

Product Specification

Product group: MCC
 Brand name: Pharmacel® 200
 Article code: SAP 1147140;
 Navision 13114-5355
 Product description: Microcrystalline Cellulose
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Production site: DFE Pharma India Private Limited, Cuddalore, India
 Product name: Pharmacel® 200
 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:

Identification A (USP, Ph.Eur.), 2 (JP)
 Identification B (USP, Ph.Eur.), 1 (JP)
 Identification C (USP, Ph.Eur.), 3 (JP)
 Identification C (IP)
 Solubility in ammoniacal copper tetrammine
 pH
 Conductivity
 Ether soluble substances
 Water soluble substances
 Heavy metals
 Assay (IP)
 Arsenic (IP)
 Starch and Dextrins (IP)
 Organic impurities (IP)
 Loss on Drying
 Residue on ignition
 Bulk density
 Nitrite

Specification

Pass
 Pass
 Max. 350
 Pass
 Pass
 5.5 - 7.0
 Max. 75 µS/cm
 Max. 0.05 %
 Max. 0.20 %
 Max. 10 ppm
 97.0 - 102.0 %
 Max. 2 ppm
 Pass
 Pass
 3.0 - 5.0 %
 Max. 0.05 %
 0.29 - 0.36 g/mL
 ≤ 0.05 ppm

Microbiological data:

Total Aerobic Microbial Count
 Total Yeast and Mould Count
Escherichia coli in 10 g
Pseudomonas aeruginosa in 10 g
Staphylococcus aureus in 10 g
Salmonella species in 10 g
Shigella species in 10 g

Specification

Max. 100 cfu/g
 Max. 20 cfu/g
 Negative
 Negative
 Negative
 Negative
 Negative

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Particle size (Airjet, Malvern)

Particle size %< 150 µm
Particle size %< 250 µm
Particle size D10
Particle size D50
Particle size D90

Specification

Max. 50.0 %
Max. 90.0 %
Max. 175 µm
142-280 µm
275-480 µm

Packaging:

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