

Bagian: QC

Due date : 18-Jun-26

Tanggal : 24-Apr-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	IMO11439	Kolom Welch Ultisil	Un	0	2	-2	0	2	0	0

Catatan :

Kolom Ultisil C18 3.9 x 150 mm 10 µm, Part number : H00201-41064

- Memisahkan senyawa dengan cara melewati fase gerak melalui kolom pada penetapan kadar dan cemaran bahan baku Thiamine HCl dan Thiamine Mononitrat
- Estimasi Harga : \$460.00/unit
- Pemesanan ini merupakan yang pertama kali untuk kebutuhan dept QC

Latar Belakang Permintaan

- Sehubung dengan adanya pengujian bahan baku Thiamine HCl dan Thiamine Mononitrat parameter penetapan kadar dan cemaran maka diperlukan pengadaan kolom tersebut. Saat ini dilakukan peminjaman kepada Dept. RnD
- Kolom tersebut digunakan setiap kali analisa Thiamine HCl dan Thiamine Mononitrat
- **Penawaran harga, Metode Pengujian Thiamine HCL dan rencana kebutuhan**

Dibuat

 24/26
JWS 04

Mengetahui

 24/26
RnD 04



P/N: H00201-41064

Ultisil XB-C18, 10µm, 3.9×150mm (1pcs/pk)

Welch Materials, Inc.

\$460.00 USD

4 interest-free installments, or from **\$41,52/mo** with [shop Pay](#)

[View sample plans](#)

Quantity:

—

1

+

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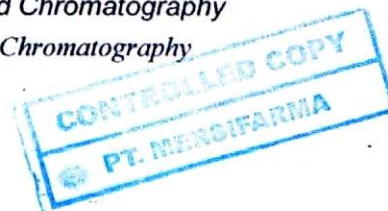
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Ultisil XB-C18 is one of the most versatile C18 analytical columns on the market. It features advanced bonding and double-endcapping technology, delivering nearly perfect peak shapes. This column is ideal for analyzing complex matrix samples and provides excellent peak shapes for acidic and basic compounds. It is particularly effective for the separation of traditional Chinese medicine compounds.

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 mersi PT. MERSIFARMA TM DIVISI MANUFACTURING SUKABUMI-INDONESIA	METODE PENGUJIAN BAHAN AWAL TIAMIN HIDROKLORIDA RAW MATERIAL ANALYSIS METHOD THIAMINE HYDROCHLORIDE		Pages 9 of 17 Document Number : RD.02-MBA/108.02 Valid Date : 25 APR 2023
	DEPARTEMENT RESEARCH AND DEVELOPMENT	SECTION ANALYTICAL DEVELOPMENT	
Dibuat Oleh : Prepared by :  Julia Ayu Nurmala AD Staff Date : 24/03/23	Diperiksa Oleh : Checked by :   Juwita Ristiani Robertus Luki Praptono AD Manager QC Manager Date : 24/03/23 Date : 24/03/23	Disetujui Oleh : Approved by :   Head of R&D QA Manager Date : 24/03/23 Date : 15/04/23	Changed Number : RD.02-MBA/108.01 Date : 15 th September 2023
	3. Tambahkan 50 mL <i>purified water</i> , aduk sampai larut. <i>Add 50 mL of purified water, stir until dissolved.</i> 4. Pipet 2 mL, masukkan ke dalam tabung reaksi. <i>Pipette 2 mL, put it into a test tube.</i> 5. Tambahkan 2 mL asam sulfat P, dinginkan dengan cara didiamkan sampai suhu ruang. <i>Add 2 mL of sulfuric acid P, cool by letting it cool to room temperature.</i> 6. Teteskan lewat dinding tabung 2 mL Besi (II) Sulfat LP. <i>Drop through the wall of the tube 2 mL of Iron (II) Sulfate TS.</i> 7. Amati cincin yang terjadi pada batas ke dua lapisan. <i>Observe the ring that occurs at the boundary of the two layers.</i>		
CEMARAN ORGANIK (1) ORGANIC IMPURITIES	Persyaratan : Sesuai dengan spesifikasi bahan awal yang berlaku. <i>Requirements Meets the requirements for raw material specifications.</i> Metode : High Performance Liquid Chromatography <i>Method High Performance Liquid Chromatography</i> Cara Pemeriksaan : <i>Inspection method</i> <u>Kondisi Pengerjaan HPLC</u> <i>HPLC working conditions</i> 1. Kolom : Kolom C18 150 mm x 3.9 mm, 10 µm (L1) <i>Column 150 mm x 3.9 mm, 10 µm C18 column (L1)</i> 2. Aliran pompa : 0.75 mL/menit <i>Pump flow 0.75 mL/minute</i> 3. Panjang gelombang : 254 nm <i>Detector wavelength 254 nm</i> 4. Volume suntikkan : 10 µL <i>Injecting volume 10 µL</i> 5. Pelarut : Larutan A : Larutan B (60:40) <i>Solvent Solution A : Solution B (60:40)</i> 6. Fase gerak : Larutan A : Larutan B (60:40) <i>Mobile phase Solution A : Solution B (60:40)</i> <u>Larutan Asam Asetat Glasial P (1 dalam 100)</u> <i>Glacial Acetic Acid Solution P (1 in 100)</i>		



