

VIVASOL® GF
 Croscarmellose Sodium, Ph. Eur., NF, JP, ChP
Specifications

Description

Appearance White or greyish-white, very hygroscopic powder
 Solubility Practically insoluble in acetone, ethanol, ether and toluene.
 Produced from wood cellulose.

Characteristics

Acceptance criteria

Reference

Identification (A, B, C), (1, 2, 3)	Passes	Ph. Eur., NF, JP, ChP
Content of water-soluble material	1.0 – 10.0 %	Ph. Eur., NF, JP, ChP
Degree of Substitution	0.60 – 0.85	Ph. Eur., NF, JP, ChP
Heavy metals	Max.10 ppm	JRS Method
Loss on drying	Max. 10.0 %	Ph. Eur., NF, JP, ChP
pH	5.0 – 7.0	Ph. Eur., USP, JP, ChP
Residue of ethanol	Max. 0.5 %	JRS Method
Settling volume	10.0 – 30.0 ml	Ph. Eur., NF, JP, ChP
Sodium chloride and Sodium glycolate	Max. 0.5 %	Ph. Eur., NF, JP, ChP
Sulphated ash	14.0 – 28.0 %	Ph. Eur., NF, JP, ChP
TAMC (Total Aerobic Microbial Count)	10 ² cfu/ g	Ph. Eur., USP, JP
TYMC (Total Yeast and Mold Count)	20 cfu/ g	Ph. Eur., USP, JP
E. coli	Absent in 1 g	Ph. Eur., USP, JP
Pseudomonas aeruginosa	Absent in 1 g	Ph. Eur., USP, JP
Salmonella species	Absent in 10 g	Ph. Eur., USP, JP
Staphylococcus aureus	Absent in 1 g	Ph. Eur., USP, JP
Particle size distribution (laser diffraction)		JRS Method
d10	Max. 25 µm	
d50	25 – 55 µm	
d90	Min. 60 µm	

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The raw materials, manufacturing process, and product do not contain any of the solvents listed in Residual Solvents (Ph. Eur.<5.4>, USP<467>, JP<2.46>) except for Ethanol limited to 0.5 %. 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: 4 years from manufacturing date

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