

Material No.: 9403-26
Batch No.: 23B2361020
Manufactured Date: 2022-10-16
Expiration Date: 2023-10-16
Release Date: 2023-03-08
Revision No.: 0

Certificate of Analysis

Meets B.P. Chemical Specifications, Meets J.P. Chemical Specifications, Meets U.S.P Requirements, Meets E.P. Chemical Specifications, GMP Manufactured Product

Test	Specification	Result
USP – Specific Gravity at 25°/25°C	1.035 – 1.037	1.036
USP – Acidity	Passes Test	Passes Test
USP – Identification A (IR)	Passes Test	Passes Test
USP – Identification B – Diethylene Glycol	≤ 0.10 %	< 0.10 %
USP – Identification B – Ethylene Glycol	≤ 0.10 %	< 0.10 %
USP – Identification C	Passes Test	Passes Test
USP – Residue on Ignition	≤ 0.007 %	< 0.001 %
USP – Chloride (Cl)	≤ 0.007 %	< 0.007 %
USP – Sulfate (SO ₄)	≤ 0.006 %	< 0.006 %
USP – Water (H ₂ O)(by Karl Fischer titrn)	≤ 0.20 %	0.07 %
USP – Assay (CH ₃ CHOHCH ₂ OH)	≥ 99.5 %	99.7 %
Endotoxin Concentration (EU/g)	≤ 2.5	< 2.5
EP/BP – Relative Density (d ₂₀ ²⁰)	1.035 – 1.040	1.037
EP/BP – Refractive Index at 20°C	1.431 – 1.433	1.433
EP/BP – Identification A	Passes Test	Passes Test
EP/BP – Identification B	Passes Test	Passes Test
EP/BP – Identification C	Passes Test	Passes Test
EP/BP – Identification D	Passes Test	Passes Test
EP/BP – Appearance	Passes Test	Passes Test
EP/BP – Acidity	Passes Test	Passes Test
EP/BP – Oxidizing Substances	Passes Test	Passes Test
EP/BP – Reducing Substances	Passes Test	Passes Test
EP/BP – Water (H ₂ O)	≤ 0.2 %	0.1 %
EP/BP – Ash (sulfated)	≤ 0.01 %	< 0.01 %
JP – Identification A	Passes Test	Passes Test
JP – Identification B	Passes Test	Passes Test
JP – Specific Gravity at 20°/20°C	1.035 – 1.040	1.037
JP – Acidity	Passes Test	Passes Test

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Test	Specification	Result
JP - Chloride (Cl)	$\leq 0.007 \%$	$< 0.002 \%$
JP - Sulfate (SO ₄)	$\leq 0.002 \%$	$< 0.002 \%$
JP - Heavy Metals (as Pb)	$\leq 5 \text{ ppm}$	$< 1 \text{ ppm}$
JP - Arsenic (As)	$\leq 2 \text{ ppm}$	$< 2 \text{ ppm}$
JP - Glycerin	Passes Test	Passes Test
JP - Water (H ₂ O)	$\leq 0.5 \%$	0.1 %
JP - Residue on Ignition	$\leq 0.005 \%$	$< 0.001 \%$
JP - Distilling Range (Lower)	184 - 189 °C	187 °C
JP - Distilling Range (Upper)	184 - 189 °C	188 °C
JP - Ethylene Glycol	$\leq 0.1 \%$	$< 0.1 \%$
JP - Diethylene Glycol	$\leq 0.1 \%$	$< 0.1 \%$
JP - Any Other Impurity	$\leq 0.1 \%$	$< 0.1 \%$
JP - Total Impurities	$\leq 1.0 \%$	$< 0.1 \%$

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Propylene Glycol, U.S.P.
Multi-Compendial



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Test	Specification	Result
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GMP Manufactured Product
Bulk Pharmaceutical Chemical
CAUTION: For Manufacturing, processing or repackaging
No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.
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.

Country of Origin: USA
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0020001
Manufacturer source batch: BR22J16030


Jamie Ethier
Vice President Global Quality

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.386.1700
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