Product Specification

Product group:	Co-Processed MCC
Brand name :	Pharmacel® sMCC 50
Article code:	SAP 1277998 ; Navision 13106-5355
Product description:	Silicified Microcrystalline Cellulose
Document No.:	PD-0926

Production site:	Contract manufacturing location at Chemfield Cellulose Private Limited., Nagpur, India
Product name:	Pharmacel® sMCC 50 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

Microbiological Data	**Specification**
Total Aerobic Microbial Count	Max. 100 CFU/g
Total Yeast and Mould Count	Max. 20 CFU/g
Escherichia coli in 10g	Negative
Pseudomonas aeruginosa in 10g	Negative
Staphylococcus aureus in 10g	Negative
*Salmonella spec*ies in 10g	Negative

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Release date: 02-09-2026

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Particle Size Distribution (Airjet, Malvern)	**Specification**
Particle size %> 75µm	10-30 % w/w
Particle size %> 250µm	≤1.0 % w/w
Particle size D10	15-30 µm
Particle size D50	45-80 µm
Particle size D90	100-180 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 : B. Dickhoff

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