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

Microcrystalline Cellulose (MCC 101) USP-NF, ChP, E 460 (1), FCC

SPECIFICATIONS

Batch No.:	FAxxxxxxxx
Re-evaluation date:	May-2029
Manufacturing date:	May-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	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	43 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%	3.9%	USP-NF, ChP
pH	5.5 - 7.0	6.0	USP-NF, ChP
Starch	Negative	Passes	ChP
Organic impurities	Passes	Passes	IP
Assay	97.0 - 102.0%	99.7%	IP
Sulphated ash / residue on ignition	Max. 0.05%	0.02%	USP-NF, ChP
Water-soluble substances	Max. 0.2%	0.12%	USP-NF, ChP
TAMC (Total Aerobic Microbial Count)	Max. 10^2 cfu/ g	20 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	0.26 - 0.34 g/ml	0.29 g/ml	USP-NF
Particle size (retained on air jet sieve)			In-house Method
> 250µm (60 mesh)	Max. 1.0%	0.0%	
> 75µm (200 mesh)	10. 0 - 30.0%	23.1%	
Particle size distribution (laser diffraction)			In-House Method
d10	15 - 30µm	22 µm	
d50	45 - 75µm	64 µm	
d90	110 - 170 µm	129 µm	
Technical unavoidable particles (TUP)	Max. 8 / 600 cm^2	4 / 600 cm^2	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. Material 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.