



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 Page 1 of 2

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 ChP¹ 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) ¹ | 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

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 : 

This document is controlled by a validated, electronic system and is valid without signature.
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