Product Specification

Product group:	MCC
Brand name :	Pharmacel® 112
Article code:	SAP 743842; Navision 13115-5355
Product description:	Microcrystalline Cellulose
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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.,IP), 2 (JP)	Pass
Identification B (USP, Ph.Eur.,IP), 1 (JP, ChP)	Pass
Identification C (USP, Ph.Eur.,IP), 3 (JP), 2 (ChP)	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)	Max. 10 ppm
Assay (IP)	97.0 - 102.0 %
Arsenic	Max. 2 ppm
Starch (ChP)	Pass
Loss on Drying	Max. 1.5 %
Residue on ignition	Max. 0.05 %
Bulk density	0.28 - 0.34 g/mL
Chlorides (ChP)	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 %< 32µm	Max. 30.0%
Particle size %< 75µm	30.0 - 55.0 %
Particle size %< 250µm	Min. 92.0 %
Particle size D10	20 - 50 µm
Particle size D50	80 - 130 µm
Particle size D90	160 - 240 µm

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