

Bagian : QC

Due Date : 27-Jul-26

Tangga : 29-Jun-26

ANALISA PERMINTAAN BARANG

No	Kode Barang	Nama Barang	Satuan	Stok Saat Ini (A)	Rencana Kebutuhan (B)	Kekurangan (A -B + C)	Pending Penerimaan (C)	Jumlah	Realisasi Pembelian	Realisasi Penggunaan
1	IMO10028	Jasa analisa KadarBahan Baku HPC-LH 11	Js	0	1	-1	0	1	0	0

Catatan :

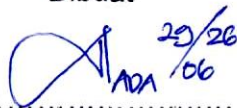
- Pemenuhan pemeriksaan parameter kadar pada bahan baku LHPC-LH11 (Low Substituted Hydroxypropyl Cellulose) No. Batch : 6043095 ex. Shin-Etsu 1. 6043095 Ex. Shin-Etsu
- Estimasi harga pengujian : Rp 3.996.000/Batch
- Pengujian eksternal dilakukan di PT. TUV NORD Indonesia.
- Pengujian terakhir pada bulan Maret 2026 No. SPB : PF000491

Latar belakang permintaan :

- Sebagai pemenuhan parameter menurut kompedial terkini. Parameter tersebut belum bisa dilakukan analisa secara internal dikarenakan metode yang digunakan instrumen GC dengan detektor TCD dan kolom G1 3µm 0.53 mm x 30 m belum tersedia di Dept. QC.

Terlampir CoA bahan baku, USP terkini dan penawaran harga.

Dibuat


29/06/26

Mengetahui


29/06/26

Certificate of Analysis

Shin-Etsu Chemical Co., Ltd.
Naoetsu Plant Quality Assurance Department
28-1, Nishifukushima, Kubiki-ku,
Joetsu-shi, Niigata, Japan

Product Name L-HPC
(Low-Substituted Hydroxypropyl Cellulose, NF)
Grade LH-11
Lot Number 6043095
Quantity 1850kg
Manufacture Date 2026/04/12
Recommended Re-Evaluation Date * 2029/04/11
Analysis Date 2026/04/20
Issue No. D5120260502347002-1-01

Remark

This product complies with the specifications described in the current NF, EP and JP.

This product is manufactured in accordance with GMP.

* Shin-Etsu Chemical recommends that the customer's quality control unit may re-evaluate the quality of this material on its own responsibility prior to use after the Recommended Re-Evaluation date.

Storage Conditions: Store containers sealed and in a dry place. Keep away from heat or sunlight.

Test Item	Unit	Test Result	Specification	Method
Description		Conforms	Conforms	JP/NF
Characters		Conforms	Conforms	EP
Identification (1)/B		Conforms	Conforms	JP/NF/EP
Identification (2)/C		Conforms	Conforms	JP/NF/EP
Identification (3)/A		Conforms	Conforms	JP/NF/EP
pH		6.7	5.0 - 7.5	JP/NF/EP
Chloride	%	Not more than 0.36	Not more than 0.36	NF
Loss on drying	%	2.9	Not more than 5.0	JP/NF/EP
Residue on ignition	%	0.10	Not more than 0.8	JP/NF/EP
Hydroxypropoxy content	%	11.2	10.0 - 12.9	JP/NF/EP
Particle size: Average (D50)	μm	54.1	45 - 65	Shin-Etsu
Particle size: 90% cumulation (D90)	μm	173.1	150 - 200	Shin-Etsu

lawsim

Shin-Etsu No. : 76052003-01-01

Issue:

Shin-Etsu Chemical Co., Ltd.
Cellulose Department
4-1, Marunouchi 1-chome, Chiyoda-ku, Tokyo, Japan
TEL 01-2-6012-2441 FAX 01-2-6012-2442

Judgment:

Shin-Etsu Chemical Co., Ltd.
Naoetsu Plant Quality Assurance Department
28-1, Nishifukushima, Kubiki-ku,
Joetsu-shi, Niigata, Japan

Naosuke Maruyama
General Manager, Q. A. Dept.

