



maple biotech pvt. ltd.

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CERTIFICATE OF ANALYSIS MICROCRYSTALLINE CELLULOSE PH 200

Batch No	MCC200240708	
Manufacturing Date	12.07.2024	
Expiry Date	11.07.2024	
Material supplied to		
Delivery Challan No. / Date	EX/24-25/043, DATE. 03.08.2024	
QUANTITY	5000 KGS	
TEST	OBSERVATIONS	SPECIFICATIONS
Description	Complies	: White or almost white, fine, granular powder, practically insoluble in water, in acetone, in ethanol, in toluene, in dilute acids and in 50 g/l solution of sodium hydroxide
Identification	Passes USP/NF specifications	USP/NF Monograph Identification Tests A,B,C&D
Assay	99.9%	97 to 102 %
pH	5.9	5 to 7 (Pharma Eur. / JP/ USP) 5 to 7.5 (IP)
Starch	Negative	Negative(Pharma Eur./USP/JP/IP)
Water Soluble Matter	0.14%	max. 0.24%(Pharma Eur/NF/JP) max. 0.2% (IP)
Residue on Ignition	0.07%	max 0.2% (IP) 0.05% USP
Sulphated Ash	0.05%	max 0.1%(Pharma Eur/NF/JP) max 0.2% (IP)
Moisture	3.9%	7% (Pharma Eur./USP/JP/IP)
Heavy Metals	Max. 10 ppm	Max. 10 ppm (USP/ IP/Pharma Eur)
Seive Analysis		
Retention on 60 mesh :	16%	Min. 10%
Retention on 100 mesh :	57%	Min. 50%
Conductivity	55 μ S/Cm	Max. 75 μ S/Cm
Organic Volatile Impurities	Meets The Requirement	As per USP
Ether-soluble substances	0.03%	Max. 0.05%
Foreign Particles	Complies	Free from foreign particles
Total Aerobic Microbial Count	Meets The Requirement	max. 1000 cfu/gm (Ph. Eur /USP)
Total Molds and Yeast Count	Meets The Requirement	Max. 100 cfu/gm (Ph. Eur / USP)
E. Coli	absent	absent (Pharma Eur/ USP)
Salmonella	absent	absent (Pharma Eur/ USP)
S. Aureus	absent	absent (Pharma Eur/ USP)
Pseudomonas	absent	absent (Pharma Eur/ USP)
MATERIAL COMPLIES WITH ALL THE TEST GIVEN ABOVE OF IP / USP/ Ph Eur. And JP		

For Maple Biotech Pvt. Ltd.


CHEMIST




Q.C. MANAGER