Bagian : QC

ANALISA PERMINTAAN BARANG

Due date : 10-Feb-26
Tanggal : 9-Jan-26

No	Kode Barang	Nama Barang	Satuan	Stok Saat Ini	Rencana	Kekurangan	Pending	Jumlah	Realisasi	Realisasi
				Saat Ini (A)	Kebutuhan (B)	(A -B + C)	Penerimaan (C)		Pembelian	Penggunaan
1	IMO10028	Jasa Analisa pemeriksaan kadar pada bahan tambahan HPC-LH 11	Js	0	1	-1	0	1	0	0

Catatan :

- Jasa pemenuhan pemeriksaan parameter kadar/assay pada bahan tambahan HPC LH-11 dengan no batch :

1. 5093242 ex. ShinEtsu

- Estimasi biaya pengujian Rp.2.000.000

Latar belakang permintaan:

- Sebagai pemenuhan parameter menurut kompedial, parameter tersebut belum dapat dilakukan analisa secara internal dikarenakan penunjang belum tersedia di lab.Qc
- Metode yang digunakan dengan instrumen GC menggunakan detektor TCD yang saat ini belum tersedia di QC
- kolom yang digunakan yaitu kolom G1 3um 0.53 mm x 3.0 m dan belum tersedia di QC
- Terlampir latar belakang pemesanan, Penawaran harga, dan USP terkini.

Pemohon

09/26
01

Mengetahui

09/26
01

mersi PT. MERSIFARMA TM SUKABUMI-INDONESIA	**FORMULIR LATAR BELAKANG PERMINTAAN JASA** **DEPARTEMEN: QUALITY CONTROL**	*Diisi oleh Pemohon* No. : 002 LBPJ/ I /2026

Nama Jasa:

Analisa parameter pemeriksaan kadar/Assay pada bahan tambahan HPC-LH 11

Rencana Waktu Penggunaan:

20 Februari 2026

Lead time Purchasing:

45 Hari

Estimasi Harga: Rp. 2.000.000 Jumlah: 1 batch

☐ Jasa Perizinan ☐ Jasa Rental ☐ Jasa Sertifikasi ☐ Jasa Kalibrasi

☑ Jasa Pengujian ☐ Jasa Pemusnahan Limbah ☐ Jasa Perbaikan Mesin/Alat ☐ _____

SYARAT WAJIB : 1. Lampirkan Jadwal Kerja/Timetable
2. Lampirkan Estimasi Harga/Penawaran Harga
Lampirkan Berita Acara Kerusakan

Penggunaan jasa untuk	Untuk pemenuhan pemeriksaan parameter kadar/assay pada bahan tambahan HPC LH-11 dengan no batch sebagai berikut: 1. HPC LH-11 batch: 5093242 ex. ShinEtsu
Latar belakang permintaan	- Sebagai pemenuhan parameter menurut kompendial, parameter tersebut belum dapat dilakukan analisa secara internal dikarenakan penunjang belum tersedia di Lab.QC. - Metode yang digunakan dengan instrumen GC menggunakan detektor TCD (belum tersedia di QC) - Kolom yang digunakan yaitu kolom G1 3 um 0.53 mm x 30 m (belum tersedia di QC)

Dibuat:	Diperiksa:	Menyetujui:	
JABLOLA B.D	RONTA A		- NA -
Tgl. 07/01/26	Tgl. 07/01/2026.	Tgl. 07/01/26	Tgl.
(Staf/Koord)	(Koord./Spv/Ast. Mgr)	(Kepala Departemen)	(Kepala Divisi/Plant Manager)

Nomor Dokumen : COM-FPT/001D.00	Tanggal Berlaku : 11 SEP 2023	Disetujui oleh :

TÜVNORD

QUOTATION

Quotation Date May 06, 2025
Expiration Date June 06, 2025
Quotation No. QT.25050122

To	Ms Julfriaeni La Sabatini Br Bangun	**Phone**	-
Company	PT. Mersifarma Tirmaku Mercusana	**Fax**	
Address	Jl. Raya Pelabuhan Km.18 Cikembar, Cikembar, Kab. Sukabumi, Sukabumi Jawa Barat Indonesia	**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 Hypermellose monograph - % Hydroxy Propoxy Group | USP 43 NF 38 2022 Hypermellose 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.

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

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TÜVNORD

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: _____

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

TÜVNORD

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 confidentially to all of our partners. Not only do we have the right systems in place, but we alo 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, Block B3-F1 Kawasan Industri Jababeka V Cibatu Cikarang - Bekasi 17530
(Exit Tol Cibatu, Km. 34)

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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 exten 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 shallbe 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 interractions 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 circumtances 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 direcly 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 indentifef 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. Howeever, 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.

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WARRANTY AND LIMITS OF LIABILITY TÜV NORD Laboratory warrants that all services will be performed in a timely manner by competent personel. Any services performed by TÜV NORD Laboratory under proper technical direction by Client. Which are determined by Client 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 whatsoever nature and howsoever arising in respect of any breach of contract and/or any failure to exercise due skillkk and care by the TÜV NORD Laboratory shall in no circumtances 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 for indirect or consequential loss including loss of profit and/or loss of future busniniess and/or loss of productions 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 performanc 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 limiad to war, civil disturbance, requisitioning, governmental or parliamentary restriction, prohibitions or enactment of any kind, import or export regulations, strike or trade dipute (whetsver incoiving 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 the purpose for which the Client uses the test result or reports, and shall have no legal responsibility forany consequence of such use. Client agrees ti indemnify and defend TÜV NORD Laboratory all claims, damages, liabilities, and expenses relating ti 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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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 ($-OCH_2CHOHCH_3$), ▲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 × 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)