25

Low-Substituted Hydroxypropyl Cellulose

Add the following:

▲Portions of this monograph that are national USP text, and are not part of the harmonized text, are marked with symbols (*, ▲) to specify this fact.▲ (NF 1-May-2019)

Add the following:

▲Cellulose, 2-hydroxypropyl ether CAS RN@: 9004-64-21.▲ (NF 1-May-2019)

Change to read:

DEFINITION

Low-Substituted Hydroxypropyl Cellulose is a low-substituted ▲O-(2-hydroxypropylated)▲ (NF 1-May-2019) cellulose. ▲It▲ (NF 1-May-2019) contains NLT 5.0% and NMT 16.0% of hydroxypropoxy groups (–OCH₂CHOHCH₃), ▲calculated on the dried basis.▲ (NF 1-May-2019)

IDENTIFICATION

Delete the following:

▲▲ A.
Sample: 20 mg
Analysis: Shake the Sample with 2 mL of water, and cautiously add 1 mL of a solution of anthrone in sulfuric acid (350 µg/mL).
Acceptance criteria: A blue to greenish-blue color develops at the zone of contact.▲ (NF 1-May-2019)

Change to read:

▲▲ A. ▲SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197K.▲ (CN 1-May-2020) Meets the requirements▲ (NF 1-May-2019)

Change to read:

● B.
Sample: 0.1 g
Analysis: Shake the Sample thoroughly with 10 mL of water.▲▲ (NF 1-May-2019)
Acceptance criteria: ▲It does not dissolve.▲ (NF 1-May-2019)

Change to read:

● C.
Sample solution: ▲To the suspension obtained in Identification B add 1 g of sodium hydroxide and shake until it becomes homogeneous.▲ (NF 1-May-2019)
Analysis: ▲Transfer 5 mL of Sample solution to a suitable container, add▲ (NF 1-May-2019) 10 mL of a mixture of acetone and methanol (4:1), ▲and shake.▲ (NF 1-May-2019)
Acceptance criteria: A white, flocculent precipitate is formed.

ASSAY

Change to read:

● ▲HYDROXYPROPOXY GROUPS▲ (NF 1-May-2019)
[CAUTION—Hydriodic acid and its reaction byproducts are highly toxic. Perform all steps of the Standard solution and the Sample solution in a properly functioning hood. Specific

safety practices to be followed are to be identified to the analyst performing this test.]
Apparatus: For the reaction vial, use a 5-mL pressure-tight serum vial, 50 mm in height, 20 mm in outside diameter, and 13 mm in inside diameter at the mouth. The vial is equipped with a pressure-tight septum with a polytetrafluoroethylene-faced butyl rubber and an air-tight seal using an aluminum crimp or any sealing system that provides sufficient air-tightness. Use a heater with a heating module that has a square-shape aluminum block with holes 20 mm in diameter and 32 mm in depth, into which the reaction vial fits. The heating module is also equipped with a magnetic stirrer capable of mixing the contents of the vial, or use a reciprocal shaker that performs a reciprocating motion of approximately 100 times/min.
Hydriodic acid: Use a reagent with a typical concentration of hydrogen iodide (HI) of about 57%.
Internal standard solution: 30 mg/mL of n-octane in o-xylene
Standard solution: Into a suitable serum vial, weigh between 60 and 100 mg of adipic acid, and add 2.0 mL of Hydriodic acid and 2.0 mL of Internal standard solution into the vial. Close the vial securely with a suitable septum stopper. Weigh the vial and contents, add 15–22 µL of isopropyl iodide through the septum with a syringe, weigh again, and calculate the weight of isopropyl iodide added, by difference. ▲Shake the reaction vial well, and use▲ (NF 1-May-2019) the upper layer as the Standard solution.
Sample solution: Transfer 0.065 g of ▲▲ (NF 1-May-2019) Low-Substituted Hydroxypropyl Cellulose to a 5-mL, thick-walled reaction vial equipped with a pressure-tight septum-type closure, add between 60 and 100 mg of adipic acid, and pipet 2.0 mL of Internal standard solution into the vial. Cautiously pipet 2.0 mL of Hydriodic acid into the mixture, immediately cap the vial tightly, and weigh. Using the magnetic stirrer equipped in the heating module, or using a reciprocal shaker, mix the contents of the vial continuously, heating and maintaining the temperature of the contents at 130 ± 2° for 60 min. If a reciprocal shaker or magnetic stirrer cannot be used, shake the vial well by hand at 5-min intervals during the initial 30 min of the heating time. Allow the vial to cool, and weigh. ▲If the weight loss is less than 26 mg and there is no evidence of a leak, use the upper layer of the mixture as the Sample solution.▲ (NF 1-May-2019)
Chromatographic system
(See Chromatography (621), System Suitability.)
Mode: GC
Detector: Thermal conductivity or hydrogen flame ionization
Column: ▲0.53-mm × 30-m fused silica capillary, coated with a 3-µm layer of phase G1. Use a guard column if necessary.
Temperatures
Detector: 280°
Injection port: 250°
Column: See Table 1.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
50	0	50	3
50	10	100	—
100	34.9	250	8▲ (NF 1-May-2019)

