

# Product Specification

Product group: Co-Processed MCC  
Brand name: Pharmacel® sMCC 90  
Article code : SAP :1177333, Navision:13127-5355  
Product description : Silicified Microcrystalline Cellulose  
Document No. : PD- 0835      Page 1 of 2

**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

<u>Physical - Chemical Data</u>	<u>Specification</u>
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

Product group: Co-processed MCC  
Brand name: Pharmacel® sMCC 90  
Article code : SAP :1177333, Navision :13127-5355  
Product description : Silicified Microcrystalline Cellulose  
Document No. : PD- 0835      Page 2 of 2

## 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  
Negative

## Particle Size Distribution (Airjet, Malvern)

Particle size %> 75µm  
Particle size %> 250µm  
Particle size D<sub>10</sub>  
Particle size D<sub>50</sub>  
Particle size D<sub>90</sub>

## 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** : 

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