Polysorbate 20, N.F.
Multi-Compendial

Material No.: 4116-07
:
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_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 – Cap	≤ 1,0 %
EP/BP – Composition of Fatty Acids – Cap	≤ 10,0 %
EP/BP – Composition of Fatty Acids – Cap	≤ 10,0 %
EP/BP – Composition of Fatty Acids – Lau	40,0 – 60,0 %
EP/BP – Composition of Fatty Acids – Myr	14,0 – 25,0 %
EP/BP –Composition of Fatty Acids – Palm	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 - Ste	≤ 7,0 %
EP/BP - Composition of Fatty Acids - Ole	≤ 11,0 %
EP/BP - Composition of Fatty Acids - Lin	≤ 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_2O)	≤ 3,0 %
EP - Ethylene Oxide	≤ 1,0 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_2/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 C	≤ 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

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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: Aurora Mfg Ctr & DC