



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

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).

Table with 4 columns: Characteristics, Acceptance criteria, Batch result, Reference. Rows include Identification A-C, Arsenic, Chloride, Conductivity, Ether-soluble substances, Heavy metals, Loss on drying, pH, Starch, Organic impurities, Assay, Sulphated ash, Water-soluble substances, TAMC, TYMC, Escherichia coli, Pseudomonas aeruginosa, Salmonella species, Staphylococcus aureus, Bulk density, Particle size (retained on air jet sieve), Particle size distribution (laser diffraction), and Technical unavoidable particles (TUP).

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 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.