



## Recent Trends in Hazards in the Pharmaceutical Industry and Safety Precaution

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### ABSTRACT

Hazards is a situation that poses a level of threat to life, health, property or environment. Any real or potential conditions produced by industries that can cause injury or death to personnel or loss of product or property. Industrial hazards is a major issue in present scenario. Some industrial plants, by the nature of their activities and the substances they use, constitute hazards which are all the greater when they are located close to residential areas for these and their residents are particularly exposed in the events for accidents. Industrial hazards may be defined as the contamination of the Pharmaceutical industries that may cause irritation, toxicity and damage of the product, which are also harmful for product quality in the Pharmaceutical Manufacturing.

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### Introduction

Little is known about the health risks of working in the pharmaceutical industry. On the surface, the industry looks clean. The production of medicinals demands a carefully maintained and sterile working environment and the white lab coats worn by workers add to the illusion of safety. The appearances are deceptive, though. Producing drugs and other medicinals may involve exposure to toxic industrial chemicals. And while the finished products may be lifesaving medications for sick people, they can be dangerous to healthy workers who are inhaling or absorbing them during the production process. Hazard is a term associated with a substance that is likelihood to cause an injury in a given environment or situation. Industrial hazard may be defined as any condition produced by industries that may cause injury or death to personnel or loss of product or property. Safety in simple terms means freedom from the occurrence of risk or injury or loss. Industrial safety refers to the protection of workers from the danger of industrial accidents.

#### Types of industrial hazards

Industrial hazards: Physical Chemical Biological Psychological Mechanical

#### Physical hazards:

physical hazards noise vibration fire temperature Electricity pressure fibres lighting humidity cold stress (hypothermia) heat stress (hyperthermia) dehydration (due to sweating) oxygen deficiency pressure non-ionizing radiation (Ultraviolet, Visible, Infrared radiation)

#### Chemical hazards:

Chemical hazards flammable/explosive materials, liquid or gases, vapours, solids, mists, smoke, fog or smogs, sensitising agents

#### Biological hazards:

Biological hazards dust viruses bacteria fungi protozoa helminthes blood borne pathogens mould recombinant DNA molecules human tissues cell culture

#### Psychosocial hazards:

Psychosocial hazards workplace practices & systems, payment systems, type of work, risks involved in work, monotony, long working hours, lack of recognition, job

satisfaction poor remuneration, poor man management, lack of welfare activities tensions at home Strikes unexplained reduction in production.

#### Mechanical hazards:

Mechanical hazards By type of agent: Impact force Collisions Falls from height Struck by objects Confined space Slips and trips Falling on a pointed object Compressed air/high pressure fluids (such as cutting fluid) Entanglement Equipment-related injury By type of damage: Crushing and Cutting Friction and abrasion Shearing Stabbing and puncture Poor maintenance/housekeeping

#### Health Hazards

General health hazards in the manufacture of pharmaceuticals include: dust and noise exposures, repetitive motion disorders, exposure to formaldehyde, and exposure to ultraviolet radiation.

Dust becomes airborne during manufacture and is a problem for operators; in addition, filling and packaging of the finished product may pose an allergic hazard from dust.

Ensuring sterility of the product often involves exposure to formaldehyde and ultraviolet radiation. Formaldehyde may cause lung cancer, Hodgkins disease, and prostate cancer. Acute exposures can cause pulmonary edema (lungs fill with fluid, making breathing impossible) and pneumonia leading to death. Formaldehyde also causes allergic dermatitis.

Ultraviolet lamps used to maintain sterility pose a problem too. Although non-ionizing (meaning the radiation does not have an electrical charge and therefore causes less damage to cells), ultra-violet radiation is dangerous and can cause skin cancer. The first sign of overexposure is dry, inelastic, and wrinkled skin. Various localized skin sores may develop and should be interpreted as a warning signal. Light-skinned people are most susceptible since their skin lacks pigments that would protect them from overexposure.

The constant repetitive motion associated with packaging and filling could lead to carpal tunnel syndrome or tendinitis. Tendinitis is most commonly caused by repetitive and twisting hand motions. Tendinitis symptoms usually are pain and tenderness in the affected area - hand, wrist, or forearm.

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Swelling can also be a symptom. The ability to use the hand is often greatly reduced, with exertion only causing greater pain. Tendinitis can be effectively treated with rest, perhaps in combination with heat and use of a splint. But the cause must be eliminated or tendinitis will develop again.

Carpal tunnel syndrome is usually caused by repeated bending and twisting of the wrist, especially when force is applied. Carpal tunnel symptoms include pain in the hand, numbness, tingling, and burning sensations, a dry shiny palm, and clumsiness of the hands. The symptoms often are most acute at night and usually are confined to one side of the hand. Carpal tunnel syndrome can best be treated by eliminating the twisting and bending that caused it in the first place, by switching jobs or changing the way a job is done. Medical treatments include wearing a wrist splint at night and physical therapy.

