

Material No.: 2071-05
Batch No.: 0000256624
Manufactured Date: 2017/09/22
Retest Date: 2022/09/21
Release Date: 2020/04/29
Revision No: 1

Certificate of Analysis

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

Test	Specification	Result
USP – Assay (C ₃ H ₇ NO ₂ S · HCl) (dried basis)	98.5 – 101.5 %	101.0
USP – Identification	Passes Test	PT
USP – Specific Rotation [α] ²⁵ ^D (+)	5.7 – 6.8 Degree	6.3
USP – Loss on Drying	8.0 – 12.0 %	11.7
USP – Residue on Ignition	<= 0.1 %	< 0.1
USP – Sulfate (SO ₄)	<= 0.03 %	< 0.03
USP – Iron (Fe)	<= 0.003 %	< 0.003
USP – Related Compounds – Individual Impurities	<= 0.5 %	< 0.5
USP – Related Compounds – Total Impurities	<= 2.0 %	< 2.0
EP/BP – Assay (C ₃ H ₇ NO ₂ S · HCl) (dried basis)	98.5 – 101.0 %	100.4
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Identification E	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Specific Rotation [α] ²⁰ ^D (+)	5.5 – 7.0 Degree	6.8
EP/BP – Ninhydrin–Positive Substances – Impurity A	<= 0.5 %	< 0.1
EP/BP–Ninhydrin–Positive Substances–Each	<= 0.2 %	< 0.1
EP/BP–Ninhydrin–Positive Substances–Total Impurities	<= 1.0 %	< 0.1
EP/BP – Sulfate (SO ₄)	<= 300 ppm	< 300
EP/BP – Ammonium (NH ₄)	<= 0.02 %	< 0.02
EP/BP – Iron (Fe)	<= 20 ppm	< 20
EP/BP – Loss on Drying	8.0 – 12.0 %	11.0
EP/BP – Ash (sulfated)	<= 0.1 %	< 0.1

Test	Specification	Result
Endotoxin Concentration, IU/mg, For Information Only		< 0.005

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.

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.

Country of Origin: JP
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0063001
Manufacturer source batch: 189093



Jamie Ethier
Vice President Global Quality