



## Maple Biotech Pvt. Ltd.

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### SPECIFICATIONS MICROCRYSTALLINE CELLULOSE 102

TEST	SPECIFICATIONS
Description	White or almost white, fine, granular powder,
Solubility	Practically insoluble in water, in acetone, in anhydrous ethanol, in toluene, in dilute acids and in a 50 g/l solution of sodium hydroxide.
Solubility in ammonia solution of Copper tetramine	Dissolves completely leaving no residue
Identification	USPNF/BP Monograph Identification Tests, BP 2009, Ph Eur 0316 (A & B) A. Place about 10 mg on a watch-glass and disperse in 2 ml of <i>iodinated zinc chloride solution R</i> . The substance becomes violet-blue. B. The degree of polymerisation is not more than 350.
Assay	97 to 102 %
pH	5 to 7.5 (BP 2009. / JP/ USP/IP )
Starch	Negative (BP 2009./USP/JP/IP)
Water Soluble Matter	max. 0.25% (BP 2009/NF/JP) max. 0.2% (IP)
Residue on Ignition	max 0.2% (IP), 0.1% USP, BP 2009
Loss on Drying	Max 7.0% (USP/JP/IP), 7% BP 2009
Heavy Metals	Max. 10 ppm (USP/ IP/BP 2009)
Seive Analysis	
Retention on 100 mesh :	Min. 20%
Retention on 200 mesh :	Min. 40%
Retention on 240 mesh :	Min. 60%
Bulk Density	0.28-0.33 g/cm <sup>3</sup>
Conductivity	Max. 75 $\mu$ S/Cm
Organic Volatile Impurities	USP
Ether-soluble substances	Max. 0.05%
Total Aerobic Microbial Count	max. 1000 cfu/gm ( Bp 2009 /USP)
Total Molds and Yeast Count	Max. 100 cfu/gm (Bp 2009 / USP)
E. Coli	absent (BP 2009/ USP)
Salmonella	absent (BP 2009/ USP)
S. Aureus	absent (BP 2009/ USP)
Pseudomonas	absent (BP 2009/ USP)
MATERIAL COMPLIES WITH ALL THE TEST GIVEN ABOVE OF IP / USP/ BP 2009/ Ph Eur 0316 And JP	