

Bagian : QC

Due Date : 09-Aug-26

Tanggal : 08-Jul-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 Ethylene Oxide Bahan Baku Kollicoat IR	Js	0	1	-1	0	1	0	0
2	IMO10028	Jasa Analisa 1,4 Dioxane Bahan Baku Kollicoat IR	Js	0	1	-1	0	1	0	0

Catatan :
- Pemenuhan pemeriksaan parameter Ethylene Oxide dan 1,4 Dioxane pada bahan baku Kollicoat IR dengan No. Batch :
1. 35649988Q0 Ex. BASF

- Estimasi harga pengujian : Rp 2.886.000/Batch
- Pengujian eksternal dilakukan di PT. Eurofins Angler Biochemlab.
- Pengujian terakhir pada bulan Maret 2026 No. SPB : PF000341

Latar belakang permintaan :

- Pengujian ini dilakukan untuk pemenuhan laporan registrasi komitmen pengujian bahan baku Kollicoat IR sesuai dengan kompendial terkini. Saat ini parameter Ethylene Oxide dan 1,4 Dioxane belum bisa dilakukan pengujian internal dikarenakan keterbatasan penunjang berupa; Kolom 0.25-mm × 30-m glass or quartz capillary column; 1.0-µm layer of phase G1.

Terlampir spesifikasi pengujian bahan awal, penawaran harga dan CoA bahan baku.

Dibuat

 08/26
ADA 07

Mengetahui

 08/26
07

LIST PARAMETER BAHAN BAKU BELUM BISA DIKERJAKAN OLEH QC

No.	Parameter	Nama Bahan	Kendala di QC	Keterangan (Bisa/Tidak oleh R&D)
57	Kadar	Metolose (Hypromellose)	Belum tersedia instrumen GC dengan detektor TCD. Belum tersedia reagen - adipic acid - methyl iodine belum tersedia kolom - 0.53 -mm x 30-m fused silika capillary, lapisan 3- μ m fase GI.	Belum tersedia instrumen GC dengan detektor TCD. Belum tersedia reagen - adipic acid - methyl iodine belum tersedia kolom - 0.53 -mm x 30-m fused silika capillary, lapisan 3- μ m fase GI.
58	Difraksi Sinar-X	Vortioxetine	Tidak terdapat instrumen XRD	Tidak terdapat instrumen XRD
59	Difraksi Sinar-X	Brintellix	Tidak terdapat instrumen XRD	Tidak terdapat instrumen XRD
60	Ethylene Oxide	Kollicoat IR	Belum dapat dilakukan pengujian di internal karena belum tersedia kolom 0.25-mm x 30-m glass or quartz capillary column; 1.0- μ m layer of phase G1 dan pada MPBB dinyatakan pengujian dilakukan ke lab eksternal	
61	1,4 Dioxane	Kollicoat IR	Belum dapat dilakukan pengujian di internal karena belum tersedia kolom 0.25-mm x 30-m glass or quartz capillary column; 1.0- μ m layer of phase G1 dan pada MPBB dinyatakan pengujian dilakukan ke lab eksternal	

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08.

Please note that the certificates of analysis are also conveniently available on your BASF online portal.

PT. GLOBAL CHEMINDO MEGATRAIDING

2024-05-23

Certificate No 1675

Page 1 of 3

KAV. II G5 NO. 23 LT.4 UNIT A, JALAN RAYA PULOGADUNG

Hr. Dr. Florian Wildschek

ENT/QA

florian.wildschek@basf.com

13930 JAKARTA TIMUR

KEC. CAKUNG

Indonesia

Certificate of Analysis according to DIN 55350-18-4.2.2

Kollicoat® IR

Material

55554797

Order

6012125224 000010

Delivery

3198152658 000010

Lot

35649988Q0

Lot/Qty

1600.000 KG

Total

1600.000 KG

Transport

TCLU3290323

20KG Plastic drums

Purchase order/Customer material

PO03537

55554797

Test Parameter	Requirements	UoM	Results
Appearance	white to faintly yellow powder		conforms
Identification (IR)	must conform		conforms
Heavy metals	Max.: 20	mg/kg	<10
Viscosity (Brookfield, Spindle 2)	Min.: 50 Max.: 250	mPas	116
pH-value	Min.: 5.0 Max.: 8.0		6.6
Sulphated ash / residue on ignition	Max.: 2.0	g/100g	0.9
Ester value	Min.: 10.0 Max.: 70.0	mg KOH/g	14.9
Loss on drying	Max.: 5.0	g/100g	1.1
Vinyl acetate (Ph.Eur. impurity A)	Max.: 20	mg/kg	<10
Acetic acid (Ph.Eur. impurity B)	Max.: 15000	mg/kg	6400

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of fitness for a specific purpose. No liability of ours can be derived therefrom.

