International Journal of Pharmaceutical Development & Technology

www.ijpdt.com

e ISSN - 2248 - 910X

Print ISSN - 2248 - 9096

MECHANICAL HAZARDS IN PHARMACEUTICAL INDUSTRY: RISK ASSESSMENT, SAFETY GUARDS AND CONTROL STRATEGIES

Elsa George[1]*, Archana P[1], Sona Siby[1], Aleena Varghese[1], Meenu James[1], Krishnarajan D[2]

[1]B.Pharm Students of Pushpagiri College of Pharmacy, KUHS, Thiruvalla-689107, Kerala
[2]Professor of Department of Pharmaceutics, Pushpagiri College of Pharmacy, KUHS, Thiruvalla-689107, Kerala.

ABSTRACT

Mechanical hazards in the pharmaceutical industry represent a significant risk to worker safety and operational efficiency. This journal article presents a detailed study on the types, impacts, and mitigation strategies associated with mechanical hazards in pharmaceutical manufacturing environments. The research identifies common mechanical dangers, such as moving components, mechanical failures, and ergonomic concerns, using data from current industry publications, safety studies, and incident case studies. The study reveals that moving parts, such as rotating shafts and conveyor belts, are common sources of entanglement and injury. Mechanical failures, such as gear malfunctions and hydraulic leaks, often lead to unpredictable machine behavior and operational disruptions. Mitigation strategies are examined, focusing on equipment design improvements, regular maintenance schedules, and enhanced safety training programs. The study highlights the effectiveness of incorporating safety guards, emergency stop mechanisms, and rigorous lockout/tagout procedures. In addition, it highlights that following legal requirement like OSHA guidelines is essential to lowering the risk of mechanical risks. The results emphasize the necessity of a proactive safety management strategy in the production of pharmaceuticals. Precautions that should be taken include putting modern safety technologies into practice, encouraging a safety-conscious culture, and regularly upgrading safety protocols to handle changing hazards. This study offers insightful information that can help the pharmaceutical sector improve operational dependability and worker safety.

Keywords: Mechanical hazards, Safety measures, Safety management, Equipment maintenance, OSHA Guidelines.

INTRODUCTION

Health risk of working in the pharmaceutical industry is a less discussed topic. On the surface level, the industrial risk looks easy and less concerning. The production and manufacturing of medicines demands a carefully maintained and sterile working environment including a well-maintained machinery support. Producing of drugs and its manufacturing involves exposure to many industrial hazards. Inadequate knowledge about the machinery involved in the production can put the workers life at risk. Industrial hazards may be defined as any condition produced by the industries that may cause injury or death to personnel or loss of product or property. Safety in the simpler terms is defined as the prevention form the occurrence of risk or injury or loss. Industrial safety refers to the protection of workers from the danger of industrial accidents.

Mechanical hazards are likely from machines powered by steam, hydraulic and electric energy, regardless of whether they are automated or manually operated. These risks are amplified by the variety and quantity of equipment's, crowded workspace, insecurely fixed machines, failure of SOP, and the interaction between workers and machines. Over the past decades, successive major accidents, more than two thousand deaths from the deadly toxic gas release in Bhopal, India, the deepwater horizon oil spill in gulf Mexico in 2010, have caused death, numerous injuries, significant environmental pollution and massive economic loss which drew world attention to the seriousness towards the importance of industrial safety. Industrial safety refers to reduce the risk of injury or loss and danger to persons, property from industrial hazards. Effective management of workers safety and health protection is a decisive factor in reducing the extent and severity of work-related injuries and sickness and their related costs. [1, 2]

Types of mechanical hazards

Mechanical hazards by Motion

A wide variety of mechanical motions and actions may present hazards to the worker. The basic types of hazardous mechanical motions and actions are:

Corresponding Author: - **Elsa George Email**: - elsageorge090@gmail.com

a) Rotary Motion Hazards
Can catch hair or clothing and draw the operator into the machine. Can force a hand or arm into a dangerous position, causing laceration, broken bone or amputation.
Hazard is increased when projection is preset on rotating compound which can strike the operator
b) Reciprocal motion hazards
Struck by or caught between stationary part and moving part of the ups and down or back and forth motion.
Also consider cons and forklift trucks
c) Transverse motion hazard
Transverse (movement in straight, continuous line) creates a hazard because a worker maybe struck or caught in a pinch or shear point by the moving part.

