

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



Material No.: 0582-01

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 anhydride	≤ 0.1 %
USP – Related Compounds: Monochloroacetic acid (For Information Only)	%
USP – Related Compounds: Iminodiacetic acid	≤ 0.1 %
USP – Related Compounds: Diglycine	≤ 0.1 %
USP – Related Compounds: Triglycine	≤ 0.1 %
USP – Related Compounds: Hexamethylenetetramine	≤ 0.1 %
USP – Related Compounds: Any unspecified impurity (For Information Only)	%
USP – Related Compounds: Total impurities	≤ 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 anhydride	≤ 0.10 %
EP/ BP – Related substances: Diglycine	≤ 0.10 %
EP/ BP – Related substances: Triglycine	≤ 0.10 %
EP/ BP – Related substances: Unspecified impurities, each	≤ 0.10 %
EP/ BP – Related substances: Total impurities	≤ 0.2 %

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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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Test	Specification
EP/BP-Ninhydrin Positive Substances-Each	$\leq 0.10 \%$
EP/BP-Ninhydrin-Positive Substances-Total Impurities	$\leq 1.0 \%$
EP/BP – Ammonium (NH ₄)	$\leq 0.02 \%$
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)	$\leq 0.021 \%$
JP – Sulfate (SO ₄)	$\leq 0.028 \%$
JP – Ammonium (NH ₄)	$\leq 0.02 \%$
JP – Related Substances	Passes Test
JP – Loss on Drying at 105°C	$\leq 0.30 \%$
JP – Residue on Ignition	$\leq 0.10 \%$

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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