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PT. MERSIFARMA TM.
SUKABUMI-INDONESIA

METODE PENGUJIAN BAHAN AWAL
KOLLI COAT IR
RAW MATERIAL ANALYSIS METHOD
KOLLI COAT IR

Halaman : 14 of 18
Pages 14 dari 18
No. Dokumen : RD.02-MBP/042.01
Document No.
Tanggal Dokumen Disetujui : 2 OCT 2025
Document Approval Date
Menggantikan No. : RD.02-MBP/042.00
Supersedes Number

Perhitungan cemaran etilen glikol dan dietilen glikol
Calculation impurity of ethylene glycol and diethylene glycol

$$\% \text{Cemaran} = \frac{\left(\frac{R_{spl}}{BI_{spl}} \right)}{\left(\frac{R_{std}}{BI_{std}} \right)} \times 100\%$$

Keterangan :

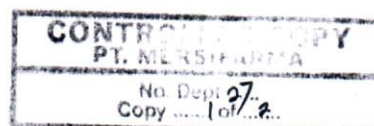
Description

R spl = Respons puncak larutan sampel
Peak response of sample solution

R std = Respons puncak larutan standar
Peak response of standard solution

BI spl = Respons puncak larutan baku internal sampel
Peak response internal standard of sample solution

BI std = Respons puncak larutan baku internal standar
Peak response internal standard of standard solution



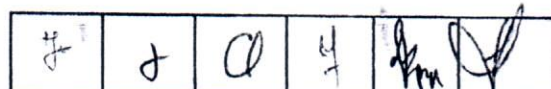
No.	Nama Name	Waktu retensi relatif Relative retention time
1.	Etilen Glikol Ethylene Glycol	0.8
2.	Propilen Glikol Propylene Glycol	1.0
3.	2,2,2-Trikloroetanol 2,2,2-Trichloroethanol	1.7
4.	Dietilen Glikol Diethylene Glycol	2.4

CEMARAN ORGANIK⁽³⁾
ORGANIC IMPURITY

Persyaratan : Sesuai dengan spesifikasi bahan awal yang berlaku
Requirements Meets the requirements for raw material specification
Cara pemeriksaan :
Inspection method
Pengujian etilen oksida dan dioksan dilakukan di laboratorium eksternal.
Ethylene Oxide and Dioxane testing was conducted at external laboratory.

UJI MIKROBIOLOGI⁽²⁾
MICROBIOLOGICAL TESTS

Persyaratan : Sesuai dengan spesifikasi bahan awal yang berlaku
Requirements Meets the requirements for raw material specification
Cara pemeriksaan :
Inspection method



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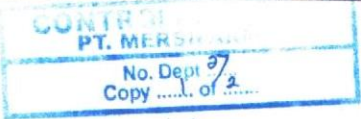


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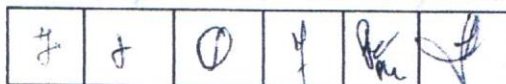
**SPESIFIKASI PENGUJIAN BAHAN
AWAL KOLLI COAT IR**
**RAW MATERIAL SPECIFICATION OF
KOLLI COAT IR**

Halaman : 2 of 5
Pages : 2 dari 5
No. Dokumen : RD.02-SBP/042.01
Document No.
Tanggal Dokumen Disetujui : 22 OCT 2025
Document Approval Date
Menggantikan No. : RD.02-SBP/042.00
Supersedes Number

