



**ANKIT PULPS &
BOARDS PVT. LTD.** *Bettering Lives*

Manufacturer of Microcrystalline Cellulose & Co-Processed MCC

(Pharma Division)

(An ISO 9001 : 2015 Certified Company)

US FDA allotted Type IV DMF

Microcrystalline Cellulose USP (Various Grades) USDMF No. 026433

Silicified Microcrystalline Cellulose USP (Various Grades) USDMF No. 031300

Microcrystalline Cellulose and Carboxymethylcellulose Sodium USP-NF

(Various Grades) USDMF No. 031677

CIN : U21010MH1988PTC049007

Registered Office & Factory Address

39/2, Bhilgaon, Post Khairi, Kamptee Road.

Dist. Nagpur 440026 (India)

E-Mail : rajesh@celluloseankit.com,

Website : <http://www.celluloseankit.com>

Phone No : +91-712-2043300, 2043301

Mobile No : +91-9970057661

CERTIFICATE OF ANALYSIS

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

Batch No:	2211034-C	Batch Size:	6100 KG
Date of Manufacturing:	18/11/2022	Analysis Report No:	QCD/MCC/22-23/419
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 :	Cargo Trade LLC, Russia	Pharmacopoeia Standard:	BP
		Grade :	MICCEL-102

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	231.5
Solubility in Copper Tetramine	Should dissolved completely, leaving no residue.	Passes
pH	5.0 to 7.5	6.64
Conductivity, $\mu\text{S}/\text{cm}$	NMT 75	61
Ether soluble substances, %	NMT 0.05	0.03
Water Soluble Substances, %	NMT 0.25	0.17
Loss on Drying, %	NMT 7.0	4.6
Sulfated Ash, %	NMT 0.1	0.08
PSD, Weight % retained on 60 mesh (By Retsch, Model-AS200 Digit)	NMT 8 (IH)	0
PSD, Weight % retained on 200 mesh (By Retsch, Model-AS200 Digit)	NLT 45 (IH)	62.0
Bulk Density, g/ml	Between 0.28 to 0.37 (IH)	0.34
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: 19/11/2022

Date of Release : 26/11/2022

Q.C. Head/Designee

Q.A. Head/Designee

Format No. QC114/F01-02

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CERTIFICATE OF ANALYSIS

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

Batch No:	2211040-C	Batch Size:	6100 KG
Date of Manufacturing:	20/11/2022	Analysis Report No:	QCD/MCC/22-23/423
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 :	Cargo Trade LLC, Russia	Pharmacopoeia Standard:	BP
		Grade :	MICCEL-102

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	231.6
Solubility in Copper Tetramine	Should dissolved completely, leaving no residue.	Passes
pH	5.0 to 7.5	6.56
Conductivity, $\mu\text{S}/\text{cm}$	NMT 75	65
Ether soluble substances, %	NMT 0.05	0.02
Water Soluble Substances, %	NMT 0.25	0.16
Loss on Drying, %	NMT 7.0	4.2
Sulfated Ash, %	NMT 0.1	0.06
PSD, Weight % retained on 60 mesh (By Retsch, Model-AS200 Digit)	NMT 8 (IH)	0
PSD, Weight % retained on 200 mesh (By Retsch, Model-AS200 Digit)	NLT 45 (IH)	59.0
Bulk Density, g/ml	Between 0.28 to 0.37 (IH)	0.34
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: 21/11/2022

Date of Release : 28/11/2022

Q.C. Head/Designee

Q.A. Head/Designee

Format No. QC114/F01-02

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