

Polysorbate 20, N.F.  
Multi-Compendial



Material No.: 4116-03

Revision No.: 0

## Product Specification

Meets N.F. Requirements, Meets JPE Specifications, Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications,  
GMP Manufactured Product

Test	Specification
NF - Acid Value	≤ 2.0
NF - Residue on Ignition	≤ 0.25 %
NF - Dioxane	≤ 10 ppm
NF - Ethylene Oxide	≤ 1 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 <sub>2</sub> O)	≤ 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 %

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For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700

Avantor Performance Materials, LLC

100 Matsonford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone 610.386.1700

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Test	Specification
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 - 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 <sub>2</sub> O)	≤ 3.0 %
EP - Ethylene Oxide	≤ 1 ppm
EP - Dioxan	≤ 10 ppm
Appearance	Passes Test
pH of 5% Solution at 25°C	5.0 - 7.0
Arsenic (As)	≤ 1 ppm
Peroxide Value, meqO <sub>2</sub> /kg	≤ 2.0
Microbiological - Total Aerobic Microbial Count (cfu/g)	≤ 100
Microbiological - Escherichia Coli	Passes Test
Microbiological - Pseudomonas aeruginosa	Passes Test
Microbiological - Salmonella	Passes Test
Microbiological - Staphylococcus aureus	Passes Test
Microbiological - Total Yeast and Mold Count (cfu/g)	≤ 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 <sup>2</sup> /S)	350 - 550
JPE - Heavy Metals (as Pb)	≤ 20 ppm
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Test	Specification
JPE - Arsenic (As)	≤ 2 ppm
Ethylene Glycol	≤ 0.10 %
Diethylene Glycol	≤ 0.10 %

GMP Manufactured Product

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

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 (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%.

Suitable for use in injectable dosage forms.

Elemental Impurities (USP 232, EP 5.20) - Information on elemental impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Storage Condition: Store in airtight container, protected from light

Packaging Site: Paris Mfg Ctr & DC

  
Jamie Ethier  
Vice President Global Quality

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