In some cases, anti-inflammatory drugs are prescribed, and surgery may be required in very severe cases. It is very important to remember that treatments for tendinitis and carpal tunnel syndrome will not work unless the cause of the problem, the job or tool design, is changed to eliminate the twisting and bending of the hand and wrist.

#### **Some Specific Health Hazards**

Hazards specific to the pharmaceutical industry result from exposure to the active drug which usually takes place during the last phase of production.

**Hormones** Health impairment due to pharmaceuticals has been described and observed mainly in hormone and antibiotics production workers. The effects of occupational exposure to hormones may be severe. For male workers, exposure to estrogens may give rise to breast development; for female workers, there may be menstrual disorders, abnormal overgrowth of the endometrium and excessive bleeding during menopause.

Exposure of male workers to progestogen may bring about a lack of sexual drive and testicular pain. On the other hand, exposure of female workers to androgens is known to cause menstrual and ovarian function disorders, diminished fertility, increased frequency of spontaneous abortions, and symptoms of masculinity.

#### **Antibiotics**

Antibiotics are chemical substances capable of destroying micro-organisms such as bacteria and viruses that cause infection in animals and humans. The principal ones are: erythromycin, the penicillins, the tetracyclines, streptomycin, and clindamycin.

The effects of occupational exposure to antibiotics can include:

**Allergic reactions:** itching and redness of the eyes, runny nose, skin rashes, asthma, and occasionally shock due to an allergic reaction (anaphylaxis).

**Vitamin deficiency:** Workers with repeated exposure to antibiotics experience a change in the number and type of bacteria which are normally present in the intestines which break down and absorb vitamins in the intestines.

**Fungal infections:** Daily exposure to antibiotic dust can lead to fungal infections of the skin and nails. Additionally, women workers may develop vaginal yeast infections following exposure to antibiotics.

**Toxic effects:** Exposure to certain antibiotics may lead to development of some of the toxic side effects that occur when that drug is given as medicine.

**Other Effects:** Older female workers have been incorrectly told that flushing may be due to hormonal changes rather than the antibiotic drugs they are inadvertently taking in. Headaches

and stuffy nose are other common complaints. Allergic heart disorders, bronchial asthma, poisoning, and allergic disorders of the liver have also been reported. Some experts are concerned that prolonged contact with antibiotics may cause cancer, although there have been no studies confirming this suspicion. Described below are common adverse reactions to some specific antibiotics.

**Penicillin.** Because of the highly allergenic nature of the penicillins and their extensive use, many people have become allergic to them. The most serious reaction is shock. This type of acute reaction usually occurs minutes after exposure. Symptoms are tightness in the chest, asthmatic breathing, dizziness, swelling of the lips, tongue, or face, edema of the lungs, heart failure and in some cases, death. Other reactions are hives, "black hairy tongue," fungus infection, and rectal itch.

**Tetracycline.** Modification of the bacteria of the intestines and other organs has been reported following occupational exposure to tetracycline (as well as to streptomycin and penicillin). In workers exposed to tetracycline and to streptomycin, modification of the bacteria led to a drop in the body's vitamin content, especially of the B vitamins. Another problem associated with occupational exposure to tetracycline is drug resistance. Workers may develop infections that are resistant to treatment with tetracycline.

#### **Drugs for Heart Disease**

Nitroglycerin, commonly used in dynamite, is also the basis of several medicines for heart patients -- isosorbide dinitrate, pentaerythritol tetranitrate, and mannitol hexanitrate. Nitrates act on the blood vessels of the body and their effects are felt in several ways. Almost everyone exposed to nitro dust experiences a severe pounding headache which is caused by the relaxation of the blood vessels within the skull. Headaches may be accompanied by a rapid heart beat and a flushed face.

Nitrates dilate the blood vessels and make blood pressure fall. As a result, dizziness and even fainting may occur. Other more serious effects are heart pain, heart attacks, and sudden death following "withdrawal" from exposure.

#### **Tranquilizers**

Both chlordiazepoxide and meprobamate are prescribed as sedatives. Both are habituating and addictive. In combination with alcohol, they may cause a person to lose consciousness and in high doses, can lead to coma and death. Workers producing tranquilizers are at risk of these adverse effects and have found that they pass out over a beer after work. There is a real danger of accidents, both in the plant and on the way home, when workers become drowsy as a result of exposure to tranquilizers and barbiturates.

#### **Antidepressants**

Tricyclic antidepressants like amitriptyline, nortriptyline, and imipramine can cause irregular heartbeat (cardiac arrhythmias), posing a particular problem for production workers with heart conditions.

#### **Standards for Exposure Prevention**

There are no OSHA standards regulating exposure to pharmaceuticals. The lack of knowledge about workplace effects of pharmaceuticals explains why there are no Threshold Limit Values (TLVs) for pharmacologically active substances (except for acetylsalicylic acid -- a value of 5 mg/m<sup>3</sup>, 1979). Now and then threshold limits are recommended for pharmaceuticals by research workers, mostly in the former USSR. The almost complete absence of official data shows that it is necessary to reduce exposures to the lowest possible levels.

