



Accent Microcell Limited

FACTORY- SURVEY NO.533/P, PALDI KANKAJ,KAMOD-PIRANA ROAD,PIRANA ..AHMEDABAD-382425

Quality Control

CERTIFICATE OF ANALYSIS

Product Name : MICROCRYSTALLINE CELLULOSE 200 USP	Batch No. : 90230145
Customer Name : TRINITY PHARMACEUTICALS &FOOD PVT LTD.	Mfg. Month : FEB-2023
Grade : ACCEL 200	Exp. Month : JAN-2028
MOA : USP 42	Batch Size : 3000 KG

Sr. No.	Test	Specification	Result
1	Description	White or almost white, fine or granular, Slightly hygroscopic powder.	Complies
2	Solubility	Practically insoluble in water, in acetone, in anhydrous alcohol, in toluene, dilute acid and in a 50 g/l solution of sodium hydroxide.	Complies
3	Identification A (IR Spectroscopic test)	The IR transmittance spectrum of the sample should be concordant with the spectrum of microcrystalline cellulose working standard.	Complies
4	Identification B (Zinc Chloride test)	The substance become violet blue	Complies
5	Identification C (Degree of polymerization)	NMT 350	Complies
6	Solubility (coppertetramine solution)	It dissolves completely, leaving no residue.	Complies
7	pH	5.0 to 7.5	6.02
8	Conductivity	NMT 75 $\mu\text{s}/\text{cm}^{-1}$	Complies
9	Ether Soluble Substance	NMT 0.05 %	0.0239 %
10	Water Soluble Substance.	NMT 0.25 %	0.1496 %
11	Loss On Drying	NMT 7.0 %	2.93 %
12	Residue on Ignition	NMT 0.1 %	0.0572 %
13	Particle Size Distribution	D10 : < 70 μ D50 : 150-200 μ D90 : > 260 μ	63 μ 180 μ 298 μ
14	Total Viable Aerobic Count	NMT 1000 cfu/g	55
15	Total Yeast & Mould Count	NMT 100 cfu/g	Nil
16	Escherichia Coil	Should be Absent /g	Absent
17	Pseudomonas Aeruginosa	Should be Absent /g	Absent
18	Staphylococcus aureus	Should be Absent /g	Absent
19	Salmonella Species	Should be Absent /10g	Absent
20	Bulk Density	0.26 to 0.40 g/ml	0.3648 g/ml
21	Sieve Analysis (%Retention)		
21.1	60 Mesh	NLT 10.0 %	11.2046 %
21.2	100 Mesh	NLT 50.0 %	56.3658 %

The Raw Material, manufacturer process and product do not contain any of solvent listed in organic volatile Impurities & residual solvent. Abbreviation : NMT (Not More Then), NLT (Not Less Then)

Storage recommendation: Preserve in tight containers.

Prepared By

Checked By

Approved By





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Quality Control

CERTIFICATE OF ANALYSIS

Product Name : MICROCRYSTALLINE CELLULOSE 200 USP	Batch No. : 90230161
Customer Name : TRINITY PHARMACEUTICALS &FOOD PVT LTD.	Mfg. Month : FEB-2023
Grade : ACCEL 200	Exp. Month : JAN-2028
MOA : USP 42	Batch Size : 3000 KG

Sr. No.	Test	Specification	Result
1	Description	White or almost white, fine or granular, Slightly hygroscopic powder.	Complies
2	Solubility	Practically insoluble in water, in acetone, in anhydrous alcohol, in toluene, dilute acid and in a 50 g/l solution of sodium hydroxide.	Complies
3	Identification A (IR Spectroscopic test)	The IR transmittance spectrum of the sample should be concordant with the spectrum of microcrystalline cellulose working standard.	Complies
4	Identification B (Zinc Chloride test)	The substance become violet blue	Complies
5	Identification C (Degree of polymerization)	NMT 350	Complies
6	Solubility (coppertetramine solution)	It dissolves completely, leaving no residue.	Complies
7	pH	5.0 to 7.5	6.24
8	Conductivity	NMT 75 $\mu\text{s}/\text{cm}^{-1}$	Complies
9	Ether Soluble Substance	NMT 0.05 %	0.0251 %
10	Water Soluble Substance.	NMT 0.25 %	0.1538 %
11	Loss On Drying	NMT 7.0 %	3.56 %
12	Residue on Ignition	NMT 0.1 %	0.0584 %
13	Particle Size Distribution	D10 : < 70 μ D50 : 150-200 μ D90 : > 260 μ	62 μ 181 μ 302 μ
14	Total Viable Aerobic Count	NMT 1000 cfu/g	60
15	Total Yeast & Mould Count	NMT 100 cfu/g	Nil
16	Escherichia Coil	Should be Absent /g	Absent
17	Pseudomonas Aeruginosa	Should be Absent /g	Absent
18	Staphylococcus aureus	Should be Absent /g	Absent
19	Salmonella Species	Should be Absent /10g	Absent
20	Bulk Density	0.26 to 0.40 g/ml	0.3552 g/ml
21	Sieve Analysis (%Retention)		
21.1	60 Mesh	NLT 10.0 %	11.4056 %
21.2	100 Mesh	NLT 50.0 %	58.3426 %

The Raw Material, manufacturer process and product do not contain any of solvent listed in organic volatile Impurities & residual solvent. Abbreviation : NMT (Not More Then), NLT (Not Less Then)

Storage recommendation: Preserve in tight containers.

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