

Bagian : QC

Due Date : 05 - ^{Oct}Nov - 26

Tanggal : 03 - Sep - 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 Ultisil C18 (5µm) 3.9 x 150mm	Un	0	1	-1	0	1	0	0

Catatan :

Kolom Ultisil 5µm XB-C18 120Å 150mm x 3.9mm Ex. Welch Part. No: H00201- 31064

- Digunakan untuk memisahkan senyawa dari sampel dengan cara melewatkan fase gerak (pelarut) melalui kolom.
- Kolom ini digunakan pada prosedur penetapan kadar dan cemaran produk jadi Fluphenazine Decanoate Injeksi 25mg/mL.
- Estimasi harga : Rp.6.500.000/unit
- Pemesanan pertama kali dept.QC

Latar belakang permintaan :

- Sehubung dengan adanya transfer metode analisa identifikasi kadar dan batas cemaran yang terelusi lambat dalam produk jadi Fluphenazine Decanoate Injeksi 25mg/mL dan saat ini Dept. QC belum memiliki kolom tersebut maka diperlukan pengadaan untuk menunjang kegiatan analisa.
- Dibutuhkan sebanyak 1 unit kolom (rencana kebutuhan terlampir) karena produk tersebut merupakan OBM.

Terlampir metode analisa, rencana kebutuhan dan penawaran harga.

Dibuat


03/26
SWS/09

Mengetahui


03/26
onw/09



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SUKABUMI-INDONESIA

PROTOKOL TRANSFER METODE ANALISIS IDENTIFIKASI, KADAR, BATAS FLUPHENAZINE DAN BATAS CEMARAN YANG TERELUSI LAMBAT DALAM PRODUK JADI FLUPHENAZINE DECANOATE INJEKSI 25 mg/mL
TRANSFER PROTOCOL OF ANALYSIS METHOD OF IDENTIFICATION, ASSAY, LIMIT OF FLUPHENAZINE AND LIMIT OF SLOWLY ELUTERATED IMPURITIES IN FINISHED PRODUCT FLUPHENAZINE DECANOATE INJECTION 25 mg/mL

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No.	Nama Bahan Material Name	Nomor Katalog Catalog Number	Manufature
6	Fluphenazine Decanoate Dihydrochloride RS Fluphenazine Decanoate Dihydrochloride RS	1280803	USP
7	Fluphenazine Decanoate Injeksi 25 mg/mL Fluphenazine Decanoate Injection 25 mg/mL	IPJ00122	PT Mersifarma

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

7.2.2. Kondisi pengerjaan HPLC
HPLC Operating Conditions

7.2.2.1. Kolom : Kolom Brand Ultisil C18 3,9 x 150 x 5 µm (L1) katalog nomor : H00201-31064
Column : Column Brand Ultisil C18 3,9 x 150 x 5 µm (L1) catalog number : H00201-31064

7.2.2.2. Aliran pompa : 2,0 mL / menit
Flow rate : 2,0 mL / minute

7.2.2.3. Panjang gelombang detektor : 254 nm
Detector wavelengths : 254 nm

7.2.2.4. Volume penyuntikkan : 20 µL
Injection volume : 20 µL

7.2.2.5. Fase gerak : Acetonitrile : Methanol : 0,05 M Ammonium Acetate (2:2:1)
Mobile Phase : Acetonitrile : Methanol : 0,05 M Ammonium Acetate (2:2:1)

7.2.2.6. Pelarut : Acetonitrile : methanol (50 : 50)
Solvent : Acetonitrile : methanol (50 : 50)

7.2.2.7. Waktu Retensi
Retention Time
a. Fluphenazine Hydrochloride : 2,0 menit ± 1 menit
Fluphenazine Hydrochloride : 2,0 minutes ± 1 minutes
b. Fluphenazine Decanoate Dihydrochloride : 52 menit ± 10 menit
Fluphenazine Decanoate Dihydrochloride : 52 minutes ± 10 minutes

7.2.2.8. Waktu Berhenti : ± 130 minutes (2,5 kali dari RT Fluphenazine Decanoate)
End Time : ± 130 minutes (2,5 times that of RT Fluphenazine Decanoate)

7.2.3. Pembuatan Larutan
Solution Making

7.2.3.1. Pembuatan Larutan Ammonium acetate 0,05 M
Preparation of 0,05 M Ammonium Acetate Solution

- Timbang 3,85 gram Ammonium acetate, Masukkan kedalam gelas piala 1000 mL
Weigh 3,85 grams of Ammonium acetate, put it into a 1000 mL beaker.
- Tambahkan Purified water hingga 1000 mL aduk dengan magnetic Stirer selama 10 menit hingga larut
Add Purified Water to a volume of 1000 mL, then stir using a magnetic stirrer for 10 minutes until completely dissolved.
- Saring larutan menggunakan saringan vakum
Filter the solution using a vacuum filter

7.2.3.2. Pembuatan Larutan Fase Gerak
Preparation of Mobile Phase

- Ukur 400 mL asetonitril menggunakan gelas ukur.
Measure 400 mL of acetonitrile using a graduated cylinder
- Ukur 400 mL metanol menggunakan gelas ukur.
Measure 400 mL of methanol using a graduated cylinder.