Mechanical hazards by Action

Mechanical injuries may occur in different ways. In industrial setting, people operate machines that are designed to drill, cut, shear, punch, staple, stitch, abrade, shape, stamp and slit material such as metals, composites, and plastics. These processes are purely mechanical. They cause material to be deformed or broken into smaller pieces. If appropriate safeguards are not in place or if the operators themselves fails to follow safety precautions, they may get hurt by these machines

Wound and tearing

A cut occurs when our skin suddenly comes into contact with a sharp edge. Tearing implies further opening of a cut through strong forces.

Shearing

Shearing injury occurs when the mechanical force that acts on the area of the skin in a direction parallel to the body surface. It depends on the pressure exerted. Shearing actions applies power to a slide or a knife in order to trim or shear metal or other materials. The danger of shearing action exists at the point of the operation. To understand what shearing means, imagine using a paper cutter. Power driven shears for cutting paper, metal, plastic, and composite material are dangerous because of their extreme cutting various material to different sizes. Certain news reports about how such machines often commutated fingers and hands of careless workers are reported. Such tragedies typically occurred when the operators reached under the shearing blade to make an adjustment or placed materials there and accidentally activated the blade before fully removing their hands

Crushing

Injury occurs when the body part is caught between two hard surface that progressively move together. Thereby crushing anything between them. It is mostly painful and difficult to heal. Crushing hazards can be divided into two categories:

i. Squeeze-point types
ii. Run in points

- Squeeze-point types:

It exists where two hard surfaces, at least one of which must be in motion, close in together to crush any object that may be between them.

- Run-in point hazards:

It exists where two objects, at least one of which is rotating, come progressively closer together. Any gap between them need not become completely closed. It needs only need to be smaller than the width of the object or body point hazards

Fractured

Machines used to deform raw materials such as wood and steel in factories can easily break human bones is known as fracture. Fracture is classified as:

a. Simple b. Compared c. Complete d. Incomplete

Straining and spraining

There are numerous situations in an industrial setting when straining of muscles or spraining of ligaments is possible. A strain result when muscles are overstretched or torn. Strain and sprain can cause swelling and intense pain.

- **Puncturing**

Puncturing machines that have sharp tools can puncture a body part if safety precautions are not observed or if appropriate safeguards are not in place. Puncturing results when an object penetrates straight into the body and pulls straight out, creating a wound in the shape of the piercing object. The greatest risk with puncture wound is causing damage to internal organs.

- **Cutting**

Cutting action may involve rotating, reciprocating or transverse. The danger of cutting action exists at the point of operation where finger, arm and body injuries can occur and where flying chips or sharp materials can strike the head, particularly in the area of the eyes or face. Such hazards are present at the point of operation in cutting wood, metal and other material.

E.g.: bandsaws, circular saws, drilling machines.

- **Punching**

Punching action results when power is applied to a slide in order to blank, draw or stamp metal or other material. The danger of punching action exists at the point of operation.

- **Bending**

Bending action occurs when power is applied to a slide in order to shape, draw or stamp materials. The dangers of bending action exist at the points of operations.

Examples of non-mechanical hazards that can injure operators, or others in the area, including chips, splashes, sparks or sprays that are created as the machine is running. Machine entrapment injuries can be severe. Machine operation instructions can lead to less risk of injury because the instructions explain the machines operation and how to prevent, or at least recognize a malfunction.

Employes who work in the company should thereby ensure that the machine is being run correctly and safely. This includes all the machine safety measures and safeguards. [2-4]

General Principles of Risk Assessment

The best way to prevent injuries or illness in workplace is to fine the hazards that could cause injury or illness and fix them. Four steps include: Spot the hazard, Assess the risk, Fix the problem, Evaluate results. This process is often called risk assessment. Any improvement to the machine's safety begins with the risk assessment. This operation includes a risk analysis, followed by a risk evaluation.

