

Material No.: 4106-01 Batch No.: 0000179244 Manufactured Date: 2017/05/18

Retest Date: 2022/05/17

## Certificate of Analysis

## **GMP Manufactured Product**

Test	Specification	Result
Assay (NH2C(CH2OH)3·HCl)	>= 99.0 %	99.8
Appearance (colorless crystals to white crystalline powder)	Passes Test	PT
Absorbance of a 1M Solution - 260 nm	<= 0.06	< 0.06
Absorbance of a 1M Solution – 280 nm	<= 0.06	< 0.06
Absorbance of a 1M Solution – 400 nm	<= 0.01	< 0.01
Identification (by IR)	Passes Test	PT
Loss on Drying at 105°C	<= <b>0.5</b> %	0.3
Endotoxin Concentration (EU/g)	<= 2.5	< 1.0
Melting Point	147 – 153 °C	151
oH of 0.5M Solution at 25°C	3.5 - 5.0	4.2
Trace Impurities – Arsenic (As)	<= 10 ppm	< 1
Frace Impurities – Calcium (Ca)	<= 10 ppm	< 1
Trace Impurities – Copper (Cu)	<= 10 ppm	< 1
Trace Impurities – Iron (Fe)	<= 10 ppm	< 1
Trace Impurities - Lead (Pb)	<= 10 ppm	< 1
Trace Impurities – Magnesium (Mg)	<= 10 ppm	< 1

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. Manufactured exclusively for Avantor Performance Materials, LLC., by BioSpectra, Inc., Stroudsburg, PA

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Country of Origin: US

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0064001

Manufacturer source batch: TH7201-117-0517



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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For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or  $\pm 1.610.573.2600$