification required
14	Chloroform	Not Applicable	Not Applicable	Zone classification not required
15	Hydrogen chloride	Not Applicable	Not Applicable	Zone classification not required
16	Hydrochloric acid	Not Applicable	Not Applicable	Zone classification not required

The solvent storage area, where solvents like Toluene, Dimethyl formamide, cyclo-hexane, Isopropyl alcohol, Acetone, methanol, Ethylene acetate and Ethylene dichloride are stored in the form of a raw material, which are used in the process. There is a frequent release of the vapours from the solvent storage yard is the major concern, which contributes to the VOC. The solvent storage yard is classified as zone 1 (Table 4). The warehouse, where the dry chemical powder is stored are classified as Zone 22. In the warehouse there is a substantial release of the dry chemical powder material while dispensing in the Reverse Laminar air flow (RLF) cabinet, where negative air pressure is maintained. It will not allow the outside air to come inside the cabinet Sophie (2013), the fine dust particles are collected in the filter bag. By using the RLF we are not only dispensing the dry chemical powder in a safer way but also, we are avoiding the cross

Table 4

Table 4 Hazardous Area Classification in the Different Areas in the Pharmaceutical Industry

S. No	Area	Description	Zonal classification
1	**Solvent storage yard storage tanks** (Tanks Containing flammable liquid)	**Type of Release**: Continuous Grade **Rate of release:** Substantial Quantity Good Ventilation	Zone 1
2	**Warehouse** Storage of the dry chemical powder	**Type of Release**: Secondary Grade **Rate of release:** small quantity Good ventilation	Zone 22
3	**Unloading of the Solvents**	**Type of Release:** Primary Grade **Rate of release:** Small Quantity Good Ventilation	Zone 1
4	**Empty solvent drums storage yard Effluent treatment plant area**	**Type of Release:** Secondary Grade **Rate of release:** Small Quantity Good Ventilation	Zone 2
5	**Hazardous shed - Spent carbon storage area**	**Type of Release**: Secondary Grade **Rate of release:** small quantity	Zone 22
6	**Production block -1** (Ground floor) Raw materials storage area	**Type of Release**: Secondary Grade **Rate of release:** Small Quantity Good Ventilation	Zone 2
7	**Production block -1** (First floor) - Intermediate processing area. SSR Reactor, Centrifuge, Candy filter and Leaf filter	**Type of Release**: Continuous Grade **Rate of release**: Substantial Quantity Restricted Ventilation	Zone 1
8	**Production block -2** Drying block	**Type of ease**: Continuous Grade **Rate of Release**: Substantial Quantity Restricted Ventilation	Zone 21
9	**Production block -3** (Ground floor) i) Clean Rooms – I (ANFD & Reactor Room) ii) Clean Rooms – II (Centrifuge & Reactor Room) iii) ML'S TUB Area (up to 3 meters)	**Type of Release:** Continuous Grade **Rate of release:** Substantial Quantity Restricted Ventilation	Zone 1
10	**Production block -3** First floor i) Clean Rooms – III (Multi milling, jet milling and Blender)	**Type of Release:** Continuous Grade **Rate of Release:** Substantial Quantity Restricted Ventilation	Zone 21
11	Boiler Area	**Type of Release:** Continuous Grade **Rate of Release:** Substantial Quantity Restricted Ventilation	Zone 21

