

Product Specification

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets N.F. Requirements, GMP Manufactured Product

Test	Specification
NF – Identification A	Passes Test
NF – Identification B	Passes Test
NF – Water (H ₂ O)	12.0 – 15.0 %
NF – Assay (Na ₂ CO ₃) (anhydrous basis)	99.5 – 100.5 %
NF – Endotoxin Concentration (EU/g)	≤ 2.5
EP/BP – Assay (Na ₂ CO ₃)	83.0 – 87.5 %
EP/BP – Identification A	Passes Test
EP/BP – Identification B	Passes Test
EP/BP – Identification C	Passes Test
EP/BP – Appearance of Solution	Passes Test
EP/BP – Alkali Hydroxides and Bicarbonat	Passes Test
EP/BP – Chloride (Cl)	≤ 125 ppm
EP/BP – Sulfate (SO ₄)	≤ 250 ppm
EP/BP – Iron (Fe)	≤ 50 ppm

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.

Packaging Site: Paris Mfg Ctr & DC



Jamie Ethier
Vice President Global Quality