

Material No.: 2068-06  
Batch No.: 0000257202  
Manufactured Date: 2018/10/24  
Retest Date: 2023/10/23  
Release Date: 2020/05/18  
Revision No: 1

## Certificate of Analysis

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

Test	Specification	Result
NF - Assay (dried basis)	98.0 - 101.5 %	99.9
NF - Identification	Passes Test	PT
NF - Specific Rotation @ 20 °C (+)	33.0 - 36.5 Degree	35.7
NF - Loss on Drying at 130°C	11.5 - 12.5 %	11.7
NF - Residue on Ignition	<= 0.1 %	< 0.1
NF - Chromatographic Purity: Individual Impurities	<= 0.5 %	< 0.5
NF - Chromatographic Purity: Total Impurities	<= 1.0 %	< 1.0
NF - Lead (Pb)	<= 5 ppm	< 5
NF - Total Aerobic Microbial Count, cfu/g	<= 1000	< 1
NF - Total Yeast and Mold Count, cfu/g	<= 100	< 1
EP/BP - Assay (dried basis)	99.0 - 101.0 %	99.9
EP/BP - Identification A	Passes Test	PT
EP/BP - Identification B	Passes Test	PT
EP/BP - Identification D	Passes Test	PT
EP/BP - Appearance of Solution	Passes Test	PT
EP/BP - Specific Rotation @ 20 °C (+)	33.7 - 36.0 Degree	35.7
EP/BP - Chloride (Cl)	<= 200 ppm	< 200
EP/BP - Sulfate (SO <sub>4</sub> )	<= 200 ppm	< 200
EP/BP - Ammonium (NH <sub>4</sub> )	<= 0.1 %	< 0.1
EP/BP - Iron (Fe)	<= 10 ppm	< 10
EP/BP - Loss on Drying at 130° C	10.5 - 12.5 %	11.7
EP/BP - Sulfated Ash	<= 0.1 %	< 0.1

Test	Specification	Result
EP/BP – pH	4.0 – 6.0	5.3
EP/BP – Related Substances – Impurity A	<= 0.5 %	< 0.5
EP/BP – Related Substances – Impurity C	<= 0.1 %	< 0.1
EP/BP – Related Substances – Unspecified impurities, each	<= 0.05 %	< 0.05
EP/BP – Related Substances – Total impurities	<= 0.8 %	< 0.8
Endotoxin Concentration, IU/mg, For Information Only		< 0.001

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

Residual solvents: Only the Class 2 solvent methanol is likely to be present from use in the manufacturing process. Methanol content is controlled to <200 ppm as a manufacturing process limit.

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.

Storage Conditions: Store in well-closed, light-resistant containers

Country of Origin: JP

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0062001

Manufacturer source batch: 180213



Jamie Ethier  
Vice President Global Quality