

MICROCRYSTALLINE CELLULOSE SPECIFICATIONS AS PER USP/EP/BP/IP/IH

Sr. No.	Tests	Specifications
1	Description (IP/BP/EP/USP)	Fine or granular, white or almost white powder. White or almost white fine or granular slightly hygroscopic powder. It consists of free-flowing, non-fibrous particles. Odorless, tasteless.
2	Solubility (BP/EP)	Practically Insoluble in water, in Acetone, in Anhydrous ethanol, in Toluene, in dilute acids and in a 50g/L solution of sodium hydroxide.
3	Identification	
	Identification A (BP/EP/USP) (IR Spectroscopy)	IR Spectroscopy Disregard any band between 800 cm ⁻¹ and 825 cm ⁻¹ or between 950 cm ⁻¹ and 1000 cm ⁻¹
	Identification A (IP) Chemical Test	A red colour is produced
	Identification B (BP/EP/USP) (Iodinated Zinc Chloride Solution)	The substance takes violet blue color
	Identification B (IP) Chemical Test	A blue-purple colour is produced
	Identification C (BP/EP/USP) Degree of Polymerization	The degree of polymerization is not greater than 350.
	Identification C (IP) Dispersion Test	A white, opaque, bubble-free dispersion is obtained that does not produce a supernatant liquid.
4	Solubility (BP/EP) Copper Tetramine solution	It dissolves completely leaving no residue
5	Conductivity. (EP/BP/USP)	The conductivity of the supernatant solution should not exceed 75 µS per cm.
6	pH (EP/BP/USP/IP)	pH of the supernatant solution should lie between 5.0 to 7.5.
7	Loss on Drying (EP/BP/USP/IP)	Not More than 6.0% w/w. (IP) Not More than 7.0% w/w (EP/BP/USP)
8	Residue on ignition/ Sulphated Ash (EP/BP/USP/IP)	Not More than 0.1% (EP/BP/USP) Not More than 0.2% (IP)
9	Water Soluble Substances (EP/BP/USP/IP)	Not More than 0.25% w/w. (EP/BP/USP) Not More than 0.25% w/w -0.2% (IP)
10	Ether Soluble Substances (EP/BP/USP)	Not More than 0.05% w/w.
11	Heavy Metals (IP)	Not More than 10 ppm.
12	Organic volatile Impurities (IP) Chemical Test	No red colour is produced
13	Assay (Dried) (IP)	97.0% – 102.0%
14	Arsenic (IP)	Not More than 2 ppm
15	Starch & Dextrin (IP) Chemical Test	No Blue or Brownish red Colour is Produced
16	Microbial limits (EP/BP/USP)	a) Total aerobic microbial count: Max.:1000 cfu/ g b) Total combined molds & yeasts: Max.: 100 cfu/g c) Staphylococcus aureus: absent/1 g d) Pseudomonas aeruginosa: absent/1 g e) Escherichia coli: absent / 1 g f) Salmonella species: absent /10 g

17. ADDITIONAL IN-HOUSE TESTS					
	Grade of MCC	Bulk density g/ml	Loss on drying	Sieve Analysis (% Retention)	Technical Unavoidable particles (TUP)
A	AMCELL 101	0.26 - 0.34	7.0 % MAX	60 mesh \leq 1.0 % 200 mesh \leq 30.0%	NMT 08 Nos/600 cm ²
B	AMCELL 102	0.27 - 0.34	7.0 % MAX	60 mesh \leq 8.0 % 200 mesh \geq 45.0%	NMT 08 Nos/600 cm ²
C	AMCELL 105	0.20 - 0.30	7.0 % MAX	60 mesh \leq 0.1 % 400 mesh \leq 10.0%	NMT 08 Nos/600 cm ²
D	AMCELL -112	0.28 - 0.36	1.5 % MAX	60 mesh \leq 8.0 % 200 mesh \geq 45.0%	NMT 08 Nos/600 cm ²
E	AMCELL -200	0.31 - 0.39	7.0 % MAX	60 mesh \geq 10.0 % 100 mesh \geq 50.0%	NMT 08 Nos/600 cm ²
F	AMCELL 101 PLUS	0.27 – 0.31	7.0 % MAX	60 mesh \leq 1.0 % 200 mesh \leq 30.0%	NMT 03 Nos/600 cm ²
G	AMCELL 102 PLUS	0.28 – 0.34	7.0% MAX	60 mesh \leq 8.0 % 200 mesh \geq 45.0%	NMT 03 Nos/600 cm ²