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PT. MERSIFARMA TM.
DIVISI MANUFACTURING
SUKABUMI-INDONESIA

METODE PENGUJIAN BAHAN AWAL
TIAMIN MONONITRAT
RAW MATERIAL ANALYSIS METHOD
THIAMINE MONONITRATE

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Document Number
RD.02-MBA/115.02

Valid Date

DEPARTEMEN
RESEARCH AND DEVELOPMENT

SECTION
ANALYTICAL DEVELOPMENT

Disusun Oleh :

Prepared by :

Diperiksa Oleh :

Checked by :

Disetujui Oleh :

Approved by :

Changed Number

RD.02-MBA/115.01

Date

15th December 2023

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AD Staff

Date : 19/04/25

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AD Manager

Date : 15/04/25

Robertus Luki Praptono
QC Manager

Date : 24/04/25

Head of R&D

Date : 17/04/25

QA Manager

Date : 02/05/25

CEMARAN ORGANIK
(1)

ORGANIC IMPURITIES

Persyaratan : Sesuai dengan spesifikasi bahan awal yang berlaku.
Requirements : *Meets the requirements for raw material specifications.*
Metode : *High Performance Liquid Chromatography*
Method : *High Performance Liquid Chromatography*

Cara Pemeriksaan :
Inspection method

Kondisi Pengerjaan HPLC

HPLC working conditions

- Kolom** : Kolom C18 150 mm x 3.9 mm, 10 µm (L1)
Column : *150 mm x 3.9 mm, 10 µm C18 column (L1)*
- Aliran pompa** : 0.75 mL/menit
Pump flow : *0.75 mL/minute*
- Panjang gelombang** : 254 nm
Detector wavelength : *254 nm*
- Volume suntikkan** : 10 µL
Injecting volume : *10 µL*
- Pelarut** : Larutan A : Larutan B (60:40)
Solvent : *Solution A : Solution B (60:40)*
- Fase gerak** : Larutan A : Larutan B (60:40)
Mobile phase : *Solution A : Solution B (60:40)*

Larutan Asam Asetat Glisial P (1 dalam 100)

Glacial Acetic Acid Solution P (1 in 100)

- Pipet 1 mL larutan Asam Asetat Glisial, masukkan ke dalam labu ukur 100 mL.
Pipette 1 mL of Glacial Acetic Acid solution, put it into a 100 mL volumetric flask.
- Tambahkan 50 mL air murni, aduk sampai homogen.
Add 50 mL of purified water, stir until homogeneous.
- Tambahkan pelarut sampai tanda batas, kocok sampai homogen.
Add solvent up to the limit mark, shake until homogeneous.

Larutan A (Larutan Natrium-1-Oktanesulfonat 0.005 M dalam larutan Asam Asetat Glisial P (1 dalam 100))

A Solution (0.005 M Sodium-1-Octanesulfonate solution in Glacial Acetic Acid P solution (1 in 100))

- Timbang dengan saksama 1,08 g sodium-1-oktanesulfonat.
Weight 1,08 g of sodium-1-oktanesulfonate.



24/04/25

RENCANA PENGGUNAAN KOLOM WELCH ULTISIL 150 X 3.9 mm 10 um C18

Rencana Kedatangan BB Tahun 2026-2027

Bahan Baku	Jan	Feb	Mar	Apr	Mei	Jun	Jul	Agu	Sep	Okt	Nov	Des	Total
Thiamin HCl		2		2	2	2		2		2		2	14
Thiamin Mononitrat			1		1		1		1		1		5
Total													19

Perhitungan Kebutuhan Kolom untuk Bahan Baku

Kadar dan Cemaran = 20 injekan/batch = 380

Total seluruh injekan

380 injekan : 500 injekan = 0.76 kolom/tahun

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