

SAFETY METHODS IN PHARMACEUTICAL INDUSTRY

WHAT IS INDUSTRIAL SAFETY?

Industrial safety refers to reduce the risk of injury or loss and danger to persons, property from the industrial hazards.

These are the policies and protections put in place to ensure plant and factory worker protection from hazards that could cause injury. Safety policies put in place by the Occupational Safety & Health Administration are examples of industrial safety policies.

WHAT DOES INDUSTRIAL HAZARD MEANT?

Hazard is a term associated with a substance, that is likely to cause injury to personnel or A substance that might prove fatal to the personnel.

- ❖ Toxic corrosive chemicals, fire explosions and personnel falling into accident are major health and safety hazards encountered in the operations of chemical and pharmaceutical industries.
- ❖ Identification of hazards and employing protective measures to control the hazards are important to protect the people from their consequences.

OBJECTIVES OF INDUSTRIAL SAFETY

- Understand the harmful effects of industrial hazards
- Define the relationship between hazard and risk
- Explore the routes of exposure to industrial hazards
- Shed lights on type of toxicity by industrial hazards
- Know the most toxic environmental hazardous substances

TYPES OF HAZARDS

- Chemical hazards
- Mechanical hazards
- Fire hazards
- Inflammable Gasses
- Dust hazards



FIRE HAZARDS

Fire is an exothermic chemical reaction between oxygen and fuel at certain temperature. Some chemicals have the potential to cause fires and explosions and other serious accidents.

SOURCES OF FIRE HAZARDS

Fuels include solids, liquids, vapors and gases.

SOLID FUELS:

solid fuels wood, fabrics, synthetic materials, packing materials, papers etc.

LIQUID FUELS:

Liquid fuels flammable liquids (e.g., nitro phenol, ammonium nitrate and potassium chlorate, paint and oil soaked rags, cotton or cellulose soaked with sulphuric acid etc.

Other sources include flame, sparks, spontaneous ignition and self-combustible chemicals.

CASUSES:

- ❖ Smoking in the factory
- ❖ Defective heating equipment,
- ❖ electrical equipment & wiring.
- ❖ Explosive gas leakage.
- ❖ Inadequate protection of electric motors
- ❖ Sparking of electric wires
- ❖ Inadequate equipment Protection & prevention



PREVENTION OF FIRE HAZARDS:

- ❖ Well planned design and layout
- ❖ Proper ventilated systems
- ❖ Chemical data sheets
- ❖ Proper training of personnel
- ❖ Proper maintenance of surroundings
- ❖ Use of fire extinguishers, alarms, sensors, detectors
- ❖ Firefighting equipment
- ❖ Sprinkler systems

FIRE SUPPRESSION:

It is done by using

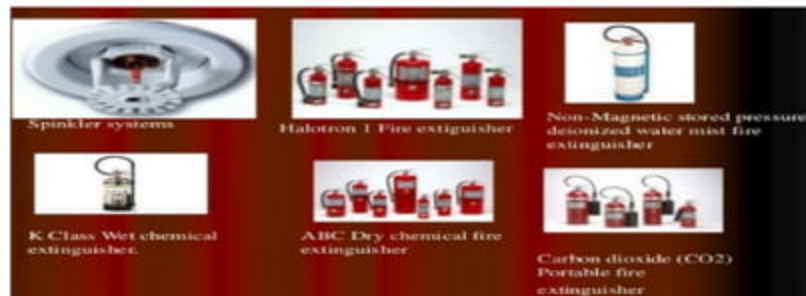
1. hydrant systems/water sprinkler systems
2. fire extinguishers.

Hydrant systems include:

- ❖ Water sprinklers
- ❖ Semi-automatic hydrant system
- ❖ Automatic sprinkler
- ❖ Manually hydrant system

Fire extinguishers include:

- ❖ Water and water based extinguishers
 - o Portable extinguishers
 - o Soda acid extinguishers
 - o Antifreeze extinguishers
- ❖ Foam extinguishers.
- ❖ Dry chemical extinguishers.
- ❖ Carbon dioxide extinguishers
- ❖ Halon extinguishers
 - o Halon1301 (bromo tri fluoromethane)
 - o Vaporizing liquid.



Exit Points:

The exit points of adequate capacity should be provided so as to enable the employees to reach a place of safety outside the building, in case of fire

**Fire Alarm Equipment:**

Fire alarm systems are placed in conspicuous locations in all parts of the plant for promptly notifying the fire brigade and for exit of employees.



