



Product Specification

Product group: MCC
 Brand name: Pharmacel® 101
 Article code: SAP 743678; Navision 13101-5355
 SAP 733326; Navision 13121-5355
 Product descriptions: Microcrystalline Cellulose
 Document No.: PD-0472 Page 1 of 2

Manufacturer : DFE Pharma India Private Limited, India

Production site : DFE Pharma India Private Limited, Cuddalore, India and Contract manufacturing location at Chemfield Cellulose Private Limited., Nagpur, India

Product name : Pharmacel® 101
 Conforms to USP-NF, Ph. Eur., JP, and IP Specifications on date of manufacture

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, dilute acids and in a 50 g/L solution of Sodium hydroxide

Physical - Chemical Data

Specification

Identification A (USP, Ph. Eur.), 2 (JP)	Pass
Identification B (USP, Ph. Eur.), 1 (JP)	Pass
Identification C (USP, Ph. Eur.), 3 (JP)	Max. 350
Identification C (IP)	Pass
Solubility in ammoniacal copper tetrammine	Pass
pH	5.5 - 7.0
Conductivity	Max. 75 µS/cm
Ether soluble substances	Max. 0.05 %
Water soluble substances	Max. 0.20 %
Heavy metals	Max. 10 ppm
Assay (IP)	97.0 - 102.0 %
Arsenic	Max. 2 ppm
Starch and Dextrins (IP)	Pass
Organic impurities (IP)	Pass
Loss on Drying	3.0 - 5.0 %
Residue on ignition	Max. 0.05 %
Bulk density	0.26 - 0.31 g/mL



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Microbiological Data

Total Aerobic Microbial Count

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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 species in 10g

Negative

Shigella species in 10g

Negative

Particle Size Distribution (Airjet, Malvern)

Specification

Particle size %< 75µm

70.0 - 90.0 %

Particle size %< 250µm

Min. 99.0 %

Particle size D10

14 - 30 µm

Particle size D50

40 - 75 µm

Particle size D90

90 - 156 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 blue ink facsimile signature of B. Dickhoff.

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