Contamination while indulging in the activity James et al. (2015). The solvents unloading bay there may be certain leakages of the solvent or vapours, which may occur during the transferring the solvents from the road tankers to the above ground storage tanks, which are classified as zone 1. The solvent empty drum storage area and the ETP area are classified as zone -2. The hazardous spent carbon storage area is classified as zone 22. In this zone, the dust particle is generated during the loading of the spent carbon into the hazardous transportation vehicle by using the Joseph Cyril Bamford Excavators (JCB). Production block – 1 ground floor where the raw materials, which are required for the production activities will be procured from the warehouse on daily basis and it would be stored on the ground floor, which is classified as zone 2 (Table 4). In the intermediate process Production block - 1 first floor, where the procured raw materials are used in stainless-steel reactors (SSR) or glass lined reactors (GLR), centrifugation of the reaction mass is carried out in the centrifuge is classified as zone 1. There is a continuous release of the VOC concentration from the condenser vents of the reactor, while opening the manhole for charging the dry chemical powder, charging of the solvents into the various process equipment and the fugitive emissions getting liberated during operations of the process equipment's Zhao & Chen (2018) and Zhang et al. (2021). There is a substantial release of the dry chemical powder while charging into the reactor manhole. During the operation appropriate PPE has been used while indulging in the intermediate process. Trained people are involved in the operations, in case of the untrained people indulged in handling of the reactor will lead to the pressure build up and explosion Ji et al. (2023). Production block -2 is classified as zone 21, where drying activities of the intermediates takes places in the drying block. Due to cross contamination, these blocks have restricted ventilation. Fresh air is supplied by air handling unit (AHU) and the blower exhaust facility is also provided as per the recommendations of the European unition good manufacturing practices (EU-GMP). By using the local exhaust, it reduces the dust accumulation in the extracted place, so the classification has been downgraded from zone 20 to zone 21 Rogala (2015). There is a continuous release of the dust particles while unloading of the dried intermediates from the drying block. We have used N95 dust mask in the drying block. The national institute of occupational health (NIOSH) recommended N95 mask, which has an efficiency of restricting 95 % of dust particles (0.3 micron) entering the nose and mouth. Production block -3 (Clean room I and II) ground floor is a clean room, where the fresh air is supplied through the AHU, which has high efficiency particle arresting (HEPA) filters to remove the harmful particles present in the air. All the clean rooms are designed as per the guidelines recommended by EU-GMP for the pharmaceutical industries. In this clean room the various process equipment's such as reactors, agitated nutsche filter dryers (ANFD) and centrifuges are operated as per the standard operating procedure (SOP), where purification activities take place to get final product. During the operational VOC is getting liberated from the process equipment's, which are classified as zone 1. Organic cartridge mask is used by the operators while indulging in the operations. Production block -3 (Clean room -III) first floor, where multi milling, Jet milling and blending activities takes place are classified as zone 21, there is continuous release of dust particle in a substantial form. These dust particles are hazardous and effects the occupational health of the workers. We have used powered air purifying respirator (PAPR), which are recommended Occupational safety and health administration Han (2021). The dust cloud explosion can only happen when enough combustible dust, sufficient oxygen and the ignition source is

available Tsai et al. (2021) and Lele (2012). The blower exhaust facility, which is connected to the dust collection system to avoid the accumulation of the dust particles. The collected dust particles are not removed from the bag filter in regular basis. Chen et al. (2022) have reported the by not removing the dust particle in regular basis from the bag filter will lead to the malfunctioning of the dust collection system. It is recommended to clean the bag filter on daily basis and maintain the dust collection system by applying proper preventive maintenance techniques, so that we can avoid the abnormal functioning of the dust collection system Li et al. (2022). It is recommended to` check the mechanical integrity of the operational equipment's such as the reactors, ANFD, centrifuges, dryers, multi miller, Jet millers and blender to avoid the hazard's operational circumstances in the occupational environment Hirak (2021). The accumulation of the vapour and the dust particles in the intermediates and the final product area, which helps the formation of the vapour or dust cloud, which are explosive in nature Paul et al. (2021), so highest care has been taken to avoid the accumulation of vapours or dust while indulging in the operations of the processing equipment's in the pharmaceutical industry. It is recommended to upgrade with the latest technology to prevent the anticipating hazardous in the working environment Li et al. (2022), There is a huge consumption of coal, which is used in the boiler area for the combustion process, the final by-product of the combustible coal is fly ash, which is generated in the huge concentration Han et al. (2021) and Luo et al. (2021), which leads to the deteriorating effect on the soil content when the fly ash is not properly maintained Wu et al. (2021), which are more hazardous to the environment, as it contains toxic heavy metals Han et al. (2021). The boiler area is classified as zone 21 (Table 4), where the loading of the fly ash into the lorry happens on the daily basis, which has resulted in the substantial fly ash dust pollution.

