

Product group : MCC
 Brand name : Pharmacel®112
 Article code : SAP 743842; Navision 13115-5355
 Product description: Microcrystalline Cellulose
 Document No. : PD-0601 Page 1 of 2

Manufacturer : DFE Pharma India Private Limited, India

Production site : DFE Pharma India Private Limited, Cuddalore, India

Product name : Pharmacel® 112
 Conforms to USP-NF, Ph. Eur., JP, IP and ChP 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	Max. 1.5 %
Residue on ignition	Max. 0.05 %
Bulk density	0.28 - 0.34g/mL
Chlorides (ChP)	Max. 0.03%

Product group: MCC
Brand name: Pharmacel®112
Article code: SAP 743842; Navision 13115-5355
Product description: Microcrystalline Cellulose
Document No.: PD-0601 Page 2 of 2

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. 100CFU/g
Max. 20CFU/g
Negative
Negative
Negative
Negative
Negative

Particle Size Distribution (Airjet, Malvern)

Particle size % < 32µm
Particle size % < 75µm
Particle size % < 250µm
Particle size D10
Particle size D50
Particle size D90

Specification

Max. 30.0%
30.0 - 55.0 %
Min. 92.0 %
20 - 50 µm
80 - 130 µm
160 - 240 µm

Packaging : A white multi-layered polyethylene-aluminum bag with a polyethylene inner liner, 25Kg net.

Storage : Keep in original, unopened packing in ambient conditions, protected from humidity and away from strongly odorous materials. The storage of Pharmacel® 112 in original special packaging ensures complete protection from moisture absorption. If the packaging is opened, we strongly recommend closing the bag by heat-sealing, when material is not fully used.

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.
The above facsimile signature is only for display.