

# 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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