



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

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 |
| pH | 5.0-7.0 |
| Loss on Drying | ≤6.0% w/w |
| 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 | 0.37-0.50 g/ml |



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Microbiological Data

Total Aerobic Microbial Count

Total Yeast and Mould Count

Escherichia coli in 10g

Pseudomonas aeruginosa in 10g

Staphylococcus aureus in 10g

Salmonella species in 10g

Shigella species in 10g

Specification

Max. 100 CFU/g

Max. 20 CFU/g

Negative

Negative

Negative

Negative

Negative

Particle Size Distribution (Airjet, Malvern)

Particle size % < 75µm

Particle size % < 250µm

Particle size D10

Particle size D50

Particle size D90

Specification

45-80 % w/w

≤8.0 % w/w

20-50 µm

90-150 µm

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

Signature :

A handwritten signature in blue ink that reads 'B. Dickhoff'.

This document is controlled by a validated, electronic system and is valid without signature. The above facsimile signature is only for display.