All the people who are entering into the respective blocks have utilized the touch pad facility, which is kept in the entrance of the block to avoid the static electricity in the human body. Safety management plays a crucial role for the process equipment's. We have used continuous earth monitoring systems (CEMS), double earthing and bonding, jumpers to the process equipment's to avoid the static electricity during the process. In the solvent unloading area, we have provided with the earth rite system to avoid the static energy generation during the unloading of the solvents from the road tankers to the above ground storage tanks. In order avoid the shrinking and imploding of the above ground solvent storage tanks, we have provided breather valves, where 150 mm / wc has be maintained in the above ground storage tanks. Glor (2006) reported the various precautious to be taken while handling the solvents in the explosive atmosphere by using the various ways to control the static energy. We have provided level indicator view glasses for the above ground storage tanks. Transferring the solvents or the chemicals to the production blocks are carried out in the closed loop piping system by using level and pressure transmitter, flow meter with the control valves, which are operated with pneumatic system by getting control signals from digital control system (DCS). During the process we have ensured that inert nitrogen of 0.5 ppm is maintained in the process equipment's. Any pressure built up in the reactors during the operations will be released though the safety relief system and rupture disk, which is connected to the dump tank. To prevent such type of pressure, build up we have only employed trained people to operate the various process equipment's as per the SOP. According to the Ayman et al. (2021) insisted that the formation of global groups, which includes various chemist, engineers and process scientist will help the global pharmaceutical sector for the safer operations, the various advantages of sharing

the information and knowledge in a common plat form is to stop the thermal run-away reactions.

Table 5

Table 5 Highest Voc Concentration, which are Present in the Various Zones

Month	Solvent storage Yard (PPM)	Unloading of the solvents (PPM)	Empty solvent drums storage yard (PPM)	Production block -1 (Raw material storage room) - Ground floor (PPM)	Production block - 1 (Intermediate processing area) - First floor (PPM)	Production block -3 (Clean room - I, II) -Ground floor (PPM)
Mar-21	3	0.1	0.21	0.21	0.21	2
Apr-21	2	0.7	0.12	0.12	0	3.2
May-21	0.7	0.62	0.31	0	0.52	4.1
Jun-21	0.5	0	0	0	3.9	0.5
Jul-21	1.2	0.21	0	0	0	1.1
Aug-21	0	0.1	0	0.6	0.42	8
Sep-21	1.36	0.2	0	0	4	0.2
Oct-21	0.41	0.21	0.11	0	0	3.1
Nov-21	0.72	0.6	0.21	0	5.3	6.2
Dec-21	0.5	0	0.1	0.9	0.4	0.5
Jan-22	1.2	0	0.21	0.42	0.4	0.32
Feb-22	2.3	0.5	0	0.8	0.62	0.52
Mar-22	0.5	0.12	0.02	0	3	1.2
Apr-22	0.2	0.21	0.4	0	0.3	0.2
May-22	0.2	0	0.3	0	0	0.5
Jun-22	1.6	1.2	0.25	0	7	0.7
Jul-22	2.1	0.31	0.34	0	0	0.67

