



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

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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 ¹ 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 Dextrans (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) ¹	Max. 0.03%



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Microbiological Data

	<u>Specification</u>
Total Aerobic Microbial Count	Max. 100 CFU/g
Total Yeast and Mould Count	Max. 20 CFU/g
<i>Escherichia coli</i> in 10g	Negative
<i>Pseudomonas aeruginosa</i> in 10g	Negative
<i>Staphylococcus aureus</i> in 10g	Negative
<i>Salmonella</i> species in 10g	Negative
<i>Shigella</i> species in 10g	Negative

Particle Size Distribution (Airjet, Malvern)

	<u>Specification</u>
Particle size %< 75µm	70.0 - 90.0 %
Particle size %< 250µm	Min. 99.0 %
Particle size D ₁₀	14 - 30 µm
Particle size D ₅₀	40 - 75 µm
Particle size D ₉₀	90 - 156 µm

¹ 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 :

A handwritten signature in blue ink that reads 'B. Dickhoff'.

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