



## Maple Biotech Pvt. Ltd.

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### SPECIFICATIONS MICROCRYSTALLINE CELLULOSE 101

| 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 ammoniacal solution of Copper tetramine                                    | Dissolves completely leaving no residue  |
| Identification   | USPNF/BP Monograph Identification Tests, BP 2009, Ph Eur 0316 (A & B)<br>iA. 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.<br>iB. 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  | 0.1% USP   |
| Loss on Drying   | 7% (USP/JP/IP), 6% BP 2009   |
| Heavy Metals   | Max. 10 ppm (USP/ IP/BP 2009)  |
| Bulk Density   | 0.26-0.31 g/cm <sup>3</sup>  |
| Seive Analysis   |  |
| Retention on 60 mesh :   | Max. 1%  |
| Retention on 200 mesh :  | Max. 30%   |
| Conductivity   | Max. 75 $\mu$ S/Cm   |
| Organic Volatile Impurities  | USP  |
| Ether-soluble substances   | Max. 0.05%   |
| Total Aerobic Microbial Count  | max. 1000 col/gm ( BP 2009 /USP)   |
| Total Molds and Yeast Count  | Max. 100 col/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 |  |