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PHARMACEUTICAL ENGINEERING

UNIT 5

TOPIC :

- **Materials of pharmaceutical plant construction, Corrosion and its prevention :** Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and there prevention. Ferrous and nonferrous metals, inorganic and organic non metals, basic of material handling systems

Pharmaceutical Plant Construction

- In the pharmaceutical industry, plant construction involves the use of specialized materials for equipment, pipelines, reactors, dryers, filters, and storage units. The correct choice of materials is critical to ensure product quality, process efficiency, regulatory compliance, and safety.

Factors Affecting Choice of Material

1. **Physical Factors**
   - **Strength and Durability**:
     Materials must withstand mechanical stresses, pressure, vibration, and wear during operations.
     Example: Cast iron and stainless steel are widely used in high-pressure applications.
   - **Thermal Properties**:
     Materials should have suitable thermal conductivity, heat resistance, and minimal thermal expansion, especially in processes involving heating/cooling.
     Prevents structural deformation and maintains efficiency.
   - **Ease of Fabrication and Maintenance**:
     Materials that are easy to machine, weld, or mold reduce construction and operational costs.
     Example: Plastics can be molded into complex shapes, giving design flexibility.
   - **Cleanability & Sterilizability**:
     Surfaces must be smooth, non-porous, and easy to clean to maintain hygienic conditions.
     Essential for pharmaceutical GMP compliance.

2. **Chemical Factors**
   - **Corrosion Resistance**:
     Materials should resist corrosion due to chemicals, solvents, and moisture.
     Example: Stainless steel is highly resistant to corrosion.

- **Contamination Prevention**:
  The material should not react with drugs or intermediates, ensuring purity and safety.
  Example: Glass and high-grade steel prevent contamination.

3. **Economical Factors**
   - **Cost-Effectiveness**:
     Selection must balance initial cost, durability, and maintenance. Long-lasting, low-maintenance materials are preferred.
     Example: Stainless steel is costly initially but more economical in the long run compared to mild steel.

4. **Regulatory Compliance**
   - Materials must comply with GMP (Good Manufacturing Practices), FDA, and pharmacopeial guidelines.
   - Should not leach harmful substances into products.
   - Ensures safety, efficacy, and quality of pharmaceuticals.

5. **Environmental & Safety Considerations**
   - Materials should be eco-friendly and safe for workers and end-users.
   - Must withstand sterilization procedures (steam, radiation, chemical disinfectants).
   - Preference for recyclable and non-toxic materials.

Classification of Materials

➢ Materials used in pharmaceutical plant construction are broadly classified into:

A. Metals

Metals are hard, shiny materials with high thermal & electrical conductivity, malleability, and ductility.

They are classified into:

(1) Ferrous Metals (Iron-based)

- **Mild Steel**
  - Contains low carbon (~0.05–0.25%).
  - High mechanical strength, used for bars, pipes, plates.
  - Limited corrosion resistance → used where no chemical exposure occurs.
- **Cast Iron**
  - High carbon content (~2–4%).
  - Cheap, strong, used for jackets of steam pans.
  - Susceptible to corrosion → requires protective coating.
- **Stainless Steel**
  - Alloy of iron with chromium & nickel.
  - Excellent **heat resistance, corrosion resistance, and cleanability**.
  - Widely used in pharmaceutical plant construction (tanks, reactors, pipelines).

(2) Non-Ferrous Metals

- **Aluminium**
  - Lightweight, corrosion-resistant, cheap.
  - Used for transport containers (drums, barrels).
- **Copper**

    - Excellent thermal & electrical conductivity.
    - Used in **heating/cooling systems** and **electrical wiring**.
- **Titanium**
    - Strong, lightweight, highly corrosion resistant.
    - Used in **critical equipment** like heat exchangers and units exposed to aggressive chemicals.

B. Non-Metals

Non-metals lack metallic properties; they are generally poor conductors, lightweight, and chemically resistant.

They are divided into:

(1) Organic Non-Metals

- **Rubber**
    - Used as lining for tanks & pipes to prevent corrosion.
    - Provides insulation against friction and chemical attack.
- **Plastics**
    - Lightweight, resistant to chemicals, easy to fabricate.
    - Used for containers, pipes, and storage of salts & other chemicals.