CHEMICAL HAZARDS:

- ❖ Many chemicals can cause severe burns, if these coming to contact with living tissue or other routes like inhalation.
- ❖ Living tissue may be destroyed by chemical reactions such as dehydration, digestion, oxidation etc.
- ❖ Eye and mucus membrane of the throat are particularly susceptible to the effect of corrosive dust, mist and gases.
- ❖ Chloroform, benzene, chlorinated hydro carbons, low boiling fractions of petroleum are some of the common organic solvents used in pharmaceutical industry.

SOURCES OF CHEMICAL HAZARDS:

AIR BORN TOXICS:

- **Irritants:**
 - Ipecac
 - podophyllumetc
- **Asphyxiants:**
 - Carbon dioxide
 - Monoxide
 - Methane
 - Ethane
 - Hydrogen cyanide
 - Hydrogen sulphide
 - Helium
 - Nitrogen etc.
- **Narcotics/anesthetics**
 - Acetone
 - Ether
 - Chloroform
 - methyl-ethyl ketone etc.



CARCINOGENS:

- Coal tar
- creosote oil
- anthracene oil
- paraffin oils
- chromium
- nickel
- cobalt

The degree of danger varies according to the form of the chemical and the factors like,

- ✓ Its physical properties
- ✓ Its toxicity
- ✓ The way it is used
- ✓ The environment in which it is encountered.

PREVENTIONS:

- ❖ Train employees to follow safe handling and application procedures for maintenance or pesticides chemicals.
- ❖ Do not use excessive grease or lubricants on equipment.
- ❖ Regularly re-evaluate all procedures to ensure they effectively remove chemicals.
- ❖ Store chemicals in designated areas away from food, ingredients and packaging.
- ❖ Ensure chemical container are clearly labeled or color coded, and that they are used only for chemicals.
- ❖ Receive raw ingredients from reputable suppliers that effectively control chemical hazards.
- ❖ Ensure restricted ingredients and additives are correctly measured. e.g Hexachlorophene. Because of its toxic effect it penetrates human skin. So it used only

when an alternative preservative has not been shown to be as effective.



Safety measures:

- Respirator must be used in all the gas storage places. (specifically chemical gas)
- Body should be fully covered whenever people are interacting with hazardous chemicals.
- When skin burn happens due to chemicals use alkaline solution always instead of water.

MANAGEMENT OF OVER-EXPOSURE TO CHEMICALS:

Removal from Exposure:

- ✓ Prompt removal of the person from the exposure site is the first step.
- ✓ Air respirators and lifelines are mandatory first aid.

Resuscitation:

- ✓ Resuscitation means restoration of life of one who is apparently dead (collapsed or shocked).
- ✓ Further supportive care should be provided as with any other medical emergency.

Decontamination:

- ✓ A victim whose skin or clothing has been contaminated requires immediate removal of garments and shoes. Then vigorous showering with soap and water, including attention to the fingernails and scalp is advised.

Symptomatic Treatment:

- ✓ Acute over-exposure may result in a variety of signs and symptoms that require general supportive medical management regardless of the specific agent. Examples include the control of convulsive seizures, treatment of bronchospasm etc.

