



Product Specification

Product group : MCC
Brand name : Pharmacel® 112
Article code : SAP 743842; Navision 13115-5355
Product description: Microcrystalline Cellulose
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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

<u>Physical-Chemical data</u>	<u>Specification</u>
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%

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Microbiological data

	<u>Specification</u>
Total Aerobic Microbial Count	Max. 100CFU/g
Total Yeast and Mould Count	Max. 20CFU/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 %< 32µm	Max. 30.0%
Particle size %< 75µm	30.0 - 55.0 %
Particle size %< 250µm	Min. 92.0 %
Particle size D ₁₀	20 - 50 µm
Particle size D ₅₀	80 - 130 µm
Particle size D ₉₀	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 : 

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