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Dust Explosion Hazard And Safety In Pharmaceutical Industries

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Abstract— **Some of the solid ingredients handled in pharmaceutical industries manufacturing oral solid dosage are combustible and have inherent explosion hazard. This article presents experimental results on explosion parameters- minimum of some products and excipients- acetyl salicyclic acid, aminophenazone, ascorbic acid, benzoic acid, carboxy methyl cellulose, cellulose, citrus pellets, dextrin, dimethylaminophenazone, 2-Ethoxy-benzamide, glucose, isosorbide dinitrate/lactose(50:50), L-cystine, lactose, methyl cellulose, paracetamol, polyethylene LDPE, sorbitol, starch-maize and sugar- processed in these facilities measured with CSIR-CBRI 20-L sphere, Hartmann apparatus and Godbert-Greenwald furnace. The data may be used for designing explosion safety measures for explosion-prone units and areas.**

Index Terms—**Dust, carboxy methyl cellulose, cellulose, citrus pellets**

I. INTRODUCTION

Many of the powders processed in pharmaceutical oral solid dosage (OSD) manufacturing industries are combustible and pose explosion hazard in various operations like material charging, blending, granulation, fluid bed drying, vacuum drying, grinding, sieving, milling, compression, coating, dust collection, micronization and pneumatic transport. Dust explosion occurs in these units due to simultaneous presence of explosive dust-air mixture and potential ignition source viz. electrical or mechanical spark, static electricity discharges, hot surfaces, etc. The dust-air mixture may be in explosive range by design (e.g. fluidized bed drying) or unintentional formation (e.g. vessel charging). The process equipment that have combustible dust concentrations routinely in at least a portion of the equipment volume are blenders, dryers, dust collectors, grinders, pulverizers, etc. It takes only microseconds for a violent explosion to occur in a confined space and subsequent rise in explosive pressure can have devastating consequences. Dust explosions originating in an equipment propagate to other equipment, and finally emerge from the equipment to produce a massive deflagration in a process building.

In a new project or review of an existing process, safety is required to be defined and documented for each operation. The basis of safe operation is a function of type of operation, potential ignition sources and explosibility properties of materials being handled which depend on particle size, moisture content, oxidant concentration and presence of flammable vapours. The pharmaceutical industries are aware of explosion risk of pharmaceutical ingredients but that of excipients used by them is not well understood. An excipient is a pharmacologically inactive substance formulated alongside the active pharmaceutical ingredient (API) of a medication to provide bulk to formulation, facilitate drug absorption or solubility and other pharmacokinetic considerations, aid in handling API during manufacture, etc. The excipients include: fillers (cellulose, diabasic calcium phosphate, lactose, sucrose, glucose, sorbitol, etc.), binders (cellulose, methyl cellulose, cellulose derivatives, starch, sucrose, etc.), disintegrants (polyvinylpyrolidone, carboxy methyl cellulose, etc.), sorbents (peat mass, sawdust, polyethylene, etc.), antiadherents (magnesium stearate, talk, starch, etc.), lubricants (polyethylene glycol, magnesium stearate, etc.), preservatives (methyl and ethyl parabens, benzoic acid, etc.), antioxidants (sodium sulphite, ascorbic acid,etc.), flavouring agents(clove oil, citric acid), sweeting agents (sugar, sucrose, sorbitol).

The dust explosion characteristics required for evaluating the explosion risk, identifying probability and severity of dust explosion and designing explosion safety measures are: minimum explosible concentration (MEC), maximum explosion pressure (P_{max}), rate of rise of explosion pressure ($(dP/dt)_{max}$), deflagration index (K_{St}), minimum ignition temperature (MIT), minimum ignition energy (MIE) and limiting oxygen concentration (LOC). The explosion characteristics of number of dusts handled in various industries are available in literature (Eckhoff, 1991; BIA,1997). Those for materials handled in pharmaceutical industries are lacking.

