

Product Specification

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

Test	Specification
USP – Identification A	Passes Test
USP – Identification B	Passes Test
USP – Assay (NH ₂ CONH ₂)	98.0 – 102.0 %
USP – Residue on Ignition	≤ 0.1 %
USP – Alcohol Insoluble Matter	≤ 0.04 %
USP – Organic impurities: Urea related compound A	≤ 0.1 %
USP – Organic impurities: Any individual unspecified impurity	≤ 0.1 %
USP – Organic impurities: Total impurities	≤ 2.0 %
USP – Endotoxin Concentration (EU/g)	≤ 2.5
EP/BP – Assay (NH ₂ CONH ₂) (dried basis)	98.5 – 101.5 %
EP/BP – Identification A	Passes Test
EP/BP – Identification B	Passes Test
EP/BP – Appearance of Solution	Passes Test
EP/BP – Alkalinity	Passes Test
EP/BP – Biuret	≤ 0.1 %
EP/BP – Ammonium (NH ₄)	≤ 500 ppm
EP/BP – Loss on Drying at 105°C	≤ 1.0 %
EP/BP – Ash (sulfated)	≤ 0.1 %
JP – Assay (NH ₂ CONH ₂)	99.0 – 101.0 %
JP – Identification A	Passes Test
JP – Identification B	Passes Test
JP – Chloride (Cl)	≤ 0.007 %
JP – Sulfate (SO ₄)	≤ 0.010 %
JP – Heavy Metals (as Pb)	≤ 20 ppm
JP – Alcohol Insoluble Matter	≤ 0.040 %
JP – Residue on Ignition	≤ 0.10 %
JP – Melting Point	132.5 – 134.5 °C

Urea, U.S.P.
Multi-Compendial



Material No.: 4203-60

Test

Specification

GMP Manufactured Product

Bulk Pharmaceutical Chemical

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

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

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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