



# 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  
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**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.