

Material No.: 4942-06  
Batch No.: 0000267303  
Manufactured Date: 2019/10/22  
Expiration Date: 2022/10/21  
Release Date: 2020/09/23  
Revision No: 1

## Certificate of Analysis

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

Test	Specification	Result
EP/BP – Assay ( $C_6H_9N_3O_2 \cdot HCl$ ) (dried basis)	98.5 – 101.0 %	100.1
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Identification C	Passes Test	PT
EP/BP – Identification F	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – pH	3.0 – 5.0	4.0
EP/BP – Specific Rotation $[\alpha]^{20}_D (+)$	9.2 – 10.6 Degree	10.0
EP/BP–Ninhydrin–Positive Substances–Each	$\leq 0.2 \%$	$< 0.1$
EP/BP–Ninhydrin–Positive Substances–Total Impurities	$\leq 0.5 \%$	$< 0.1$
EP/BP – Sulfate ( $SO_4$ )	$\leq 300$ ppm	$< 300$
EP/BP – Ammonium ( $NH_4$ )	$\leq 0.02 \%$	$< 0.02$
EP/BP – Iron (Fe)	$\leq 10$ ppm	$< 10$
EP/BP – Loss on Drying at 150°C	7.0 – 10.0 %	8.6
EP/BP – Ash (sulfated)	$\leq 0.1 \%$	$< 0.1$
JP – Identification	Passes Test	PT
JP – Optical Rotation (+)	9.2 – 10.6	10.0
JP – pH	3.5 – 4.5	4.0
JP – Clarity and Color of Solution	Passes Test	PT
JP – Sulfate ( $SO_4$ )	$\leq 0.028 \%$	$< 0.028$
JP – Ammonium ( $NH_4$ )	$\leq 0.02 \%$	$< 0.02$
JP – Heavy Metals (as Pb)	$\leq 10$ ppm	$< 10$
JP – Iron (Fe)	$\leq 10$ ppm	$< 10$

Test	Specification	Result
JP – Related Substances	Passes Test	PT
JP – Water	7.2 – 10.0 %	9.8
JP – Residue on Ignition	<= 0.1 %	< 0.1
JP – Assay (anhydrous basis)	99.0 – 101.0 %	99.3
Endotoxin Concentration, IU/mg ,For Information Only		< 0.01

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.

Storage Conditions: Store in airtight container.

Country of Origin: CN

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0005111

Manufacturer source batch: 19100633

  
Jamie Ethier  
Vice President Global Quality