A REVIEW ON “OCCUPATIONAL HAZARDS AND SAFETY IN PHARMACEUTICAL INDUSTRY”

*V.P. Aher¹, Shweta S. Shelke², Dr. V.D. Wagh³ and Prashant T. Aher⁴

¹Assistant Professor, PRES’s College of Pharmacy, Chincholi, Nashik.
²PRES’s College of Pharmacy, Chincholi, Nashik.
³Principal, PRES’s College of Pharmacy, Chincholi, Nashik.
⁴Deputy Manager, Glenmark Pharmaceuticals Pvt. Ltd, Nashik.

ABSTRACT

Occupational hazards is an industrial hazards which has the potential of causing injury to personnel, damage to equipment or structures, loss of material, or lessening of the ability to perform prescribed function. Chemical exposure, Fire exposure, Oxygen deficiency, Ionising radiation, Biological hazards, Safety hazards can cause injury to the health and workers may face many problems such as heart diseases, neurological, nephrological problems as well as the reproductive disorders, and often cause death. Occupational hazards are fatal in such a way that it may lead to hereditary disorders and cannot be cured. Present study give us an idea about the guideline developed by NIOSH/OSHA, a control measures and safety aspects which will help to suppress such occupational hazards and improve the quality of working of pharmaceutical industry and help to maintain a healthy organisation.

KEYWORDS: Occupational hazards, NIOSH/OSHA, hazards, safety.

INTRODUCTION

Occupational hazard is a condition with the potential of causing injury to personnel, damage to equipment or structures, loss of material, or lessening of the ability to perform a prescribed function. When hazard is present, the possibility exists of these adverse effects.
TYPES OF OCCUPATIONAL HAZARDS

Occupational hazards are the hazards arising in course of and out of occupation or employment and safety. It includes:

1. Chemical exposure.
2. Fire and explosion.
3. Oxygen deficiency.
4. Ionizing radiation.
5. Biologic hazards.
   a) Noise
   b) Temperature
   c) Cold stress
   d) Electricity
   e) Machinery

DISEASES DUE TO OCCUPATIONAL HAZARDS IN PHARMACEUTICAL INDUSTRY

Table no.1 The physical form, route of entry, affected organ and type of toxicity of some common industrial chemicals.[1]

