



CERTIFICATE OF ANALYSIS

MICROCRYSTALLINE CELLULOSE IP/BP/Ph.Eur./EP/USP/NF/JP/IHS

Batch No:	2209047-C	Batch Size:	3800 KG
Date of Manufacturing:	22/09/2022	Analysis Report No:	QCD/MCC/22-23/343
Retest Date:	5 years from the date of manufacturing	Item Code :	MCC1
Customer Item Code :	N.A.	Specification No. & Rev. No. :	SPEC/FP/MCC/BP & 12
Customer Name :	N.A.	Pharmacopoeia Standard:	BP
		Grade :	MICCEL 200

Parameters	Specification	Result
Appearance	White or almost white, fine or granular, slightly hygroscopic powder.	Complies
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	Passes
Identification Test - A	Infrared Absorption.	Complies
Identification Test - B	Violet-blue colour should be produced.	Passes
Identification Test - C	The degree of polymerization should not more than 350	230.7
Solubility in Copper Tetramine	Should dissolved completely, leaving no residue.	Passes
pH	5.0 to 7.5	6.70
Conductivity, $\mu\text{S}/\text{cm}$	NMT 75	57
Ether soluble substances, %	NMT 0.05	0.03
Water Soluble Substances, %	NMT 0.25	0.17
Loss on Drying, %	NMT 7.0	4.1
Sulfated Ash, %	NMT 0.1	0.06
PSD, Weight % retained on 60 mesh (By Retsch, Model-AS200 Digit)	NLT 10 (IH)	21.0
PSD, Weight % retained on 100 mesh (By Retsch, Model-AS200 Digit)	NLT 50 (IH)	54.0
Bulk Density, g/ml	Between 0.29 to 0.36 (IH)	0.35
Total Aerobic Microbial Count, CFU/g	NMT 1000	90
Total Combined Yeasts & Molds Count, CFU/g	NMT 100	10
Escherichia coli /g	Should be absent	Absent
Pseudomonas aeruginosa /g	Should be absent	Absent
Staphylococcus aureus /g	Should be absent	Absent
Salmonella species / 10g	Should be absent	Absent

Above batch product complies as per BP - 2020 / In-House Specification / Customer Specification.

The raw materials, manufacturing process and product do not contain any of the solvents listed in Residual Solvents. (I.P./Ph.Eur.<5.4>, USP<467>).

Note: NMT-Not More Than, NLT- Not Less Than, IH-In-House. PSD-Particle Size Distribution. In-house specification may be changed as per customer requirement.

Date of Sampling: 23/09/2022

Date of Release: 30/09/2022

Q.C. Head/Designee

Q.A. Head / Designee

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