



Material No.: 3501-20 Revision No.: 0

## **Product Specification**

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

Test	Specification
NF - Identification A	Passes Test
NF - Identification B	Passes Test
NF – Identification C	Passes Test
NF - Alkalinity	Passes Test
NF - Water (H <sub>2</sub> O)	≤ 1.5 %
NF - Assay (C <sub>6</sub> H <sub>5</sub> COONa) (anhydrous basis)	99.0 - 101.0 %
EP/BP – Identification A	Passes Test
EP/BP - Identification B	Passes Test
EP/BP - Appearance of Solution	Passes Test
EP/BP – Acidity or Alkalinity	Passes Test
EP/BP - Halogenated Compounds (as Cl) - Ionized Chlorine	≤ 200 ppm
EP/BP - Halogenated Compounds (as Cl) - Total Chlorine	≤ 300 ppm
EP/BP – Loss on Drying	≤ 2.0 %
EP/BP - Assay(C <sub>6</sub> H <sub>5</sub> COONa)(dried basis)	99.0 - 100.5 %

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