



Material No.: V264-02 Batch No.: 2111362007 Manufactured Date: 2019-10-25 Expiration Date: 2022-10-24 Release Date: 2021-09-10 Revision No.: 0

Certificate of Analysis

GMP Manufactured Product

Test	Specification	Result
Appearance (white to off-white solid)	Passes Test	Passes Test
Identification (IR)	Passes Test	Passes Test
pH of 5% Solution	5.00 - 7.00	5.68
Specific Rotation @ 25 °C	-34.528.5 °	-32.0 °
Melting Point	110 – 122 °C	114 °C
Water (H2O), For Information Only		0.1 %
Purity (by HPLC) (anhydrous basis)	≥ 98 %	100 %
Assay (by HPLC) (anhydrous basis)	98 - 102	100
Endotoxin Concentration, EU/g		< 0.1
Residual Methanol	≤ 3000 ppm	< 1 ppm
Residual Ethanol	≤ 5000 ppm	74 ppm
Residual Isopropanol	\leq 5000 ppm	< 1 ppm
Residual Ethyl Acetate	≤ 5000 ppm	381 ppm
Total Aerobic Microbial Count	\leq 100 CFU/g	< 1 CFU/g
Total Yeast and Mold Count	\leq 100 CFU/g	< 1 CFU/g
Biological Induction Characterization (induction response @ 1mM)		> 1
Arsenic (As), For Information Only		< 0.05 ppm
Cadmium (Cd), For Information Only		< 0.05 ppm
Mercury (Hg), For Information Only		< 0.05 ppm
Lead (Pb), For Information Only		< 0.05 ppm
Cobalt (Co), For Information Only		< 0.05 ppm
Nickel (Ni), For Information Only		< 0.05 ppm
Vanadium (V), For Information Only		< 0.05 ppm
Silver (Ag), For Information Only		< 0.05 ppm
Gold (Au), For Information Only		< 0.05 ppm
Iridium (Ir), For Information Only		< 0.05 ppm
Osmium (Os), For Information Only		< 0.05 ppm
Palladium (Pd), For Information Only		< 0.05 ppm

>>> Continued on page 2 >>>

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.386.1700 Avantor Performance Materials, LLC 100 Matsonford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone 610.386.1700





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Test	Specification	Result
Platinum (Pt), For Information Only		< 0.05 ppm
Rhodium (Rh), For Information Only		< 0.05 ppm
Ruthenium (Ru), For Information Only		< 0.05 ppm
Selenium (Se), For Information Only		< 0.05 ppm
Thallium (TI), For Information Only		< 0.05 ppm
Barium (Ba), For Information Only		0.15 ppm
Chromium (Cr), For Information Only		< 0.05 ppm
Copper (Cu), For Information Only		< 0.05 ppm
Lithium (Li), For Information Only		< 0.05 ppm
Molybdenum (Mo), For Information Only		< 0.05 ppm
Antimony (Sb), For Information Only		< 0.05 ppm
Tin (Sn), For Information Only		< 0.05 ppm
Aluminum (Al), For Information Only		< 0.05 ppm
Iron (Fe), For Information Only		< 0.05 ppm
Manganese (Mn), For Information Only		< 0.05 ppm
Zinc (Zn), For Information Only		0.21 ppm

>>> Continued on page 3 $\rightarrow>>$





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Test Specification Result		_	
	Specification	Result	

GMP Manufactured Product

CAUTION: For Manufacturing, processing or repackaging

Residual Solvents: The Class 3 solvents Ethanol, Isopropanol, Ethyl Acetate and the Class 2 solvent Methanol are likely to be present. These solvents are quantified and reported on each batch. No other Class 1,2,3, or other solvents are used or produced in the production process. Dioxane was not used in the manufacturing process. Bacterial Induction characterization: Test performed at 1 mM of IPTG (E. Coli. protein expression)

IPTG is highly hygroscopic. Allow packaging/container to equilibrate to room temperature before opening for analysis. Ensure sample is kept dry (such as in a desiccator) after opening.

Storage Condition: Store and ship product between 2 and 8 $^{\circ}$ C

Country of Origin: USA Packaging Site: Phillipsburg Mfg Ctr & DC Manufacturer: PBG Manufacturer source batch: 0000243990

James Techie

Jamie Ethier Vice President Global Quality

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Page 3 of 3