



Polysorbate 80, N.F. Multi-Compendial

Product No. 4117
Specifications current as of: Jun 8
2011

TEST	SPECIFICATION
GMP Manufactured Product	
Vegetable Based	
This product utilizes ingredients of non-animal origin and non-peanut origin.	
Meets N.F. Requirements	
Acid Value	max. 2.0
Heavy Metals (as Pb)	max. 10 ppm
Hydroxyl Value	65 - 80
Identification	Passes Test
Residue on Ignition	max. 0.25 %
Saponification Value	45 - 55
Specific Gravity at 25°/25°C	1.06 - 1.09
Viscosity at 25.0°C, cSt	300 - 500
Water (H ₂ O)	max. 3.0 %
Peroxide Value	max. 10
Ethylene Oxide	max. 1 ppm
Dioxane	max. 10 ppm
Composition of Fatty Acids	
Myristic Acid	max. 5.0 %
Palmitic Acid	max. 16.0 %
Palmitoleic Acid	max. 8.0 %
Stearic Acid	max. 6.0 %
Oleic Acid	min. 58.0 %
Linoleic Acid	max. 18.0 %
Linolenic Acid	max. 4.0 %
Meets Ph.Eur. Chemical Specifications	
Acid Value	max. 2.0
Total Ash	max. 0.25 %
Heavy Metals (as Pb)	max. 10 ppm
Hydroxyl Value	65 - 80
Identification A	Passes Test

Identification D	Passes Test
Peroxide	max. 10.0
Ethylene Oxide	max. 1 ppm
Dioxan	max. 10 ppm
Saponification Value	45 - 55
Water (H ₂ O)	max. 3.0 %
Composition of Fatty Acids	
Myristic Acid	max. 5.0 %
Palmitic Acid	max. 16.0 %
Palmitoleic Acid	max. 8.0 %
Stearic Acid	max. 6.0 %
Oleic Acid	min. 58.0 %
Linoleic Acid	max. 18.0 %
Linolenic Acid	max. 4.0 %
Meets JP Chemical Specifications	
Appearance	Passes Test
pH of 5% Aqueous Solution	5.5 - 7.5
Identification A	Passes Test
Identification B	Passes Test
Identification C	Passes Test
Identification D	Passes Test
Viscosity at 25.0°C, (mm/S) ²	345 - 445
Specific Gravity at 20°/20°C	1.065 - 1.095
Acid Value	max. 2.0
Saponification Value	45 - 55
Iodine Value	19 - 24
Heavy Metals (as Pb)	max. 20 ppm
Arsenic (As)	max. 2 ppm
Water (H ₂ O)	max. 3.0 %
Residue on Ignition	max. 0.1 %
Additional Tests:	
Color (Gardner)	max. 7
Odor (Faint)	Passes Test
Water (H ₂ O)	max. 0.2 %
Peroxides, meq/1000g	max. 2.0

Endotoxin Concentration (EU/mL)	max. 10
Organic Volatile Impurities:	
Free Ethylene Oxide	max. 1 ppm
1,4-Dioxane	max. 5 ppm
Microbiological:	
Total Plate Count (opg)	max. 100
Escherichia Coli	Passes Test
Pseudomonas aeruginosa	Passes Test
Salmonella	Passes Test
Staphylococcus aureus	Passes Test
Yeast and Mold (opg)	max. 50
Residual Solvents:	
Ethylene Glycol	Actual Value Reported
Acetic Acid	Actual Value Reported
2-Propanol	Actual Value Reported

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 solvent is <0.5%.

Bulk Pharmaceutical Chemical

Typical Oleic Acid Content, 77%

CAUTION: For manufacturing, processing or repacking.

For a Certificate of Lot Analysis, visit www.avantormaterials.com.

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