Polysorbate 20, N.F.

Multi-Compendial

Product No. 4116
Specifications current as of: Feb 28 2017

TEST	SPECIFICATION
GMP Manufactured Product	
Meets B.P. Chemical Specifications	
Meets E.P. Chemical Specifications	
Meets JPE Specifications	
Meets N.F. Requirements	
Store in airtight container, protected from light	
CAUTION: For Manufacturing, processing or repackaging	
Bulk Pharmaceutical Chemical	
NF - Acid Value	<= 2.0
NF - Residue on Ignition	<= 0.25 %
NF - Dioxane	<= 10 ppm
NF - Ethylene Oxide	<= 1 ppm
NF - Heavy Metals (as Pb)	<= 10 ppm
NF - Hydroxyl Value, mg KOH/g	96 - 108
NF - Identification A	Passes Test
NF - Identification B	Passes Test
NF - Saponification Value, mg KOH/g	40 - 50
NF - Caproic Acid (Composition of Fatty Acids)	<= 1.0 %
NF - Caprylic Acid (Composition of Fatty Acids)	<= 10.0 %
NF - Capric Acid (Composition of Fatty Acids)	<= 10.0 %
NF - Lauric Acid (Composition of Fatty Acids)	40.0 - 60.0 %
NF - Myristic Acid (Composition of Fatty Acids)	14.0 - 25.0 %
NF - Palmitic Acid (Composition of Fatty Acids)	7.0 - 15.0 %
NF - Stearic Acid (Composition of Fatty Acids)	<= 11.0 %
NF - Oleic Acid (Composition of Fatty Acids)	<= 11.0 %
NF - Linoleic Acid (Composition of Fatty Acids)	<= 3.0 %
NF - Peroxide Value	<= 5.0
NF - Water (H_2O)	<= 3.0 %
Endotoxin Concentration (EU/mL)	<= 10
EP/BP - Acid Value	<= 2.0
EP/BP - Total Ash	<= 0.25 %
EP/BP - Composition of Fatty Acids - Caproic Acid	<= 1.0 %
EP/BP - Composition of Fatty Acids - Caprylic Acid	<= 10.0 %

EP/BP - Composition of Fatty Acids - Capric Acid	<= 10.0 %
EP/BP - Composition of Fatty Acids - Lauric Acid	40.0 - 60.0 %
EP/BP - Composition of Fatty Acids - Myristic Acid	14.0 - 25.0 %
EP/BP -Composition of Fatty Acids - Palmitic Acid	7.0 - 15.0 %
EP/BP - Composition of Fatty Acids - Stearic Acid	<= 7.0 %
EP/BP - Composition of Fatty Acids - Oleic Acid	<= 11.0 %
EP/BP - Composition of Fatty Acids - Linoleic Acid	<= 3.0 %
EP - Heavy Metals	<= 10 ppm
EP - Identification A	Passes Test
EP - Identification D	Passes Test
EP/BP - Hydroxyl Value	96 - 108
EP - Peroxide Value	<= 10.0
EP - Saponification Value	40 - 50
EP - Water (H_2O)	<= 3.0 %
EP - Ethylene Oxide	<= 1 ppm
EP - Dioxan	<= 10 ppm
Water (H_2O)	<= 0.2 %
Appearance	Passes Test
pH of 5% Solution at 25°C	5.0 - 7.0
Arsenic (As)	<= 1.000 ppm
Peroxides, meq/1000g	<= 2.0
Microbiological - Total Plate Count (opg)	<= 100
Microbiological - Escherichia Coli	Passes Test
Microbiological - Pseudomonas aeruginosa	Passes Test
Microbiological - Salmonella	Passes Test
Microbiological - Staphylococcus aureus	Passes Test
Microbiological - Yeast and Mold (opg)	<= 50
JPE - Identification 1	Passes Test
JPE - Identification 2	Passes Test
JPE - Identification 3	Passes Test
JPE - Moisture Content	<= 3.0 %
JPE - Acid Value	<= 4.0
JPE - Saponification Value (mg KOH/g)	43 - 55
JPE - pH	4.0 - 7.0
JPE - Residue on Ignition	<= 0.25 %
JPE - Specific Gravity at 20°C	1.090 - 1.130
JPE - Viscosity (mm^2/S)	350 - 550
JPE - Heavy Metals (as Pb)	<= 20 ppm
JPE - Arsenic (As)	<= 2 ppm

Vegetable Based

This product utilizes ingredients of non-animal origin and non-peanut
origin.
Only Class 2 (1,4 Dioxane, Ethylene Glycol) and Class 3 (acetic acid, 2-propanol) solvents are likely to be prese Class 2 solvents are below the Option 1 limits and any Class 3 solvent is
<0.5%.
Suitable for use in injectable dosage forms.
Metallic Residues: No metal catalysts or metal reagents, as defined by
EMA Guideline EMEA/CHMP/SWP/4446/2000 , are used in the production of
this material.