Carrier gas: Helium[▲] (NF 1-May-2019)

Flow rate: With the *Standard solution*, adjust the flow rate so that the retention time of the internal standard is about 10 min [▲](about 4.3 mL/min). [NOTE—The relative retention time for isopropyl iodide (with reference to the *n*-octane) is about 0.8.][▲] (NF 1-May-2019)

Injection volume: 1–2 µL

Injection type: Split; split ratio, 40:1

Run time: 20.3 min

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 5 between isopropyl iodide and *n*-octane

Relative standard deviation: NMT 2.0%, using the peak area ratio between isopropyl iodide and the internal standard for 6 injections[▲] (NF 1-May-2019)

Analysis

Samples: Upper layer of the *Standard solution* and the *Sample solution*

Calculate the percentage of hydroxypropoxy

[▲] (NF 1-May-2019) in the sample taken:

$$\text{Result} = (Q_{Tb}/Q_{Sb}) \times (W_{Sb}/W_U) \times 44.17$$

Q_{Tb} = ratio of the peak area of isopropyl iodide to *n*-octane in the *Sample solution*

Q_{Sb} = ratio of the peak area of isopropyl iodide to *n*-octane in the *Standard solution*

W_{Sb} = weight of isopropyl iodide in the *Standard solution* (mg)

W_U = weight of Low-Substituted Hydroxypropyl Cellulose calculated on the dried basis, taken for the *Sample solution* (mg)

[▲]44.17 = molar mass of hydroxypropoxy group/molar mass of isopropyl iodide $\times 100$ [▲] (NF 1-May-2019)

Acceptance criteria: 5.0%–16.0% on the dried basis

IMPURITIES

Change to read:

• RESIDUE ON IGNITION (281)

[▲]Sample: 1.0 g

Acceptance criteria: NMT 0.8%[▲] (NF 1-May-2019)

Change to read:

• [▲] (NF 1-May-2019) CHLORIDE AND SULFATE (221), Chloride

Sample solution: Shake 0.50 g of Low-Substituted Hydroxypropyl Cellulose thoroughly with 30 mL of boiling water, heat on a water bath for 10 min, and filter the supernatant by decantation while hot. Wash the residue thoroughly with 50 mL of boiling water, combine the washings with the filtrate, and add water to make 100 mL after cooling.

Control solution: 0.25 mL of 0.02 N hydrochloric acid

Analysis: Using 10 mL of the *Sample solution* and the *Control solution*, proceed as directed in the chapter, starting with the addition of the nitric acid.

Acceptance criteria: NMT 0.36%; the *Sample solution* shows no more chloride than the *Control solution*.[▲] (NF 1-May-2019)

SPECIFIC TESTS

Add the following:

• [▲] PH (791)

Sample solution: 10 mg/mL suspension, prepared by evenly distributing 1.0 g of the powder with 100 mL of carbon dioxide-free water and stirring the mixture with a magnetic stirrer

Acceptance criteria: 5.0–7.5[▲] (NF 1-May-2019)

Change to read:

• LOSS ON DRYING (731)

[▲]Sample: 1 g[▲] (NF 1-May-2019)

Analysis: Dry the *Sample* at 105° for 1 h.

Acceptance criteria: NMT 5.0%

ADDITIONAL REQUIREMENTS

• PACKAGING AND STORAGE: Preserve in tight containers.

Add the following:

• [▲] USP REFERENCE STANDARDS

USP Low-Substituted Hydroxypropyl

Cellulose RS[▲] (NF 1-May-2019)

QUOTATION

To Ms Julfriaeni La Sabatini Br Bangun
Company PT. Mersifarma Tirmaku Mercusana
Address Jl. Raya Pelabuhan Km.18 Cikembar,
 Cikembar, Kab. Sukabumi,
 Sukabumi
 Jawa Barat
 Indonesia

Quotation Date May 06, 2025
Expiration Date June 06, 2025

Quotation No.



