



(Unit II)

**VIVASOL® GF**

Croscarmellose Sodium Ph. Eur., NF, JP

**CERTIFICATE OF ANALYSIS**

R1-0177  
R-13521  
4-14-22

Batch-no: 71121100759 Manufacturing site: Nandasan, India  
Re-evaluation date: October-2025  
Manufacturing date: October-2021

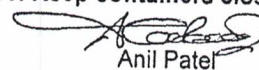
**Description** White or greyish-white powder, practically insoluble in acetone, ethanol, ether and toluene. Very hygroscopic powder; Produced from wood cellulose.

Characteristics	Acceptance criteria	Batch Result	Reference
Identification (A, B, C), (1, 2, 3)	Passes	Passes	Ph. Eur., NF, JP
Arsenic	Max. 2 ppm	< 2 ppm	JRS Method
Content of water-soluble material	1.0 - 10.0 %	6.99%	Ph. Eur., NF, JP
Degree of substitution	0.60 - 0.85	0.72	Ph. Eur., NF, JP
Heavy metals	Max. 10 ppm	< 10 ppm	JRS Method
Loss on drying	Max. 10.0 %	6.00%	Ph. Eur., NF, JP
pH	5.0 - 7.0	6.84	Ph. Eur., USP, JP
Residue of ethanol	Max. 0.5 %	< 0.5 %*	JRS Method
Sodium chloride and sodium glycolate	Max. 0.5 %	< 0.5 %	Ph. Eur., NF, JP
Sulphated ash	14.0 - 28.0 %	20.84%	Ph. Eur., NF, JP
TAMC (Total aerobic microbial count)	10 <sup>2</sup> CFU / g	30 CFU / g	Ph. Eur., USP, JP
TYMC (Total yeast and mold count)	20 CFU / g	< 15 CFU / g	Ph. Eur., USP, JP
E. coli	Absent in 1 g	Absent	Ph. Eur., USP, JP
Pseudomonas aeruginosa	Absent in 1 g	Absent	Ph. Eur., USP, JP
Salmonella species	Absent in 10 g	Absent	Ph. Eur., USP, JP
Staphylococcus aureus	Absent in 1 g	Absent	Ph. Eur., USP, JP
Settling volume	10.0 - 30.0 ml	15.5 ml	Ph. Eur., NF, JP
Particle size distribution (laser diffraction)			JRS Method
d10	Max 25 µm	22	
d50	25 - 55 µm	43	
d90	Min 60 µm	78	

\* Results reported are expected results based on periodic testing.

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 ethanol limited to < 0.5%. Elements listed in ICH Q3D Guideline for elemental impurities are not used in manufacturing and not analyzed per batch; detailed information is available on request.

**Storage recommendation: Protect from excessive heat and moisture. Keep containers closed.**



Anil Patel

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JRS PHARMA & GMW

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