

Polysorbate 20, N.F.
Multi-Compendial

TWEEN 20 HP-LQ-(MH)



Material No.: 4116-02
Batch No.: 0000180242
Manufactured Date: 2016/11/29
Retest Date: 2021/11/28

Certificate of Analysis

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

Test	Specification	Result
NF - Acid Value	≤ 2.0	1.4
NF - Residue on Ignition	$\leq 0.25 \%$	0.14
NF - Dioxane	$\leq 10 \text{ ppm}$	< 10
NF - Ethylene Oxide	$\leq 1 \text{ ppm}$	< 1
NF - Heavy Metals (as Pb)	$\leq 10 \text{ ppm}$	< 10
NF - Hydroxyl Value, mg KOH/g	96 - 108	99
NF - Identification A	Passes Test	PT
NF - Identification B	Passes Test	PT
NF - Saponification Value, mg KOH/g	40 - 50	47
NF - Caproic Acid (Composition of Fatty Acids)	$\leq 1.0 \%$	< 0.1
NF - Caprylic Acid (Composition of Fatty Acids)	$\leq 10.0 \%$	1.9
NF - Capric Acid (Composition of Fatty Acids)	$\leq 10.0 \%$	2.5
NF - Lauric Acid (Composition of Fatty Acids)	40.0 - 60.0 %	50.2
NF - Myristic Acid (Composition of Fatty Acids)	14.0 - 25.0 %	18.7
NF - Palmitic Acid (Composition of Fatty Acids)	7.0 - 15.0 %	12.7
NF - Stearic Acid (Composition of Fatty Acids)	$\leq 11.0 \%$	7.0
NF - Oleic Acid (Composition of Fatty Acids)	$\leq 11.0 \%$	5.7
NF - Linoleic Acid (Composition of Fatty Acids)	$\leq 3.0 \%$	< 0.1
NF - Peroxide Value	≤ 5.0	< 0.1
NF - Water (H ₂ O)	$\leq 3.0 \%$	0.1
Endotoxin Concentration (EU/mL)	≤ 10	< 10
EP/BP - Acid Value	≤ 2.0	1.3
EP/BP - Total Ash	$\leq 0.25 \%$	0.14

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.573.2600
Avantor Performance Materials, LLC.

3477 Corporate Parkway, Center Valley, PA 18034. U.S.A. Phone: 610.573.2600 . Fax: 610.573.2610

Test	Specification	Result
EP/BP – Composition of Fatty Acids – Caproic Acid	<= 1.0 %	< 0.1
EP/BP – Composition of Fatty Acids – Caprylic Acid	<= 10.0 %	2.4
EP/BP – Composition of Fatty Acids – Capric Acid	<= 10.0 %	2.8
EP/BP – Composition of Fatty Acids – Lauric Acid	40.0 – 60.0 %	51.9
EP/BP – Composition of Fatty Acids – Myristic Acid	14.0 – 25.0 %	18.2
EP/BP – Composition of Fatty Acids – Palmitic Acid	7.0 – 15.0 %	11.9
EP/BP – Composition of Fatty Acids – Stearic Acid	<= 7.0 %	6.4
EP/BP – Composition of Fatty Acids – Oleic Acid	<= 11.0 %	5.1
EP/BP – Composition of Fatty Acids – Linoleic Acid	<= 3.0 %	< 0.1
EP – Heavy Metals	<= 10 ppm	< 10
EP – Identification A	Passes Test	PT
EP – Identification D	Passes Test	PT
EP/BP – Hydroxyl Value	96 – 108	100
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
EP – Dioxan	<= 10 ppm	<10
Water (H ₂ O)	<= 0.2 %	0.1
Appearance	Passes Test	PT
pH of 5% Solution at 25°C	5.0 – 7.0	5.7
Arsenic (As)	<= 1 ppm	< 1
Peroxides, meq/1000g	<= 2.0	< 0.1
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
JPE – Identification 1	Passes Test	PT
JPE – Identification 2	Passes Test	PT
JPE – Identification 3	Passes Test	PT
JPE – Moisture Content	<= 3.0 %	0.1
JPE – Acid Value	<= 4.0	1.3
JPE – Saponification Value (mg KOH/g)	43 – 55	47

Test	Specification	Result
JPE – pH	4.0 – 7.0	5.3
JPE – Residue on Ignition	<= 0.25 %	0.14
JPE – Specific Gravity at 20°C	1.090 – 1.130	1.107
JPE – Viscosity (mm ² /S)	350 – 550	475
JPE – Heavy Metals (as Pb)	<= 20 ppm	< 20
JPE – Arsenic (As)	<= 2 ppm	< 2

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.

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.

Storage Conditions: Store in airtight container, protected from light

Country of Origin: US

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0103002

Manufacturer source batch: 0001178580



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, 13485:2012
 Selangor, Malaysia 9001:2008
 Dehradun, India, 9001:2008, 14001:2004, 13485:2003
 Mumbai, India, 9001:2008
 Panoli, India 9001:2008



Jamie Ethier
 Vice President Global Quality

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