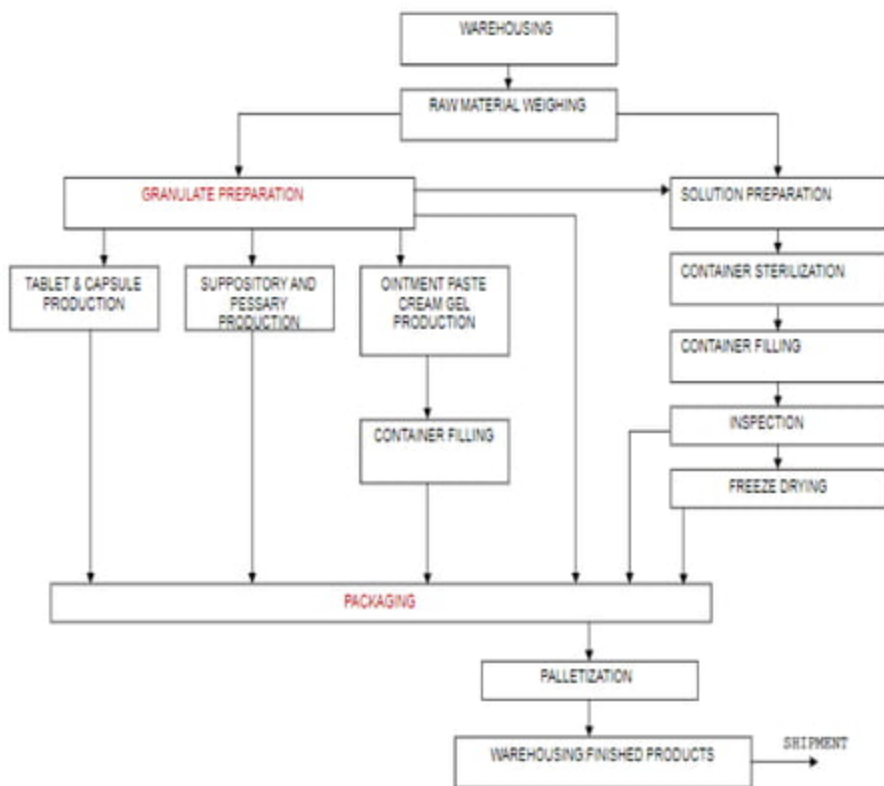


MECHANICAL HAZARDS

INTRODUCTION:

- Mechanical hazards may occur due to the large numbers and different designs of equipment, crowded workplace conditions and frequent interaction between workers and equipment.
- Hazardous electrical, pneumatic and thermal energy must be released or controlled before working on active equipment and utilities.
- Workers are protected from sources of hazardous energy by
 - ✓ Implementing lock out / tag out procedures.
 - ✓ Interlocked guards, control switches, emergency stop devices and operator training are important means of reducing mechanical hazards.

HAZARDS WITH MECHANICAL EQUIPMENT:



Most of mechanical hazards are due to:

- Faulty inspection
- Inability of employee
- Poor discipline
- Lack of concentration
- Unsafe practice
- Mental & physical unfit for job
- Faulty equipment or improper working condition
- Improper training regarding the safety aspects

MECHANICAL EQUIPMENTS USED IN PHARMACEUTICAL INDUSTRIES AND THE RELATED HAZARDS:

WAREHOUSE EQUIPMENTS:

- The raw materials and excipient store is generally located close to the production areas. Products are stored on multi-level racks and shelves. Manually operated trolleys and electrical pallet handlers are used to move boxes/containers.

EXPECTED INJURIES

- Muscular-skeletal complaints
- Cutting injuries



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Electronic and/or mechanical weighing scales:

The pharmaceutical industry uses the classic single/twin platter mechanical scales. The more modern electronic scales are characterized by a metal box enclosing the apparatus and by a weighing system generally including a platter. Electronic scales are fitted with local powder/dust exhaust devices or laminar flow exhaust hoods.

RISK FACTORS:

- Exposure to dust

EXPECTED INJURIES:

- Allergic asthma
- Contact dermatitis



Work performed in the presence of moving machinery parts:

DESCRIPTION:

Manual cleaning of certain machine may entail the operator being snagged, dragged or crushed by the machine's parts in motion. By way of an example, an operator may clean a mixer/blender by pouring the cleaning fluid in the vat and starting the machine in order to better clean the internal surfaces.

Other operators may accidentally start the machine while staff is cleaning the machine's internal parts.

EXPECTED INJURIES:

Lesions and bruises.

PREVENTIVE MEASURES:

Hazardous zones must be shielded by fixed guards or fitted with interlocking safety devices to reduce the risk of operators being snagged and dragged. Machinery must be fitted with emergency shut down and accidental start-up lockout devices such as safety devices blocking machine start up when power is restored after a temporary blackout.



PROCESSING OF SEMI-SOLID PHARMACEUTICAL FORMS

DESCRIPTION

Careful cleaning of plant systems especially where processing of semi- solid pharmaceutical forms particularly rich in lubricating agents such as suppositories, ovules and ointments takes place, require manual operations involving fatiguing tasks and anomalous work postures.

EXPECTED INJURIES:

Muscular-skeletal complaints.

PREVENTIVE MEASURES:

Consider the feasibility of employing built-in, closed-cycle automatic washing and/or sterilization systems (cleaning in place). - Accurate task organization and operator information and training.

MECHANICAL EQUIPMENTS USED IN GRANULATE PREPARATION

EQUIPMENT USED:

- Miller/grinders
- Compactor
- Twin Whisk Blender
- Planetary or crown wheel Blender
- Rotating Tub Blender
- Fluid Bed Granulator-Dryer
- Dynamic Tunnel Dryer System
- Dynamic Revolving Drum Dryer System
- Vacuum Dryers

RISK FACTORS:

Exposure to dust

DESCRIPTION

Operators may be exposed to dust during miller/grinder loading/unloading, compacting, blending and granulation operations. ESTIMATE Field assays have yielded ambient air dust concentration levels ranging from 342 to 3.462 $\mu\text{g}/\text{m}^3$ in the blender shop, from 307 to 1.884 $\mu\text{g}/\text{m}^3$ in the granulator shop.

