



RAW MATERIAL SPECIFICATION AND ANALYSIS FORM

MATERIAL DESCRIPTION

SPECIFICATION VERSION: C

Storage Conditions: Ambient

Material Name: Micro. Crys. Cell. 102 Powder Bulk

Item Number: 300393

Lot Number: 21012378

Primary Vendor: EM Sergeant ✓

Category: Chemical Entity

REQUIRED TESTS AND EXAMINATION

1. APPEARANCE:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Color	VISUAL	White almost white	Conforms
Texture	MACROSCOPIC	Free Flowing Powder	Conforms

2. IDENTIFICATION:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Identity	USP Microcrystalline Cellulose Test A	Conforms	Conforms

3. STRENGTH (POTENCY):

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Assay	N/A	N/A	N/A

4. PHYSICAL CHARECTERISTIC:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Bulk Density	COA	NLT 0.35 g/mL	Acceptable by R+D
Particle Size	COA/In-house	100% through 60 mesh	Conforms

5. COMPOSITION (EXCIPIENT/CARRIER):

SPECIFICATION	Verified
N/A	N/A



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6. CONTAMINANTS:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Microbiology	COA	TAMC <1,000 cfu/g TYMC <100 cfu/g E. Coli Absent/10g Salmonella Absent/10g	<i>conforms</i>
Heavy Metals	COA	Arsenic < 15µg/g Cadmium < 5µg/g Lead < 5µg/g Mercury < 2µg/g	<i>Conforms</i>

7. QC NOTES:

Bulk Density	N/A
Particle Size	Mandatory for R&D
Strength	N/A
Micro	N/A
Metals	N/A

8. REVISION HISTORY:

Version	Effective Date	Reason for Change
A	03/13/2018	New Document
B	05/24/2018	Revised E. Coli absent to /g from 10/g Spelling correction
C	10/29/2020	Update to New Template

9. DOCUMENT FORM HISTORY (See form history in SOP 03.011-F03.004)

Prepared by:	ORIGINAL SIGNATURES OF FILE
Approved by:	ORIGINAL SIGNATURES OF FILE



CERTIFICATE OF ANALYSIS

PRODUCT **MICROCRYSTALLINE CELLULOSE 102 NF
(MICCEL-102)**
LOT No. 201105-C
MFG DATE: NOVEMBER 05, 2020
EXP DATE: NOVEMBER 04, 2025
COUNTRY OF ORIGIN **INDIA**

White or almost white, free-flowing powder consisting of non-fibrous particles, insoluble in water, dilute acid and most organic solvents. Practically insoluble/very slightly soluble in dilute NaOH solution (1 in 20)

<u>TEST ITEMS</u>	<u>SPECIFICATIONS</u>	<u>RESULTS</u>
Identification A	Infrared Absorption	Complies
Identification B (Zinc Chloride)	Should produce a violet-blue color	Positive
Identification C (Degree of Polymerization)	NMT 350	231.6
pH	5.0 – 7.5	6.51
Conductivity	NMT 75 $\mu\text{S}\cdot\text{cm}^{-1}$	60 $\mu\text{S}\cdot\text{cm}^{-1}$
Water Soluble Substances	NMT 0.25%	0.15%
Ether Soluble Substances	NMT 0.05%	0.03%
Loss on Drying	NMT 7.0%	4.1%
Heavy Metals	NMT 10 ppm	Complies
Arsenic	NMT 3 ppm	Complies
Lead	NMT 0.5 ppm	Complies
Cadmium	NMT 2 ppm	Complies
Mercury	NMT 0.1 ppm	Complies
Residue on Ignition	NMT 0.1%	0.07%
Bulk Density	0.30 – 0.36 g/mL	0.35 g/mL
Sieve Analysis (% Retention)		
60 Mesh	$\leq 8.0\%$	0%
200 Mesh	$\geq 45.0\%$	58.0%
Particle Size Distribution		
D ₁₀	20 – 50 μm	28.6 μm
D ₅₀	90 – 150 μm	96.7 μm
D ₉₀	190 – 300 μm	204.9 μm
Total Plate Count	NMT 1,000 cfu/g	80 cfu/g
Yeast & Mold	NMT 100 cfu/g	10 cfu/g
Escherichia coli	Absent/g	Absent
Staphylococcus aureus	Absent/g	Absent
Salmonella species	Absent/10g	Absent
Pseudomonas aeruginosa	Absent/g	Absent

The raw materials, manufacturing process, and product do not contain any of the solvents listed in Residual Solvents (Ph.Eur. 5.4; USP<467>). This batch complies with the requirements of USP. Tested according to USP.

This is a copy of the original Manufacturer's/Supplier's Certificate of Analysis

Ivaylo Balabanov, Quality Assurance