

Glycine, U.S.P.
Multi-Compendial
(aminoacetic acid)



Material No.: 0582-07
Revision No.: 0

Product Specification

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
USP – Identification	Passes Test
USP – Loss on Drying at 105°C	≤ 0.2 %
USP – Residue on Ignition	≤ 0.1 %
USP – Chloride (Cl)	≤ 0.007 %
USP – Sulfate (SO ₄)	≤ 0.0065 %
USP – Hydrolyzable Substances	Passes Test
USP – Assay (C ₂ H ₅ NO ₂) (dried basis)	98.5 – 101.5 %
USP – Endotoxin Concentration (EU/g)	≤ 2.5
USP – Related Compounds: Glycine anhydri	≤ 0.1 %
USP – Related Compounds: Monochloroaceti	%
USP – Related Compounds: Iminodiacetic a	≤ 0.1 %
USP – Related Compounds: Diglycine	≤ 0.1 %
USP – Related Compounds: Triglycine	≤ 0.1 %
USP – Related Compounds: Hexamethylenete	≤ 0.1 %
USP – Related Compounds: Any unspecified	%
USP – Related Compounds: Total impuritie	≤ 1.0 %
EP/BP – Assay (C ₂ H ₅ NO ₂) (dried basis)	98.5 – 101.0 %
EP/BP – Identification A	Passes Test
EP/BP – Appearance of Solution	Passes Test
EP/BP – pH	5.9 – 6.4
EP/BP – Chloride (Cl)	≤ 75 ppm
EP/BP – Loss on Drying at 105°C	≤ 0.5 %
EP/BP – Ash (sulfated)	≤ 0.1 %
EP/ BP – Related substances: Glycine anh	≤ 0.10 %
EP/ BP – Related substances: Diglycine	≤ 0.10 %
EP/ BP – Related substances: Triglycine	≤ 0.10 %
EP/ BP – Related substances: Unspecified	≤ 0.10 %
EP/ BP – Related substances: Total impur	≤ 0.2 %

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Test	Specification
EP/BP – Ninhydrin Positive Substances –	≤ 0.10 %
EP/BP–Ninhydrin–Positive Substances–Tota	≤ 1.0 %
EP/BP – Ammonium (NH ₄)	≤ 0.02 %
JP – Assay (C ₂ H ₅ NO ₂) (dried basis)	98.5 – 101.0 %
JP – Identification	Passes Test
JP – pH (1 in 20)	5.6 – 6.6
JP – Clarity and Color of Solution	Passes Test
JP – Chloride (Cl)	≤ 0.021 %
JP – Sulfate (SO ₄)	≤ 0.028 %
JP – Ammonium (NH ₄)	≤ 0.02 %
JP – Heavy Metals (as Pb)	≤ 20 ppm
JP – Arsenic (As)	≤ 2 ppm
JP – Related Substances	Passes Test
JP – Loss on Drying at 105°C	≤ 0.30 %
JP – Residue on Ignition	≤ 0.10 %

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Test	Specification
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GMP Manufactured Product
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.
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.

Packaging Site: Paris Mfg Ctr & DC


Jamie Ethier
Vice President Global Quality

For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700

Avantor Performance Materials, LLC

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