(2) Inorganic Non-Metals

- **Glass**
    - Transparent, inert, resistant to most chemicals.
    - Cheap, attractive, available in various shapes & colors.
    - Used for laboratory apparatus, containers, and sight glasses in equipment.

Material Handling Systems

- Material handling systems refer to the equipment, methods, and processes used to move, store, control, and protect materials during different stages of manufacturing, distribution, utilization, and disposal. In the pharmaceutical industry, material handling is crucial because it directly impacts product integrity, worker safety, process efficiency, and regulatory compliance. Since pharmaceutical products are sensitive to contamination, breakage, and environmental factors, efficient handling systems ensure that raw materials, intermediates, and finished products are moved safely and hygienically.

Objectives of Material Handling Systems

1. **Efficient Movement** – To reduce time, effort, and cost during the movement of materials.
2. **Safety** – Protects workers and materials from accidents, spills, or contamination.
3. **Cost Effectiveness** – Optimizes labor and equipment use to reduce operational expenses.
4. **Product Integrity** – Prevents contamination, degradation, or physical damage to materials.
5. **Regulatory Compliance** – Ensures that handling follows GMP (Good Manufacturing Practices) and international safety standards.
6. **Space Utilization** – Improves use of available factory/warehouse space.
7. **Flexibility** – Handles a wide range of materials with minimal adjustments.

Types of Material Handling Systems

1. **Manual Material Handling (MMH)**
    - Involves human effort for lifting, carrying, pushing, or pulling materials.
    - **Examples:** Hand trolleys, lifting bags, manual carts.
    - **Applications:** Used for small-scale handling in warehouses, labs, and production units.
    - **Limitations:** Risk of injury, fatigue, contamination, and inefficiency in large operations.
2. **Mechanical Material Handling**
    - Uses **machines and equipment** to assist in moving or lifting loads.
    - **Examples:** Cranes, conveyors, forklifts, hoists, and elevators.
    - **Advantages:** Reduces human effort, increases efficiency, and improves safety.
    - **Applications:** Transporting heavy raw materials, bulk powders, and drums in pharmaceutical plants.
3. **Automated Material Handling Systems (AMHS)**
    - Employs **automated equipment** and digital control systems with minimal human intervention.
    - **Examples:** Automated Guided Vehicles (AGVs), robotics, conveyor systems, and robotic arms.
    - **Advantages:** High accuracy, reduced contamination risk, 24/7 operation.
    - **Applications:** Large-scale pharmaceutical industries, sterile product handling, warehouse automation.
4. **Bulk Material Handling Systems**
    - Designed to handle **large quantities of solid or powdered materials**.
    - **Examples:** Belt conveyors, bucket elevators, pneumatic conveyors, screw conveyors.
    - **Applications:** Handling of bulk powders like lactose, starch, excipients, salts, and granules in pharma production.

Advantages of Material Handling Systems

- **Improved Productivity** – Faster movement of goods reduces downtime.
- **Enhanced Safety** – Minimizes accidents, contamination, and manual strain.
- **Flexibility** – Can handle different types of materials (solid, liquid, powder).
- **Better Quality Control** – Reduces handling errors and product damage.
- **Cost Reduction** – Optimizes labor and equipment costs.
- **Compliance** – Meets GMP and ISO standards for clean and safe handling.

Corrosion

- Corrosion is a natural process in which metals undergo deterioration due to chemical or electrochemical reaction with their environment.
- It alters the physical and mechanical properties of metals, leading to loss of strength, durability, and functionality.
- Most commonly, corrosion is an oxidation process forming oxides, hydroxides, or other compounds.
- Example: Rusting of iron when exposed to moisture and oxygen.

Theories of Corrosion

Several theories explain the mechanism of corrosion:

1. Acid Theory

- Proposed in early studies of corrosion.
- States that corrosion occurs due to the action of acids present in the environment.
- Example: Carbonic acid (H_2CO_3) formed when CO_2 dissolves in water reacts with metals like iron.

