A STUDY ON DUST EXPLOSION OF ACTIVE PHARMACEUTICAL INGREDIENTS

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ABSTRACT

Active Pharmaceutical Ingredients which is simply known as API's are the major components which are found in tablets, capsules and oral syrups. These API's are found in the form of dusts which are microns in size. Since they are present in the form of dust, there is a chance of dust explosion to occur. Dust explosion is one of the biggest threats to the pharmaceutical Industry. To find whether the present dust is prone to dust explosion the tests are taken to find the minimum ignition temperature and minimum ignition energy. With the help of thetse values it gets cross checked with the occupational exposure limit and its control banding several layers of control measures has been suggested to decrease the sxplosion. These control measures are suggested based on the hierarchy of controls.

Keywords—
Active Pharmaceutical Ingredients (API's), Dust Explosion, Minimum Ignition Energy, Minimum Ignition Temperature, Occupational Exposure Limit, Minimum Exposure Banding, Hierarchy of Control.

1. INTRODUCTION

There are various chemicals included in the drugs and the portion that actually works in the treating condition i.e. the active part is known as active pharmaceutical ingredient or API in short. Sometimes a drug may also contain several API and the reaction and response to any particular drug will depend on the dosage prescribed, which varies on person to person. The function of the API is not limited to treatment or cure of the disease or symptoms alone though, they are also used for diagnosis or prevention at times.

A dust explosion is one kind of chemical explosion. A dust explosion is the rapid combustion of fine particles suspended in the air, often but not always in an enclosed location. Dust explosions can occur where any dispersed powdered combustible material is present in high enough concentrations in the atmosphere or other oxidizing gaseous medium such as oxygen.

There are five necessary conditions for a dust explosion. These are also called as Dust Explosion Pentagon. They are,

- A combustible dust.
- The dust is suspended in the air at a sufficiently high concentration.
- There is an oxidant (typically atmospheric oxygen).
- There is an ignition source.
- The area is confined - a building can be considered an enclosure.

Minimum Ignition Energy is defined as the minimum amount of energy released at a point in a combustible mixture that caused flame propagation away from the point, under specified test conditions. The lowest value of the minimum ignition energy is found at a certain optimum mixture.

Minimum Ignition Temperature is defined as the minimum ignition temperature (MIT) is the lowest temperature of a hot surface that will cause a dust cloud, rather than a dust layer, to ignite and propagate flame.

An occupational exposure limit is an upper limit on the acceptable concentration of a hazardous substance in workplace air for a particular material or class of materials. It is typically set by competent national authorities and enforced by legislation to protect occupational safety and health. It is an important tool in risk assessment and in the management of activities involving handling of dangerous substances. There are many dangerous substances for which there are no formal occupational exposure limits. In these cases, occupational exposure banding or hazard banding or control banding strategies can be used to ensure safe handling.

Occupational exposure banding, also known as hazard banding, is a process intended to quickly and accurately assigns chemicals into specific categories (bands), each corresponding to a range of exposure concentrations designed to protect worker health.

Occupational Exposure Band	A	B	C	D	E
Airborne Target Range for Particulate Concentration (mg/m^3)	>10 mg/m^3	>1 to 10 mg/m^3	>0.1 to 1 mg/m^3	>0.01 to 0.1 mg/m^3	≤0.01 mg/m^3
Airborne Target Range for Gas or Vapor Concentration (ppm)	>100 ppm	>10 to 100 ppm	>1 to 10 ppm	>0.1 to 1 ppm	≤0.1 ppm

Hierarchy of hazard control is a system used in industry to minimize or eliminate exposure to hazards. It is a widely accepted system promoted by numerous safety organizations. This concept is taught to managers in industry, to be promoted as standard practice in the workplace.

2. PROCESS IN PHARMACEUTICAL INDUSTRY

The process undergone in the manufacturing unit is the production of tablets, capsules and oral Syrup. The production of all these will have similar process with the raw materials of Active Pharmaceutical Ingredients. They are Milling, Blending, Sieving, Tablet Compression / Powder Filling and Coating.

3. TESTING OF API'S

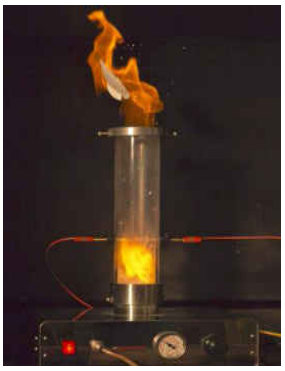
3.1 MINIMUM IGNITION ENERGY

The test is conducted to determine the minimum energy of an electrical spark that will result in ignition of a dust cloud under specified test conditions.

