

## **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
рН	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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<u>Microbiological Data</u> <u>Specification</u>

Total Aerobic Microbial Count Max. 100 CFU/g

Total Yeast and Mould Count Max. 20 CFU/g

Escherichia coli in 10gNegativePseudomonas aeruginosa in 10gNegativeStaphylococcus aureus in 10gNegativeSalmonella species in 10gNegativeShigella species in 10gNegative

Particle Size Distribution (Airjet, Malvern) Specification

Particle size %<  $75\mu m$  70.0 - 90.0 % Particle size %<  $250\mu m$  Min. 99.0 % Particle size D10 14 - 30  $\mu m$  Particle size D50 40 -  $75\mu m$  Particle size D90 90 -  $156\mu m$ 

**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

B. Dickhaff

Signature

This document is controlled by a validated, electronic system and is valid without signature.

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