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- Ukur 200 mL larutan amonium asetat 0,05 M menggunakan gelas ukur.
Measure 200 mL of 0,05 M ammonium acetate solution using a graduated cylinder.
- Masukkan 400 mL asetonitril, 400 mL metanol, dan 200 mL larutan amonium asetat 0,05 M ke dalam gelas beker berkapasitas 2 L.
Transfer 400 mL of acetonitrile, 400 mL of methanol, and 200 mL of 0,05 M ammonium acetate solution into a 2 L beaker.
- Homogenkan campuran menggunakan magnetic stirrer selama 10 menit.
Mix the solution using a magnetic stirrer for 10 minutes until homogeneous.
- Masukkan kedalam botol fase gerak, sonikasi selama 10 menit.
Put into mobile phase bottle, sonicate for 10 minutes.

7.2.4. Pembuatan Larutan Standar
Preparation of Standard Solution

7.2.4.1. Larutan Standar Stok A (Konsentrasi 0,1 mg/mL)
Standard Solution Stock A (Concentration 0,1 mg/mL)

- Timbang 5 mg Fluphenazine Hydrochloride, masukan kedalam labu ukur 50 mL
Weigh 5 mg of Fluphenazine Hydrochloride, put it into a 50 mL measuring flask
- Tambahkan 20 mL Isopropyl Alkohol, Sonikasi selama 10 menit
Add 20 mL Isopropyl Alcohol, Sonicate for 10 minutes
- Tambahkan Isopropil Alkohol sampai tanda batas, kocok sampai homogen.
Add Isopropyl Alcohol up to the volume, shake until homogeneous.

7.2.4.2. Larutan standar stok B
Standard Solution Stock B

Konsentrasi : - 0,5 mg/mL Fluphenazine Decanoate Dihydrochloride;
Concentration : 0,5 mg/mL Fluphenazine Decanoate Dihydrochloride;
- 0,02 mg/mL Fluphenazine Hydrochloride;
0,02 mg/mL Fluphenazine Hydrochloride;

- Timbang 5 mg Fluphenazine Decanoate Dihydrochloride, masukan kedalam labu ukur 10 mL
Weigh 5 mg of Fluphenazine Decanoate Dihydrochloride, put it into a 10 mL measuring flask.
- Pipet 2 mL Larutan standar Stok A.
Pipette 2 mL of standard solution A
- Tambahkan 4 mL Isopropyl Alkohol, Sonikasi selama 10 menit
Add 4 mL Isopropyl Alcohol, Sonicate for 10 minutes
- Tambahkan Isopropil Alkohol sampai tanda batas, kocok sampai homogen.
Add Isopropyl Alcohol up to the volume, shake until homogeneous.

7.2.4.3. Larutan Standar
Standard Solution

Konsentrasi : - 0,1 mg/mL Fluphenazine Decanoate Dihydrochloride;
Concentration : 0,1 mg/mL Fluphenazine Decanoate Dihydrochloride;
- 0,004 mg/mL Fluphenazine Hydrochloride;
0,004 mg/mL Fluphenazine Hydrochloride;

- Pipet 2 mL larutan dari larutan standar stok B, masukan ke dalam labu ukur 10 mL.
Pipette 2 mL of standard solution B, put into a 10 mL volumetric flask.
- Tambahkan Asetonitril sampai tanda batas, kocok sampai homogen.
Add Acetonitrile up to the volume, shake until homogeneous.
- Saring larutan menggunakan syringe filter 0,45 µm PTFE.
Filter the solution using PTFE 0,45 µm syringe filter.
- Masukkan ke dalam vial HPLC.
Put each into HPLC vial.

Rencana Kolom Ultisil 150 x 3,9 mm; 5 µm (C18)

No	Nama Produk	Parameter	Validasi Proses (OBM) (Pengujian)	Total Injeksi (kali)	Kebutuhan Total (mg)
1	Fluphenazine Decanoate Injeksi 25 mg/mL	Kadar dan Cemaran	3	64	192
Total (mg)					192

Kesimpulan : Dibutuhkan sebanyak 192 / 500 injeksi = 0,3 ~ 1 Kolom Ultisil 150 x 3,9 mm; 5 µm (C18)



PT. SURYA BUANA NUSANTARA

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

PT. SURYA BUANA NUSANTARA

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

Company	: PT Mersifarma Tirmaku Mercusana	From : Sunarti
Attn	: Mrs. Dea Putri A	Page : 1 including this page)
Title	: QC Department	April 7, 2026
Re.	: Quotation	No. : 451/SBN/IV/26-001/A

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	Ultisil 5 µm XB-C18 120 Å, LC Column 150 x 3.9mm Welch Part Number : H00201-31064	1 Ea	6.500.000	6.500.000

Note:

Price Exclude PPN

Delivery Time : Ready Stock

Terms of Payment : 14 Days After Document Date

Thank you so much and regards,

PT. SURYA BUANA NUSANTARA

Sunarti
Direktur

Our Partnership :



Ultron® ES-QVM



JAI RADHE SALES