The present work reports the explosion characteristics of some excipients and products handled in pharmaceutical industries measured at CSIR-CBRI. The information and data from this study add to the current literature on explosion characteristics of dusts handled in these industries. These data can be used to evaluate the explosion hazard of units/areas handling similar dusts and designing the explosion safety measures.

II. EXPERIMENTAL PROCEDURES

The explosion characteristic- MEC, P_{max}, $(dP/dt)_{max}$, MIT, MIE and LOC- were determined for 20 number of dusts using CSIR-CBRI 20-L Sphere, Hartmann apparatus and Godbert-Greenwald furnace (Mittal,1996,2012). The APIs and excipients dusts studied are: acetyl salicyclic acid, aminophenazone, ascorbic acid, benzoic acid, carboxy methyl cellulose, cellulose, citrus pellets, dextrin, dimethylaminophenazone, 2-Ethoxy-benzamide, glucose, isosorbide dinitrate/lactose (50:50), L-cystine, lactose, methyl cellulose, paracetamol, polyethylene LDPE, sorbitol, starch-maize and sugar.

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The particle sizes of dusts selected for present study are: 106, 74, 38, 22 and 10 µm. Samples for particle sizes 106, 74 and 38 µm were prepared using traditional sieve analysis. Other samples were collected from the manufacturer and particle sizes were taken to be as reported by them. No further size analysis was performed for these sizes in laboratory. Some dusts were investigated for all the particle sizes chosen while others for limited sizes.

Explosion indices- MEC, P_{max} and $(dP/dt)_{max}$, and LOC were measured in 20-L Sphere (Mittal, 2012). The sphere consists in a spherical combustion chamber, a dust storage container connected with chamber via a dust outlet valve, a pair of electrodes holding two pyrotechnic ignitors at sphere centre, and two piezoelectric and one strain gauge pressure sensors to record explosion development. Typical pressure-time curve recorded during dust explosion experiments is shown in Figure 1. Pressure trace starts at partially evacuated value of 0.4 bar(a). The blast of air that disperses dust starts at 40 ms and ends at 90 ms on pressure-time trace. Ignitor is activated at 100 ms at a chamber pressure of 1.0 bar(a). P_{ex} is the maximum explosion pressure. Value of P_{ex}, for a test at a given concentration, is highest deflagration pressure (absolute) minus pressure at ignition (normally 1 bar). $(dP/dt)_{ex}$ is maximum rate of pressure rise reached during the course of a single explosion experiment.

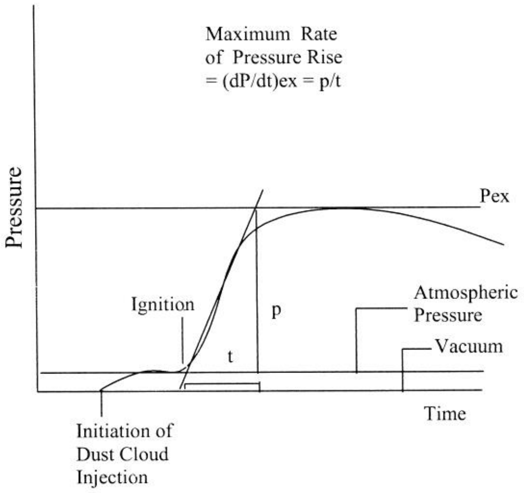

Fig. 1. Typical pressure-verses-time trace during a dust explosion experiment in 20-L Spherical Vessel

MEC, the lowest concentration of dust in air that ignites on contact with an ignition source and propagate a dust explosion, is determined following the standard procedure (ASTM, 2007a) using chemical ignitor with 2.5 kJ energy. The test commences with experiments at a high powder concentration. If this concentration of powder ignites, the dust concentration is reduced in steps until no ignition is evident. An ignition is deemed to have occurred if the maximum explosion pressure is at or above 2 bar(a). The test is then repeated with a lower dust concentration which is reduced further until a concentration is reached at which no ignition of dust/air mixture is observed in three consecutive tests.

