

Certificate of Analysis

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

Test	Specification	Result
NF – Acid Value	≤ 2.0	1.2
NF – Residue on Ignition	≤ 0.25 %	0.05 %
NF – Dioxane	≤ 10 ppm	< 10 ppm
NF – Ethylene Oxide	≤ 1 ppm	< 1 ppm
NF – Hydroxyl Value, mg KOH/g	96 – 108	106
NF – Identification A	Passes Test	Passes Test
NF – Identification B	Passes Test	Passes Test
NF – Saponification Value, mg KOH/g	40 – 50	45
NF – Caproic Acid (Composition of Fatty Acids)	≤ 1.0 %	< 0.1 %
NF – Caprylic Acid (Composition of Fatty Acids)	≤ 10.0 %	1.9 %
NF – Capric Acid (Composition of Fatty Acids)	≤ 10.0 %	2.6 %
NF – Lauric Acid (Composition of Fatty Acids)	40.0 – 60.0 %	53.2 %
NF – Myristic Acid (Composition of Fatty Acids)	14.0 – 25.0 %	18.9 %
NF – Palmitic Acid (Composition of Fatty Acids)	7.0 – 15.0 %	12.5 %
NF – Stearic Acid (Composition of Fatty Acids)	≤ 11.0 %	5.8 %
NF – Oleic Acid (Composition of Fatty Acids)	≤ 11.0 %	5.1 %
NF – Linoleic Acid (Composition of Fatty Acids)	≤ 3.0 %	< 0.1 %
NF – Peroxide Value	≤ 5.0	< 0.1
NF – Water (H ₂ O)	≤ 3.0 %	0.1 %
Endotoxin Concentration (EU/mL)	≤ 10	< 10
EP/BP – Acid Value	≤ 2.0	1.3
EP/BP – Total Ash	≤ 0.25 %	0.06 %
EP/BP – Composition of Fatty Acids – Caproic Acid	≤ 1.0 %	< 0.1 %
EP/BP – Composition of Fatty Acids – Caprylic Acid	≤ 10.0 %	2.3 %
EP/BP – Composition of Fatty Acids – Capric Acid	≤ 10.0 %	2.8 %
EP/BP – Composition of Fatty Acids – Lauric Acid	40.0 – 60.0 %	53.2 %
EP/BP – Composition of Fatty Acids – Myristic Acid	14.0 – 25.0 %	18.4 %
EP/BP – Composition of Fatty Acids – Palmitic Acid	7.0 – 15.0 %	12.0 %

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Test	Specification	Result
EP/BP – Composition of Fatty Acids – Stearic Acid	≤ 7.0 %	5.6 %
EP/BP – Composition of Fatty Acids – Oleic Acid	≤ 11.0 %	4.9 %
EP/BP – Composition of Fatty Acids – Linoleic Acid	≤ 3.0 %	< 0.1 %
EP – Identification A	Passes Test	Passes Test
EP – Identification D	Passes Test	Passes Test
EP/BP – Hydroxyl Value	96 – 108	105
EP – Peroxide Value	≤ 10.0	< 0.1
EP – Saponification Value	40 – 50	46
EP – Water (H ₂ O)	≤ 3.0 %	0.1 %
EP – Ethylene Oxide	≤ 1 ppm	< 1 ppm
EP – Dioxan	≤ 10 ppm	< 10 ppm
Water (H ₂ O)	≤ 0.2 %	0.1 %
Appearance	Passes Test	Passes Test
pH of 5% Solution at 25°C	5.0 – 7.0	5.5
Arsenic (As)	≤ 1 ppm	< 1 ppm
Peroxide Value, meqO ₂ /kg	≤ 2.0	< 0.1
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
JPE – Identification 1	Passes Test	Passes Test
JPE – Identification 2	Passes Test	Passes Test
JPE – Identification 3	Passes Test	Passes Test
JPE – Moisture Content	≤ 3.0 %	0.1 %
JPE – Acid Value	≤ 4.0	1.2
JPE – Saponification Value (mg KOH/g)	43 – 55	45
JPE – pH	4.0 – 7.0	5.7
JPE – Residue on Ignition	≤ 0.25 %	0.16 %
JPE – Specific Gravity at 20°C	1.090 – 1.130	1.108
JPE – Viscosity (mm ² /S)	350 – 550	475

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Polysorbate 20, N.F.
Multi-Compendial



Material No.: 4116-04
Batch No.: 22E0461025

Test	Specification	Result
JPE - Heavy Metals (as Pb)	≤ 20 ppm	< 20 ppm
JPE - Arsenic (As)	≤ 2 ppm	< 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.

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%.

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

Country of Origin: USA

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0103002

Manufacturer source batch: 0001682055

Jamie Ethier
Vice President Global Quality

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.386.1700
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