



Product Specification

Product group: MCC
 Brand name: Pharmacel® 102
 Article code: SAP 743679; Navision 13102-5355
 SAP 733317; Navision 13122-5355
 Product descriptions: Microcrystalline Cellulose
 Document No. PD-0473

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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® 102
 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	0.28 - 0.33 g/mL



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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

30.0 - 55.0 %
Min. 92.0 %
15 - 50 µm
80 - 130 µm
170 - 283 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 : 

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