

Bagian : QC

Due Date : 28-Aug-26

Tanggal : 7-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	IMO11208	Kolom HPLC L1 (C18)	Pc	0	2	-2	0	2	0	0

Catatan :

Kolom Bondclone C18 10 μ m 300 x 3,9 mm Ex. Phenomenex cat.no. 00H-2117-C0

- Digunakan untuk Memisahkan senyawa dari sampel dengan cara melewati fase gerak melalui kolom. Kolom ini digunakan pada prosedur penetapan kadar vit B1 dan B6 serta disolusi Mersibion KSS dan Mersibion 5000 KSS

- Estimasi harga : Rp.14.400.000/Unit.

- Terakhir kali pemesanan 2025 (PW023699)

Latar belakang permintaan :

- Sehubungan dengan adanya update MPOJ Mersibion KSS dan Mersibion 5000 KSS, serta QC saat ini hanya memiliki 1 kolom tersebut untuk produk Miniaspi maka diperlukan pengadaan kolom tersebut

Terlampir metode analisa, rencana kebutuhan dan penawaran harga.

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**PROTOKOL TRANSFER METODE ANALISIS
PENETAPAN KADAR PYRIDOXINE HCL, THIAMINE
MONONITRATE, DAN CYANOCOBALAMIN, SERTA UJI
DISOLUSI PYRIDOXINE HCL DALAM PRODUK JADI
MERSIBION KAPLET SALUT SELAPUT**
**ANALYTICAL METHOD TRANSFER PROTOCOL FOR
THE ASSAY OF PYRIDOXINE HCL, THIAMINE
MONONITRATE, AND CYANOCOBALAMIN,
DISSOLUTION TEST OF PYRIDOXINE HCL IN
FINISHED PRODUCT MERSIBION FILM-COATED
TABLETS**

Halaman : 6 dari 18
Pages : 6 of 18
No. Dokumen : RD.02-PTP/178.00
Document No.
Tanggal Dokumen Disetujui :
Document Approved Date :
Menggantikan No. :
Supersedes Number :

7.1.1.2. Bahan yang digunakan

Materials Used

No.	Nama Bahan Material Name	Nomor Katalog Catalog Number	Manufacture
1	Asetonitril Acetonitrile	A998-4	Fisher Brand
2	Asam asetat glasial Glacial acetic acid	AR1002	RCI
3	Purified Water Purified Water	-	-
4	Metanol Methanol	A452-4	Fisher Brand
5	Na 1-heksanasulfonat Sodium 1-hexanesulphonate	396671000	Thermo
6	Tiamin Mononitrat (B1) WS Thiamine Mononitrate (B1) WS	-	-
7	Piridoksin HCl (B6) WS Pyridoxine HCl (B6) WS	-	-
8	Granul Mersibion 5000 Mersibion 5000 Gramules	-	-
9	Kaplet atau Kaplet Salut Selaput Mersibion 5000	-	-
10	Mersibion 5000 Caplets or Film- Coated Caplets	-	-
11	Air es Ice water	-	-

7.1.1.3. Metode yang digunakan : High Performance Liquid Chromatography

Method Used

7.1.2. Kondisi pengerjaan HPLC

HPLC Operating Conditions

- 7.1.2.1. Kolom : Kolom Brand Phenomenex C18 300 x 3.9 mm 10 μ m (L1)
Column : Column Brand Phenomenex C18 300 x 3.9 mm 10 μ m (L1)
- 7.1.2.2. Aliran pompa : 1.0 mL / menit
Flow rate : 1.0 mL / minutes
- 7.1.2.3. Panjang gelombang detektor : 280 nm
Detector wavelengths : 280 nm
- 7.1.2.4. Volume penyuntikkan : 10 μ L
Injection volume : 10 μ L
- 7.1.2.5. Pelarut : Asetonitril : Asam Asetat Glasial : Purified Water (5 : 1 : 94)
Solvent : Acetonitrile : Asetic Acid Glacial : Purified Water (5 : 1 : 94)
- 7.1.2.6. Waktu Retensi :
Retention Time
- a. Thiamine Mononitrate (Vit. B1) : 16 menit $\pm$ 3 menit
Thiamine Mononitrate (Vit. B1) : 16 menit $\pm$ 3 minutes
- b. Pyridoxine HCl (Vit. B6) : 6,5 menit $\pm$ 2 minutes
Pyridoxine HCl (Vit. B6) : 6,5 menit $\pm$ 2 minutes
- 7.1.2.7. Waktu Berhenti : 25 menit
End Time : 25 minutes