EXPECTED INJURIES

Allergic asthma, contact dermatitis.

Specific pharmacological effects due to active principles.

FLAMMABLE GASES HAZARDS

Various volatile and flammable liquids used in the chemical industry, vaporize when exposed to room temperature or above, causing atmospheric pollution. The steam turns on causing fire accidents and explosions which tend to spread rapidly in the surrounding environment, causing loss of lives and property.

Therefore, the storage and handling of these hazardous gases require special attention to avoid any life threatening risks.

Combustible Gases

- Explosion hazard
- Must maintain below lower explosive limit

Toxic Gases

- Hazardous to human health
- Employee exposure must be limited

Oxygen Displacing Gases

- Indirect human health hazard
- Deficiency of breathing oxygen

HYDROGEN SULFIDE

H₂S in Air

Toxic Symptoms

1 ppm	Odor detected, irritation of respiratory tract
10 ppm	Allowable for 8 hours' exposure
20 ppm	Protective equipment is necessary
100 ppm	Smell killed in 5 to 15 minutes. May burn eyes and throat; coughing
500 ppm	Respiratory disturbances in 2 to 15 minutes. Coughing, collapse & unconsciousness
1,000 ppm	immediate unconsciousness, Brain damage may result unless rescued promptly. Death in 3 to 5 minutes.

OXYGEN DEFICIENCY

Oxygen Symptoms Developed:

20.9%	Normal oxygen concentration in air
15 - 19%	Decreased ability to work strenuously
12 - 14%	Respiration increases in exertion, pulse up, impaired coordination, perception & judgment
8 - 10%	Mental failure, fainting, unconsciousness, blueness of lips, nausea & vomiting
6 - 8%	8 min, 100% fatal; 6min, 50% fatal; 4 - 5min, recovery with treatment
4 - 6%	Coma in 40 seconds, convulsions, respiration ceases, death.

HAZARDOUS GASES MANAGEMENT:

Compressed gases are filled in cylinders and transported to the place of use. The important precautions to be followed are given below:

1. Cylinders should not be dropped or permitted to strike against each other.
2. Special and standard tools should be used on valves. Normally these are provided by manufacturers.
4. Cylinders should be protected against extremities of weather, particularly against excessive rise in the temperature.
5. Cylinders (received) should bear a conspicuous standard label indicating the kind of gas. The color of the label shows whether gas is inflammable, corrosive or inert.

6. Full cylinders should be separated from empty cylinders.



GAS SENSOR PLACEMENT:

- ✓ Place sensors close to possible gas source.
- ✓ Place sensors in areas where gas might accumulate.
- ✓ Place toxic gas and oxygen deficiency sensors in the "breathing zone".
- ✓ Consider accessibility and maintenance issues.



DUST HAZARDS:

What is pharmaceutical dust?

Pharmaceutical dust is generated during the production and packaging processes in pharmaceutical manufacturing plants. This hazardous dust can occur when grinding, drying, mixing, pressing, and coating in the production of a pill as well as during the cleaning of the equipment.

How can pharmaceutical dust be harmful?

Some substances, such as steroids, hormones, or narcotics, may pose a risk if they escape into the atmosphere. If the operator is exposed by breathing or touching them, it may cause side effects such as respiratory illness, skin reactions, and other physiological effects.

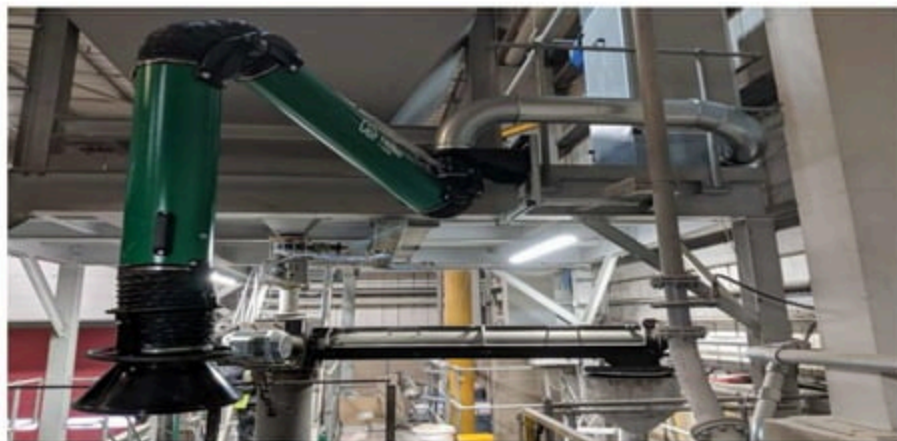
Many substances, including cellulose, corn-starch, dextrin, lactose, and other organic ingredients, have the potential to explode. In addition, cross-contamination of dust with other materials can impact on product quality and safety.

