ROQUETTE
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PRODUCT SPECIFICATIONS SHEET

# MICROCEL® 103 SD

## Definition

### Product Identifier

**Product name:** MICROCEL® 103 SD

Microcrystalline Cellulose

## Specifications

### PHYSICO-CHEMICAL SPECIFICATIONS

| | |
|---|---|
| Appearance | White, non-fibrous powder |
| Odour | Odourless |
| Identification tests | Complies |
| Loss on drying | 3.0 % max. |
| pH in solution | 5.0 - 7.0 |
| Water soluble substances | 0.24 % max. |
| Ether soluble substances | 0.05 % max. |
| Residue on ignition | 0.1 % max. |
| Conductivity | 75 uS/cm max. |
| Solubility in copper tetrammine solution | Positive |
| Bulk density | 0.26 - 0.31 g/cm3 |
| Degree of polymerization | 350 max. |
| Heavy metals | 10 mg/kg max. |
| Arsenic | 2 mg/kg max. |
| Chlorides | Complies |
| Starch | Complies |
| Particle size distribution(Laser diffraction) | |
| - D10 | 8 - 30 |
| - D50 | 36 - 75 |
| - D90 | 80 - 175 |
| Particle size (Air jet) | |
| - Retained on 60 mesh (250 microns) | 1.0 % max. |
| - Retained on 200 mesh (75 microns) | 30.0 % min. |

### MICROBIOLOGICAL SPECIFICATIONS

| | |
|---|---|
| Total aerobic microbial count | 1000 cfu/g max. |

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| | |
|---|---|
| Total yeasts and molds count | 100 cfu/g max. |
| Escherichia coli | Not detected in 1g |
| Pseudomonas aeruginosa | Not detected in 1g |
| Salmonella species | Not detected in 10g |
| Staphylococcus aureus | Not detected in 1g |

## Indicative Values

Solubility information:

Practically insoluble in sodium hydroxide solution (1 in 20),

insoluble in water, in dilute acids, and in most organic solvents.

## Comments

Methods used by ROQUETTE may be Pharmacopoeia methods or alternative validated methods which have been compared to the Pharmacopoeia methods.

## Conformity

Conforms to the requirements of the current monograph

- European Pharmacopoeia CELLULOSE,MICROCRYSTALLINE (0316)
- National Formulary from USP-NF MICROCRYSTALLINE CELLULOSE
- Japanese Pharmacopoeia MICROCRYSTALLINE CELLULOSE
- Chinese Pharmacopoeia MICROCRYSTALLINE CELLULOSE

Please contact us for any statement regarding compliance to the general chapter (elemental impurities, residual solvent, organic volatile impurities, metal catalyst, metal reagent).

## Storage

Store in dry area, in tight containers.

**Retest date** manufacturing date + 12 months.

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## Disclaimer

SPECIFIC DISCLAIMER:

Not intended for use in manufacture of parenteral dosage form, nor preparation for dialysis.
This product is not recommended to be used as active ingredient since it is not fully manufactured according to pharma cGMPs.
Please contact us for further information.

GENERAL DISCLAIMER:

The information provided in this Product Specification Sheet relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process. Analytical criteria are tested either on each batch or monitored or guaranteed, based on the Product Risk Analysis. For each batch, the status of the analysis may be indicated in the Certificate of Analysis. All information and instructions provided in this Product Specification Sheet are based on the current state of our knowledge at the latest revision date indicated. The ultimate use of this Product in any finished product is the responsibility of the purchaser.
This Product may have restrictions with respect to its use and/or usage levels, and such may vary on a country-by-country basis. The purchaser is responsible for its use of the Product and for its finished product, and that any claims made regarding its use of the Product and/or the finished product comply with applicable laws and regulations.