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TABLETS**

Halaman : 13 dari 18
Pages : 13 of 18
No. Dokumen : RD.02-PTP/178.00
Document No.
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Menggantikan No. :
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No.	Nama Bahan Material Name	Nomor Katalog Catalog Number	Manufacture
4	Metanol Methanol	A452-4	Fisher Brand
5	Asam klorida 32% Hydrochloric acid (HCl) 32%	A-1050F	Smart Lab
6	Na 1-heksanasulfonat Sodium 1-hexanesulphonate	396671000	Thermo
7	Tiamin Mononitrat (B1) WS Thiamine Mononitrate (B1) WS	-	-
8	Piridoksin HCl (B6) WS Pyridoxine HCl (B6) WS	-	-
9	Kaplet atau Kaplet Salut Selaput Mersibion 5000 Mersibion 5000 Caplets or Film- Coated Caplets	-	-
11	Air es Ice water	-	-

7.3.1.3. Metode yang digunakan : High Performance Liquid Chromatography
Method Used

7.3.2. Kondisi Pengerjaan Disolusi
Dissolution Working conditions

7.3.2.1. Media disolusi : 900 mL larutan Asam Hidroklorida (HCl) 0.1 N
Dissolution medium 900 mL 0.1 N Hydrochloric Acid (HCl) solution

7.3.2.2. Alat disolusi : Tipe 2
Aparatus Dissolution Type 2

7.3.2.3. Kecepatan putaran : 100 rpm
Rotation speed 100 rpm

7.3.2.4. Waktu pengambilan cuplikan : 60 menit
Time of taking the clip 60 Minutes

Catatan : Lakukan uji disolusi sesuai dengan Protap pemakaian alat disolusi

Notes : Perform dissolution tests in accordance with the dissolution equipment usage procedure.

7.3.3. Kondisi pengerjaan HPLC
HPLC Operating Conditions

7.3.3.1. Kolom : Kolom Brand Phenomenex C18 300 x 3.9 mm 10 µm (L1)
Column Column Brand Phenomenex C18 300 x 3.9 mm 10 µm (L1)

7.3.3.2. Aliran pompa : 1.0 mL / menit
Flow rate 1.0 mL / minutes

7.3.3.3. Panjang gelombang detektor : 280 nm
Detector wavelengths 280 nm

7.3.3.4. Volume penyuntikkan : 10 µL
Injection volume 10 µL

7.3.3.5. Pelarut : Acetonitrile : Asam Asetat Glisial : Purified Water (5 : 1 : 94)
Solvent Acetonitrile : Asetic Acid Glacial : Purified Water (5 : 1 : 94)

7.3.3.6. Waktu Retensi :
Retention Time

a. Thiamine Mononitrate (Vit. B1) : 16 menit ± 3 menit
Thiamine Mononitrate (Vit. B1) 16 menit ± 3 minutes

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Halaman : 6 dari 18
Pages : 6 of 18
No. Dokumen : RD.02-PTP/179.00
Document No.
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6	Tiamin Mononitrat (B1) WS Thiamine Mononitrate (B1) WS	-	-
7	Piridoksin HCl (B6) WS Pyridoxine HCl (B6) WS	-	-
8	Granul Mersibion 5000 5000 Mersibion 5000 5000 Granules	-	-
9	Kaplet atau Kaplet Salut Selaput Mersibion 5000 5000	-	-
10	Mersibion 5000 5000 Caplets or Film- Coated Caplets	-	-
11	Air es Ice water	-	-

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Flow rate : 1.0 mL / minutes
- 7.1.2.3. Panjang gelombang detektor : 280 nm
Detector wavelengths : 280 nm
- 7.1.2.4. Volume penyuntikkan : 10 µL
Injection volume : 10 µL
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- 7.1.2.7. Waktu Berhenti : 25 menit
End Time : 25 minutes