Risk analysis

- Determining the limits of the machine
- Identifying the hazards
- Estimating the risks

Risk evaluation

Last step of the risk assessment process consists of making a conclusion on the estimated risk level. At this step, it is determined whether the risk is tolerated or not.

Risk reduction

Once the assessment step has been completed, if the final evaluation prescribes a reduction of risk which is intolerable then, means to achieve the risk reduction objectives must be selected.[3]

OSHA's Standard For Machine Guarding

The intention of the Occupational Safety and Health Act (OSHA) of 1970 is "to assure so far as possible every working man and woman in the nation safe and healthy working conditions and to preserve our human resources," two of the standards directly related to workers health and important in design work are:

1) Toxic hazardous substances.
2) Occupational noise exposure.

Other standards in the safety area most often cited by OSHA are the National Electric Code and Machinery Guarding. Which must be considered in detailed designs.

Effective controls protect workers from workplace hazards, help avoid injuries, illnesses, and incidents, minimize or eliminate safety and health risk, and help employers provide workers with safe and healthful working conditions.

To effectively control and prevent hazards, employers should:

- Involve workers, who often have the best understanding of the conditions create hazards and insights into how they can be controlled.
- Identify and evaluate options for controlling hazards, using a "hierarchy of controls."
- Use a hazard control plan to guide the selection and implementation of controls and implement controls according to the plan.
- Develop plans with measures to protect workers during emergencies and nonroutine activities.
- Evaluate the effectiveness of existing controls to determine whether they continue to provide protection, or whether different controls may be more effective. Review new technologies for their potential to be more protective, more reliable, or less costly.[5][15]

Guards and Protective Devices

Guards whether they are fixed or interlocking guards or interlocking guards with guard locking, ranks just below inherently safe design in terms of effectiveness in the hierarchy of risk reduction measures.

Safeguards or Safety Measure

Each piece of the machinery has its own unique mechanical and non-mechanical hazards. Machines can cause severe injuries that include amputations, fractures, lacerations or crushing injuries. Therefore, working with safety measures and safeguards is important.

Prevent contact:

A safeguard must prevent hands, arms and any other part of a worker's body from making contact with dangerous moving parts. A good safeguarding system eliminates the possibility of the operator of another workers placing parts of their bodies near hazardous moving parts.

Secure and durable:

Workers should not be able to easily remove the safeguard, guards and safety devices should be made of durable material that will withstand the conditions of normal use. They must be firmly secured to the machine. This is critical because removing safeguards in an attempt to speed up production is common practice.

Protect from falling objects:

The safeguards should ensure that no object can fall into moving parts. A small tool which is dropped into a cycling machine could easily become a projectile that could strike and injure someone.

Allow safe lubrication:

If possible, one should be able to lubricate the machine without removing the safeguards. Locating oil reservoirs outside the guard with a line leading to the lubrication point, will reduce the need for the operator or maintenance worker to enter the hazardous area.

Create no new hazards:

Safeguard should overcome the hazards in question without creating new ones.

Create no interference:

Safeguard can interfere with the progress of work if they are not properly designed such safeguard are likely

to be disregarded or disabled by worker who find such safeguards a nuisance rather than a safety factor.

Training

- Even the most elaborate safeguarding system cannot offer effective protection unless the worker knows how to use it and why.
- Specific and detailed training is therefore a crucial part of any effort to provide safeguarding against machine related hazards.

Though this training should involve:

- A description and identification of the hazards associated with particular machines.
- he safeguards themselves provide protection, and the hazards for which they are intended.
- How to use the safeguards and why.
- How and under what circumstance safeguards can be removed, and by whom (in most cases, repair or maintenance personnel only).

Types of Safeguarding

- Point of operation guards
- Feeding/ejection methods
- Lockout/Tagout system

Point of Operation Guards

They are classified as:

- Fixed guards
- Interlocked guards
- Adjustable guards
- Self-adjusting guards

A. Fixed Guards

Provide a permanent barrier between workers and point of operation (Figure 2). It is not dependent upon moving parts to function. It is constructed of sheet metal, screen, wire cloth, bars, or any other material that is substantial enough to withstand whatever impact It may receive and to endure prolonged use.it is relatively simple guard therefore preferable to all other types. They provide maximum protection. Minimum maintenance.