We have classified the different areas in the working environment in the form of various zones, where VOC concentration in the solvent storage yard were highest in the month of March 2021 were 3 ppm (Zone 1), in case of solvent unloading bay was 1.2 ppm (Zone 1) in the month of June 2022, empty solvent drum storage area was 0,4 ppm (Zone 2) in the month of April 2022, production block – 1 (Raw material storage area) ground floor, were 0.9 ppm (zone 2) in the month of December 2021, production block -1 (intermediate process area) first floor were 7 ppm (zone 1) in the month of June 2022 and production block – 3 (clean room I, II) ground floor were 8 ppm (zone 1) in the month of August 2021. The highest concentration of the VOC was more in in the zone 1 area compared to the zone 2 area. Although in all the zones the highest concentration exceeded more than 0. 5 ppm of the permissible exposure limit (PEL) of the VOC except the solvent empty drum storage area, which was 0.1 ppm less than the PEL values limit. In the production blocks intermediate area and the clean room, I and II area, where while opening the manholes of reactors, drying of the intermediates, centrifuge separation, sampling points of the reactors, condenser vents, corks of the solvent drums kept open way and leakage in the pipeline are responsible for the 80 % of the fugitive emission, which increases the VOC concentration in the working environment Lin et al. (2023). In consistent to our present findings, it has been reported by many of the authors that the process equipment's are the important cause of the VOC emission in the pharmaceutical industry Zhang et al. (2021). Further Zhao & Chen (2018) reported that research in China shows that there is

emission from the pipeline components and storage tanks, which contribute to the 76 % of the VOC emission from coal, chemical and pharmaceutical industries.

In the Zone 1, 2, 21 and 22 we have used Ex d motors and fittings, which are flame proof and Ex p grade are the protection enclosure for the electrical equipment's, to restrict against the entry of flammable gas or vapours. In case of fire pump house and gardening pumps, we have used Ex n motors in the non-hazardous classification zone. These Ex-n pumps are not capable for withstanding to the increase in temperature, mechanical stresses, and the explosive atmosphere. All the power distribution systems, transformers, and the capacitors, which are used in the zone 1 are having Ex d protections. In case of oil filled transformers, all the safety precautions have been taken as per IS 1646-1961 to avoid the spread of fire. For the control, instrument panels. In DCS systems we have used Ex i protection in the Zone 1, 2, 21 and 22. In case of electrical repairs for opening of the instruments and switches we have used non sparkling zinc coated tools. In the Zone 1, 2, 21 and 22, where the light fittings and cables are guarded properly to provide protection against the informal displacement. The light fixtures, which are used in the Zones 1, 2, 21 and 22 are having the protection EX e or Ex n. In case of switch gear, breakers, fuses, and other equipment's, which are used in the Zones 1, 2, 21 and 22 are having enclosures with the type of Ex d protection. In consistent to the present findings Bhagirath et al. (2015) reported the importance of the usage of Ex d, Ex i, Ex e, Ex n, EX o, Ex p, Ex q, Ex m and Ex s standards has been presented in his review paper. Annual reviews have been carried out to achieve the engineering integrity of the plant and if any alterations are made, the area classification will be reviewed and same will be informed to the safety department. Abraham (2021) reported that the focus of the manufacturing sectors is to include the ATEX standards as a tool to achieve excellence in the manufacturing of the electrical components by implanting the design, manufacture and comply with the ATEX standard.

Application of various temperature classes in the occupational environment

The maximum surface temperature of the equipment, which is used during the process are considered for determining the Temperature Class (T). Any of the surface temperatures, which are below T6, which are not covered under any of the classifications. The ETP area, where we have a stripper, multiple effective evaporator (MEE) and agitated thin film dryer (ATFD), the surface temperature of the equipment during operations are 98 (T6), 110 (T5) and 120^{o} C (T5). Production block 1 second floor, clean room I and II, where the highest surface temperature, which reaches to more than 135^{o} C (T4), the stream is used as a medium of heating to the jacket of the reactor as per the instructions, which are given the batch management record (BMR). Further this surface temperature of the reactor may vary from 85 (T6) to 100^{o} C (T5) based on the different types of reaction carried out in the production blocks and the various equipment's used during the process. Product block -2, where drying of the intermediate takes up to T4 to T6 in the drying block as per the instructions, which are given in the BMR. Inside the boiler, the temperature is very high as it goes up 400^{o} C (T2) due to the combustion process. The boiler surface area has the highest surface temperature compared to the other equipment's, which are used in the intermediate and clean room area. Bhagirath et al. (2015) reported that globally European norms (EN 60079-0), IEC 60079-0 and Indian standard (IS 60079-0) have formulated the temperature class from T1 to T6, it is based on the maximum temperature, which is attained during the normal operations.

