Polysorbate 80, N.F.

Multi-Compendial

Product No. 4117
Specifications current as of: Feb 28 2017

TEST	SPECIFICATION
GMP Manufactured Product	
Meets B.P. Chemical Specifications	
Meets E.P. Chemical Specifications	
Meets J.P. Chemical Specifications	
Meets N.F. Requirements	
CAUTION: For Manufacturing, processing or repackaging	
Bulk Pharmaceutical Chemical	
NF - Acid Value	<= 2.0
NF - Heavy Metals (as Pb)	<= 10 ppm
NF - Hydroxyl Value	65 - 80
NF - Identification A	Passes Test
NF - Identification B	Passes Test
NF - Residue on Ignition	<= 0.25 %
NF - Saponification Value	45 - 55
NF - Specific Gravity at 25°/25°C	1.06 - 1.09
NF - Viscosity at 25.0°C, cSt	300 - 500
NF - Water (H_2O)	<= 3.0 %
NF - Peroxide Value	<= 10.0
NF - Ethylene Oxide	<= 1 ppm
NF - Dioxane	<= 10 ppm
NF - Composition of Fatty Acids - Myristic Acid	<= 5.0 %
NF - Composition of Fatty Acids - Palmitic Acid	<= 16.0 %
NF - Composition of Fatty Acids - Palmitoleic Acid	<= 8.0 %
NF - Composition of Fatty Acids - Stearic Acid	<= 6.0 %
NF - Composition of Fatty Acids - Oleic Acid	>= 58.0 %
NF - Composition of Fatty Acids - Linoleic Acid	<= 18.0 %
NF - Composition of Fatty Acids - Linolenic Acid	<= 4.0 %
EP - Acid Value	<= 2.0
EP - Total Ash	<= 0.25 %
EP - Heavy Metals (as Pb)	<= 10 ppm
EP - Hydroxyl Value	65 - 80
EP - Identification A	Passes Test
EP - Identification D	Passes Test

EP - Peroxide Value	<= 10.0
EP - Ethylene Oxide	<= 1 ppm
EP - Dioxan	<= 10 ppm
EP - Saponification Value	45 - 55
EP - Water (H_2O)	<= 3.0 %
EP/BP - Composition of Fatty Acids - Myristic Acid	<= 5.0 %
EP/BP - Composition of Fatty Acids - Palmitic Acid	<= 16.0 %
EP/BP - Composition of Fatty Acids - Palmitoleic Acid	<= 8.0 %
EP/BP - Composition of Fatty Acids - Stearic Acid	<= 6.0 %
EP/BP - Composition of Fatty Acids - Oleic Acid	>= 58.0 %
EP/BP - Composition of Fatty Acids - Linoleic Acid	<= 18.0 %
EP/BP - Composition of Fatty Acids - Linolenic Acid	<= 4.0 %
Appearance	Passes Test
JP - Acid Value	<= 2.0
JP - Composition of Fatty Acids - Myristic Acid	<= 5.0 %
JP - Composition of Fatty Acids - Palmitic Acid	<= 16.0 %
JP - Composition of Fatty Acids - Palmitoleic Acid	<= 8.0 %
JP - Composition of Fatty Acids - Stearic Acid	<= 6.0 %
JP - Composition of Fatty Acids - Oleic Acid	>= 58.0 %
JP - Composition of Fatty Acids - Linoleic Acid	<= 18.0 %
JP - Composition of Fatty Acids - Linolenic Acid	<= 4.0 %
JP - Dioxane	<= 10 ppm
JP - Ethylene Oxide	<= 1 ppm
JP - Heavy Metals (as Pb)	<= 20 ppm
JP - Hydroxyl Value, meq KOH/g	65 - 80
JP - Identification	Passes Test
JP - Peroxide Value	<= 10.0
JP - Residue on Ignition	<= 0.25 %
JP - Water (H_2O)	<= 3.0 %
JP - Saponification Value	45 - 55
Additional Tests - Color (Gardner)	<= 7
Additional Tests - Odor (Faint)	Passes Test
Additional Tests - Water (H_2O)	<= 0.2 %
Additional Tests - Peroxides, meq/1000g	<= 2.0
Additional Tests - Endotoxin Concentration (EU/mL)	<= 10
Free Ethylene Oxide	<= 1 ppm
1,4-Dioxane	<= 5 ppm
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
Residual Solvents - Ethylene Glycol, For Information Only	
Residual Solvents - Acetic Acid, For Information Only	
Residual Solvents - 2-Propanol, For Information Only	
Vegetable Based	
This product utilizes ingredients of non-animal origin and non-peanut	
origin.	
Suitable for use in the manufacture of parenteral dosage forms.	
Only Class 2 (1,4 Dioxane, Ethylene Glycol) and Class 3 (acetic acid,	
2-propanol) solvents are likely to be present. Class 2 solvents are below the Option 1 limits and any Class 3 solv	
<0.5%.	
Typical Oleic Acid Content, 77%	
TWEEN 80-LQ-(MH)™ is a trademark of Croda International Plc.	
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.	
Due to the anhydrous nature of this product, sodium oleate, a	
carboxylate salt/soap formed naturally in the process and which can be	
white to brown in color, can precipitate with time and may affect	
product viscosity.	