

Glycine, U.S.P.
Multi-Compendial

(aminoacetic acid)



Material No.: 0582-01
Batch No.: 0000169135
Manufactured Date: 2016/10/05
Retest Date: 2021/10/04

Certificate of Analysis

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

Test	Specification	Result
USP – Identification	Passes Test	PT
USP – Loss on Drying at 105°C	<= 0.2 %	< 0.1
USP – Residue on Ignition	<= 0.1 %	< 0.1
USP – Chloride (Cl)	<= 0.007 %	< 0.007
USP – Sulfate (SO ₄)	<= 0.0065 %	< 0.0065
USP – Heavy Metals (as Pb)	<= 0.002 %	< 0.002
USP – Hydrolyzable Substances	Passes Test	PT
USP – Assay (C ₂ H ₅ NO ₂) (dried basis)	98.5 – 101.5 %	99.7
USP – Endotoxin Concentration (EU/g)	<= 2.5	0.1
EP/BP – Assay (C ₂ H ₅ NO ₂) (dried basis)	98.5 – 101.0 %	99.5
EP/BP – Identification A	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – pH	5.9 – 6.4	6.2
EP/BP – Chloride (Cl)	<= 75 ppm	< 75
EP/BP – Heavy Metals (as Pb)	<= 10 ppm	< 10
EP/BP – Loss on Drying at 105°C	<= 0.5 %	< 0.1
EP/BP – Ash (sulfated)	<= 0.1 %	< 0.1
EP/ BP – Related substances: Glycine anhydride	<= 0.10 %	< 0.10
EP/ BP – Related substances: Diglycine	<= 0.10 %	< 0.10
EP/ BP – Related substances: Triglycine	<= 0.10 %	< 0.10
EP/ BP – Related substances: Unspecified impurities,	<= 0.10 %	< 0.10

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.573.2600
Avantor Performance Materials, LLC.

3477 Corporate Parkway, Center Valley, PA 18034. U.S.A. Phone: 610.573.2600 . Fax: 610.573.2610

Test	Specification	Result
each		
EP/ BP – Related substances: Total impurities	<= 0.2 %	< 0.1
EP/BP – Ninhydrin Positive Substances – Each Impurity	<= 0.10	< 0.05
EP/BP–Ninhydrin–Positive Substances–Total Impurities	<= 1.0 %	< 0.1
EP/BP – Ammonium (NH ₄)	<= 0.02 %	< 0.02
JP – Assay (C ₂ H ₅ NO ₂) (dried basis)	98.5 – 101.0 %	99.7
JP – Identification	Passes Test	PT
JP – pH (1 in 20)	5.6 – 6.6	6.2
JP – Clarity and Color of Solution	Passes Test	PT
JP – Chloride (Cl)	<= 0.021 %	< 0.021
JP – Sulfate (SO ₄)	<= 0.028 %	< 0.028
JP – Ammonium (NH ₄)	<= 0.02 %	< 0.02
JP – Heavy Metals (as Pb)	<= 20 ppm	< 20
JP – Arsenic (As)	<= 2 ppm	< 2
JP – Related Substances	Passes Test	PT
JP – Loss on Drying at 105°C	<= 0.30 %	< 0.10
JP – Residue on Ignition	<= 0.10 %	< 0.05

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

Only Class 2 Solvents (Methanol) are likely to be present. All are below Option 1 limits.

Country of Origin: US
 Packaging Site: Paris Mfg Ctr & DC
 Manufacturer: P0023001
 Manufacturer source batch: BXP1849



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



Jamie Ethier
 Vice President Global Quality

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