Explosion severity measurement experiments are conducted over a range of dust concentration in accordance with standard procedure (ASTM, 2010). Pyrotechnic ignitors with energy 10 kJ are used. P_{max} is maximum pressure and $(dP/dt)_{max}$ is maximum value for rate of pressure increase per unit time reached during the course of explosion for optimum dust concentration and equals maximum slope of a tangent through the point of inflexion in the rising portion of pressure vs. time curve. Deflagration constant, $K_{St,}$ characterizes explosibility of the material. K_{St} is maximum value of dP/dt normalized to a 1.0 m^3 volume measured at optimum dust concentration and defined by equation 1 (Eckhoff, 1991):

$$K_{St} = (\frac{dP}{dt})_{\max} . Vs^{1/3} \qquad (1)$$

Where,

P - Pressure, bar

T - Time, s

Vs - Vessel volume, m^3

K_{St} - Dust explosibility constant, bar.m/s

K_{St} values rounded to nearest integer are used. Dusts are given explosion severity classifications St1 (K_{St}<200 bar.m/s), St2 (200 bar.m/s >K_{St} <300 bar.m/s) and St3(K_{St}>300 bar.m/s).

MIE, used to represent the ease or difficulty of powder ignition by electrical sparks and arcs or electrostatic discharge was measured in 1.2-L Hartmann apparatus as per standard procedure (Mittal, 1996; ASTM, 2007b). The minimum ignition energy determines the sensitivity of the explosive atmosphere to ignition sources specifically static discharges. In the pharmaceutical industry, the main ignition source tends to be from an electrostatic discharge which can be generated by processes such as sieving, milling, pouring, mixing and pneumatic transport.

The apparatus used for this test consists of a glass tube placed over a dispersion cup and fitted with two brass electrodes (3 mm diameter) connected to a circuit which produces an electrical spark of known energy. The spark generating system has three units: variable capacitor bank having capacitors with different values; variable voltage supply/ continuous spark unit; and step-up transformer. The spark is triggered by high voltage transformer using two-electrode system connected to the secondary winding of the transformer and fitted in the Hartmann tube. The self-inductance of the secondary coil of the trigger transformer is 1 mH. Electrodes with rounded tips have been used to reduce corona effects as for circuit in which high voltage is maintained across the gap prior to spark breakdown. The spacing between the electrodes is varied between 2-6 mm while carrying tests. With variable combination of capacitance and voltage, it is possible to obtain sparks with ignition energies in the range 0.5 mJ – 3.2 J using this circuit. There is precise electronic synchronization between dust dispersion and spark onset. The ignition delay times can be selected between 20 to 200 ms with an increment of 20 ms. Energy discharged from the capacitor is calculated from the following formula, assuming no energy losses in the transformer,

$$W = \frac{1}{2} C(V_i^2 - V_f^2) \qquad (2)$$

Where,
W - Discharge energy, J
C - Total capacitance of discharge circuit, F
V_i - Initial voltage of charged capacitor, V
V_f - Final voltage of charged capacitor, V

To establish MIEs, the tests are done by starting at relatively high spark energy levels using relatively large discharge capacitance. The capacitance is then reduced in steps until no ignition occurs for ten ignition trials. A weighed sample of dust is placed in the dispersion cup. A blast of compressed air is used to disperse the dust in the glass cylinder where it is ignited by a spark between two electrodes. Ignition trials of this dust-air mixture are then attempted, after a specific ignition delay time, by a spark discharge from the charged capacitor. The stored energy discharged into the spark and the occurrence or non-occurrence of flame is recorded by visual observation of flame propagation away from the spark gap. If flame propagation is observed, the energy of the spark is reduced until no flame propagation is seen for ten consecutive tests. The minimum ignition energy is sought by varying the dust concentration, the spark discharge energy and the ignition delay time. When changing the ignition delay time, only points of non-ignition are tested. Experiment is started with a dust loading corresponding to dust concentration twice as high as the experimentally determined MEC or 250-500 g/m^3 and 'go/no-go' spark energy is estimated. Once a limit is found for a particular dust concentration, the procedure is repeated for higher and lower dust concentrations until a roughly parabolic curve is obtained for ignition energy verses dust concentration. Ten tests are conduced at most ignitable dust concentration. MIE is determined from the MIE vs. concentration curve.

