Polysorbate 80, N.F.
Multi-Compendial

Material No.: 4117-04
Batch No.: 22L1661017
Manufactured Date: 2022-02-26
Retest Date: 2027-02-25
Release Date: 2023-01-20
Revision No.: 0

Certificate of Analysis

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

Test	Specification	Result
NF – Acid Value	≤ 2.0	1.2
NF – Hydroxyl Value	65 – 80	73
NF – Identification A	Passes Test	Passes Test
NF – Identification B	Passes Test	Passes Test
NF – Residue on Ignition	≤ 0.25 %	0.10 %
NF – Saponification Value	45 – 55	49
NF – Specific Gravity at 25°C	1.06 – 1.09	1.07
NF – Viscosity at 25°C, cSt	300 – 500	416
NF – Water (H_2O)	≤ 3.0 %	0.1 %
NF – Peroxide Value	≤ 10.0	< 0.1
NF – Ethylene Oxide	≤ 1 ppm	< 1 ppm
NF – Dioxane	≤ 10 ppm	< 10 ppm
NF – Composition of Fatty Acids – Myristic Acid	≤ 5.0 %	0.4 %
NF – Composition of Fatty Acids – Palmitic Acid	≤ 16.0 %	8.0 %
NF – Composition of Fatty Acids – Palmitoleic Acid	≤ 8.0 %	< 0.1 %
NF – Composition of Fatty Acids – Stearic Acid	≤ 6.0 %	1.8 %
NF – Composition of Fatty Acids – Oleic Acid	≥ 58.0 %	72.5 %
NF – Composition of Fatty Acids – Linoleic Acid	≤ 18.0 %	< 0.1 %
NF – Composition of Fatty Acids – Linolenic Acid	≤ 4.0 %	< 0.1 %
EP – Acid Value	≤ 2.0	1.2
EP – Total Ash	≤ 0.25 %	0.10 %
EP – Hydroxyl Value	65 – 80	73
EP – Identification A	Passes Test	Passes Test
EP – Identification D	Passes Test	Passes Test
EP – Peroxide Value	≤ 10.0	< 0.1
EP – Ethylene Oxide	≤ 1 ppm	< 1 ppm
EP – Dioxan	≤ 10 ppm	< 10 ppm
EP – Saponification Value	45 – 55	48

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For questions on this Certificate of Analysis 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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Material No.: 4117-04
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Test	Specification	Result
EP - Water (H_2O)	≤ 3.0 %	0.1 %
EP/BP - Composition of Fatty Acids - Myristic Acid	≤ 5.0 %	0.4 %
EP/BP - Composition of Fatty Acids - Palmitic Acid	≤ 16.0 %	8.0 %
EP/BP - Composition of Fatty Acids - Palmitoleic Acid	≤ 8.0 %	< 0.1 %
EP/BP - Composition of Fatty Acids - Stearic Acid	≤ 6.0 %	1.8 %
EP/BP - Composition of Fatty Acids - Oleic Acid	≥ 58.0 %	72.5 %
EP/BP - Composition of Fatty Acids - Linoleic Acid	≤ 18.0 %	< 0.1 %
EP/BP - Composition of Fatty Acids - Linolenic Acid	≤ 4.0 %	< 0.1 %
Appearance	Passes Test	Passes Test
JP - Acid Value	≤ 2.0	1.2
JP - Composition of Fatty Acids - Myristic Acid	≤ 5.0 %	0.4 %
JP - Composition of Fatty Acids - Palmitic Acid	≤ 16.0 %	8.0 %
JP - Composition of Fatty Acids - Palmitoleic Acid	≤ 8.0 %	< 0.1 %
JP - Composition of Fatty Acids - Stearic Acid	≤ 6.0 %	1.8 %
JP - Composition of Fatty Acids - Oleic Acid	≥ 58.0 %	72.5 %
JP - Composition of Fatty Acids - Linoleic Acid	≤ 18.0 %	< 0.1 %
JP - Composition of Fatty Acids - Linolenic Acid	≤ 4.0 %	< 0.1 %
JP - Dioxane	≤ 10 ppm	< 10 ppm
JP - Ethylene Oxide	≤ 1 ppm	< 1 ppm
JP - Heavy Metals (as Pb)	≤ 20 ppm	< 20 ppm
JP - Hydroxyl Value, meq KOH/g	65 - 80	73
JP - Identification	Passes Test	Passes Test
JP - Peroxide Value	≤ 10.0	< 0.1
JP - Residue on Ignition	≤ 0.25 %	0.10 %
JP - Water (H_2O)	≤ 3.0 %	0.1 %
JP - Saponification Value	45 - 55	48
Additional Tests - Color (Gardner)	≤ 7	6
Additional Tests - Odor (Faint)	Passes Test	Passes Test
Additional Tests - Water (H_2O)	≤ 0.2 %	0.1 %
Additional Tests - Peroxide Value, meqO_2/kg	≤ 2.0	< 0.1
Additional Tests - Endotoxin Concentration (EU/mL)	≤ 10	< 10
Free Ethylene Oxide	≤ 1 ppm	< 1 ppm

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Test	Specification	Result
1,4-Dioxane	≤ 5 ppm	< 5 ppm
Microbiological - Total Aerobic Microbial Count (cfu/g)	≤ 100	< 10
Microbiological - Escherichia Coli	Passes Test	Passes Test
Microbiological - Pseudomonas aeruginosa	Passes Test	Passes Test
Microbiological - Salmonella	Passes Test	Passes Test
Microbiological - Staphylococcus aureus	Passes Test	Passes Test
Microbiological - Total Yeast and Mold Count (cfu/g)	≤ 50	< 10
Residual Solvents - Ethylene Glycol, For Information Only		< 1 ppm
Residual Solvents - Acetic Acid, For Information Only		369 ppm
Residual Solvents - 2-Propanol, For Information Only		2 ppm

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.
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%.
Typical Oleic Acid Content, 77%
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.
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.

Country of Origin: USA
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0103002
Manufacturer source batch: 0001942567

Jamie Ethier
Vice President Global Quality