## Studies

Some researchers have concluded that it is difficult to evaluate causes of morbidity in pharmaceutical workers because manufacturing processes and additives differ between factories and exposures are to multiple chemicals.

**Mortality.** A 1988 study of 826 pharmaceutical workers found increased death risk from cancer and suicide. Men had elevated rates of cancers of the colon, central nervous system, and kidney; women had elevated rates of breast cancer.

**Morbidity.** Many workers develop allergic reactions to medicinals that involve bronchial sensitivity, asthma, and difficulty in breathing. It is difficult to evaluate morbidity in pharmaceutical workers because of the wide diversity of chemicals used in the manufacturing process.

**Asbestosis.** The respiratory disease found most often among OCAW members working at pharmaceutical plants is asbestosis, a disease which often leads to increased mortality. The threat of asbestos-induced disease is potentially present at all pharmaceutical plants built before the '70s. Maintenance workers are especially at risk.

**Reproductive Effects.** One study of women found an increase in spontaneous abortion increasing with exposure to methylene chloride, benzene, estrogens, and toluene. Twelve of the 24 female production workers had intermenstrual bleeding. Exposure to solvents and methylene chloride in particular may have harmful effects on pregnancy.

## Suggestions For Controlling Exposures

**Dust.** The best long-term solution to overexposure is to improve the ventilation and replace machinery so that drug dust does not get into the air. In the short term, you can do the following:

1. Use a respirator with a high-efficiency (HEPA) filter. All respirators should be checked to make sure they fit well enough to really protect you.
2. Wear gloves that will protect your skin from contact.
3. Wear long sleeves to keep the drug from getting on your arms.
4. Wash your hands whenever you leave your work area.

**Noise.** Exposure to noise can be alleviated by acoustic enclosures of high-noise sections of packaging lines. Also, programmed job rotation for the personnel working on manufacturing and packaging lines may be useful in reducing monotony and limiting exposure to noise.

**Mechanical hazards.** Appropriate devices doing away with, or guarding against, possible "hand traps" should be installed.

## Control of Fire and Explosion

1. Government regulations are available for safety and fire protection
2. Careful plant layout and judicious choice of constructional materials can reduce fire and 3. explosion hazards.
4. Hazardous operations should be isolated by conducting them in separate buildings
5. The roof is designed to lift easily under an explosive force.
6. Possible sources of fire are reduced by eliminating the unnecessary ignition sources
7. The installation of sufficient fire alarms, temperature alarms
8. Fire resistance brick-walls can limit the effects of an explosion.

## Chemical Hazards and Safety

Chemicals found in industrial work environments have the potential to be hazardous. According to OSHA, the U.S. Occupational Safety and Health Administration, certain chemicals have dangerous reactivity properties that lead to fires, explosions, burns or blindness. OSHA requires employees to use

personal protective equipment (PPE) when working with industrial chemicals. PPE, such as face shields and gloves, protects employees from direct exposure to chemicals.

## Electrical Hazards and Safety

Electricity powers industrial machines and equipment. Adhering to OSHA's electrical safety standards protects employees from shocks, electrocutions and fires. If electrical wires and cords are frayed or damaged, they must be replaced. Electrical devices should never be mixed with water or liquids, and only authorized employees should work with electrical equipment.

## Machine Hazards and Safety

Industrial machines can cause severe injuries to employees. Crushed fingers, broken bones and severed limbs are potential safety hazards that industrial machines pose. To eliminate such risks, employers safeguard machinery. Covers, for instance, keep sharp machine edges or blades from being exposed. Also, locking machinery prevents it from moving when workers are not prepared.

## Electrical Hazards Safety Tips

Electrical hazards cause more than 300 electrocutions and 4,000 injuries in the workplace each year, disrupting lives and impacting the productivity of companies. While electrical hazards are not the leading cause of on-the-job injuries, accidents and fatalities, they are disproportionately fatal and costly.

### Safety tips to help avoid injuries include:

1. Identify the electric shock and arc flash hazards, as well as others that may be present.
2. Use the right tools for the job.
3. Isolate equipment from energy sources.
4. Test every circuit and every conductor every time before you touch it.
5. Work on electrical equipment and conductors only when de-energized.
6. Lock out/tag out and ground before working on equipment.
7. Treat de-energized electrical equipment and conductors as energized until lockout/tagout, test, and ground procedures are implemented.
8. Wear protective clothing and equipment and use insulated tools in areas where there are possible electrical hazards.

## Conclusion

Industrial hazards are anything that jeopardizes employee welfare, and they must be addressed by safety measures. Identifying industrial hazards allows employers to protect their workers from accidents, injuries and fatalities. Safety in simple terms means freedom from the occurrence of risk or injury or loss. Industrial safety refers to the protection of workers from the danger of industrial accidents.

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