B. Interlocked Guards

They shut down the machine when the guard is not working in place (Figure 3). When this type of guard is opened or removed, the tripping mechanism and/or powered automatically shutsoff or disengages, the moving parts of the machine are stopped, and the machine cannot cycle or be started until the guard is back in place. To be effective, all removeable guards should be interlocked to prevent occupational hazards. They provide maximum protection. Allows access to the machine for removing jams without time consuming. The major drawback include carefull adjustment and maintainance. Easy to disengage.

C. Adjustable Guards

Provide a barrier against a variety of different hazards (Figure 4). They are usefull because they allow flexibility in accomodating various sizes of stock. They can be constructed to suit many specific application. Can be adjusted to admit varying sizes of stock. Major drawback include frequent mainatainance or/and adjustments. They may interfere with visibility. The guards may be ineffective by the operator.

D. Self-Adjusting Guards

The opening of this barriers are determined by the movement of the stock (Figure 5). As the operator moves the stock into the danger area, the guard is pushed away, providing an opening which is only larger enough to admit the stock. After the stock is removed, the guard returns to the rest position. This guard protects the operator by placing a barrier between the danger area and the operator. These guards are made of plastic, metal, or other substantial materials. Self adjusting guards offer difeerent degree of protection. The major drawbacks include interfering with visibility, require frequent maintanance and adjustments, does not always provide maximum protection.

Feeding/Ejection System

Automatic feed system feed the stocks to the machine from rolls (Figure 6). It eliminates the need to operator to enter the danger zone. They do not reach in the damage zone to retrieve work pieces. It involves a high degree of automation where materials are loaded, positioned, conveyed to the machines using sensors, robotics, and conveyor systems. Automatic ejection system is properly designed automated ejection methods they do not require any operator involvement after the machine starts to function. These systems may create hazards for themselves. For instance, a robot may eliminate the need for an operator to be near the machine but may create a new hazard itself by the movement of its own arm.

Lockout/Tagout System

It is a method that was especially designed to protect against unexpected startup of the machine. In the lockout system a padlock system is placed through the gate covering. The lock usually has the label that gives the name, department and telephone extension of the person. The lock is measured only by the process. OSHA's Control of Hazardous Energy standard, 29 CFR 1910.147, commonly referred to as the "Lockout/Tagout" standard, requires the adoption and implementation of practices and procedures to shut down equipment, isolate it from its energy sources and prevent the release of potentially hazardous energy while maintenance and servicing activities are being performed. This standard covers the servicing and maintenance of machines and equipment in which the "unexpected" energization or startup of the

machines or equipment or release of stored energy could cause injury to workers. [6-8]

OSHA Specifications for Machine Guards

The OSHA requirements for machine guards alludes to:

- **1910.212(a) (1) –** Guarding types. One or several methods of machine guards shall be provided to protect the machine operator and other employees in the machinery area from dangers like those made by point of nip points that are ingoing, operation, spinning parts, sparks, and flying pieces. Examples of guarding methods are two-hand tripping, devices barrier guards, electronic safety devices, etc.
- **1910.212(a) (2) -** Machine guards' general requirements. Guards shall be attached to the machinery where possible and secured anywhere else if for any reason joining to the machine is impossible. The guard shall be in such a way that it will not offer an accident danger in itself.
- **1910.212(a) (3) -** Point of operation guarding.
- **1910.212(a) (3) (i) -** Point of operation is the place on machinery where work is carried out upon the material undergoing processing.
- **1910.212(a) (3) (ii) -** Operation of machinery which exposes employees to injury, must be guarded. The guarding part will be in adherence with any appropriate safety standards thereof.
- **1910.212(a) (3) (iii) -** Special tools for detaching and putting material will be such that they allow simple handling of materials without the machine operator placing his hand in a dangerous area.
- **1910.212 (a) (4) -** Barrels, drums, and containers. Revolving barrels, containers, and drums shall be guarded by a cover which is interlocked with the drive device, so that the drum, container, or barrel cannot rotate unless the guard cover is in place.
- **1910.212 (a) (5) -** Exposure of blades. When the margin of the fan blade is under than seven feet over the working floor, the blades will be guarded. The guards shall have openings no bigger than one-half inch. [9, 10]