The MIT is the lowest temperature of a hot surface that will cause a dust cloud to ignite and propagate flame. This parameter determines the temperature classes of electrical equipment. Godbert-Greenwald furnace (heated section: 3.9 cm diameter, 23 cm long, 0.27 l volume) was used to measure MIT as per standard procedure (Mittal, 1996; ASTM, 2006). The initial tests are carried out at dust concentrations at which the maximum pressure, P_{max}, and the maximum normalized rate of pressure-rise, K_{St}, are found. The dust is placed in a dust holder at the top of temperature controlled furnace with an open bottom. The temperature of the furnace is set at a predetermined value. The dust is dispersed by the compressed air downwards past the hot surface of the furnace to see if ignition occurs and flame is produced. Ignition is defined as the flame exiting from the furnace chamber. Furnace temperature, as well as dust concentrations are varied to ensure that the auto ignition temperature is measured at the most easily ignitable concentration. At least five tests over a range of concentrations are run at the highest temperature at which ignition is not observed. At the temperature at which ignition is observed, dust concentration is varied to determine the range over which ignition occurs. To assure repeatability of data, at least 3 ignitions are observed over a range of concentrations at the lowest temperature at which ignition occurs. The MIT is usually relatively independent of dust concentration.

LOC, the highest permissible oxygen concentration below which dispersed dust ignition is not possible at ambient temperature and pressure, is determined in 20-L Sphere by conducting experiments at various oxygen levels over a wide range of dust concentration as per standard procedure (BS EN 14034-4, 2005) using two chemical ignitors with total energy of 2kJ. The experiments are started with an oxygen concentration of 21% and continued at reduced oxygen concentrations lowered in steps of 3 % initially and 1 % when it comes closer to LOC. The pressure-time data for each experiment is recorded. An ignition/ explosion of dust is considered to have taken place, when the measured overpressure (influence of chemical ignitors included) relative to the initial pressure P_i is $\geq$ 0.5 bar ($P_{ex} \geq (P_i+0.5$ bar)). Optimum dust concentration at which the highest explosion pressure occurs at any experimental oxygen concentration, is determined. By increasing the ratio of inert gas to air step by step and varying the dust concentration, the oxygen concentration is reduced to a level at which explosions no longer occur at any dust concentration. The highest oxygen concentration where no ignition occurs in three consecutive tests is reported as the LOC.

III. RESULTS & DISCUSSIONS

The MEC is the minimum amount of dust that needs to be suspended in order for explosible conditions to occur. The MEC measured for the dusts is presented in Fig.2. The value of this parameters for the dusts tested here ranged from 20 to 130 g/m^3. These data can be used for evaluation of probability of explosion in a stated dust-air environment.

