

Quality Control

Quality Control Tests for Containers

- Containers are primary packaging materials directly in contact with pharmaceutical formulations.
- They must be inert, safe, robust, chemically compatible, and impermeable to ensure drug stability.

Types of Containers



A. Glass Containers (Ampoules, Vials, Bottles)

- Commonly used for parenteral preparations, oral liquids, tablets, and capsules.
- Classified based on hydrolytic resistance:
 - **Type I:** Borosilicate glass (high resistance)
 - **Type II:** Treated soda-lime glass (moderate resistance)
 - **Type III:** Soda-lime glass (lower resistance)

B. Plastic Containers (Bottles, Sachets, Syringes)

- Made from materials such as:
 - Polyethylene (PE)
 - Polypropylene (PP)
 - Polyethylene terephthalate (PET)
 - Polyvinyl chloride (PVC)
- Commonly used for oral liquids, topical formulations, eye/ear drops, and inhalation devices.

C. Metal Containers

- Less commonly used for direct contact with pharmaceuticals.
- Often used for aerosols and ointments.
- Quality tests include corrosion resistance and protective lining checks.

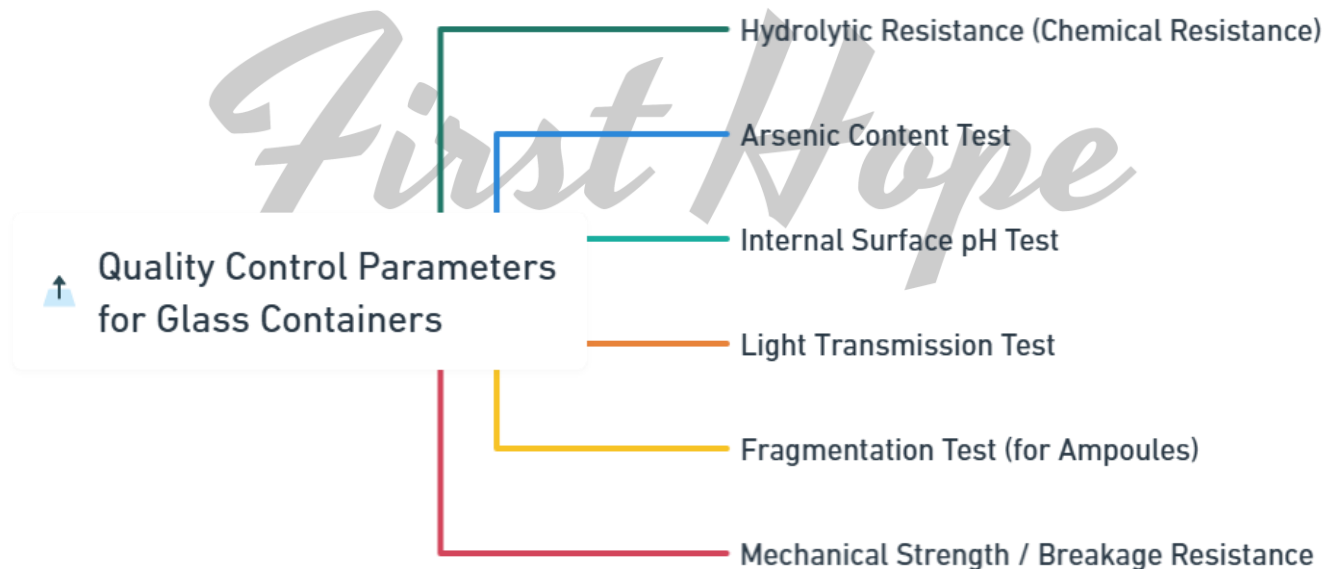
Quality Control Parameters for Glass Containers

Types of glass container

Here is the **types of glass containers** used in the pharmaceutical industry:

Glass Type	Name	Chemical Resistance	Common Pharmaceutical Applications
Type I	Borosilicate Glass	Highest	Injectable products, parenteral preparations, sensitive drugs
Type II	Treated Soda-Lime Glass	High (Treated)	Acidic or neutral injectables, infusions
Type III	Regular Soda-Lime Glass	Moderate	Oral liquids, tablets, capsules, powders
Type NP	General-Purpose Soda-Lime Glass	Lowest	Topical preparations, oral products not sensitive to glass interactions

Quality Control Parameters for Glass Containers



1. Hydrolytic Resistance (Chemical Resistance)

- Evaluates how much alkali is extracted from the glass surface when exposed to water.
- Testing involves:
 - Washing the container
 - Filling with purified water
 - Autoclaving
 - Titrating the solution to measure extracted alkali
- Used to classify glass into **Type I, Type II, or Type III** based on resistance.

