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Physicochemical Testing

Physicochemical testing provides an overall assessment of extractable substances and evaluates container components or systems to confirm material purity and the absence of potentially harmful contaminants or manufacturing residues.

Common Routine Physicochemical Tests Include:

USP <661.1> Plastic Materials • USP <661.2> Plastic Packaging System

USP <660> Glass Containers • USP <381> Elastomers • USP <383> Silicone Elastomers

EP 3.1.3 Polyolefins • EP 3.1.4 Polyethylene without Additives • EP 3.1.5 Polyethylene with Additives

EP 3.1.6 Polypropylene • EP3.1.7 Poly (Ethylene - Vinyl Acetate) (PEVA) • EP 3.1.9 Silicone Elastomers

EP 3.1.10 Non-Plasticized Poly (Vinyl Chloride) for Containers for Non-Injectable, Aqueous Solutions

EP 3.1.11 Non-Plasticized Poly (Vinyl Chloride) for Containers for SODFs

EP 3.1.14 Plasticized Poly (Vinyl Chloride) for Containers for Aqueous Solutions for Intravenous Infusion

EP 3.1.15 Polyethylene Terephthalate • EP 3.1.16 Cyclo-olefin Polymers

EP 3.1.17 Cyclo-olefin Copolymers • EP 3.1.18 Styrene Block Copolymers

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PLASTIC ADDITIVES TESTING

Plastic additives are substances intentionally incorporated into plastic materials to achieve desired performance during processing or in the finished container.

- Phenolic antioxidants
- Non-phenolic antioxidants
- Amides and stearates

CONTAINER PERFORMANCE TESTING

Container performance testing evaluates the ability of a package or component to meet its intended function - such as protecting against light or moisture ingress and maintaining an adequate seal.

Common container performance tests include:

- USP <671> Permeation Testing
- USP <671> / USP <661.2>/ USP <660>
- Light Transmission Testing

AUXILIARY PACKAGING COMPONENTS TESTING

Auxiliary packaging components are articles that are used to support or enhance container-closure systems.

Testing as per USP <670> for:

- Cotton, Rayon, and Polyester Coils
- Desiccants and adsorbents: Bentonite, Calcium Chloride (Anhydrous), Calcium Oxide, Activated Carbon, Molecular Sieves, Silica Gel

EXTRACTABLE ELEMENTS TESTING

Quantitative heavy metal screening evaluates the potential for metals from plastic materials and closure systems to migrate into drug substances, excipients, or finished drug products.

- USP <232> and USP <233>
- ICH Q3D (R2)
- EP 2.4.35