

Product Specification

Product group: Co-Processed MCC

Brand name: Pharmacel® sMCC 90

Article code : SAP :1177333, Navision:13127-5355
Product description : Silicified Microcrystalline Cellulose

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Manufacturer : DFE Pharma India Private Limited, India

Production site : Contract manufacturing location at Chemfield Cellulose Private Limited.,

Nagpur, India

Product name : Pharmacel® sMCC 90

Conforms to USP-NF and JPE Specifications on date of manufacture. Compounded from Microcrystalline Cellulose (USP-NF, Ph. Eur., JP, and IP) and Colloidal silicon dioxide USP-NF, IP/ Silica, Colloidal Anhydrous Ph.

Eur./Light Anhydrous Silicic Acid JP

Product description: A white or almost white, fine, crystalline, or granular, slightly hygroscopic

powder having fluidity and odorless

Solubility : Practically insoluble in water, acetone, anhydrous ethanol, toluene, diethyl

ether and dilute acids and swells in 50 g/L sodium hydroxide solution

0.37-0.50 g/ml

Physical - Chemical Data Specification Identification A (USP-NF) **Pass** Identification B, 1 (USP-NF, JPE) **Pass** Identification C, 2 (USP-NF, JPE) **Pass** Identification D, 3 (USP-NF, JPE) ≤0.02 Conductivity ≤75 μS/cm рΗ 5.0-7.0 ≤6.0% w/w Loss on Drying Degree of Polymerization ≤350 Water soluble substances ≤0.24% Ether soluble substances ≤0.05% Heavy metals ≤ 10 ppm Solubility in Cu tetrammine Dissolves Residue on ignition 1.8-2.2% **Bulk density** 0.25-0.37 g/ml

Tapped density



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<u>Microbiological Data</u> <u>Specification</u>

Total Aerobic Microbial Count Max. 100 CFU/g

Total Yeast and Mould Count Max. 20 CFU/q

Escherichia coli in 10g

Pseudomonas aeruginosa in 10g

Staphylococcus aureus in 10g

Negative

Salmonella species in 10g

Negative

Shigella species in 10g

Negative

Particle Size Distribution (Airjet, Malvern)

 Particle size %< 75μm</td>
 45-80 % w/w

 Particle size %< 250μm</td>
 ≤8.0 % w/w

 Particle size D10
 20-50 μm

 Particle size D50
 90-150 μm

 Particle size D90
 190-300 μm

Packaging: A white multi-layered polyethylene bag with a polyethylene inner liner, 25kg net.

Storage: Keep in original, un-opened packing in ambient conditions, protected from humidity

and away from strongly odorous materials.

Shelf life: For storage periods exceeding 48 months, we recommend re-testing.

This document substitutes all previous versions issued for the brand names mentioned above. We trust this information, which is made up to the best of our knowledge, will be helpful to you.

Name : Dr. Bastiaan Dickhoff

Job title : Director Innovation & Technical Solutions

B. Dickhof

Signature :

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