Machine Guard's Maintenance

Guards must be inspected as part of the machine guard maintenance schedule. A guard must be replaced in the event there are tearing or visible cracks or, Dents from impact or bulges, Holes. Guards must be cleaned with a plastic cleaner which is nonabrasive. Guards must never be cleaned with cleaning products which are based on ammonia (like glass cleaner). Yellowing of transparent guards is not a primary concern as the guards are manufactured from PETG plastic and not polycarbonate. [11]

Preventive Measures

Building planning:

- Floor must be non-slippery type.
- Enough space to move easily.
- Easy access of workers to safety switches.

Safe material handling:

- All material handling equipment's should be repaired and maintained properly.
- Personnel protective devices:
- Protection of head by using head a hats and helmets.
- Ears by using ear muffins and plugs.
- Face by using face masks. [12]

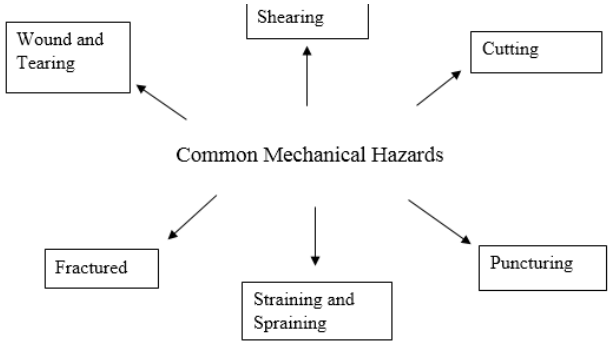

Figure 1: Common Mechanical Hazards

Figure 2: Characterized by type of harm caused.

Figure 3: Fixed Guards

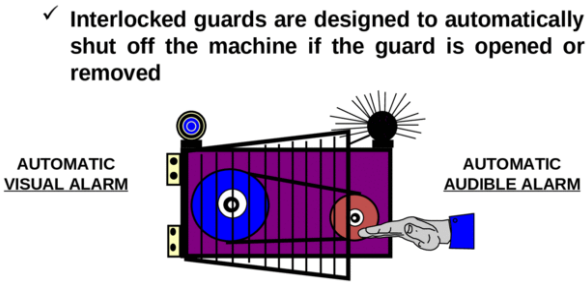

Figure 4: Interlocked Guards

Figure 5: Adjustable Guards

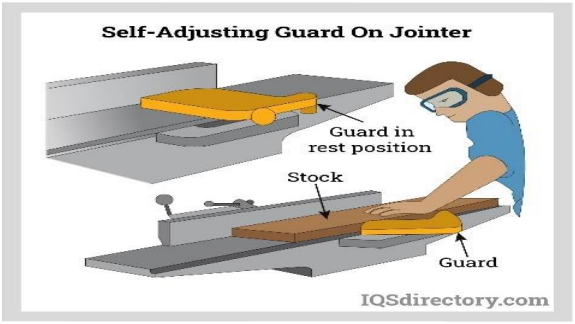

Figure 6: Self-Adjusting Guards

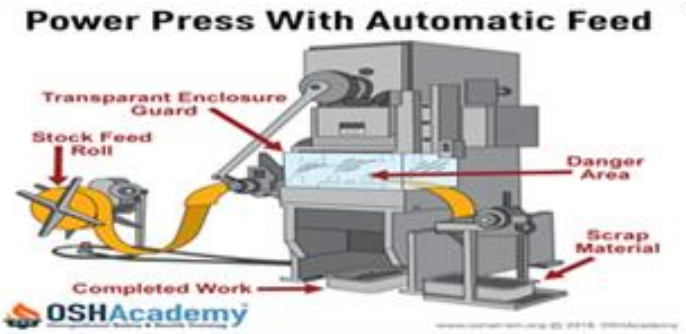

Figure 7: Feeding/Ejection System

General Precautions

- All the operator should be trained in the safe operations and maintenance of their machine.
- All the machine operator should be trained in the emergency procedure to be taken when accident occur.
- All employes should know how to activate emergency shut down controls.
- Careless handling of heavy materials and components should be avoided.
- Full use of mechanical handling equipment.
- All material handling equipment's should be repaired and maintained properly.
- Protection of ears by using earmuffs and plugs.
- Efforts should be made to reduce the noise to a safe level.
- Inspection, maintenance, adjustments, repair and calibration of safe guard should be carries our regularly.
- Supervisors should ensure the safeguard is properly in place when machine are in use.
- Shortcuts that violate safety principle and practice should be avoided.
- Provide employees with the correct PPE.
- Schedule regular preventive maintenance for machines. [13, 14]

