

Factory address: Factory: Plot No.763/2,Jhagadia Dist.Bharuch,Gujarat(India) Phone:+91-2645226230

CERTIFICATE OF ANALYSIS

Product	: MICROCRYSTALLINE CELLULOSE: USP 41-NF 36	Country of Origin	: India
Batch No.	: SJ/25013445	Quantity	: 10000 Kgs
Grade	: 101	Sl. No.of bags	: 001 - 500
Consignee	: M/S. Medpharma General Trading L.L.C.	Mfg. Date	: Jan-2025
		Exp. Date	: Dec-2029

AceCel[®]

Sr. No.	CHARACTERISTICS	SPECIFICATIONS	RESULTS
A. CHEMICAL TESTS:			
1.	Description	White or almost white, Fine or granular powder. It consists of free flowing, non fibrous particles.	Almost white, powder.
2.	Solubility	Practically insoluble in sodium hydroxide solution (1 in 20); insoluble in water; in dilute acids and in most-organic solvents.	Complies
3.	Identification	A. The IR Spectrum is similar with reference standard/working standard	Complies
		B. The substance becomes violet-blue with iodinated Zinc Chloride Solution.	Complies
		C. The degree of Polymerization should not be more than 350	253.6
4.	pH	5.0 – 7.5	6.70
5.	Conductivity	<75 µs/cm	63
6.	Ether Soluble Substance	<0.05 %	0.022
7.	Water Soluble Substance	<0.25 %	0.16
8.	Heavy metals	<10 PPM	Complies
9.	Loss on drying	<7.0 %	4.29
10.	Residue on ignition	<0.10 %	0.053
11.	Residual Solvents	\$	-----
B. PHYSICAL TESTS:			
12.	Bulk Density	Un Tapped	0.28 – 0.34 g/cc
13.	Sieve Analysis	(+) 60 Mesh	<1.0%
		(-) 200Mesh	>70.0%
C. MICROBIAL TESTS:			
14.	Total Aerobic Microbial count	<1000 cfu / g	<40
15.	Total combined Molds & Yeast Count	<100 cfu / g	<20
16.	Escherichia coli	Absent in 1 g	Absent
17.	Salmonella species	Absent in 10 g	Absent
18.	Staphylococcus aureus	Absent in 1 g	Absent
19.	Pseudomonas aeruginosa	Absent in 1 g	Absent

OPINION:

The above product batch complies as per the monograph of USP41-NF36/I.H
 \$ Not applicable, The raw material, manufacturing process, and product do not contain any of the solvents listed in residual Solvent (ph.Eur <5.4>, USP<467>).
 Storage: Store protected from light and moisture.



Prepared By
Krishna Rai
 (Asst. Manager-Quality Control)




Reviewed & Approved By
Dr. Pravinsinh Dodia
 (Manager-Quality Control)

Corporate Office : SIGACHI INDUSTRIES LIMITED

#229/1 & 90, 4th Floor, Kalyan's Tulasiram Chamber's, Madinaguda, Hyderabad -500 049, Telangana State, India.

Tel.: +91-40-40114874 / 75 / 76, ♦ Email : customercare@sigachi.com,

♦ website: www.sigachi.com