

Polysorbate 80, N.F.
Multi-Compendial

TWEEN 80 HP-LQ-(MH)



Material No.: 4117-04
Batch No.: 0000107815
Manufactured Date: 2015/02/03
Retest Date: 2020/02/02

Certificate of Analysis

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

| Test | Specification | Result |
|--|---------------|--------|
| NF - Acid Value | <= 2.0 | 1.2 |
| NF - Heavy Metals (as Pb) | <= 10 ppm | < 10 |
| NF - Hydroxyl Value | 65 - 80 | 75 |
| NF - Identification A | Passes Test | PT |
| NF - Identification B | Passes Test | PT |
| NF - Residue on Ignition | <= 0.25 % | 0.10 |
| NF - Saponification Value | 45 - 55 | 52 |
| NF - Specific Gravity at 25°/25°C | 1.06 - 1.09 | 1.07 |
| NF - Viscosity at 25.0°C, cSt | 300 - 500 | 352 |
| NF - Water (H ₂ O) | <= 3.0 % | 0.1 |
| NF - Peroxide Value | <= 10 | <0.1 |
| NF - Ethylene Oxide | <= 1 ppm | < 1 |
| NF - Dioxane | <= 10 ppm | <10 |
| NF - Composition of Fatty Acids - Myristic Acid | <= 5.0 % | 0.1 |
| NF - Composition of Fatty Acids - Palmitic Acid | <= 16.0 % | 8.2 |
| NF - Composition of Fatty Acids - Palmitoleic Acid | <= 8.0 % | < 0.1 |
| NF - Composition of Fatty Acids - Stearic Acid | <= 6.0 % | 2.3 |
| NF - Composition of Fatty Acids - Oleic Acid | >= 58.0 % | 73.6 |
| 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 - Heavy Metals (as Pb) | <= 10 ppm | < 10 |

| Test | Specification | Result |
|---|---------------|--------|
| EP - Hydroxyl Value | 65 - 80 | 75 |
| EP - Identification A | Passes Test | PT |
| EP - Identification D | Passes Test | PT |
| EP - Peroxide Value | <= 10.0 | 0.2 |
| EP - Ethylene Oxide | <= 1 ppm | < 1 |
| EP - Dioxan | <= 10 ppm | <10 |
| EP - Saponification Value | 45 - 55 | 52 |
| EP - Water (H ₂ O) | <= 3.0 % | 0.1 |
| EP/BP - Composition of Fatty Acids - Myristic Acid | <= 5.0 % | 0.1 |
| EP/BP - Composition of Fatty Acids - Palmitic Acid | <= 16.0 % | 8.2 |
| EP/BP - Composition of Fatty Acids - Palmitoleic Acid | <= 8.0 % | < 0.1 |
| EP/BP - Composition of Fatty Acids - Stearic Acid | <= 6.0 % | 2.3 |
| EP/BP - Composition of Fatty Acids - Oleic Acid | >= 58.0 % | 73.6 |
| 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 | PT |
| JP - Acid Value | <= 2.0 | 1.2 |
| JP - Composition of Fatty Acids - Myristic Acid | <= 5.0 % | 0.1 |
| JP - Composition of Fatty Acids - Palmitic Acid | <= 16.0 % | 8.2 |
| JP - Composition of Fatty Acids - Palmitoleic Acid | <= 8.0 % | < 0.1 |
| JP - Composition of Fatty Acids - Stearic Acid | <= 6.0 % | 2.3 |
| JP - Composition of Fatty Acids - Oleic Acid | >= 58.0 % | 73.6 |
| 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 | < 1 |
| JP - Ethylene Oxide | <= 1 ppm | < 1 |
| JP - Heavy Metals (as Pb) | <= 20 ppm | < 20 |
| JP - Hydroxyl Value, meq KOH/g | 65 - 80 | 75 |
| JP - Identification | Passes Test | PT |
| JP - Peroxide Value | <= 10.0 | 0.2 |
| JP - Residue on Ignition | <= 0.25 % | 0.10 |
| JP - Water (H ₂ O) | <= 3.0 % | 0.1 |
| JP - Saponification Value | 45 - 55 | 52 |
| Additional Tests - Color (Gardner) | <= 7 | 5 |
| Additional Tests - Odor (Faint) | Passes Test | PT |

| Test | Specification | Result |
|---|---------------|--------|
| Additional Tests – Water (H ₂ O) | <= 0.2 % | 0.1 |
| Additional Tests – Peroxides, meq/1000g | <= 2.0 | 0.2 |
| Additional Tests – Endotoxin Concentration (EU/mL) | <= 10 | < 10 |
| Free Ethylene Oxide | <= 1 ppm | < 1 |
| 1,4-Dioxane | <= 5 ppm | < 1 |
| Microbiological – Total Plate Count (opg) | <= 100 | < 10 |
| Microbiological – Escherichia Coli | Passes Test | PT |
| Microbiological – Pseudomonas aeruginosa | Passes Test | PT |
| Microbiological – Salmonella | Passes Test | PT |
| Microbiological – Staphylococcus aureus | Passes Test | PT |
| Microbiological – Yeast and Mold (opg) | <= 50 | < 10 |
| Residual Solvents – Ethylene Glycol, For Information Only | ppm | 68 |
| Residual Solvents – Acetic Acid, For Information Only | ppm | 353 |
| Residual Solvents – 2-Propanol, For Information Only | ppm | 1 |

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%

TWEEN 80-LQ-(MH)[™] is a trademark of Croda International Plc.


Metallic Residues: No metal catalysts or metal reagents, as defined by EMA Guideline EMEA/CHMP/SWP/4446/2000, are used in the production of this material.

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: US
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0103002
Manufacturer source batch: 0000957364



Phillipsburg, NJ 9001:2008, 14001:2004, FSSC 22000
Paris, KY 9001:2008
Mexico City, Mexico 9001:2008
Deventer, The Netherlands 9001:2008, 14001:2004, 13485:2003
Gliwice, Poland 9001:2008, 17025:2005
Selangor, Malaysia 9001:2008
Dehradun, India, 9001:2008, 14001:2004, 13485:2003
Mumbai, India, 9001:2008, 17025:2005
Panoli, India 9001:2008



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Vice President Global Quality

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.573.2600
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