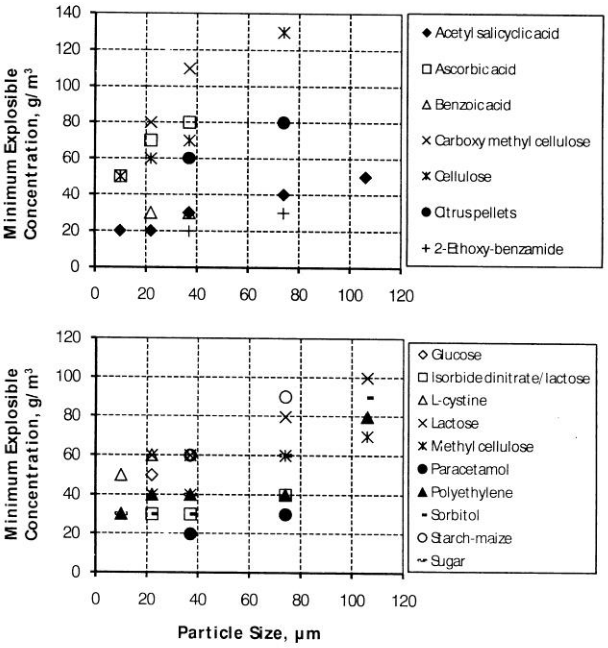

Fig.2. Minimum explosible concentration for dusts- experimental results

Experiments for explosion severity measurement were conducted for dust concentration range 30-2000 g/m^3 for all sizes of dusts. Pressure-time curves were recorded for all the experiments. The experimental curves were analysed and values of P_{ex}, $(dP/dt)_{ex}$ and $K_{St}(=dP/dt)_{ex}.V^{1/3}$ were estimated for each experiment. The values of P_{max} and K_{St} corresponding to optimum dust concentration were determined for each particle size. The P_{max} and K_{St} values at optimum dust concentration for a range of particle sizes are presented in Figs. 3 & 4. These figures indicate that P_{max} and K_{st} both increase significantly with decreasing size of dust particles from 106 to 10μm as expected.

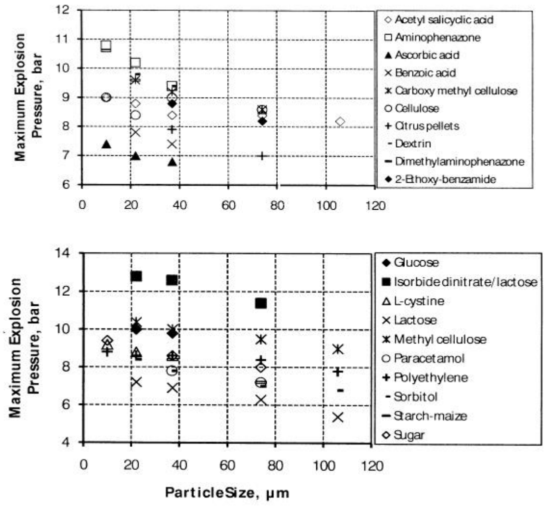

Fig.3. Maximum explosion pressure for dusts- experimental results

Explosion severity experiments examine the consequences in the event of dust explosion. The maximum explosion pressure (P_{max}) and pressure-rise rate, $(dP/dt)_{max}$, describe the violence of combustion of dust-air mixture in a closed vessel. The dust deflagration index is a normalized measure of the pressure rise rate and used to describe the severity of explosion increasing from dust explosion class St1 to St3. Fig.4. shows the maximum explosion pressure for the dusts varies from 6.4 to 12.8 bar. The deflagration index values presented in Fig. 4 indicate the explosion class of dusts as: St1- aminophenazone (37µm); ascorbic acid (10-37 µm); cellulose (74 µm); carboxy methyl cellulose (22-74µm); citrus pellets (37-74 µm); dextrin (22- 37 µm); glucose (22- 37 µm); isosorbide dinitrate/lactose (74 µm); L-cystine (10-22 µm); lactose (22-106 µm); methyl cellulose (22-106µm), paracetamol (37-74 µm), polyethylene LDPE (10-106 µm), sorbitol (22-106µ), starch-maize (37-74µm) and sugar (37-74µm); St2- acetyl salicyclic acid (10-106µm), aminophenazone (10- 22 µm), benzoic acid (22-37 µm),cellulose (10-37µm); 2-Ethoxy-benzamide (37-74 µm), isosorbide dinitrate/lactose (22-37 µm), sugar (10 µm); and St3- dimethylaminophenazone (10 -22µm). Out of the 20 dusts tested, 12 are St1, 3 are St2 , 4 are St1 and St2 both depending on particle size; and 1 is St3.

