



Solchem LLC, 42231 Amber Meadows Lane, Ashburn, VA 20148

Microcrystalline Cellulose (MCC-200), USP-NF, ChP, E 460 (i), FCC

**SPECIFICATIONS**

Batch No.: FDXXXXXX  
 Re-evaluation date: September-2028  
 Manufacturing date: September-2023

**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	Acceptance criteria	Batch result	Reference
Identification A	IR scan conforms	Passes*	USP-NF
Identification B, (1)	Violet-blue color	Passes	USP-NF, ChP
Identification C, (2)	Max. 350	Passes	USP-NF, ChP
Arsenic	Max. 0.0002 %	Passes	ChP
Chloride	Max. 0.03 %	Passes	ChP
Conductivity	Max. 75 µS/ cm	49 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 IP
Organic impurities	Passes	Passes	IP
Assay	97.0 - 102.0 %	99.8 %	USP-NF, ChP
Sulphated ash / residue on ignition	Max. 0.05 %	< 0.05 %	USP-NF, ChP
Water-soluble substances	Max. 0.2 %	0.13 %	USP-NF
TAMC (Total Aerobic Microbial Count)	Max. 10 <sup>2</sup> cfu/ g	35 cfu/ g	USP-NF
TYMC (Total Yeast and Mold Count)	Max. 20 cfu/ g	<10cfu/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	0.29 - 0.39 g/ml	0.33 g/ml	In-house Method
Particle size (retained on air jet sieve)			
> 250 µm (60 mesh)	Min. 10.0 %	23.7 %	
> 150 µm (100 mesh)	Min. 50.0 %	61.6 %	In-House Method
Particle size distribution (laser diffraction)			
d10	Max.85µm	73 µm	
d50	150 - 280 µm	213 µm	
d90	Min. 310 µm	400 µm	
Technical unavoidable particles (TUP)	Max. 8 / 600 cm <sup>2</sup>	3 / 600 cm <sup>2</sup>	In-House Method

\*Results reported are expected results based on periodic testing.

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. FLOCEL 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 ICH 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.**