

Product Specification

Meets N.F. Requirements, GMP Manufactured Product

Test	Specification
NF – Clarity and Color of Solution	Passes Test
NF – Identification A	Passes Test
NF – Identification B	Passes Test
NF – Specific Rotation $[\alpha]_D^{20}$ (+)	54.4 – 55.9 °
Microbial Limits – Total Aerobic Count (per g)	≤ 100
Microbial Limits – Total Combined Molds and Yeasts Count (per g)	≤ 50
Microbial Limits – Escherichia coli	Passes Test
NF – Acidity or Alkalinity	Passes Test
NF – Loss on Drying at 80°C	$\leq 0.5 \%$
NF – Water (H ₂ O)	4.5 – 5.5 %
NF – Residue on Ignition	$\leq 0.1 \%$
NF – Protein and Light-Absorbing Impurities	Passes Test

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.

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