Applying the Ingress Protection (IP)

The various motors, which are used in the above ground solvent storage area, unloading of the solvents, and pumping it to the blocks, which are having IP66 ingress protection. The pumps which are used in ETP are of IP 67 enclosures. The spent carbon storage area, where the switches, which are used are having IP65 protection. The production block – 1 first floor and production block 3 ground floor, where the motors, which are used for reactors, centrifuges and ANFD are having IP 66 enclosures. Similarly in the case of clean rooms in the production block – 3 first floor all the electrical motors are protected from the dust particles and jet water spray with IP 66 protection. Gaurav & Chaudhari (2015) reported that it is essential to protect all the electrical equipment in the pharmaceutical clean room with proper ingress protection from the various anticipated hazards dust in the working environment. In the case of the production block -3 first floor, where multi milling, jet milling blending takes place, there are chances of exposure of the powdery dust particles, so IP65 protection enclosures for the motors are used. Production block -2 ground floor. raw material storage area, where the sockets and switches, which are used are of IP66 protection. Production block -2 in the drying block area we have used IP65 enclosures for the motors.

4. CONCLUSION

The critical zones have been identified during the study. Zone 1, zone 2, zone 21 and zone 22 were four, two, three and two locations. We have found that the highest concentration of the VOC was 8 PPM in clean room I, II in the month of August 2021. We have found that the Ex-d, Ex e, Ex I, Ex n and Ex p ATEX standards were used for the electrical equipment / Instruments in the various zones. The highest temperature class of T2 of 400 o C, which was found inside the boiler. The ingress protection codes such as IP65, IP66 and IP67 were used as enclosures for the various equipment's in the pharmaceutical industry.

CONFLICT OF INTERESTS

None.

ACKNOWLEDGMENTS

I thank Mr. Linga Murthy and their team for helping us for successfully identifying the critical zones in the pharmaceutical industry and giving us the full support while writing the article, so that the people in the chemical and pharmaceutical industry get benefited by identifying the most critical zones in the working environment.

REFERENCES

Abbasi, T., & Abbasi, S. A. (2007). Dust Explosions-Cases, Causes, Consequences, and Control. Journal of Hazardous Materials, 140(1-2), 7-44. https://doi.org/10.1016/j.jhazmat.2006.11.007.

Abraham, S. J. (2021). New Knowledge Management Framework for Manufacturing SMEs Working in Strictly Regulated Sectors. Procedia Manufacturing, 54, 290-295. https://doi.org/10.1016/j.promfg.2021.09.001.

Ayman, D., & Allian, R. C. Flanagan, Ray Mentzer, Jeffrey B. (2021). Precompetitive Collaborations in the Pharmaceutical Industry: Process Safety Groups Work Together to Reduce Hazards, from R&D Laboratories to Manufacturing Facilities. ACS. Sperry, Han Xia and Ralph Zhao. Chemical Health and Safety, 28(5), 297-302. https://doi.org/10.1021/acs.chas.1c00049.

Bhagirath, A., Singh, A. K., & Vishwakarma, R. K. (2015). Area Classification and Types of Protection for Explosive Atmospheres: A Review. Telkomnika Indonesian Journal of Electrical Engineering, 16(2), 238-243. https://doi.org/10.11591/tijee.v16i2.1608.

Bloch, H. P. (2009). Ingress Protection Code Explained. World Pumps, 2009(11), 26. https://doi.org/10.1016/S0262-1762(09)70418-3.

