

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 ₂ 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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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 ₂ O)	≤ 3.0 %
EP – Ethylene Oxide	≤ 1 ppm
EP – Dioxan	≤ 10 ppm
Water (H ₂ O)	≤ 0.2 %
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 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 ² /S)	350 – 550

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Test	Specification
JPE – Heavy Metals (as Pb)	≤ 20 ppm
JPE – Arsenic (As)	≤ 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

Packaging Site: Paris Mfg Ctr & DC



Jamie Ethier
Vice President Global Quality