

Factors Affecting During Materials Selected for Pharmaceutical Plant Construction

A. Regulatory Compliance:

- **FDA/EMA Guidelines:** Materials must meet standards from regulatory bodies.
- **GMP:** Compliance with Good Manufacturing Practices is essential.

B. Chemical Compatibility:

- **Resistance and Non-reactivity:** Materials must resist and not react with chemicals and cleaning agents used in processes.

C. Hygiene and Cleanability:

- **Easy to Clean:** Materials should be smooth and easy to sterilize to maintain high hygiene standards.

D. Durability and Corrosion Resistance:

- **Long-lasting:** Materials should withstand operational conditions without frequent replacements.
- **Corrosion Resistant:** Especially in areas exposed to chemicals and moisture.

E. Mechanical and Thermal Properties:

- **Strength and Flexibility:** Materials should handle operational loads and stresses appropriately.
- **Heat Resistance and Insulation:** Necessary for sterilization processes and maintaining specific temperatures.

F. Cost and Availability:

- **Cost-effective:** Materials should fit budget constraints.
- **Reliable Supply:** Ensure availability from reliable suppliers to avoid construction delays.

G. Environmental and Safety Considerations:

- **Non-toxic and Sustainable:** Materials should not emit harmful substances and should be environmentally friendly.

H. Aesthetic and Functional Considerations:

- **Clean Appearance and Functionality:** Materials should provide a professional look and meet specific functional requirements.

I. Compatibility with Equipment:

- **System Integration and Maintenance:** Materials should work well with equipment and be easy to maintain.

J. Fire Safety:

- **Fire Resistance:** Comply with fire safety regulations.

Commonly Used Materials:



1. **Stainless Steel:** Highly resistant to corrosion, easy to clean, and compliant with hygiene standards.
2. **Epoxy Coatings:** Used for flooring and walls due to their durability and cleanability.
3. **PVC and Polypropylene:** For piping systems due to their chemical resistance and ease of installation.
4. **Glass:** For windows and some enclosures due to its chemical resistance and cleanliness.

Theories of corrosion

- Corrosion is a natural process that results in the deterioration of materials, usually metals, through chemical or electrochemical reactions with their environment.
- The primary theories of corrosion include acid corrosion, dry (chemical) corrosion, and galvanic (electrochemical) corrosion.

1. Acid Corrosion (Electrochemical Corrosion in Acidic Environment):

Mechanism:

- Occurs when a metal reacts with an acidic environment, leading to the metal dissolving into ions.

Example Reaction:



Common Metals Affected:

- Iron, steel, and other reactive metals.

Characteristics:

- Localized corrosion, often forming pits or holes.
- Accelerated in the presence of chloride ions (e.g., in seawater).

Prevention:

- Use of corrosion inhibitors.
- Coatings and protective films.
- Selecting more acid-resistant materials like stainless steel.

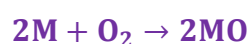
2. Dry Corrosion (Chemical Corrosion):

Mechanism:

- Involves direct chemical reactions between metal and non-liquid substances like gases at high temperatures.

Types:

- **Oxidation:** Metal reacts with oxygen to form an oxide layer.



- **Sulfurization:** Metal reacts with sulfur-containing gases.



- **Halogenation:** Metal reacts with halogens.



Characteristics:

- Usually forms a surface layer of corrosion products (e.g., rust on iron).
- Can be protective if the oxide layer is adherent and non-porous.

Prevention:

- Use of heat-resistant alloys.
- Application of protective coatings.
- Controlled atmospheres in industrial processes.

3. Galvanic Corrosion (Electrochemical Corrosion):

Mechanism:

- Occurs when two dissimilar metals are electrically connected in the presence of an electrolyte (e.g., water).

Process:

- **Anodic Reaction:** The more reactive metal (anode) loses electrons and corrodes.



- **Cathodic Reaction:** The less reactive metal (cathode) gains electrons.



- The anode corrodes faster while the cathode is protected.
- Common in marine environments and in structures with multiple metal types.

Prevention:

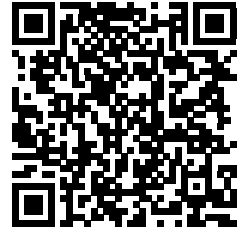


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