



# 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, IP and ChP<sup>1</sup> 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
Chlorides (ChP) <sup>1</sup>	Max. 0.03%



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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

### Particle Size Distribution (Airjet, Malvern)

Particle size % < 75µm  
Particle size % < 250µm  
Particle size D10  
Particle size D50  
Particle size D90

### Specification

70.0 - 90.0 %  
Min. 99.0 %  
14 - 30 µm  
40 - 75 µm  
90 - 156 µm

<sup>1</sup> Currently applicable to article code SAP 743678 / Navision 13101-5355 only

**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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