

CERTIFICATE OF ANALYSIS

Product Name	Hindcel® 200 (Bulk Dried) - MICROCRYSTALLINE CELLULOSE BP, USP-NF		
Lot No.	MCC/2404106		
T.R. No.	BD/TR/107/2024		
Lot Size.	4001 Kg		
Mfg. Date	April-24		
Re Test Date	April-27		
			Date of Analysis : 24/04/2024

SR. NO.	TESTS	SPECIFICATION	RESULTS	TEST METHOD
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A. CHEMICAL TEST

1.	Appearance	White or almost white, fine or granular, slightly hygroscopic powder.	Fine, white Odourless powder.	BP, USP-NF
2.	Solubility	Practically insoluble in water acetone, in anhydrous ethanol, in toluene, in dilute acids and in a 50 g/L solution of sodium hydroxide.	Complies	BP, USP-NF
	(1) Solubility in water, acetone, in anhydrous ethanol, in toluene, in dilute acids and in a 50 g/L solution of sodium hydroxide.			
3.	(2) Dissolve 50 mg in 10 mL of ammoniacal solution of copper tetrammine R.	It should be dissolves completely, leaving no residue.	Complies	
	Identification Tests:			
4.	Test (A) By IR	The sample spectrum should be concordant with that of the Reference spectrum.	Complies	BP, USP-NF
	Test (B) By chemical	The substance becomes should be violet-blue.	Complies	
	Test (C) The degree of polymerization	The degree of polymerization should not be more than 350.	Complies	
5.	pH of Solution [5.0 g with 40 mL CO ₂ free water]	5.0 to 7.5	5.54	BP, USP-NF
6.	Conductivity	The conductivity of the test solution should be does not exceed the conductivity of the water by more than 75µS.cm ⁻¹	55 µS.cm ⁻¹	BP, USP-NF
7.	Ether-soluble substances	Maximum 0.05%	0.03 %	BP, USP-NF
8.	Water-soluble substance	Maximum 0.25%	0.18 %	BP, USP-NF
9.	Heavy Metals	Maximum 10 ppm	Complies	BP, USP-NF
10.	Loss on drying (at 105° C for 3 h)	Maximum 7.00 %	4.40 %	BP, USP-NF
	Sulphated ash (Calculated on dried basis)	Maximum 0.1%	0.05 %	BP, USP-NF

B. PHYSICAL TEST

1.	Bulk Density (Untapped)	0.25 to 0.45 g/cm ³		
2.	Sieve analysis (% Retention by Sieve shaker)	60 Mesh- Minimum 10.0 %	0.44 g/cm ³	In House
		100 Mesh- Minimum 50.0 %	31.80 %	
			72.30 %	

C. MICROBIAL TEST

1.	Total Aerobic microbial Count	Not more than 1000 CFU/ g	Complies	BP, USP-NF
2.	Total yeasts and molds count	Not more than 100 CFU/ g	Complies	
3.	Escherichia coli & Salmonella	Should be Absent	Absent	
4.	Pseudomonas aeruginosa	Should be Absent	Absent	
5.	Staphylococcus aureus	Should be Absent	Absent	

Remark: The Product passes as per BP 2022 ,USP-NF 40,IH (Type 200) Specifications.

	Designation	Stamp	Signature	Date
Prepared by :	Q.C. Chemist		<i>Aravind P.</i>	24/04/2024
Reviewed & Approved by :	Manager Q.C./QA		<i>Aravind P.</i>	24/04/2024