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TABLETS**

Halaman : 13 dari 18
Pages : 13 of 18
No. Dokumen : RD.02-PTP/179.00
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7	Tiamin Mononitrat (B1) WS Thiamine Mononitrate (B1) WS	-	-
8	Piridoksin HCl (B6) WS Pyridoxine HCl (B6) WS	-	-
9	Kaplet atau Kaplet Salut Selaput Mersibion 5000 5000 Mersibion 5000 5000 Caplets or Film- Coated Caplets	-	-
11	Air es Ice water	-	-

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Thiamine Mononitrate (Vit. B1) 16 menit ± 3 minutes

b. Pyridoxine HCl (Vit. B6) : 6,5 menit ± 2 minutes
Pyridoxine HCl (Vit. B6) 6,5 menit ± 2 minutes

7.3.3.7. Waktu Berhenti : 25 menit
End Time 25 minutes

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WTC Mangga Dua, Lt. 5 Blok D No. 02, Jl. Mangga Dua Raya No. 8, Jakarta Utara 14430

Warehouse: Jl. Satria IV No. 14B, RT 012/ RW 01, Pademangan Barat – Pademangan, Jakarta Utara 14420

Tel : 021- 64703295 / Fax : 021- 6458467 | HP / WA : 0813-18631718 / e-mail : sales@suryabuana.com

www.Phenomenex.com / www.tcichemicals.com / www.suryabuana.com

Company : PT Mersifarma Tirmaku Mercusana
Attn : Mrs. Balqia Prameswari Putri
Title : Purchasing Department
Re. : Quotation

From : Ani
Page : 1 including this page)
June 26, 2026
No. : 236/SBN/VI/26-001

Quot

Dear Customer,

Thank you for your inquiry. We have the pleasure to offer you as following :

No	Description	Qty	Unit Price (Rp)	Total Price (Rp)
1	Bondclone C18 10u 300 x 3,9mm Phenomenex Cat.No. 00H-2117-C0	1 EA	14.400.000	14.400.000

Note:

Discount 10%

Price Exclude PPN

Delivery Time : 6 - 10 weeks

Terms of Payment : 14 Days After Document Date

Thank you so much and regards,

PT. SURYA BUANA NUSANTARA

Ani
MarketingDept

Our Partnership :



Ultron[®] ES-OVM



JAI RADHE SALES

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Kebutuhan Kolom Phenomenex L1 300 x 3,9 mm 10 um

Description	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Grand Total
Mersibion 5000 Kaplet 5x10s (Blister) Export	-	1	1	-	-	-	-	2
Mersibion 5000 KSS Box 5x10s (Blister)	-	1	1	-	1	-	1	4
Mersibion KSS Box 3x10s (Blister)	-	-	1	-	-	-	1	2

No	Nama Produk Jadi	Kolom	Proses	Jumlah injekan	Total Batch	Total injekan
1	Mersibion 5000 Kaplet 5x10s (Blister) Export	Kolom Phenomenex L1 300 x 3,9 10 um	Penetapan Kadar Core	11	2	22
			Penetapan Kadar Coating	11	2	22
			Keseragaman Kandungan	18	2	36
			Penetapan Disolusi	15	2	30
2	Mersibion 5000 KSS Box 5x10s (Blister)		Penetapan Kadar Core	11	4	44
			Penetapan Kadar Coating	11	4	44
			Keseragaman Kandungan	18	4	72
			Penetapan Disolusi	15	4	60
3	Mersibion KSS Box 3x10s (Blister)		Penetapan Kadar Core	11	2	22
			Penetapan Kadar Coating	11	2	22
			Keseragaman Kandungan	18	2	36
			Penetapan Disolusi	15	2	30
Total injekan						440
Worstcase (+30%)						572

Kebutuhan kolom = $572/500 = 1,15 = 2$ kolom

Oleh karena itu diperlukan sebanyak 2 Kolom Phenomenex L1 300 x 3,9 mm 10 um

Jika ada hasil TMA terbaru yang berhasil atau perubahan rencana produksi maka akan dilakukan pemesanan kolom kembali.

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