

## 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 <sub>2</sub> 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 <sub>2</sub> O)                           | ≤ 3.0 %       |
| EP – Ethylene Oxide                                     | ≤ 1 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 <sub>2</sub> /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 <sup>2</sup> /S)                    | 350 – 550     |
| JPE – Heavy Metals (as Pb)                              | ≤ 20 ppm      |

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Polysorbate 20, N.F.  
Multi-Compendial



Material No.: 4116-06

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| Test               | Specification |
|--------------------|---------------|
| JPE – Arsenic (As) | ≤ 2 ppm       |

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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: Paris Mfg Ctr & DC

For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700

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