Boeck, L. R., Bauwens, C. R. L., & Dorofeev, S. B. (2023). Large-Scale Dust Explosions in Vessel-Pipe Systems. Journal of Loss Prevention in the Process Industries, 82. https://doi.org/10.1016/j.jlp.2023.104980.

Boltic, Z., Ruzic, N., Jovanovic, M., Savic, M., Jovanovic, J., & Petrovic, S. (2013). Cleaner Production Aspects of Tablet Coating Process in Pharmaceutical Industry : Problem of Vocs Emission. Journal of Cleaner Production, 44, 123-132. https://doi.org/10.1016/j.jclepro.2013.01.004.

Bozek, A., Gordon, C., & Phillips, N. (2014). Electrical Hazardous Area Classification Design as a Basis for Safer Operations. Record of Conference Papers - Annual Petroleum and Chemical Industry Conference, 459-464. https://doi.org/10.1109/PCICon.2014.6961911.

Cashdollar, K. L. (2000). Overview of Dust Explosibility Characteristics. Journal of Loss Prevention in the Process Industries, 13(3-5), 183-199. https://doi.org/10.1016/S0950-4230(99)00039-X.

Chen, X., Mao, Y., Fan, C., Wu, Y., Ge, S., & Ren, Y. (2022). Experimental Investigation on Filtration Characteristic with Different Filter Material of Bag Dust Collector for Dust Removal. International Journal of Coal Preparation and Utilization, 42(12), 3554-3569. https://doi.org/10.1080/19392699.2021.1975686.

EPCS. (2014). 2014/34/EU the Harmonisation of the Laws of the Member States Relating to Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (recast) ; European Parliament and of the Council : Bruxelles, Belgium. European Parliament and of the Council. Directive, 2014.

Eckhoff, R. K. (2006). Differences and Similarities of Gas and Dust Explosions : A Critical Evaluation of the European "ATEX"Directives in Relation to Dusts. Journal of Loss Prevention in the Process Industries, 19(6), 553-560. https://doi.org/10.1016/j.jlp.2006.01.001.

Gaurav, A., & Chaudhari, S. H. (2015). Sarje. Clean Room Classification for Pharmaceutical Industry. International Journal of Engineering and Technical Research (IJETR), 3(4), 241-244.

Glor, M. (2006). Transfer of Powders into Flammable Solvents Overview of Explosion Hazards and Preventive Measures. Journal of Loss Prevention in the Process Industries, 19(6), 656-663. https://doi.org/10.1016/j.jlp.2005.12.005.

Han, D. H. (2021). Selection Guide to Wearing Respirators According to Work Situations and On-Site Applicability. Safety and Health at Work, 12(4), 424-431. https://doi.org/10.1016/j.shaw.2021.07.011.

Han, D., Xu, L., Wu, Q., Wang, S., Duan, L., Wen, M., Li, Z., Tang, Y., Li, G., & Liu, K. (2021). Potential Environmental Risk of Trace Elements in Fly Ash and Gypsum from Ultra-Low Emission Coal-Fired Power Plants in China. Science

of the Total Environment, 798. https://doi.org/10.1016/j.scitotenv.2021.149116.

Hirak, D. (2021). Asset and Mechanical Integrity Management, Process Safety Management and Human Factors (A Practitioner's Experiential Approach) Chapter 8. Elsevier Publications. https://doi.org/10.1016/B978-0-12-818109-6.00008-3.

Hoffmann, R., & Kögl, T. (2017). An ATEX-Proof Gamma Tomography Setup for Measuring Liquid Distribution in Process Equipment. Flow Measurement and Instrumentation, 53(A), 147-153. https://doi.org/10.1016/j.flowmeasinst.2016.05.009.

