

VIVASOL[®]

Croscarmellose Sodium Ph. Eur., NF, JP Specifications

Description

Almost white, very hygroscopic powder; practically insoluble in acetone, ethanol, ether and toluene.

Characteristics

Specification

Reference

Particle size distribution (laser diffraction)		
d10	max. 25 µm	T220F (MCW)
d50	25 – 55 µm	
d90	min. 60 µm	
Identification (A, B, C), (1, 2, 3)	passes	Ph. Eur., NF, JP
Degree of Substitution	0.60 – 0.85	Ph. Eur., NF, JP
Loss on drying	max. 10.0 %	Ph. Eur., NF, JP
pH	5.0 – 7.0	Ph. Eur., USP, JP
Content of water-soluble material	1.0 – 10.0 %	Ph. Eur., NF, JP
Sulphated ash	14.0 – 28.0 %	Ph. Eur., JP
Settling volume	10.0 – 30.0 ml	Ph. Eur., NF, JP
Sodium chloride and Sodium glycolate	max. 0.5 %	T CC 013 (CHP)
Heavy metals	max. 10 ppm	T CC 043 (CHP)
Arsenic	max. 2 ppm	T CC 043 (CHP)
Residue of Methanol	max. 1.0 %	T CC 019 (CHP)
Total aerobic microbial count	max. 10 ² CFU/g	Ph. Eur., USP, JP
Fungi / molds and yeasts	max. 20 CFU/g	Ph. Eur., USP, JP
E. coli, Pseudomonas aeruginosa	absent in 1 g	Ph. Eur., USP, JP
Staph. aureus		
Salmonella spec.	absent in 10 g	Ph. Eur., USP, JP

The raw materials, manufacturing process, and product do not contain any of the solvents listed in Residual Solvents (Ph. Eur.<5.4>, USP<467>) except for Methanol limited to <1.0%.

This product may contain raw materials derived from unauthorized genetically modified cotton and is not suitable for the production or marketing of food or dietary supplements in the EC.

SVSOL_10

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