

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

**CERTIFICATE OF ANALYSIS**

Product	: <b>MICROCRYSTALLINE CELLULOSE: USP 41-NF 36</b>	Country of Origin	: <b>India</b>
Batch No.	: <b>SJ/25013432</b>	Quantity	: <b>13000 Kgs</b>
Grade	: <b>102</b>	Sl. No.of bags	: <b>001 - 650</b>
Consignee	: <b>M/S. Medpharma General Trading L.L.C.</b>	Mfg. Date	: <b>Jan-2025</b>
		Exp. Date	: <b>Dec-2029</b>

**AceCel**<sup>®</sup>

Sr. No.	CHARACTERISTICS	SPECIFICATIONS	RESULTS
<b>A.</b>	<b>CHEMICAL TESTS:</b>		
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	254.1
4.	pH	5.0 – 7.5	6.62
5.	Conductivity	<75 µs/cm	65
6.	Ether Soluble Substance	<0.05 %	0.022
7.	Water Soluble Substance	<0.25 %	0.17
8.	Heavy metals	<10 PPM	Complies
9.	Loss on drying	<7.0 %	4.51
10.	Residue on ignition	<0.10 %	0.057
11.	Residual Solvents	\$	----
<b>B.</b>	<b>PHYSICAL TESTS:</b>		
12.	Bulk Density	Un Tapped	0.28 – 0.34 g/cc
13.	Sieve Analysis	(+) 60 Mesh	<8.0%
		(+) 200Mesh	>45.0%
<b>C.</b>	<b>MICROBIAL TESTS:</b>		
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**  
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**Reviewed & Approved By**  
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**(Manager-Quality Control)**

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