

PLASTICS FOR PHARMACEUTICAL USE

SGS Life Sciences will help you ensure that your plastic packaging systems for pharmaceutical use are safe and effective for consumer use. SGS has evaluated the changes to USP 39 (effective May 1, 2016) for container testing. SGS is prepared to perform testing on this revised chapter. The USP has harmonized to the following EP General Chapters:

- (3.1.3) Polyolefins
- (3.1.5) Polyethylene with Additives for Containers for Parenteral Preparations and for Ophthalmic Preparations
- (3.1.6) Polypropylene Containers and Closures for Parenteral Preparations and Ophthalmic Preparations
- (3.1.11) Material Based on Non-Plasticised Poly (vinyl chloride) for Containers for Dry Dosage Forms for Oral Administration
- (3.1.1.4) Materials Based on Plasticised Poly (vinyl chloride) for Containers for Aqueous Solutions for Intravenous Infusion
- (3.1.15) Polyethylene Terephthalate for Containers for Preparations not for Parenteral Use
- (3.2.2.1) Plastic Containers for Aqueous Solutions for Infusion

Minor differences have been noted between the USP and EP chapters.

The USP revision retained tests for Polyethylene Containers; High Density Polyethylene (HDPE) and Low Density Polyethylene (LDPE). Tests which include infrared spectroscopy (IR), differential scanning calorimetry (DSC), heavy metals, nonvolatile residue, and buffering capacity. Polypropylene Containers, including tests for; IR, DSC, heavy metals, and nonvolatile residue. Polyethylene Terephthalate Bottles and Polyethylene Terephthalate G

Containers, including tests for; IR, DSC, Colorant Extraction, heavy metals, total terephthaloyl moieties, and ethylene glycol. Traditional physicochemical tests also remained, including tests for; nonvolatile residue, residue on ignition, heavy metals, and buffering capacity.

The USP added <661.1> which covers Plastic Materials of Construction. This chapter provides the testing guidelines for plastic materials of construction and packaging systems used in the pharmaceutical industry. The following tests have been added:

POLYOLEFINS

Identification by IR and DSC

Physiochemical Tests for absorbance, acidity or alkalinity, and total organic carbon (TOC)

Extractable Metals; aluminum, titanium, and zinc

POLYPROPYLENE

Identification by IR and DSC

Physiochemical Tests for absorbance, acidity or alkalinity, and total organic carbon (TOC)

Extractable Metals; aluminum, chromium, titanium, vanadium, and zinc

POLYETHYLENE TEREPHTHALATE AND POLYETHYLENE TEREPHTHALATE G

Identification by IR and DSC

Physiochemical Tests for absorbance, acidity or alkalinity, and total organic carbon (TOC)

Extractable Metals; aluminum, antimony, barium, cobalt, germanium, manganese, titanium, and zinc

POLYVINYL CHLORIDE

Identification by IR and DSC

Physiochemical Tests for absorbance, acidity or alkalinity, and total organic carbon (TOC)

Extractable Metals; barium, cadmium, calcium, tin and zinc

Plastic Additives; Di(2-ethylhexyl) phthalate, N'N"-Diacylethylenediamines, Epoxidized soya oil, Epoxidized linseed oil, and vinyl chloride

The USP also added <661.2> which covers Plastic Packaging Systems for Pharmaceutical Use. This chapter provides the testing guidelines for packaging systems that are intended to contain a pharmaceutical drug product. The following tests have been added:

PHYSICOCHEMICAL TESTS

Water Extraction; Appearance of Solution, Absorbance, Acidity or Alkalinity

Total Organic Carbon (TOC)

Total Terephthaloyl Moieties in Polyethylene Terephthalate and Polyethylene Terephthalate G Packaging Systems

Ethylene Glycol in Polyethylene Terephthalate and Polyethylene Terephthalate G Packaging Systems

THE EXPERTISE AND CAPACITY OF THE LARGEST GLOBAL NETWORK

SGS has over 15 years experience performing the EP general chapters cited above and over 25 years experience performing USP <661>.

CALL OR EMAIL US NOW

TORONTO

+ 1 905 364 3757

ca.pharmaqc@sgs.com

NEW JERSEY

+ 1 973-244-2435

us.pharmaqc@sgs.com

CHICAGO

+1 847 821 8900

us.pharmaqc@sgs.com

WWW.NA.SGS.COM

WHEN YOU NEED TO BE SURE

The logo for SGS, consisting of the letters 'SGS' in a bold, sans-serif font. The letters are white and are set against a dark grey background. A thin white vertical line is positioned to the right of the letters, and a thin white horizontal line is positioned below the letters, forming an L-shaped frame around the text.