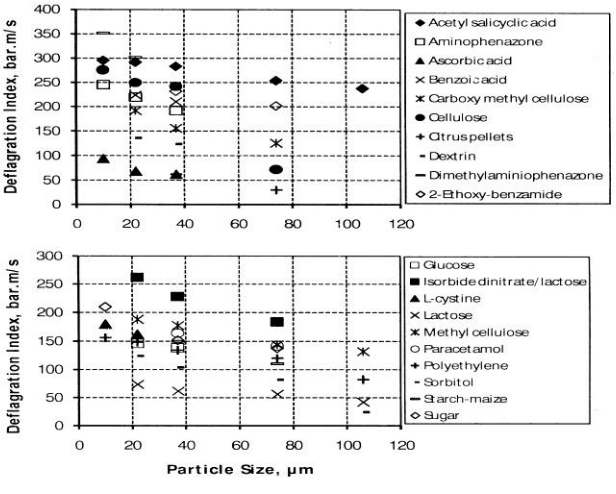

Fig.4. Deflagration index for dusts- experimental results

The MIEs were determined for 12 dusts for their various particle sizes. The MIE is the minimum input required to initiate a dust explosion. This parameter was measured over a range of dust concentration following the procedure explained above. Experimental results on MIE measurement are presented in Fig.5. The minimum value of MIE was 9 mJ for 10 µm acetyl sali-cyclic acid. The experimental data indicate that ignition sensitivity increases (MIE decreases) when moving from higher size to lower micron-particle dust clouds.

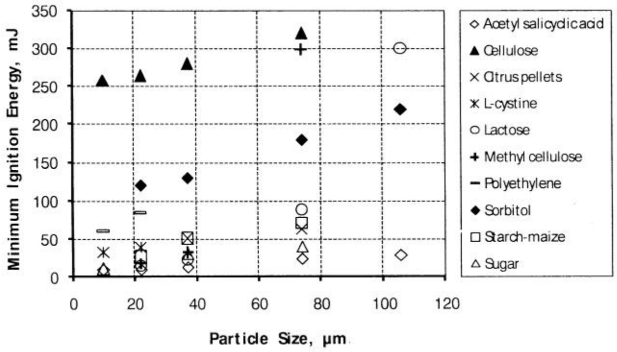

Fig.5. Minimum ignition energy for dusts- experimental results

The MIT is an indication of the sensitivity of a dust cloud to auotoignite at elevated temperatures. The MIT for each particle size of dust was determined in Godbert-Greenwald furnace starting with dust concentrations at which the maximum pressure P_{max}, and the maximum normalized rate of pressure-rise, K_{St}, were found in present study as per standard procedure. Experimental results on MIT measurement for all sizes of dusts are presented in Fig.6. Minimum ignition temperature was found to decrease with decreasing particle size, increasing the probability of explosions with small-sized particles over larger particles. Lower values of MITs for small-size than those required to ignite the larger -size dust, indicates that lower size dust particles have enhanced potential for ignition by hot surfaces and inflammation or explosion risks are inherently higher. The MIT for the dusts tested ranged from 220 to 620°C.

