

Product Specification

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

Test	Specification
NF – Acid Value	≤ 2.0
NF – Hydroxyl Value	65 – 80
NF – Identification A	Passes Test
NF – Identification B	Passes Test
NF – Residue on Ignition	≤ 0.25 %
NF – Saponification Value	45 – 55
NF – Specific Gravity at 25°C	1.06 – 1.09
NF – Viscosity at 25°C, cSt	300 – 500
NF – Water (H ₂ O)	≤ 3.0 %
NF – Peroxide Value	≤ 10.0
NF – Ethylene Oxide	≤ 1 ppm
NF – Dioxane	≤ 10 ppm
NF – Composition of Fatty Acids – Myristic Acid	≤ 5.0 %
NF – Composition of Fatty Acids – Palmitic Acid	≤ 16.0 %
NF – Composition of Fatty Acids – Palmitoleic Acid	≤ 8.0 %
NF – Composition of Fatty Acids – Stearic Acid	≤ 6.0 %
NF – Composition of Fatty Acids – Oleic Acid	≥ 58.0 %
NF – Composition of Fatty Acids – Linoleic Acid	≤ 18.0 %
NF – Composition of Fatty Acids – Linolenic Acid	≤ 4.0 %
EP – Acid Value	≤ 2.0
EP – Total Ash	≤ 0.25 %
EP – Hydroxyl Value	65 – 80
EP – Identification A	Passes Test
EP – Identification D	Passes Test
EP – Peroxide Value	≤ 10.0
EP – Ethylene Oxide	≤ 1 ppm
EP – Dioxan	≤ 10 ppm
EP – Saponification Value	45 – 55

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Test	Specification
EP – Water (H ₂ O)	≤ 3.0 %
EP/BP – Composition of Fatty Acids – Myristic Acid	≤ 5.0 %
EP/BP – Composition of Fatty Acids – Palmitic Acid	≤ 16.0 %
EP/BP – Composition of Fatty Acids – Palmitoleic Acid	≤ 8.0 %
EP/BP – Composition of Fatty Acids – Stearic Acid	≤ 6.0 %
EP/BP – Composition of Fatty Acids – Oleic Acid	≥ 58.0 %
EP/BP – Composition of Fatty Acids – Linoleic Acid	≤ 18.0 %
EP/BP – Composition of Fatty Acids – Linolenic Acid	≤ 4.0 %
JP – Acid Value	≤ 2.0
JP – Composition of Fatty Acids – Myristic Acid	≤ 5.0 %
JP – Composition of Fatty Acids – Palmitic Acid	≤ 16.0 %
JP – Composition of Fatty Acids – Palmitoleic Acid	≤ 8.0 %
JP – Composition of Fatty Acids – Stearic Acid	≤ 6.0 %
JP – Composition of Fatty Acids – Oleic Acid	≥ 58.0 %
JP – Composition of Fatty Acids – Linoleic Acid	≤ 18.0 %
JP – Composition of Fatty Acids – Linolenic Acid	≤ 4.0 %
JP – Dioxane	≤ 10 ppm
JP – Ethylene Oxide	≤ 1 ppm
JP – Heavy Metals (as Pb)	≤ 20 ppm
JP – Hydroxyl Value, meq KOH/g	65 – 80
JP – Identification	Passes Test
JP – Peroxide Value	≤ 10.0
JP – Residue on Ignition	≤ 0.25 %
JP – Water (H ₂ O)	≤ 3.0 %
JP – Saponification Value	45 – 55
ChP – Relative Density @ 20 °C	1.06 – 1.09
ChP – Viscosity @ 25 °C	350 – 550 mm ² /s
ChP – Acid Value	≤ 2.0
ChP – Saponification Value	45 – 55
ChP – Hydroxyl Value	65 – 80
ChP – Iodine Value	18 – 24
ChP – Peroxide Value	≤ 10

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Test	Specification
ChP – Identification 1	Passes Test
ChP – Identification 2	Passes Test
ChP – Identification 3	Passes Test
ChP – Identification 4	Passes Test
ChP – Acidity or Alkalinity	5.0 – 7.5
ChP – Color	Passes Test
ChP – Ethylene glycol	≤ 0.01 %
ChP – Diethylene glycol	≤ 0.01 %
ChP – Ethylene oxide	≤ 0.0001 %
ChP – Dioxane	≤ 0.001 %
ChP – Freezing Test	Passes Test
ChP – Water	≤ 3.0 %
ChP – Residue on ignition	≤ 0.2 %
ChP – Heavy Metals	≤ 0.001 %
ChP – Arsenic (As)	≤ 0.0002 %
ChP – Fatty acid composition: oleic acid	≥ 58.0 %
ChP – Fatty Acid Composition: myristic a	≤ 5.0 %
ChP – Fatty Acid Composition: palmitic a	≤ 16.0 %
ChP – Fatty Acid Composition: palmitolei	≤ 8.0 %
ChP – Fatty Acid Composition: stearic ac	≤ 6.0 %
ChP – Fatty Acid Composition: linoleic a	≤ 18.0 %
ChP – Fatty Acid Composition: linolenic	≤ 4.0 %
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
Appearance	Passes Test
Additional Tests – Color (Gardner)	≤ 7
Additional Tests – Odor (Faint)	Passes Test
Additional Tests – Peroxide Value, meqO ₂ /kg	≤ 2.0
Additional Tests – Endotoxin Concentration (EU/mL)	≤ 10

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Test	Specification
Free Ethylene Oxide	≤ 1 ppm
1,4-Dioxane	≤ 5 ppm
Residual Solvents – Ethylene Glycol, For Information Only	ppm
Residual Solvents – Acetic Acid, For Information Only	ppm
Residual Solvents – 2-Propanol, For Information Only	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.

Packaging Site: Paris Mfg Ctr & DC