

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

<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

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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
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 : 

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