QT.25050122

Phone -
Fax -
Mobile Phone -
Email Address Julfriaeni_Bangun@mersifarma.com

No	SERVICES	METHOD	PRICE	QTY	DISC%	PC%	TOTAL
HPC LH-11				Priority	normal		
1	Hypromellose Assay : - % Metoxy Group USP 43 NF 38 2022 Hypromellose monograph - % Hydroxy Propoxy Group USP 43 NF 38 2022 Hypromellose monograph		2,000,000	2	10	0	3,600,000
Sub Total (IDR)							3,600,000

Remarks :
 Min sampel : 100 gr atau 100ml
 Lead Time : 8 hari kerja

Total (IDR)	4,000,000
Discount (IDR)	400,000
Priority Chrg (IDR)	0
Sub Total (IDR)	3,600,000
VAT (IDR)	396,000
Grand Total (IDR)	3,996,000

With our experience and expertise in ITC (Inspection, Testing & Certification) business we also offer you one stop solution with special discount for another valuable services that we can provided:

Services

System Certification(Additional Scheme)	ISO 9001, ISO 14001, ISO 45001, ISO 27001, ISO 37001, ISO 50001, IATF, ISO 22000, FSSC 22000, HACCP, ISPO, ISCC, etc.
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Laboratorium PT TUV NORD Indonesia

Jl.Science Timur 1 Blok B3-F1
 Kawasan industri jababeka V
 Kel. Setajaya Kec. Cikarang Timur
 Kabupaten Bekasi - Jawa Barat - 17530

Email cs@tuv-nord.com
 Phone +62 21 29574720



TUVNORDGROUP



QUOTATION

Quotation Date May 06, 2025
Expiration Date June 06, 2025

Quotation No.



QT.25050122

Product Certification	SNI, CE, GS, etc.
Inspection	Rack Inspection, QA/QC Inspection, etc.
Training	In House Training for All Management Systems Topic (Awareness, Internal Audit, Documentation, etc.)

For complete information please feel free to contact our Sales Representative.

Created by **Jakti Dipo**

Customer Approval: _____

Laboratorium PT TUV NORD Indonesia

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Phone +62 21 29574720

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LP-411-IDN
LK-109-IDN
TUVNORDGROUP

Date

06 May, 2025

Quotation No.



QT.25050122

Term & Condition:

Shipping Product Samples

To insure the integrity and security of samples sent to TÜV NORD Laboratory, we ask that our customers observe the following guidelines when shipping samples :

- Secure each food sample in its own container. Seal each sample package completely so that no leakage will occur. This is very important to prevent cross- contamination.
- Use packing materials that are strong enough to travel without damage or leakage.
- Samples needing refrigeration should be shipped appropriately. Please mark "refrigerate" on the outside of the package to ensure continuous refrigeration.
- Label each sample individually with the identification you would like included on the final report.

Sample Privacy

At TÜV NORD Laboratory, customer privacy is of utmost importance to us because it is important to YOU. We have provided full confidentiality to all of our partners. Not only do we have the right systems in place, but we also have the right people.

Quotation and to Submit Samples

Visit our website <https://www.tuv-nord.com/id/en> to download a sample submission form and contact our marketing team to get quotation. Submit the completed form along with your samples to

Head Office (Only for durable product):

PT. TÜV NORD Indonesia
Perkantoran Hijau Arkadia, Tower F 6 th Floor, Suite 706.
JL. TB. Simatupang Kav. 88 Pasar Minggu, Jakarta Selatan.

Laboratory:

Jl. Science Timur 1, Blok B3-F1 Kawasan Industri Jababeka V Cibatu Cikarang - Bekasi 17530
(Exit Tol Cibatu, Km. 34)

Standard Term and Conditions

All services provided by TÜV NORD Laboratory ("TÜV NORD Laboratory") are subject to the terms and conditions stated herein. As our client, you ("Client") understand and agree that placement of any order for our services constitutes acceptance of the terms and conditions stated herein. To the extent that any Client order contains any terms or conditions that vary from the terms and conditions stated herein, all such additional or varying terms and conditions shall be of no force or effect, and shall not be part of the Client- TÜV NORD Laboratory relationship or contract, even if TÜV NORD Laboratory performs the requested service.

CONFIDENTIALITY confidentiality is maintained in all interactions with Clients. Appropriate confidentiality agreements are signed willingly. If information is subpoenaed and released through the operation of any judicial, regulatory, or similar process, the Client is notified. In TÜV NORD Laboratory name or data in any manner which might cause harm to TÜV NORD Laboratory reputation and/or business. Under no circumstances in the name of TÜV NORD Laboratory to be published, either alone or in association with that of any other party, without prior written approval.

PAYMENT TERMS Payment terms are Net 14 days. Minimum order per invoice is Rp 200.000,-. Prices are subject to change without notice. The payment can be transferred to PT. TÜV NORD Indonesia, Bank HSBC World Trade Centre, A/C No. 050-074269-001.