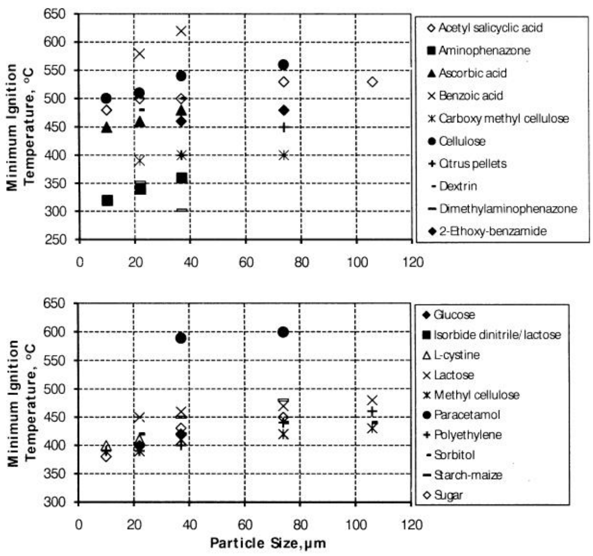

Fig. 6. Minimum ignition temperature of dust-air clouds- experimental results

Systematic experiments were conducted to determine LOC for 6 dusts at varying oxygen levels over a range of dust concentration as per standard procedure. Each experiment was repeated thrice. The pressure-time curves were recorded for all the experiments. The experimental curves were analysed and values of P_{ex} were estimated at each oxygen concentration. The dust concentration range was same as for explosion severity tests at 21 % oxygen level for each sample. The experiments, in which recorded explosion pressure was $\geq$ 0.5 bar, were considered as indicating ignition/explosion. The boundary between oxygen concentration that support combustion and that do not support combustion is the limiting oxygen concentration. The resultant values of LOC for the dust tested are presented in Fig.7.

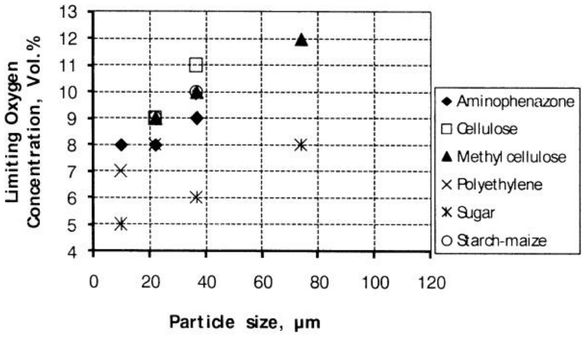

Fig. 7. Limiting oxygen concentration for dusts -experimental results

The experimental values of MEC, P_{max}, K_{St}, MIE, MIT and LOC for the dusts studied in present investigation are in close agreement to that published for dusts having sizes closer to that involved in present study (Eckhoff, 1991; BIA,1997)

IV. EXPLOSION SAFETY MEASURES- OVERVIEW

Control of explosion hazard in pharmaceutical industries manufacturing OSD should involve: evaluation of the material processed; identification of areas/units susceptible to formation of combustible dust-air mixture; defining parameters including the explosion characteristics of powders handled forming the basis of safety measures for various unit operations early in the project or process life cycle; and communication of hazard and control strategy to personnel involved in various plant operations and other concerned persons such as architects, engineers, equipment suppliers.

The explosion risk evaluation is based on identifying and defining the experimental parameters for the dusts in question, defining procedure for risk evaluation and proposing safety measures for different types of equipment based on experimental data using worksheets, supporting documents, in-house courses, etc. The explosion characteristics are used for designing explosion prevention -control of oxidation (inert gas blanketing/purging), control of dust cloud concentration (equipment maintenance, local exhaust, ventilation, and housekeeping) and control of ignition source and explosion mitigation measures- explosion venting, explosion suppression, explosion isolation and containment. Every equipment has a list of safety measures depending on explosion/safety characteristics of the powders being handled in them. Different unit operations may need some additional safety data. The products are then classified into risk group in accordance with their explosion characteristics. The worksheet for each unit contains specific safety measures for the powders processed according to risk group. The safety measures listed in worksheet may help in selecting the type of equipment for an application to a particular group of dusts. The units requiring special explosion protection are covered in more detail and supporting documents are provided for the same.

There is no substitution for exercising good housekeeping in pharmaceutical facilities. Regular removal of dust accumulation in the factory space is a primary safety precaution against explosion but is overlooked in practice. The spark detection devices are used to detect hot particles sparks flames that could become the ignition source for a fire or explosion. They can include automated shut-down systems to interrupt the feed of combustible material along the process equipment.

