

Microcel MC-101

Microcrystalline Cellulose, NF/EP

Microcel MC-101 grade of MCC is used primarily in wet granulation, but may also be used in direct compression. The small particle size of Microcel MC-101 works particularly well when used with large particle size active ingredients, because the smaller size reduces the space between the active particles. Recommended usage levels are between 10 - 50%.

Product Specifications

Chemical & Physical Properties

Appearance White, non fibrous powder Odor Odorless Identification A Positive Identification B (Degree of Polymerization) **NMT 350** Loss on drying (as shipped) NMT 7.0 % 5.0 to 7.0 Water soluble substances NMT 0.24 % Ether soluble substances NMT 0.05 % Residue on ignition NMT 0.05 % NMT 10 ppm Heavy metals Conductivity NMT 75 uS Solubility in Copper Tetrammine Solution Positive Retained on 60 Mesh (250 Microns) NMT 1.0 % Retained on 200 Mesh (74 Microns) NMT 30.0 % Bulk density 0.26-0.31 g/cm3

Solubility Information:

Dilute Alkali Partially soluble

Dilute Acid and Organic Solvents Insoluble

Water Insoluble, Dispersible

This product meets the requirement for Residual Solvents – USP<467>, EP<5.4>. No solvents are used in the manufacturing process.

Microbiological Properties

Total aerobic microbial count

NMT 1000 cfu/g

Total combined molds and yeasts count

Escherichia coli

Pseudomonas aeruginosa

Salmonella species

Staphylococcus aureus

NMT 1000 cfu/g

NMT 1000 cfu/g

Absent

Absent

Absent

General Information

- (1) This product is manufactured in accordance with the Good Manufacturing Practices, complies with the current USP/NF/EP requirements.
- (2) Package: 15 kgs plastic bag.
- (3) Store in dry area, in tight containers.
- (4) Shelf life from the manufacturing date: 3 years when preserved in tight containers.
- (5) NMT = Not More Than
- (6) DMF number 9201
- (7) CAS: 9004-34-6

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