James, M., Khan, W. S., Nannaparaju, M. R., Bhamra, J. S., & Morgan-Jones, R. J. (2015). Current Evidence for the Use of Laminar Flow in Reducing Infection Rates in Total Joint Arthroplasty. Open Orthopaedics Journal, 9, 495-498. https://doi.org/10.2174/1874325001509010495.

Ji, W., Wang, Y., Yang, J., He, J., Lu, C., Wen, X., & Wang, Y. (2023). Explosion Overpressure Behavior and Flame Propagation Characteristics in Hybrid Explosions of Hydrogen and Magnesium Dust. Fuel, 332(1). https://doi.org/10.1016/j.fuel.2022.125801.

Kuseva, C., Marinov, V., Pavlov, T., Petkov, T., Chapkanov, A., Dimitrova, D., Wombacher, T., Mullen-Hinkle, S., Zhu, W., Siebold, M., & Mekenyan, O. (2022). Predicting Explosive Properties of Chemicals Accounting for Thermodynamic and Kinetic Factors. Computational Toxicology, 23. https://doi.org/10.1016/j.comtox.2022.100230.

Lele, D. V. (2012). Risk Assessment: A Neglected Tool for Health, Safety, and Environment Management. Indian Journal of Occupational and Environmental Medicine, 16(2), 57-58. https://doi.org/10.4103/0019-5278.107064.

Li, X., Zhang, M., Jiang, Y., Zhao, X., Wang, L., Zhu, J., Xu, X., Li, Z., Jia, J., & Zhu, D. (2022). Air Curtain Dust-Collecting Technology : An Experimental Study on the Performance of a Large-Scale Dust-Collecting System. Journal of Wind Engineering and Industrial Aerodynamics, 220, 104875. https://doi.org/10.1016/j.jweia.2021.104875.

Lin, Q., Gao, Z., Zhu, W., Chen, J., & An, T. (2023). Underestimated Contribution of Fugitive Emission to VOCs in Pharmaceutical Industry Based on Pollution Characteristics, Odorous Activity and Health Risk Assessment. Journal of Environmental Sciences, 126, 722-733. https://doi.org/10.1016/j.jes.2022.03.005.

Luo, Y., Wu, Y., Ma, S., Zheng, S., Zhang, Y., & Chu, P. K. (2021). Utilization of Coal Fly Ash in China : A Mini Review on Challenges and Future Directions. Environmental Science and Pollution Research International, 28(15), 18727-18740. https://doi.org/10.1007/s11356-020-08864-4.

Paloma, L. Barros., Aurélio M. Luiz., Claudemi A. Nascimento., Antônio T.P. Neto., & José J.N. Alves. (2020). "On the Non-Monotonic Wind Influence on Flammable Gas Cloud from CFD Simulations for Hazardous Area Classification". Journal of Loss Prevention in the Process Industries, 68. https://doi.org/10.1016/j.jlp.2020.104278.

Pang, Y., Fuentes, M., & Rieger, P. (2014). Trends in the Emissions of Volatile Organic Compounds (VOCs) from Light-Duty Gasoline Vehicles Tested on Chassis Dynamometers in Southern California. Atmospheric Environment, 83, 127-135. https://doi.org/10.1016/j.atmosenv.2013.11.002.

Paul, C., Richard, W. P., & Vahid, E. (2021). Compared : A Solvent Vapor Explosion in Germany and a Combustible Dust Explosion in the United States. AIChE, Process Safety Progress Journal, 40(4), 191-194. https://doi.org/10.1002/prs.12317.

Pietraccini, M., Delon, E., Santandrea, A., Pacault, S., Glaude, P. A., Dufour, A., & Dufaud, O. (2021). Determination of Heterogeneous Reaction Mechanisms : A Key Milestone in Dust Explosion Modelling. Journal of Loss Prevention in the Process Industries, 73. https://doi.org/10.1016/j.jlp.2021.104589.

Rogala, I. (2015). Hazardous Area Classification - Dust Atmospheres New Plant Design and Operation and Re-Evaluate Changes to Existing Plant. International Electrotechnical Commission System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres, 1-23.