The dust is dispersed in the explosion vessel and sparks with a known energy are passed through the dust cloud. By varying the dust concentration and the level of turbulence as well as the spark energy, the lowest energy capable of igniting the dust cloud is determined. When using triggering by voltage increase, the moment of the spark will vary from test to test and so the dust cloud conditions are varied in a wide range, provided a sufficient number of tests are carried out. The Minimum Ignition Energy ("MIE") is quoted as the stored energy in the capacitor (gross energy), and the range between the highest "no-ignition" and the lowest "ignition" is reported.

A number of standards exist for the determination of MIE. Many of these methods use the option of either purely capacitive discharges (more representative for electrostatic hazard assessment studies) or, with the introduction of a 1 mH inductor in the ground loop, the duration of the discharge can be elongated

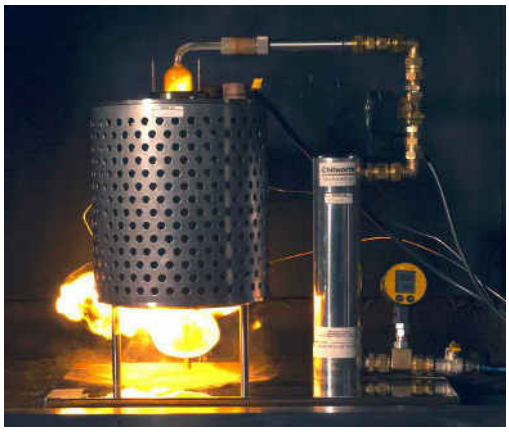
(replicating mechanical sparks/thermite reactions) depending on the application of the data.



3.2 MINIMUM IGNITION TEMPERATURE

The test is conducted to determine the minimum temperature of a hot surface that will result in ignition of a dust cloud under specified test conditions.

The dust is dispersed downwards through a heated vertical furnace by a pulse of regulated compressed air. An ignition is defined as a flame propagating from the bottom of the vertical furnace (flame observation within or from the top of the furnace does not meet the criteria for ignition). The mass of dispersed dust and the air pressure are methodically varied using a prescribed procedure to achieve a 'worst case' air/fuel mix. The temperature monitored by thermocouples is then decreased in steps of 20 K above, and in steps of 10 K below, 300°C. The Minimum Ignition Temperature ("MIT") is reported as the lowest temperature in which 10 consecutive no ignitions are observed one temperature step below the lowest observed ignition. The dispersion pressure and concentration are then varied a further temperature step below the confirmed 10 no ignitions.



Limited testing ("Dust Screen") can also be performed by way of screening at pre-determined temperature values to address specific process situations and needs. The equipment and ignition criteria remain identical to that of the full method described above.

4. TEST RESULTS

The minimum ignition energy and minimum ignition temperature tests were carried out for the three APIs (Active Pharmaceutical Ingredients) and its test results are mentioned below,

S.No	Product	OEL (µg/m	OEB	MIE	MIT

		3)		(mJ)	(° C)
1	A	400	2	30 – 100	560
2	B	1000 to 3000	1	30 – 100	480
3	C	100 to <1000	2	100 – 1000	580

5. CONTROL MEASURES

Based upon the hierarchy of controls, the suggestions are classified under engineering controls, administrative controls and personnel protective equipments.

5.1 ENGINEERING CONTROLS

1. Ensuring the equipment is appropriately rated for respective Class/zones during design phase.
2. Grounding of all equipment(fixed, mobile and portable).
3. Tolerances between high speed moving parts should be designed properly.
4. Lightening arrestor provision for buildings.
5. Mobile dust collectors[e.g. vacum cleaners] and electrical fittings in the area to match 21 standard (ATEX Standard).
6. Explosion flops in the equipment to act as pressure relief device.
7. Inertion of compact equipment.
8. Cooling coils for the heat generating equipment.
9. Magnets in the materials in-feeder to trap tramp metals getting into the rotating/moving parts.
10. Antistatic wheels for mobile equipment.

5.2 ADMINISTRATIVE CONTROLS

1. Good Preventive Maintenance Programs to ensure condition of moving/rotating parts (bearings), electrical fittings, clearances between moving parts etc.
2. Good housekeeping practices to clean up the spill of powder at the earliest regular cleaning during and after processing.

3. Dust collection bins are emptied at the end of each batch or more frequently if the dust collection is higher.
4. Bonding and earthing is checked at least annually and when equipment is maintained.
5. Usage of non-sparking tools to be ensured.
6. Antistatic flooring should be available.
7. Grounding of personnel before entering the area.

5.3 PERSONAL PROTECTIVE EQUIPMENTS

1. Antistatic shoes.
2. Antistatic clothing.
3. Antistatic gloves.

6. CONCLUSION

As the tested API's possesses minimum ignition energy in the form of micro joules, there is a chance for the dust explosion to happen. To prevent the dust explosion and to safeguard the life of the employees and equipments the above mentioned control measures has to be implemented and regular inspection has to be carried out. All employees must be trained for the emergency situation.

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