



Material No.: 9403-QM
Batch No.: 0000183531
Manufactured Date: 2017/02/09
Retest Date: 2022/02/08

Certificate of Analysis

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

Test	Specification	Result
USP – Specific Gravity at 25°/25°C	1.035 – 1.037	1.035
USP – Acidity	Passes Test	PT
USP – Water (H ₂ O)(by Karl Fischer titrn)	<= 0.2 %	< 0.1
USP – Identification A (IR)	Passes Test	PT
USP – Identification B – Diethylene Glycol	<= 0.10 %	< 0.10
USP – Identification B – Ethylene Glycol	<= 0.10 %	< 0.10
USP – Identification C	Passes Test	PT
USP – Residue on Ignition	<= 0.007 %	0.004
USP – Chloride (Cl)	<= 0.007 %	< 0.007
USP – Sulfate (SO ₄)	<= 0.006 %	< 0.006
USP – Heavy Metals (as Pb)	<= 5 ppm	< 5
USP – Assay (CH ₃ CHOHCH ₂ OH)	>= 99.5 %	99.6
Endotoxin Concentration (EU/g)	<= 2.5	< 2.5
EP/BP – Relative Density (d ₂₀ ²⁰)	1.035 – 1.040	1.038
EP/BP – Refractive Index at 20°C	1.431 – 1.433	1.433
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Identification C	Passes Test	PT
EP/BP – Identification D	Passes Test	PT
EP/BP – Appearance	Passes Test	PT
EP/BP – Acidity	Passes Test	PT
EP/BP – Oxidizing Substances	Passes Test	PT
EP/BP – Reducing Substances	Passes Test	PT

Test	Specification	Result
EP/BP – Heavy Metals (as Pb)	<= 5 ppm	< 5
EP/BP – Water (H ₂ O)	<= 0.2 %	< 0.1
EP/BP – Ash (sulfated)	<= 0.01 %	< 0.01
JP – Identification A	Passes Test	PT
JP – Identification B	Passes Test	PT
JP – Specific Gravity at 20°/20°C	1.035 – 1.040	1.038
JP – Acidity	Passes Test	PT
JP – Chloride (Cl)	<= 0.007 %	< 0.007
JP – Sulfate (SO ₄)	<= 0.002 %	< 0.002
JP – Heavy Metals (as Pb)	<= 5 ppm	< 5
JP – Arsenic (As)	<= 2 ppm	< 2
JP – Glycerin	Passes Test	PT
JP – Water (H ₂ O)	<= 0.5 %	< 0.1
JP – Residue on Ignition	<= 0.005 %	0.001
JP – Distilling Range (Lower)	184 – 189 °C	187
JP – Distilling Range (Upper)	184 – 189 °C	188
JP – Ethylene Glycol	<= 0.1 %	< 0.1
JP – Diethylene Glycol	<= 0.1 %	< 0.1
JP – Any Other Impurity	<= 0.1 %	< 0.1
JP – Total Impurities	<= 1.0 %	0.1

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.

Country of Origin: US
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0020001
Manufacturer source batch: 17DR040340



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



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 Vice President Global Quality

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