

Product Specification

GMP Manufactured Product

Test	Specification
Identification (by FTIR)	Conforms
Appearance	Passes test
Purity (by HPLC)	≥ 95 %
Assay	8,0 – 12,0 %
Acid value	≤ 10
Viscosity at 25 °C, For Information Only	cP
Density	0,9 – 1,1 g/ml
Limit of Free Ethylene Oxide, For Information Only	ppm
Total Aerobic Microbial Count	≤ 1000 CFU/g
Total Yeast and Mold Count	≤ 10 CFU/g
Endotoxin Concentration, EU/mL	EU/ml
Protein reactive impurities (100X diluted)	ppm
Arsenic (As), For Information Only	ppb
Cadmium (Cd), For Information Only	ppb
Mercury (Hg), For Information Only	ppb
Lead (Pb), For Information Only	ppb
Cobalt (Co), For Information Only	ppb
Nickel (Ni), For Information Only	ppb
Vanadium (V), For Information Only	ppb
Silver (Ag), For Information Only	ppb
Gold (Au), For Information Only	ppb
Iridium (Ir), For Information Only	ppb
Osmium (Os), For Information Only	ppb
Palladium (Pd), For Information Only	ppb
Platinum (Pt), For Information Only	ppb
Rhodium (Rh), For Information Only	ppb
Ruthenium (Ru), For Information Only	ppb
Selenium (Se), For Information Only	ppb

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Test	Specification
Thallium (Tl), For Information Only	ppb
Barium (Ba), For Information Only	ppb
Chromium (Cr), For Information Only	ppb
Copper (Cu), For Information Only	ppb
Lithium (Li), For Information Only	ppb
Molybdenum (Mo), For Information Only	ppb
Antimony (Sb), For Information Only	ppb
Tin (Sn), For Information Only	ppb

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For drug manufacturing or R&D use only.

Lowest detection limit of Total Aerobic Microbial Count is 1000 CFU/g per USP <61> with 1:1000 dilution.

Lowest detection limit of Total Yeast and Mold Count is 10 CFU/g per USP <61> with 1:10 dilution.

Product requires high dilution to isolate the inoculated organism which attributes to the microbicidal activity of the product.

Below the detection limit indicates that the article is not likely to be contaminated with the given species of the microorganism as per USP <61>.

Packaging Site: Aurora Mfg Ctr & DC