

(Unit II)

VIVASOL® GF

Croscarmellose Sodium Ph. Eur., NF, JP

CERTIFICATE OF ANALYSIS

Batch-no: 71120040263 Manufacturing site: Nandasan, India
Re-evaluation date: April-2024
Manufacturing date: April-2020

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 %	7.56%	Ph. Eur., NF, JP
Degree of substitution	0.60 – 0.85	0.71	Ph. Eur., NF, JP
Heavy metals	Max. 10 ppm	< 10 ppm	JP
Loss on drying	Max. 10.0 %	6.76%	Ph. Eur., NF, JP
pH	5.0 - 7.0	6.52	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 %	19.99%	Ph. Eur., JP
TAMC (Total aerobic microbial count)	10 ² CFU / g	23 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	14.0 ml	Ph. Eur., NF, JP
Particle size distribution (by Malvern)			JRS Method
d10	Max 25 µm	19	
d50	25 - 55 µm	39	
d90	Min 60 µm	75	

* 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

Quality Control
JRS PHARMA & GMW

Manufacturer:
INDIA
JRS PHARMA & GUJARAT MICROWAX
PRIVATE LIMITED

Sales + Marketing:
WORLDWIDE
JRS PHARMA GMBH+CO.KG

USA + CANADA
JRS PHARMA LP

Registered Office :
401/ 402 Sarthik Square
Nr GNFC Tower, S.G. Highway
Ahmedabad - 380054 (India)
Phone: +91 79 26852-181, 26852-182
Fax: +91 79 26854-169, 26854-170
info@gmpl.in
CIN : U24229GJ1989PTC011737

Holzmuhle 1
D-73494 Rosenberg (Germany)
Phone: +49 7967 152-0
Fax: +49 7967 152-345
E-mail: ExcipientsService@jrspharma.de
www.jrspharma.com
www.jrs.de

Customer Service: +49 7967 152-312

298 Route 22, Suite 1
Patterson, NY 12563-2359
Toll-Free: 800 431-2457
Phone: +1 845 878 3414
Fax: +1 845 878 3484
E-mail: info@jrspharma.com
www.jrspharma.com

Customer Service: +1 845 878-3414