Product Specification

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

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.,IP), 2 (JP)	Pass
Identification B (USP, Ph.Eur.,IP), 1 (JP, ChP[1])	Pass
Identification C (USP, Ph.Eur.,IP), 3 (JP), 2 (ChP[1])	Max. 350
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 (ChP[1])	Max. 10 ppm
Assay (IP)	97.0 - 102.0 %
Arsenic	Max. 2 ppm
Starch (ChP[1])	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%

Microbiological data:	**Specification**
Total Aerobic Microbial Count	Max. 100 cfu/g
Total Yeast and Mould Count	Max. 20 cfu/g
Escherichia coli in 10 g	Negative
Pseudomonas aeruginosa in 10 g	Negative
Staphylococcus aureus in 10 g	Negative
Salmonella species in 10 g	Negative

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Particle size (Airjet, Malvern)	**Specification**
Particle size %< 75 µm	70.0 - 90.0 %
Particle size %< 250 µm	Min. 99.0 %
Particle size D10	14 - 30 µm
Particle size D50	40 - 75 µm
Particle size D90	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, 25 kg 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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