Reaction:

$$Fe + H_2CO_3 \rightarrow FeCO_3 + H_2 \uparrow$$

2. Dry Corrosion (Chemical Corrosion) Theory

- Occurs due to direct chemical reaction between metal and gases of the environment, usually in the absence of moisture.
- Types:

(a) Oxidation Corrosion

- Metal reacts directly with oxygen.

$$4Fe + 3O_2 \rightarrow 2Fe_2O_3$$

(b) Corrosion by Other Gases

- Halogens (Cl_2, Br_2, F_2) and sulfur compounds react with metals.

$$2Ag + Cl_2 \rightarrow 2AgCl$$

(c) Liquid Metal Corrosion

- When a **solid metal** comes into contact with a **liquid metal**.

$$Zn + Hg \rightarrow Zn(Hg)$$

3. Electrochemical (Galvanic) Theory

- Most widely accepted theory.
- States corrosion is an electrochemical process involving electron transfer.
- It occurs when anodic and cathodic areas are formed on the same metal (local cell) or between two dissimilar metals (galvanic cell) in presence of an electrolyte.

(a) Corrosion on Single Metal (Local Cell Corrosion)

- Different areas of the same metal act as anode and cathode.

Reactions:

- At Anode (oxidation):

$$Fe \rightarrow Fe^{2+} + 2e^-$$

- At Cathode (reduction):

$$2H^+ + 2e^- \rightarrow H_2 \uparrow$$

(b) Corrosion Between Different Metals (Galvanic Corrosion)

- When two dissimilar metals are in contact in an electrolyte.
- The more active (less noble) metal acts as anode and corrodes, while the noble metal acts as cathode and is protected.

Example:
Iron (Fe) in contact with Copper (Cu) in acidic medium → Iron corrodes, Copper protected.

Types of Corrosion

1. **Uniform Corrosion**
   - Occurs evenly across the surface of a material.
   - Caused by exposure to air, moisture, oxygen, or chemicals.
   - Predictable in nature and manageable through coatings or maintenance.
2. **Pitting Corrosion**
   - Localized form of corrosion creating small pits or holes on the metal surface.
   - Usually caused by chloride ions, acidic environment, or breakdown of protective oxide film.
   - Very dangerous as it penetrates deep and may lead to sudden failure.
3. **Crevice Corrosion**
   - Occurs in shielded or confined areas where a solution gets trapped (gaps, folds, under washers).
   - Common in stainless steel under chloride-rich conditions.
   - Localized and often difficult to detect until severe damage occurs.
4. **Stress Corrosion Cracking (SCC)**
   - Results from the combined action of mechanical stress and corrosive environment.
   - Leads to formation and propagation of cracks.
   - Can cause catastrophic failure of pharmaceutical vessels and pipelines.

5. **Galvanic Corrosion**
    - Occurs when two dissimilar metals are electrically connected in an electrolyte.
    - The more active metal corrodes preferentially (sacrificial corrosion).
    - Example: steel in contact with copper in water.
6. **Erosion Corrosion**
    - Caused by relative movement of a fluid over a metal surface.
    - Removes the protective oxide layer, leading to accelerated wear.
    - Common in pipelines, pumps, and valves handling high-velocity liquids.

Prevention of Corrosion

1. **Protective Coatings**
    - Application of paints, powder coatings, or electroplating.
    - Forms a barrier between the metal and environment.
    - Example: Epoxy-coated steel tanks.
2. **Material Selection**
    - Use of corrosion-resistant materials such as stainless steel, aluminium, titanium, plastics, or glass-lined vessels.
    - Highly effective but costly.
3. **Environmental Control**
    - Reducing exposure to moisture, oxygen, and electrolytes.
    - Use of dehumidifiers, corrosion-free lubricants, and controlled atmosphere.
4. **Corrosion Inhibitors**
    - Chemicals added to system which react with the metal surface to suppress electrochemical reactions.
    - Example: Chromates, phosphates, amines.
    - Commonly used in cooling water systems.
5. **Design Modification**
    - Avoiding sharp corners, joints, and crevices in equipment design.
    - Use smooth surfaces and proper drainage to prevent water accumulation.