CERTIFICATE OF ANALYSIS

This is to certify that under-mentioned commodity has been duly inspected by us and meets our standard in all respects.

Commodity

: Hydroxypropyl Cellulose

CAS No.

9004-64-2 : HPC-M

Grade Lot No.

Manufacturing Date

: January, 2022

Manufacturing Place : Nihongi Plant, 950, Fujisawa, Nakago-ku, Joetsu-shi, Niigata, 949-2392, Japan

Expiry Date

: December, 2026

Retest Date *

: December, 2026

ANALYSIS RESULTS

Characteristics	Test Methods	Specifications	Results		
Identification(A,B)	USP-NF	Conforms	Conforms		
Assay for Hydroxypropoxy groups	USP-NF	53.4-80.5 %		73.7	%
Residue on ignition	USP-NF	Not more than 0.8 %		0.1	%
Lead	ICP-MS	Not more than 10 ppm	≦	10	ppm
pH	USP-NF	5.0-8.0		6.5	
Loss on drying	USP-NF	Not more than 5.0 %		1.2	%
Viscosity (2% aqueous solution at 20℃)	USP-NF	150-400 mPa · s		280	mPa · s

^{*} We do not perform retest for HPC, therefore we assure only expiry date.

This analysis is according to USP-NF 2021.

Class2 solvent, toluene listed in USP <467> is used for the manufacturing of Nisso HPC.

The amount of toluene is monthly checked, using USP <467>. The obtained results are not more than 20ppm (LOQ) for the specification of 890ppm. There is no use of the organic solvents (chloroform; 1,4-dioxane; methylene chloride; tri-chloroethylene) during the manufacturing process of Nisso HPC, and no contaminant of during shipping or storage.

Nisso HPC is free from Silica.

The amount of Silica is monthly checked, using USP-NF 2021. The obtained results are not more than 0.06% (LOQ) for the specification of 0.6%. There is no use of anti-caking agent (Silica) during the manufacturing process of Nisso HPC.

issuea By:		Reviewed By:	
S. Kaneda	January 17, 2022	T. Hayashi	January 17, 2022
Q.C.Manager	Date	Q.A.Sec.	Date
Nihongi Plant		Nihongi Plant	
Nippon Soda Co.,Ltd.		Nippon Soda Co.,Ltd.	

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Commodity : Hydroxypropylcellulose

CAS No. : 9004-64-2 Grade : HPC-M

Lot No.

Manufacturing Date : January, 2022

Manufacturing Place : Nihongi Plant, 950, Fujisawa, Nakago-ku, Joetsu-shi, Niigata, 949-2392, Japan

Expiry Date : December, 2026 Retest Date ** : December, 2026

ANALYSIS RESULTS

Characteristics	Test Methods	Specifications	Results Conforms	
Identification(A-C)	EP	Conforms		
Assay for Hydroxypropoxy groups	EP	53.4-80.5 %	73.7 %	
Sulphated ash	EP	Not more than 0.8 %	0.1 %	
рН	EP	5.0-8.0	6.5	
Loss on drying	EP	Not more than 5.0 %	1.2 %	
Apparent viscosity (2% aqueous solution at 20°C)	JP	150-400 mPa ⋅ s	280 mPa·s	

^{*} We do not perform retest for HPC, therefore we assure only expiry date.

This analysis is according to EP10.0.

Class2 solvent, toluene listed in USP <467> is used for the manufacturing of Nisso HPC.

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Nisso HPC is free from Silica.

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Issued By:		Reviewed By:		
S. Kaneda	January 17, 2022	T. Hayashi	January 17, 2022	
Q.C.Manager	Date	Q.A.Sec.	Date	
Nihongi Plant		Nihongi Plant		
Nippon Soda Co.,Ltd.		Nippon Soda Co.,Ltd.		