Source of dust hazards:

- Grinding or milling of drugs, excipients, or herbal products.
- During weighing dusts may float on air.
- During powder mixing dusts may be generated.
- During coating operation dusts are generated.
- During capsule filling and tablet punching operation dusts may be generated.

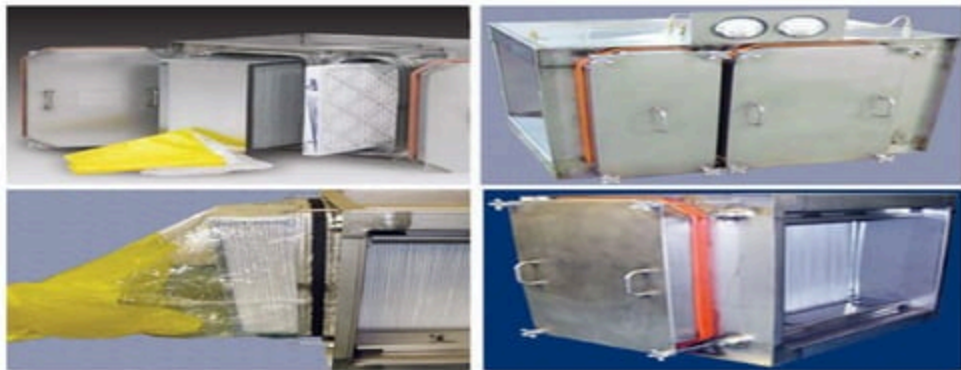
PROTECTIVE MEASUREMENTS:

Source capture: Begin by capturing and controlling the contaminant at the source. Look at where the equipment is positioned and ensure there are no leakage points around handling systems that produce dust. Source capture is the most effective means of capture and requires the least amount of energy and initial investment to accomplish. Utilize fume extraction arms or local fixed hoods incorporated as part of the machine (e.g., conveyor or mixer).



Filtration and extraction:

Installation of an industrial filtration system will ensure that compliance with regulatory standards of both related hazards and cross-contamination issues. Filtration solutions for pharmaceutical processes may also require special options or accessories to improve the safety and reliability of the system. Bag-in/bag-out filter and collection drum options can be used to eliminate exposure and cross-contamination when performing filter and dust-removal maintenance.



Bag-in/bag-out filter

HVAC SYSTEM IN PHARMA INDUSTRY:

HVAC should be used in pharmaceutical industry for dust management



SAFETY ASPECTS IN THE PHARMA INDUSTRY:

- ✓ Standard operating procedures
- ✓ Handling of hazardous materials
- ✓ Water supply and drainage
- ✓ Floors and floor coverings
- ✓ Emergency exits
- ✓ Backup plan if anything goes wrong
- ✓ Specially trained personnel

- ✓ Health polices and insurance
- ✓ Written procedures
- ✓ Safety audits
- ✓ Risk analysis
- ✓ Appropriate training and education to employee
- ✓ Regular monitoring of workplace
- ✓ Written documentation of policies
- ✓ Create awareness of the environment
- ✓ Involvement of the personnel Contingency plan

DISASTER MANAGEMENT PLAN:

- Disaster management plan is essential as it:
 - ✓ Reduces the amount of thinking time required after the incident occurred.
 - ✓ Contains the incident and minimizes the extent of the damage to the resources and business.
 - ✓ Reduces the conduct of disaster to a set of predetermined rules and a system of orderly procedure to make orderly and rational
- The success in disaster management depends on
 - ✓ Reliable early detection
 - ✓ Careful planning
 - ✓ . Efficient personnel
 - ✓ Proper training of all personnel concerned
 - ✓ Problem free communication

CONCLUSION:

- ✓ From the previous discussion it is clear that the safety aspects must be considered by the pharmaceutical industry not only in the interest of the employees or property but also in terms of the neighboring environment as well.
- ✓ The source of possible hazards, risk analysis, control procedures, preventive measures & contingency plan are the main five essentials for ensuring a complete work atmosphere in the industry.

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