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A GMP & ISO 9001	is 2015 COMPANY	E-mail: info@pcspl.net Web: www.pcspl.net Ref. SOP No	P.PCSQC-50
Product Name	CERTIFIC/	ATE OF ANALYSIS	
Lot No.	Macci 200 (Bulk Dried)	- MICROCRYSTALLINE CELLULOSE BP, USP-NF	Page 1 of 1
T.R. No.	MCC/2404106 BD/TR/107/2024	进行并继续的 医二甲甲二甲甲二甲甲二甲甲甲甲甲甲甲甲甲甲甲甲甲甲甲甲甲甲甲甲甲甲甲甲甲甲甲	
Lot Size.	4001 Kg		
Mfg. Date	April-24		
Re Test Date	April-24 April-27		
ep		Date of Anal	ysis: 24/04/2024
SR. TESTS			

SR.	TESTS		Date of Analysis :	24/04/2024				
NO		SPECIFICATION	RESULTS	TEST				
A	A. CHEMICAL TEST			METHOD				
1.	Appearance	White and the second		,CITIOD				
		White or almost white, fine or granular,	Fine, whit	e BP, USP-NF				
2.		slightly hygroscopic powder.	Odourless powder.	5.,051 11				
	(1) Solubility in water, acetone in							
	annydrous ethanol, in toluene, in	Practically insoluble in water acetone, in	Complies					
	dilute acids and in a 50 g/L solution	annydrous ethanol, in toluene in dilute saids						
	of sodium hydroxide.	and in a 50 g/L solution of sodium hydroxide.		BP, USP-NF				
	(2) Dissolve 50 mg in 10 mL of							
	ammoniacal solution of copper tetrammine R.	It should be dissolves completely, leaving no residue.	Complies					
3.		residue.						
J.	identification rests:	Identification Tests:						
	Test (A) By IR							
	The second secon	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-	6 "					
		Dlue.	Complies					
	Test (C) The degree of polymerization	The degree of polymerization should not be	Complies					
4.	pH of Solution	more than 350.	Complies					
	[5.0 g with 40 mL CO2 free water]	5.0 to 7.5	5.54					
	3 min 40 mic CO2 free water]		3.54	BP, USP-NF				
5.	Conductivity	The conductivity of the test solution should	55 μS.cm ⁻¹	DD HCD ME				
		be uses not exceed the conductivity of the		BP, USP-NF				
5.	Ether-soluble substances	water by more than 75µS.cm-1 Maximum 0.05%						
	Water-soluble substance	Maximum 0.05%	0.03 %	BP, USP-NF				
3.	Heavy Metals	Maximum 10 ppm	0.18 %	BP, USP-NF				
).	Loss on drying (at 105° C for 3 h)		Complies	BP, USP-NF				
0.	Sulphated ash	Maximum 7.00 %	4.40 %	BP, USP-NF				
	(Calculated on dried basis)	Maximum 0.1%	0.05 %					
	HYSICAL TEST			BP, USP-NF				
	Bulk Density (Untapped)	0.25 to 0.45 g/cm ³						
	Sieve analysis (% Retention by Sieve	60 Mesh- Minimum 10.0 %	0.44 g/cm ³	In House				
	shaker)	100 Mesh- Minimum 50.0 %	31.80 %					
C. M	IICROBIAL TEST	200 West- Willimum 50.0 %	72.30 %					
	Total Aerobic microbial Count	Not many the						
	Total yeasts and molds count	Not more than 1000 CFU/ g	Complies					
	Escherichia coli & Salmonella	Not more than 100 CFU/g	Complies					
	Pseudomonas aeruginosa	Should be Absent	Absent	BP, USP-NF				
	Staphylococcus aureus	Should be Absent	Absent					
nark	c: The Product passes as per BP 2022 ,US		Absent					
	Journal Passes as per BP 2022 ,US	P-NF 40.1H (Type 200.) Specific						

	Designation	Stamp		
Prepared by :	Q.C. Chemist		Signature	Date
	Q.C. Clemist	Q. C.	Lasala P.	24/04/2024
Reviewed & Approved by :	Manager Q.C./QA	APPROVED AMMEDIABAD INDIA	0	24/04/2021