

PRODUCT SPECIFICATIONS SHEET

**MICROCEL 112 SD**

Definition

Product Identifier

**Product name:** MICROCEL 112 SD

Microcrystalline Cellulose

CAS No. 9004-34-6

Specifications

PHYSICO-CHEMICAL SPECIFICATIONS

Appearance	White, non-fibrous powder
Odour	Odourless
Identification tests	Complies.
Loss on drying	1.5 % 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.
Bulk density	0.28 - 0.34 g/cm <sup>3</sup>
Heavy metals	10 mg/kg max.
Degree of polymerization	350 max.
Particle size (Air jet)	
- Retained on 60 mesh (250 microns)	8.0 % max.
- Retained on 200 mesh (75 microns)	45.0 % min.

MICROBIOLOGICAL SPECIFICATIONS

Total aerobic microbial count	1000 cfu/g max.
Total yeasts and molds count	100 cfu/g max.
Escherichia coli	Not detected 1 g
Pseudomonas aeruginosa	Not detected 1 g
Salmonella species	Not detected 10 g
Staphylococcus aureus	Not detected 1 g

Indicatives Values

## MICROCEL 112 SD

### Solubility information:

Practically insoluble in sodium hydroxide solution (1 in 20),  
insoluble in water, in dilute acids, and in most organic solvents.  
Soluble in copper tetrammine solution.

### Comments

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

### Conformity

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Complies with USP-NF; Ph. Eur., JP monograph requirements.

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

### Storage

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Store in dry area, in tight containers.

**Retest date** manufacturing date + 24 months.

### Disclaimer

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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.

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. It is the responsibility of the user to be aware of and to follow the regulations applying to our product for its possession, handling and use.

Notes : All the dates are formatted like YYYY/MM/DD.