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Physical form</th>
<th>Method of entry</th>
<th>Organ(s) that can be affected</th>
<th>Class of toxicity</th>
<th>Symptoms</th>
<th>Examples of</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cadmium metal and some of its compounds</td>
<td>Dust, vapours,</td>
<td>Inhalation</td>
<td>Lungs, throat, kidneys</td>
<td>Poisonous, causing damage to lungs, kidneys on chronic exposure.</td>
<td>Dry burning throat, chest pain, vomiting, headaches</td>
<td>Metal industries, welding processes, heavy chemicals</td>
</tr>
<tr>
<td></td>
<td>Dust</td>
<td>Ingestion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toluene di-isocyanate</td>
<td>Vapour</td>
<td>Inhalation</td>
<td>Lungs</td>
<td>Allergenic</td>
<td>Industrial asthma due to lung effects</td>
<td>Industrial processes involving polyurethane manufacture, paints and inks</td>
</tr>
<tr>
<td></td>
<td>Solid</td>
<td>Spillage on skin</td>
<td>Skin</td>
<td>Allergenic</td>
<td>Dermatitis</td>
<td></td>
</tr>
<tr>
<td>Mercury and many of its compounds</td>
<td>Vapour (mercury itself) dust</td>
<td>Inhalation</td>
<td>Brain and nervous system, kidneys</td>
<td>Poisonous. Often irreversible damage to nervous system</td>
<td>Loss of muscular coordination, loss of mental ability.</td>
<td>Heavy chemicals, laboratory workers, engineering</td>
</tr>
<tr>
<td></td>
<td>Liquids dusts</td>
<td>Spillage on skin, ingestion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substance</td>
<td>Route of Exposure</td>
<td>Effect on Target Organs</td>
<td>Other Effects</td>
<td>Workplace Exposure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-------------------</td>
<td>-------------------------</td>
<td>---------------</td>
<td>--------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chloroform, Carbon tetrachloride</td>
<td>Vapour</td>
<td>Brain, liver, kidneys, skin</td>
<td>Poisonous, Carcinogenic? Chronic exposure may lead to liver and kidney failure</td>
<td>Drowsiness</td>
<td>Light engineering, heavy chemicals, cleaning, office workers</td>
<td></td>
</tr>
<tr>
<td>Trichloroethylene</td>
<td>Liquid</td>
<td>Brain, liver, kidneys, skin</td>
<td></td>
<td>Dermalitis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auramine</td>
<td>Dust, vapour</td>
<td>Bladder</td>
<td>Carcinogenic to bladder.</td>
<td>Blood in urine</td>
<td>Dyes industry, pottery and glazing industries</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dusts</td>
<td>Skin</td>
<td>Irritant</td>
<td>Inflammation, burns</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nickel and some of its compounds</td>
<td>Dusts, powders</td>
<td>Skin</td>
<td>Dermalitis</td>
<td>Itching, burning of affected area</td>
<td>Metallurgical industries, heavy chemicals, laboratory workers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vapour</td>
<td>Lungs, nasal passages</td>
<td>Irritant in lungs (nickel carbonyl). Carcinogenic on chronic exposure</td>
<td>Breathlessness, fever</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-Naphthylamine</td>
<td>Dust</td>
<td>Bladder</td>
<td>Carcinogenic to bladder</td>
<td>Blood in urine</td>
<td>Dye and rubber industries; use of chemical banned in many countries</td>
<td></td>
</tr>
<tr>
<td>Benzene</td>
<td>Vapour</td>
<td>Brain, bone, marrow, skin</td>
<td>Poisonous. Possibly carcinogenic (leukaemia)</td>
<td>Headaches, nausea, loss of appetite, anaemia, dermatitis</td>
<td>Many industrial activities, especially chemical industry, lacquers, adhesives, paints, etc.</td>
<td></td>
</tr>
<tr>
<td>Asbestos</td>
<td>Dust particles and fibres</td>
<td>Lungs</td>
<td>Fibrogenic, carcinogenic (blue and white asbestos)</td>
<td>Breathlessness, loss of lung function</td>
<td>Many industrial activities involving manufacture or use of materials containing asbestos.</td>
<td></td>
</tr>
</tbody>
</table>

**STANDARDS AND LIMITS**

**OCCUPATIONAL EXPOSURE LIMITS (OEL)**

Occupational exposure limits (OELs) are a key component of the quantitative risk assessment/cost-benefit approach to occupational health. Official and unofficial standards for airborne chemicals, they usually are set by governments (sometimes after advice from a multi stake holder committee), industry associations, and/or an employer. OHS specialists and enforcement officials use them to judge acceptable levels of airborne chemicals and some other hazards.
Exposure control limits (ECLs) based on risk assessments from R&D data.

OEL: Airborne concentrations which will not result in adverse effects in most healthy workers (8 hr/day, 40 hours/week)

Data: Human Clinical Trials (Phase II and III)

Occupational Exposure Limits (OELs)

OEL (8 hr-TWA) = NOEL or LOEL (mg/kg/day) x BW(kg)

V(m3/day) x S(days) x UF x α

NOEL: No-Observed-Effect-Level

LOEL: Lowest-Observed-Effect-Level

BW: Average human body weight (50 - 70 kg)

V: Volume of air breathed in an 8-hour workday (10 m3)

S: Pharmacokinetics (half-life and accumulation)

UF: Uncertainty Factors

α: Used to adjust the absorption of a compound via inhalation

HAZARDS ASSESSMENT

Once the presence and concentrations of specific chemicals or classes of chemicals have been established, the hazards associated with these chemicals must be determined. This is done by referring to standard reference sources for data and guidelines on permissible levels of exposure, flammability, etc.

Threshold Limit Value (TLV)

TLVs can be used as a guideline for determining the appropriate level of worker protection. These values have been derived for many substances and can be found in Threshold Limit Values for Chemical Substances and Physical Agents, which is published annually by the American Conference of Governmental Industrial Hygienists (ACGIH) 121. The ACGIH defines three categories of TLVs: time-weighted average (TWA); short-term exposure limit (STEL); and ceiling (C).

