# Product Specification

| | |
|---|---|
| Product group: | MCC |
| Brand name : | Pharmacel® 102 |
| Article code: | SAP 743679; Navision 13102-5355 |
| | SAP 733317; Navision 13122-5355 |
| | SAP 1273545; Navision 13105 – 5355 |
| Product description: | Microcrystalline Cellulose |
| Document No.: | PD-0473 Page 1 of 2 |

| | |
|---|---|
| Production site: | DFE Pharma India Private Limited, Cuddalore, India and Contract manufacturing location at Chemfield Cellulose Private Limited., Nagpur, India |
| Product name: | Pharmacel® 102<br>Conforms to USP-NF, Ph. Eur., JP, IP and ChP[1] 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[1]) | Pass |
| Identification C (USP, Ph.Eur.,IP), 3 (JP), 2 (ChP[1]) | 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[1]) | Max. 10 ppm |
| Assay (IP) | 97.0 - 102.0 % |
| Arsenic | Max. 2 ppm |
| Starch (ChP[1]) | Pass |
| Loss on Drying | 3.0 - 5.0 % |
| Residue on ignition | Max. 0.05 % |
| Bulk density | 0.28-033 g/mL |
| Chlorides (ChP[1]) | 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 %< 75 µm | 30.0 - 55.0 % |
| Particle size %< 250 µm | Min. 92.0 % |
| Particle size D10 | 15-50 µm |
| Particle size D50 | 80-130 µm |
| Particle size D90 | 170-283 µm |

[1] Currently applicable to article code SAP 743679 / Navision 13102-5355 only.

**Packaging:**

| | |
|---|---|
| SAP 743679; Navision 13102-5355<br>SAP 733317; Navision 13122-5355 | A white multi-layered polyethylene bag with a polyethylene inner liner, 25 kg net. |
| SAP 1273545; Navision 13105 – 5355 | A fibre drum with LDPE inner liner, 40 kg net. |

**Storage:**

Keep in original, un-opened packing in ambient conditions, protected from humidity and away from strongly odorous materials.

**Shelf life:**

| | |
|---|---|
| SAP 743679; Navision 13102-5355<br>SAP 733317; Navision 13122-5355 | For storage periods exceeding 48 months, we recommend re-testing. |
| SAP 1273545; Navision 13105 – 5355 | For storage periods exceeding 12 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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