

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: 12.000 DR Shipped From: AIE BE ANTWERP ZW.W W3P CLD Order Number: 8872290/000070 Delivery: 852762909/000030 Date Shipped: April 16, 2024 Sold To Number: 635559	
KLUCEL LF PHARM DRUM 45.36KG Klucel(TM) LF PHARM Hydroxypropylcellulose Ashland Material Number: 424851 Customer Material Number: 55580		Batch: 233791	
Characteristics	Specification	Results	
Loss on Drying, as Packaged, %, USP < 731 >	0.0 - 5.0	1.7	
Moles of Substitution, NF	2.0 - 4.1	3.8	
Hydroxypropoxy Groups, %, NF	53.4 - 80.5	74.4	
5% Visc., Water, (1@30) 25 C, cps, USP < 912 >	75 - 150	115	
pH, USP < 791 >	5.0 - 8.0	6.4	
PSZE - total thru 30, %, USP < 786 > Airjet	85.0 - 100.0	96.1	
PSZE - on 20 and above, %, USP < 786 > Airjet	0.0 - 1.0	0.1	
PSZE - on 30 and above, %, USP < 786 > Airjet	0.0 - 15.0	3.9	
Residue on Ignition, % , USP < 281 >	0.0 - 0.8	0.4	
Silica, %, < or= 0.6%, NF	PASS	PASS	
5% Visc., 10 Sec-1, 20 C, cps, EP < 2.2.10 >	75 - 140	108	
Date of Manufacture		September 07, 2023	
Next Retest Date		September 06, 2026	
Best If Used By		September 05, 2028	
Shipped Quantity		12.000 DR	

Notes:

All Klucel LF PHARM and LXF PHARM products have a nominal viscosity based on the EP monograph of 100 cps and a nominal viscosity based on the USP NF of 110 cps

Certified range data below are based on intermittent testing.

Lead, ppm - not more than 2

Heavy metals, ppm - not more than 20

The quality of the above lot conforms to the monograph for Hydroxypropyl Cellulose in the compendia of the NF, Ph.Eur. and JP current editions.

GMP Compliance: Manufactured in a dedicated facility using current IPEC-PQG GMPs for excipients.

Residual Solvents: Meets requirements of USP <467> and ICH Q3C.

Identification Testing: Meets requirements of NF, Ph. Eur. and JP.

Retest Interval: Klucel el, e, l, j, and g types have a retest timeline of 5 years after the date of manufacture.

Best if used within 5 years from date of manufacture

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Data shown above are from actual lot analysis.

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

Manufactured by:
ASHLAND SPECIALTY INGREDIENTS G.P.
AFFILIATE OF ASHLAND
1111 HERCULES ROAD
HOPEWELL VA 23860

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17/04/2024