Permissible Exposure Limit (PEL)

Permissible exposure limits are enforceable standards promulgated by OSHA. In many cases they are derived from TLVs published in 1968. The PEL for a substance is the 8-hour time weighted average or ceiling concentration above which workers may not be exposed. Although sample jars are labelled prior to sampling as part of site documentation
personal protective equipment may not be required for exposures below the PEL, its use may be advisable where there is a potential for overexposure.

**Recommended Exposure Limit (REL)**

A NIOSH recommended exposure limit (REL) is the workplace exposure concentration recommended by NIOSH for promulgation by OSHA as a PEL, but is not enforceable as is the OSHA PEL. In some cases, NIOSH has described time-weighted average concentrations in terms of 10-hour, rather than 8-hour, averages.

**PREVENTIVE MEASURES AND TREATMENT**

**Ionising Radiation**

Protection Techniques include

1. Control of exposure time and distance.
2. Shielding.
3. Wearing a film badge to check dose limit.
4. Pre and post-employment medical test.
5. Prevention of radiation disease such as skin cancer, ulceration, dermatitis, cataract, damage to bones and blood etc.
6. Use of remote controlled containers.
7. Continuous monitoring and maintaining safe limits by engineering controls and PPE.
8. The sealed container should be leak proof.

**CONTROL MEASURES**

**Classification of Control Measures**

The control measures can be applied at following three levels.

(1) At Source:

i. Substitution e.g. toluene in place of benzene, silicon carbide in place of silica in grinding stone, or water in place of solvent.
ii. Change of process or technology (airless paint spraying).
iii. Enclosure of process (cover).
iv. Isolation (by space or time).
v. Wet methods (water blasting).
vi. Local exhaust ventilation (Capturing at source).
vii. Waste disposal (pollution control).
viii. Good maintenance.
Use of PICTIGRAMS play an important role:
Pictorial representation of instructions provides the type of hazard that can be easily recognised at a glance:

![Acute toxicity](image1) ![Flammable](image2) ![Warning](image3) ![Corrosive](image4) ![Human health](image5)

**Fig.1**

(2) At Air path:

i. Increasing natural ventilation.

ii. Proving exhaust ventilation (fans).

iii. Increasing distance between source and the receiver (semi-automatic or remote control).

iv. Dilution or Mechanical ventilation (supplied air).

v. Continuous Area monitoring (pre-set alarms).

vi. Good housekeeping.

vii. Good maintenance.

(3) At Receiver:

i. Personal Hygiene Methods (Washing, bathing, good diet methods, no smoking, no intoxication etc.).

ii. Use of personal protective equipment and good maintenance.

iii. Use of protective cream or lotion.

iv. Personal monitoring device (Dosimeter).

v. Enclosure of worker (AC cabin).

vi. Rotation of worker (Split up of dose).

vii. Training and Education.

viii. Medical Examination and follow up.
The control measures (technology) can also be classified under

**Engineering Controls**

In this category are included those procedures which are applied to the working environment rather than to the individual.

They are as follows:

1. Substitution and Modification: The highly toxic material (carcinogenic, mutagenic or teratogenic) and processes should be replaced by less hazardous materials and processes

**REASONS FOR ACCIDENT PREVENTION**

Five main reasons for accident prevention

![Figure 2](image.replaceAll(., '_'))

**SAFETY MANAGEMENT AND ITS RESPONSIBILITIES**

![Figure 3](image.replaceAll(., '_'))

**CONCLUSION**

Health and safety concerns are important in all phases of the continuum of pharmaceutical product production, use and waste disposal, occupational health and safety issues in this sector have not received equal attention. In particular, the hazards posed by multiple
exposures need careful consideration. A worker whose immune system is compromised by a stressful work environment and whose workplace is not well-designed ergonomically, may well suffer more harm from exposure to toxic chemicals than someone whose only exposure is to the chemical hazard. The prevailing quantitative risk assessment approach to chemical management by pharmaceutical industries and government authorities including the cost-benefit aspects that are often hidden in discussions—is doing little to prevent work-related ill-health, injuries, diseases, and deaths among pharmaceutical workers as well as offer useful examples of occupational health practices in their policies, as do the use of the precautionary principle and substitution requirements in the pharmaceutical industries.

REFERENCES
10. Dutta S., European case clearing house, tragedy, ICFAI centre for management research, Hyderabad, India.
11. Case study, PINKERTON consulting and investigations, India.