

PROSOLV[®] SMCC 90

Silicified Microcrystalline Cellulose NF, JPE

composed of

(Microcrystalline Cellulose, Ph. Eur., NF, JP, and Silica, Colloidal Anhydrous, Ph. Eur., NF, JP)

Specification

Description

Appearance	White or almost white fine or granular, slightly hygroscopic powder
Solubility	Practically insoluble in water, acetone, anhydrous ethanol and toluene, dilute acids and sodium hydroxide solution (50 g/l)

Characteristics

Identification A
 Identification B, 1
 Identification C, 2
 Identification D, 3

Acceptance criteria

IR scan conforms
 Violet-blue color
 Deep yellow color
 Variance ≤ 0.02

Reference

NF
 Ph. Eur., NF, JPE
 NF, JPE
 NF, JPE

Conductivity

Max. 75 µS/cm

Ph. Eur., NF, JPE

Degree of polymerization

Max. 350

Ph. Eur., NF, JPE

Ether-soluble substances

Max. 0.05%

Ph. Eur., NF, JPE

Heavy metals

Max. 10 ppm

JRS Method

Loss on drying

Max. 6.0%

Ph. Eur., USP, JPE

pH

5.0 – 7.0

Ph. Eur., USP, JPE

Residue on ignition

1.8 – 2.2%

Ph. Eur., USP, JPE

Water-soluble substances

Max. 0.24%

Ph. Eur., NF, JPE

TAMC (Total Aerobic Microbial Count)

10² cfu/ g

Ph. Eur., USP, JPE

TYMC (Total Yeast and Mold Count)

20 cfu/ g

Ph. Eur., USP, JPE

Escherichia coli

Absent in 1 g

Ph. Eur., USP

Pseudomonas aeruginosa

Absent in 1 g

Ph. Eur., USP

Salmonella species

Absent in 10 g

Ph. Eur., USP

Staphylococcus aureus

Absent in 1 g

Ph. Eur., USP

Residual solvents

Meets the requirements

Ph. Eur., USP

Solubility

Dissolves completely

Ph. Eur.

Bulk Density

0.25 – 0.37 g/mL

NF, JPE

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Specification

Characteristics	Acceptance criteria	Reference
Particle Size (retained on air jet sieve)		JRS Method
> 250 µm (60 mesh)	Max. 8.0 %	
> 75 µm (200 mesh)	45.0 - 80.0 %	
Particle Size (laser diffraction)		JRS Method
d10	20 – 50 µm	
d50	90 – 150 µm	
d90	190 – 300 µm	
Tapped density	0.37 - 0.50 g/mL	JRS Method

PROSOLV is manufactured under GMP for excipients according to IPEC and USP <1078>. The raw materials, manufacturing process, and product do not contain any of the solvents listed in Residual Solvents (Ph. Eur. <5.4>, USP <467>. Elements listed in ICH Q3D Guideline for elemental impurities are not used in manufacturing and not analysed per batch, detailed information is available upon request.

Re-evaluation date: 5 years from manufacturing date

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valid as of 2019-08-08