2. Arsenic Content Test

- Ensures glass does not leach harmful levels of arsenic.
- Older glass formulations contained trace heavy metals, requiring compliance with pharmacopeial limits.

3. Internal Surface pH Test

- Determines if the container's inner surface alters the product's pH.
- Similar to hydrolytic resistance testing but focuses on pH shifts that could impact drug stability.

4. Light Transmission Test

- Ensures amber or colored glass provides adequate UV and visible light protection.
- Conducted using a spectrophotometer.

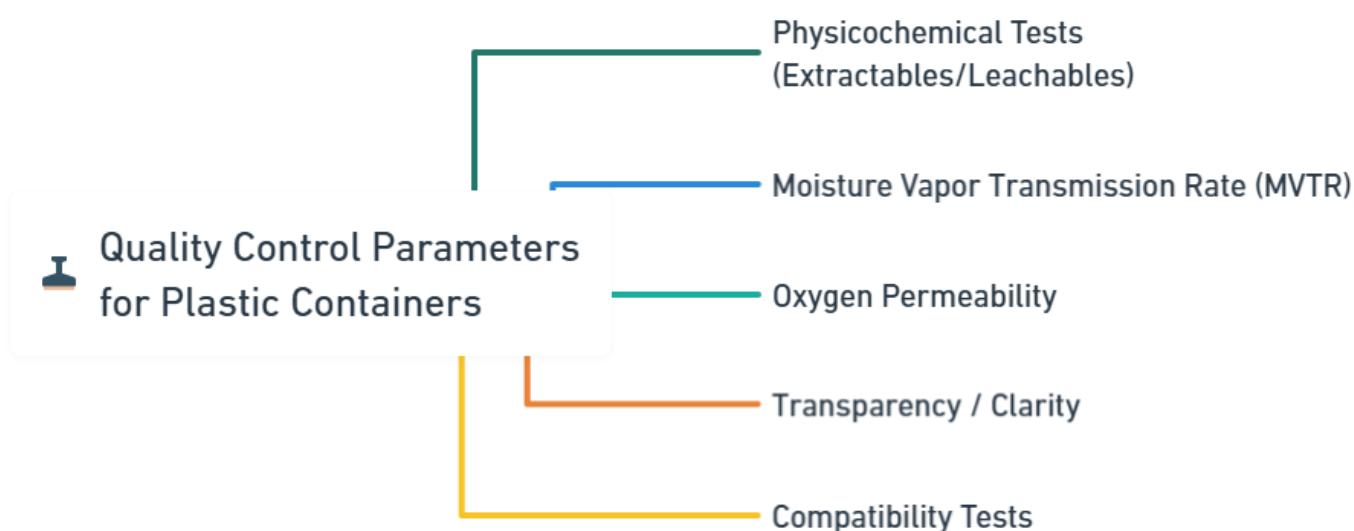
5. Fragmentation Test (for Ampoules)

- Assesses the tendency of ampoules to produce glass particles upon breaking.
- Critical for injectable products to minimize glass particulates.

6. Mechanical Strength / Breakage Resistance

- Evaluates the container's ability to withstand mechanical stress, including:
 - Vertical load resistance
 - Impact resistance

Quality Control Parameters for Plastic Containers



1. Physicochemical Tests (Extractables/Leachables)

- Determines if chemical constituents (e.g., additives, plasticizers) migrate from the plastic into the product.
- Involves exposing the plastic to stress conditions such as solvents, heat, or agitation.
- Analyzed using chromatography or spectroscopic methods.

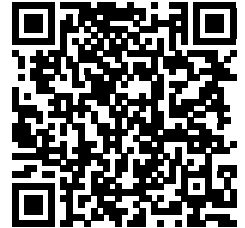


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