Explosion suppression system is designed to detect the pressure wave at the very start of an explosion and deliver dry, inert chemical extinguishing agents into a developing initial deflagration. The suppression system can be activated either by pressure, optical or vent sensors. Any deflagration travelling through interconnected equipment is quickly and efficiently extinguished, preventing any spreading explosion damage. Chemical extinguishing systems offer extremely efficient and rapid protection. They can easily protect a deflagration from travelling through ducts, piping and connecting equipment thereby preventing any spreading explosion damage. These are used most effectively when there is no risk of compromising the quality of pharmaceutical raw materials on exposure to a chemical extinguishing agent during primary explosion event. When the chemical agent may affect raw materials in the equipment, the mechanical isolation is desired. It is just as efficient at preventing any kind of deflagration or explosion from spreading to connected process equipment, just like chemically driven methods.

Venting is the preferred passive method to relieve explosion pressure in a process or storage vessel containing combustible material. Open venting, although traditionally a preferred cheaper option in most industries, is not the popular choice in the pharmaceutical industry. Flame-quench vents may be used for venting the explosion. It is not always possible /practical or safe to vent the pressure and flame to particular areas. Therefore, these vents interrupt, quench and retain all burning material, preventing them from expelling into the atmosphere

Mechanical isolation is a cleaner means of explosion protection. Explosion pressure is determined by use of isolation valves. When an explosion actually occurs, the pressure travels into a single or double acting valve which seals the pressure wave inside the valve and prevents it from spreading through the equipment. The passive isolation does not require detectors, or control and indicating equipment. There may be arrester mesh, rotating valves, lock valves, rotating screws, flap valves. Active isolation is activated by detectors and electrical control and indicating equipment.

Advanced isolation valves are manufactured with pharmaceutical grade material having which makes it easy to clean any surfaces that come into contact with the product being processed. All valves have an explosion rating that is higher than that of the dust being processed. Hence importance of dust testing in the first instance to determine what that maximum P_{max} would be. Explosion isolation protection products are passive isolation type – flanme arrester, barrier valve, flame diverter, rotary airlock, product plug, choked screw; active isolation type –require detection and control and indicating equipment to function. Detection systems are usually based on optical or pressure sensors – chemical powder isolation.

Due to the type of products used in pharmaceutical industries, explosion protection by containment is common. Vessels are designed to be either explosion-pressure-resistant or explosion-pressure shock resistant. In selecting a safety measure each method is analysed for its best application for a particular requirement to ensure reliability of the safety system and identify the hazard to personnel's inherent in each method. The safety measures are designed in accordance with standards (NFPA,2013,2014,2016, 2017c;VDI, 2002)

It may be desirable to do modification in design of existing facilities for safe processing of powders. In areas having probability of dust explosion outside the process units, it may be recommended to provide explosion venting or blast resistant walls as per building codes. In areas where combustible powders are to be handled, an electrical area classification should be used as per standard (NFPA, 2017a, 2017b)

V. CONCLUSIONS

Explosion hazards associated with powders influences the specifications of operating procedures, process equipment, air conditioning systems, electrical area classification and room construction, etc. It is therefore necessary for OSD manufacturers to understand the explosion hazard of the powders handled in these facilities and assess the level of deflagration risk that their operations may present. The catastrophic dust explosions may be avoided by recognizing the hazard, designing facilities and work practices to prevent the spread of dust, instituting effective housekeeping programs to remove dust accumulations and controlling possible ignition sources.

One of the root cause cited in major incidents involving dust explosions has been the lack of awareness of potential hazards posed by combustible dusts by both management and operations personnel. Dust explosion data specific to pharmaceutical products are not readily available and these types of explosions are generally rare at any given facility. Having a compilation of data containing actual APIs and excipients that are handled in these facilities is a powerful tool in explaining the real risk from these rarer but dangerous types of explosions to those managing and operating these facilities. The data presented in this paper is an effort in this direction. The design, selection and implementation of explosion safety measures during design of equipment in pharmaceutical industries are a specialized job. The information and data presented may be used for the units/areas handling similar types of dusts. A set of parameters covering a wide range of dusts is selected for the design. By choosing the most conservative measures equipment may be used for a larger group of dusts.

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