BILANGAN ESTER ⁽¹⁾ <i>ESTER VALUE</i>	10.0 - 75.0 mg KOH/g 10.0 - 75.0 mg KOH/g
CEMARAN ETILEN GLIKOL DAN DIETILEN GLIKOL ⁽³⁾ <i>ETHYLENE GLYCOL AND DIETHYLENE GLYCOL IMPURITY</i>	≤ 400 ppm (0.04 %) 
CEMARAN ORGANIK ⁽³⁾ <i>ORGANIC IMPURITY</i>	Eilen Oksida ≤ 1 ppm <i>Ethylene Oxide</i> ≤ 1 ppm Dioksan ≤ 10 ppm <i>Dioxane</i> ≤ 10 ppm
UJI MIKROBIOLOGI ⁽²⁾ <i>MICROBIOLOGICAL TESTS</i>	Angka Lempeng Total ≤ 10 ³ koloni/g <i>The Total Aerobic Microbial Count</i> ≤ 10 ³ colonies/g Angka Kapang Khamir ≤ 10 ² koloni/g <i>The Total Combined Molds and Yeasts Count</i> ≤ 10 ² colonies/g
WADAH DAN PENYIMPANAN ⁽¹⁾ <i>PACKAGING AND STORAGE</i>	Dalam wadah tertutup rapat pada temperatur ≤ 25°C. <i>Preserve in tight containers at temperature ≤ 25° C.</i>

SEJARAH PERUBAHAN
HISTORY OF CHANGE

No. No.	No. Dokumen Document No.	Tanggal Berlaku Valid Date	Deskripsi Perubahan Description of Changes
1.	2RD20/SPBAP/042.00	08 September 2016 <i>September 08th, 2016</i>	a. Menggantikan no. 3VA00/SPSBP/001.00 <i>Replaced Standard Procedured no.</i> 3VA00/SPSBP/001.00 b. Mengganti nama Divisi dan Departemen <i>Changed Division and Department name</i> c. Melakukan update pustaka <i>Update literature</i>
2.	2RD20/SPBAP/042.01	08 Oktober 2016 <i>October 08th, 2016</i>	a. Menggantikan no. 2RD20/SPBAP/042.00 <i>Replaced Standard Procedured no.</i> 2RD20/SPBAP/047.00 b. Melakukan update pustaka <i>Update literature</i>



Antoni 13/12/26
09/

Contact

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Eurofins_Angler_CustomerService@eurofinsasia.com

PT. MERSIFARMA TIRMAKU MERCUSANA
Reza Herlambang
JL. RAYA PELABUHAN KM. 18 CIKEMBAR
ID - 43161 SUKABUMI
Admin_RD@mersifarma.com

Quotation number MMD215250446-01

Please indicate this reference for all correspondence

Surabaya, 02/09/2025

Project quotation - Ethylene Glycol dan Vinyl Alcohol Graft Copolymer

Account: A01786234UBQ

Tax N°: 0017924341441000

Dear Customer,

We hereby provide the enclosed quotation as follows :

Price without tax in IDR					
Code	Analyses/packages	TAT	Unit price	Qty.	Total
AAA	Ethylene Glycol dan Vinyl Alcohol Graft Copolymer	7d	1,300,000.00	2	2,600,000.00 (1)
DLQUQ-2	Ethylene Oxide (HS-GC-FID)				(1)
DL09B-2	1,4 Dioxane (HS-GC-FID) (A)				(1)

- (1) A tax rate of 11.00% applies for this service. The tax rates displayed are not binding but provided merely as an indication
- TAT Turnaround time.
- (A) This Test is accredited. If the symbols (A) or (S) are present, restrictions exist for certain types of samples or test parameters.

Total before tax IDR	2,600,000.00
Tax rate (1)	+11.00%
Total price (incl. tax) IDR	2,886,000.00

Due to the rounding rules applied, the total, sub-totals and sum of the lines might slightly differ.

For your cooperation and coordination, we thank you

Payment terms and conditions

Invoice must be paid no later than thirty (30) calendar days after the invoice was issued.

By placing an order or sending samples to our laboratory the customer accepts this quotation and our General Terms and Conditions of Sale referenced therein. Our General Terms and Conditions of Sale are attached to this quotation

Please send your samples to this address

Quotation number MMD215250446-01

PT Eurofins Angler Biochemlab
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13/6/2025
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