

## Microcrystalline Cellulose (MCC-102), USP-NF, ChP, E 460 (i), FCC

## **SPECIFICATIONS**

Batch No.: FBXXXXXX

Re-evaluation date: March-2029 Manufacturing date: March 2024

## **Description**

Appearance Fine, white or almost white powder, It consists of free-flowing nonfibrous particles.

Solubility Insoluble in water, in dilute acids and in most organic solvents, practically insoluble in sodium hydroxide solution (1 in 20).

Characteristics Identification A Identification B, (1) Identification C, (2)	Acceptance criteria IR scan conforms Violet-blue color Max. 350	Batch result Passes* Passes Passes	Reference USP-NF USP-NF, ChP USP-NF, ChP
Arsenic	Max. 0.0002 %	Passes	ChP
Chloride	Max. 0.03 %	Passes	ChP
Conductivity	Max. 75 μS/ cm	54 µS/ cm	USP-NF, ChP
Ether-soluble substances	Max. 0.05 %	0.01 %	USP-NF, ChP
Heavy metals	Max. 10 ppm	< 10 ppm	In-House Method
Loss on drying	Max. 7.0 %	3.8 %	USP-NF, ChP
pH	5.5 - 7.0	6.2	USP-NF, ChP
Starch	Negative	Passes	ChP
Organic impurities	Passes	Passes	IP IP
Assay	97.0 - 102.0 %	99.7 %	USP-NF, ChP
Sulphated ash/ residue on ignition	Max. 0.05 %	< 0.05 %	USP-NF, ChP
Water-soluble substances	Max. 0.2 %	0.12 %	USP-NF
TAMC (Total Aerobic Microbial Count)	Max. 10 <sup>2</sup> cfu/ g	30 cfu/ g	USP-NF
TYMC (Total Yeast and Mold Count)	Max. 20 cfu/ g	< 10 cfu/ g	USP-NF
Escherichia coli	Absent in 1 g	Absent	USP-NF
Pseudomonas aeruginosa	Absent in 1 g	Absent	USP-NF
Salmonella species	Absent in 10 g	Absent	USP-NF
Staphylococcus aureus	Absent in 1 g	Absent	USP-NF
Bulk density	0.28 - 0.35 g/ml	0.31 g/ml	In-house Method
Particle size (retained on air jet sieve)			
> 250 µm (60 mesh)	Max. 8.0 %	2.6%	
> 75 µm (200 mesh)	45.0 - 70.0 %	56.9 %	In-house Method
Particle size distribution (laser diffraction)			
d10	Max. 50 μm	34 µm	
d50	90 - 140 μm	118 µm	
d90	Min. 170 μm	254 µm	
Technical unavoidable particles (TUP) *Results reported are expected results based	Max. 8 / 600 cm <sup>2</sup> on periodic testing.	3 / 600 cm <sup>2</sup>	In-house Method

The batch described by this certificate meets the requirements of USP-NF and ChP monographs for "Microcrystalline Cellulose" current edition, it complies with E 460 (i) monograph (231/2012), FCC and all relevant EU Food Regulations. It is released on the basis of the results ascertained. Product is manufactured under GMP for excipients according to IPEC and USP <1078>. The raw materials, manufacturing process and product do not contain any of the solvents listed in Residual Solvents (USP <467>). Elements listed in !CH O3D Guideline for elemental impurities are not used in manufacturing and not analyzed per batch; detailed information is available on request.

Storage recommendation: Protect from excessive heat and moisture. Keep containers closed.