BILLING All fees or bills are charged directly to the Client, unless a third party has been authorized via a signed statement indicating payment responsibility. It is assumed that the paperwork submitted with a sample describes the testing desired. If changes are made after the originally requested testing is initiated or completed, The Client must accept payment responsibility. Please notify TÜV NORD Laboratory immediately if changes in testing are necessary.

SAMPLE SUBMISSION sample submission should be made on a TÜV NORD Laboratory "Sample Testing Application Form (STAF)". Please contact our Laboratory staff to get complete information.

HAZARDOUS SUBSTANCES AND PATHOGEN any sample containing or suspected to contain a pathogen or substance that is considered hazardous must be clearly identified as such on the container and communicated to TÜV NORD Laboratory before shipping. TÜV NORD Laboratory reserves the right to refuse any sample which may pose a risk to employees.

ANALYSIS TÜV NORD Laboratory strives to provide a seven (7) until ten (10) working day turnaround. Rush analysis is offered contingent upon pre-notification and approval of TÜV NORD Laboratory. However, a rush fee of 100% surcharge of the list fee will be added to the invoice for each analysis completed in fewer than (5) working days at the request of the Client. TÜV NORD Laboratory reserves the right to outsource an analysis entirely at TÜV NORD Laboratory expense and without prior notification to Client, unless Client requests otherwise. Reported result relate only to the items tested and test reports shall not be reproduced except in full.

LITIGATION All costs associated with litigation or dispute, including compliance for all document, for oral or written testimony or preparation of same, or for any other purpose related to work provided by TÜV NORD Laboratory in connection with analyses/reports performed/completed for the Client, shall be paid by the Client. Such costs include, but are not limited to, hourly charges, travel accommodations, mileage, counsel, and all other expenses associated with said litigation or dispute.

WARRANTY AND LIMITS OF LIABILITY TÜV NORD Laboratory warrants that all services will be performed in a timely manner by competent personnel. Any services performed by TÜV NORD Laboratory under proper technical direction by Client. Which are determined by TÜV NORD Laboratory to have been performed improperly in light of the above warranty, and which after investigation by the TÜV NORD Laboratory are acknowledged in writing by TÜV NORD Laboratory President Director to have been performed improperly. Shall be corrected by TÜV NORD Laboratory without charge to Client, provided that Client provides TÜV NORD Laboratory with a written request for such correction within two (2) weeks after Client knew or should reasonably have known of problem. The liability of the TÜV NORD Laboratory in respect of any claims for loss, damage or expense of whatever nature and howsoever arising in respect of any breach of contract and/or any failure to exercise due skill and care by the TÜV NORD Laboratory shall in no circumstances exceed a total aggregate sum equal to ten (10) times the amount of the fee or commission payable in respect of the specific services required under the particular contract with the TÜV NORD Laboratory which gives rise to such claims or consequential loss including loss of profit and/or loss of future business and/or loss of production and/or cancellation of contracts entered into by the Client. The TÜV NORD Laboratory shall not in any event be liable for any loss or damage caused by delay in performance or non-performance of any of its services where the same is occasioned by any cause whatsoever that is beyond the TÜV NORD Laboratory control including but not limited to war, civil disturbance, requisitioning, governmental or parliamentary restriction, prohibitions or enactment of any kind, import or export regulations, strike or trade dispute (whether involving its own employees or those of any other person), difficulties in obtaining workmen or materials, breakdown of machinery, fire or accident. Should any such event occur the TÜV NORD Laboratory may cancel or suspend any contract for the provision of services without incurring any liability whatsoever. The TÜV NORD Laboratory will not be liable to the Client for any loss or damage whatsoever sustained by the Client as a result of any failure by the TÜV NORD Laboratory to comply with any time estimate given by the TÜV NORD Laboratory relating to the provision of its services. TÜV NORD Laboratory accepted no legal responsibility for the purpose for which the Client uses the test result or report, or for any consequence of such use. TÜV NORD Laboratory provide no guidance regarding and accept no legal responsibility for any consequence of such use. Client agrees to indemnify and defend TÜV NORD Laboratory all claims, damages, liabilities, and expenses relating to Client's use of TÜV NORD Laboratory's services or Client's Marketing, distribution, sale, or other dissemination of Client's products or services. The allocations of liability in this WARRANTY AND LIMITS OF LIABILITY section represent the agreed and bargained-for understanding between the Client and TÜV NORD Laboratory. TÜV NORD Laboratory fees for the services provided hereunder reflect such allocations.

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Laboratorium PT TÜV NORD Indonesia

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