# Product Specification

| | |
|---|---|
| Product group: | MCC |
| Brand name: | Pharmacel® 200 |
| Article code: | SAP 1147140; Navision 13114-5355 |
| Product description: | Microcrystalline Cellulose |
| Document No.: | PD-0771 |



| | |
|---|---|
| Production site: | DFE Pharma India Private Limited, Cuddalore, India |
| Product name: | Pharmacel® 200<br>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:** | **Specification** |
|---|---|
| Identification A (USP, Ph.Eur.,IP), 2 (JP) | Pass |
| Identification B (USP, Ph.Eur.,IP), 1 (JP) | Pass |
| Identification C (USP, Ph.Eur.,IP), 3 (JP) | 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 % |
| Assay (IP) | 97.0 - 102.0 % |
| Arsenic (IP) | Max. 2 ppm |
| Loss on Drying | 3.0 - 5.0 % |
| Residue on ignition | Max. 0.05 % |
| Bulk density | 0.29 - 0.36 g/mL |
| Nitrite | ≤ 0.05 ppm |

| **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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Release date: 06-07-2026

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| **Particle size (Airjet, Malvern)** | **Specification** |
|---|---|
| Particle size %< 150 µm | Max. 50.0 % |
| Particle size %< 250 µm | Max. 90.0 % |
| Particle size D10 | Max. 175 µm |
| Particle size D50 | 142-280 µm |
| Particle size D90 | 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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