

Certificate of Analysis

SAFIC-ALCAN ESPECIALIDADES SAU

COA

C/ BERGUEDA SN ESQUINA LLOBREGAT 08130 SANTA PERPETUA DE LA MOGODA SPAIN Customer Order: SA20240419

Shipped Quantity: 8.000 BAG Shipped From: AIE FR VIRONVAY W3P Order Number: 8872299/000010

Delivery: 852761300/000010 Date Shipped: April 16, 2024

Sold To Number: 635559

BLANOSE CMC 12M31P EP BAG 25KG

Blanose(TM) CMC 12M31P EP Sodium Carboxymethylcellulose

Ashland Material Number: 420187 Customer Material Number: 59222

Batch: C231293

Characteristics	Specification	Results
Degree of substitution, MA	1.12 - 1.21	1.19
304.1500		
ss on drying, %, MA 304.1500	0.0 - 10.0	7.4
Viscosity 2%, mPa.s, MA 304.1001	1500 - 3100	2572
Viscosity EP, mPa.s, D 304.800	1425 - 2600	2283
pH, MA 304.1004	6.5 - 8.0	7.8
Na Chloride, %, MA 304.1011	0.00 - 0.25	0.00
Na content calculated vs DS, %,	10.2 - 10.8	10.6
D 304.208		
Sulfated ash calculated vs DS,	31.6 - 33.2	32.8
%, D 304.208	ν	
Date of Manufacture		April 24, 2023
Next Retest Date		April 23, 2026
Shipped Quantity		8.000 BAG

Notes:

Best if used within 3 years of date of manufacture.

Our products have a retesting interval, which is assigned to assure that the product can still satisfy the original viscosity specifications to which this product are sold.

Recommended testing protocol: retest viscosity and loss on drying. The certified range data below are based on intermittent testing:

** Purity: 99.5 % min.

Na Glycolate: 0.4 % max.

Heavy metals: 10 ppm max.

** As: 3 ppm max.

** Pb: 2 ppm max.

** Cd: 1 ppm max.

** Hg: 1 ppm max.

Identification [EP]: pass.

Appearance of solution [EP]: pass USP Residual Solvent <467>: meets requirements

This product conforms to the monograph for Carmellose Sodium in the

current

European Pharmacopeia.

This product has been manufactured in accordance with the current joint

IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical

Excipients. This product is intended for excipient use only.

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Nº lote ACOFARMA:

241162

Firma y fecha: 10106/24



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Results

Manufactured by:
ASHLAND SPECIALTIES FRANCE SARL
AFFILIATE OF ASHLAND
ZONE INDUSTRIELLE LE CLOS PRE
27460 ALIZAY
FRANCE

Contact:

MIGUEL LAFITA

Email: miguel.lafita@ashland.com

This COA is printed from a secure computer system ensuring the batch was properly released by the Quality Department and is valid without signature.

17/04/2024

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Firma y fecha

9106/24

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