Song, Y., Zhang, Q., Wang, B., & Li, J. (2019). Numerical Study on the Internal and External Flow Field of Dust Explosion Venting. International Journal of Thermal Sciences, 145. https://doi.org/10.1016/j.ijthermalsci.2019.106008.

Sophie, S. (2013). Laminar Flow Hood System Design. Senior Project Engineering Department California Polytechnic State University, 1-46.

Sun, H., Pan, Y., Guan, J., Jiang, Y., Yao, J., Jiang, J., & Wang, Q. (2019). Thermal Decomposition Behaviours and Dust Explosion Characteristics of Nanopolystyrene. Journal of Thermal Analysis and Calorimetry, 135(4), 2359-2366. https://doi.org/10.1007/s10973-018-7329-1.

Tommasini, R. (2013). The Classification of Hazardous Areas Where Explosive Gas Atmospheres May Be Present. Safety Science, 58, 53-58. https://doi.org/10.1016/j.ssci.2013.03.010.

Tsai, Y.-T., Huang, G.-T., Zhao, J.-Q., & Shu, C.-M. (2021). Dust Cloud Explosion Characteristics and Mechanisms in MgH2-Based Hydrogen Storage Materials. AIChE Journal, 67(8). https://doi.org/10.1002/aic.17302.

Tzanakopoulou, V. E., Castro-Rodriguez, D., & Gerogiorgis, D. I. (2021). Process Modelling and Simulation of Volatile Organic Compound (Voc) Recovery from Pharmaceutical Gas Emission Streams. Computer Aided Chemical Engineering, 50, 717-723. https://doi.org/10.1016/B978-0-323-88506-5.50113-3 .

Wan Sulaiman, W. Z., Mohd Idris, M. F., Gimbun, J., & Sulaiman, S. Z. (2020). Assessment of Explosibility and Explosion Severity of Rice Flour at Different Concentration and Ignition Time. Process Safety Progress, 39(S1). https://doi.org/10.1002/prs.12107.

Wang, Y., Lin, C., Qi, Y., Pei, B., Wang, L., & Ji, W. (2020). Suppression of Polyethylene Dust Explosion by Sodium Bicarbonate. Powder Technology, 367, 206-212. https://doi.org/10.1016/j.powtec.2020.03.049.

Wei, M. C., Cheng, Y. C., Lin, Y. Y., Kuo, W. K., & Shu, C. M. (2020). Applications of Dust Explosion Hazard and Disaster Prevention Technology. Journal of Loss Prevention in the Process Industries, 68. https://doi.org/10.1016/j.jlp.2020.104304.

Wu, X., Liu, W., Gao, H., Alfaro, D., Sun, S., Lei, R., Jia, T., & Zheng, M. (2021). Coordinated Effects of Air Pollution Control Devices on Pah Emissions in Coal-Fired Power Plants and Industrial Boilers. Science of the Total Environment, 756. https://doi.org/10.1016/j.scitotenv.2020.144063.

Zhang, G., Fei, B., & Xiu, G. (2021). Characteristics of Volatile Organic Compound Leaks from Equipment Components : A Study of the Pharmaceutical Industry in China. Sustainability, 13(11). https://doi.org/10.3390/su13116274.

Zhao, J., & Chen, M. (2018). Leak Detection and Repair (LDAR) Standard Review for Self-Inspection and Management for VOC Emission in China's Traditional Energy Chemical Industry. Journal of Environmental Protection, 09(11), 1155-1170. https://doi.org/10.4236/jep.2018.911072.

Zohdirad, H., Ebadi, T., Givehchi, S., & Meysami, H. (2016). Grid-Based Individual Risk Calculation in the Classification of Hazardous Area with a Risk-Based Approach. Journal of Loss Prevention in the Process Industries, 43, 98-105. https://doi.org/10.1016/j.jlp.2016.05.007.