



## Maple Biotech Pvt. Ltd.

Works: J-253, M.I.D.C. Bhosari, Pune 411 037, India  
Phone: +91 20 27130210/30628103; Fax: 27130410; sales@maplebiotech.co.in  
www.maplebiotech.co.in

### SPECIFICATIONS MICROCRYSTALLINE CELLULOSE 302

| TEST  | SPECIFICATIONS   |
|---|--|
| Description   | White or almost white, fine, granular powder, practically insoluble in water, in acetone, in ethanol, in toluene, in dilute acids and in 50 g/l solution of sodium hydroxide |
| Identification  | USPNF Monograph Identification Tests A,B,C   |
| Assay   | 97 to 102 %  |
| Degree of Polymerization  | 130 to 180   |
| pH  | 5 to 7 (Pharma Eur. / JP/ USP) 5 to 7.5( IP )  |
| Starch  | Negative(Pharma Eur./USP/JP/IP)  |
| Water Soluble Matter  | max. 0.24%(Pharma Eur/NF/JP) max. 0.2% (IP)  |
| Residue on Ignition   | max 0.2% (IP) )0.05% USP   |
| Sulphated Ash   | max 0.1%(Pharma Eur/NF/JP) max 0.2% (IP)   |
| Moisture  | 5% (Pharma Eur./USP/JP/IP)   |
| Heavy Metals  | Max. 10 ppm (USP/ IP/Pharma Eur)   |
| Seive Analysis  |  |
| Retention on 100 mesh :   | Min. 20%   |
| Retention on 200 mesh :   | Min. 40%   |
| Retention on 240 mesh :   | Min. 60%   |
| Bulk Density  | 0.35 to -0.46 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 ( Ph. Eur /USP)   |
| Total Molds and Yeast Count   | Max. 100 cfu/gm (Ph. Eur / USP)  |
| E. Coli   | absent (Pharma Eur/ USP)   |
| Salmonella  | absent (Pharma Eur/ USP)   |
| S. Aureus   | absent (Pharma Eur/ USP)   |
| Pseudomonas   | absent (Pharma Eur/ USP)   |
| MATERIAL COMPLIES WITH ALL THE TEST GIVEN ABOVE OF IP / USP/ Ph Eur. And JP |  |