

CERTIFICATE OF ANALYSIS

Product Name: Microcrystalline Cellulose 101 (BP/USP)	Batch No.: ARO/101/12-22/160
Mfg. Date: 12/2022	Exp. Date: 11/2027
Batch Size: 2000 Kg	Grade: BP/USP

Sr. No	Test	Specific ation	Results
01	Description	White or almost white, fine or granular, slightly hygroscopic powder. (BP)	Complies
		Fine, White or almost white powder. It consists of free-flowing, nonfibrous particles. (USP)	Complies
02	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. (BP)	Complies
		Practically insoluble in sodium hydroxide solution (1 in 20), insoluble in water, in dilute acids, and in most organic solvent. (USP)	Complies
		(In copper tetramine solution) Dissolve completely, leaving no residue. (BP)	Complies
03	Identification		
	Test A: (Infrared absorption)	Disregard any band between 800 cm ⁻¹ and 825 cm ⁻¹ or between 950 cm ⁻¹ and 1000 cm ⁻¹ .	Complies
	Test B: (Iodinated Zinc chloride test)	The substance becomes violet-blue	Complies
	Test C: (Degree of polymerization)	NMT 350	Complies
04	Sulfated Ash/Residue on ignition	NMT 0.1 %	0.036 %
05	Conductivity (In supernatant)	NMT 75 μS per cm	52.3 μS/cm
06	pH (In supernatant)	5.0 to 7.5	6.44
07	Loss on Drying	NMT 7.0 %	4.7 %
08	Bulk density	0.26 g/ml to 0.34 g/ml	0.30 g/ml
09	Water soluble substances	NMT 0.25%	0.15 %
10	Ether-soluble substances	NMT 0.05 %	Complies
11	Particle Size distribution		
	Retained (+) 60 mesh	NMT 1.0 % m/m	0.00 %
	Retained (+) 200 mesh	NMT 30.0 % m/m	22.78 %
12	Microbial enumeration tests and tests for specified microorganisms		
	a. Total aerobic microbial count	NMT 1000 cfu per gm.	Complies
	b. Total molds and yeasts count	NMT 100 cfu per gm.	Complies
	c. Staphylococcus aureus	Must be absent	Absent
	d. Pseudomonas aeruginosa	Must be absent	Absent
	e. Escherichia coli	Must be absent	Absent
	f. Salmonella species.	Must be absent	Absent

OPINION/ CONCLUSION:

The above product batch complies as per BP/USP Specification

For, PERITUS INTERNATIONAL



Partner



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CERTIFICATE OF ANALYSIS

Product Name: Microcrystalline Cellulose 101 (BP/USP)	Batch No.: ARO/101/12-22/159
Mfg. Date: 12/2022	Exp. Date: 11/2027
Batch Size: 3000 Kg	Grade: BP/USP

Sr. No	Test	Specification	Results
01	Description	White or almost white, fine or granular, slightly hygroscopic powder. (BP)	Complies
		Fine, White or almost white powder. It consists of free-flowing, nonfibrous particles. (USP)	Complies
02	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. (BP)	Complies
		Practically insoluble in sodium hydroxide solution (1 in 20), insoluble in water, in dilute acids, and in most organic solvent. (USP)	Complies
		(In copper tetramine solution) Dissolve completely, leaving no residue. (BP)	Complies
03	Identification		
	Test A: (Infrared absorption)	Disregard any band between 800 cm ⁻¹ and 825 cm ⁻¹ or between 950 cm ⁻¹ and 1000 cm ⁻¹	Complies
	Test B: (Iodinated Zinc chloride test)	The substance becomes violet-blue	Complies
	Test C: (Degree of polymerization)	NMT 350	Complies
04	Sulfated Ash/Residue on ignition	NMT 0.1 %	0.036 %
05	Conductivity (In supernatant)	NMT 75µS per cm	60.1 µS/cm
06	pH (In supernatant)	5.0 to 7.5	6.45
07	Loss on Drying	NMT 7.0 %	2.2 %
08	Bulk density	0.26 g/ml to 0.34 g/ml	0.28 g/ml
09	Water soluble substances	NMT 0.25%	0.13 %
10	Ether-soluble substances	NMT 0.05 %	Complies
11	Particle Size distribution		
	Retained (+) 60 mesh	NMT 1.0 % m/m	0.00 %
	Retained (+) 200 mesh	NMT 30.0 % m/m	17.85 %
12	Microbial enumeration tests and tests for specified microorganisms		
	a. Total aerobic microbial count	NMT 1000 cfu per gm.	Complies
	b. Total molds and yeasts count	NMT 100 cfu per gm.	Complies
	c. Staphylococcus aureus	Must be absent	Absent
	d. Pseudomonas aeruginosa	Must be absent	Absent
	e. Escherichia coli	Must be absent	Absent
	f. Salmonella species.	Must be absent	Absent

OPINION/ CONCLUSION: The above product batch complies as per BP/USP Specification

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