CONCLUSION

This study provides a comprehensive evaluation of mechanical hazards in the pharmaceutical industry, highlighting their prevalence, impacts, and mitigation strategies. Mechanical hazards, including moving parts, equipment failures, and ergonomic issues, pose significant risks to worker safety and operational efficiency. Our findings demonstrate that despite advancements in technology and safety protocols, these hazards remain a

critical concern in pharmaceutical manufacturing environments. The research underscores the importance of implementing robust safety measures, such as advanced equipment design with integrated safety features, regular maintenance and inspections, and comprehensive training programs. Effective machine guarding, emergency stop systems, and adherence to lockout/tagout procedures are essential in preventing accidents and ensuring the safety of personnel. The report also emphasizes how important it is to keep enhancing safety procedures and guidelines. Because of the dynamic nature of pharmaceutical manufacturing and the rapid advancement of technologies, safety precautions must be continuously reviewed to handle new dangers. Minimizing mechanical dangers requires a proactive strategy that includes frequent safety audits, updated training, and adherence to current safety regulations. In summary, even though a lot of progress has been achieved in addressing mechanical dangers, the pharmaceutical sector still needs to be much more committed to safety and exercise greater caution to prevent health hazards and protect workers safety.

ACKNOWLEDGEMENT

The authors are sincerely thankful to the Principal Prof. Dr. Santhosh M Mathews, Faculty- Dept of Pharmaceutics, Pushpagiri College of Pharmacy, Thiruvalla, Kerala for providing the necessary facilities and encouragement to carry out this work.

REFERENCES

1. Girish K Jain, Pharmaceutical Engineering I, First edition, BS Shah Prakashan, *Ahmedabad*, 2006, 617-624
2. Ashutoshkar, Samba Murthy K, Pharmaceutical Engineering, First Edition, New Age International Publishers, New Delhi, 2019, 270
3. Subrahmanyan CVS, Thimma Setty J, Kusum Devi V, Pharmaceutical Engineering (principle and practices) First edition (6) Vallabh Prakashan, Delhi, 2008, 467-484
4. Subrahmanyan CVS, Pharmaceutical Production and Management, First Edition, Vallabh Prakashan. Delhi, 2005, 400-404
5. Subrahmanyam CVS, Nusrat Zahan, Pharmaceutical Engineering 2011, 284
6. Subrahmanyam CVS, Pharmaceutical Production and Management, 393-4122.
7. Hazard analysis by HACCP in safety management system Q.A volume-2, 200-2113
8. Perry's Chemical Engineering handbook by Robert H. Perry Don. W. Green, seventh edition, 26-49
9. Work Safe Tasmania. 4 steps to manage hazards and risk [Internet]. worksafe.tas.gov.au. 2022
10. OSHA Academy. 726 Introduction to Machine Guarding [Internet]. Oshacademy.com. 2024 [cited 2024 Aug 6].
11. Prevention of mechanical hazards [Internet]. [cited 2024 Aug 6].
12. Occupational Safety and Health Administration. Safety Management - Hazard Prevention and Control | Occupational Safety and Health Administration [Internet]. www.osha.gov. 2023.
13. Ali Z. Mechanical Hazards [Internet]. Scribd. 2024 [cited 2024 Aug 6].
14. Machine Guards: Types: Applications, Benefits, and Design [Internet]. www.iqsdirectory.com.
15. SAFETY METHODS IN PHARMACEUTICAL INDUSTRY [Internet]. SlideShare. SlideShare; 2021
16. OSHA. Laboratory Safety Guidance [Internet]. 2011.