

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	IBS00049	RS Fluphenazine Hydrochloride	mg	0	200	-200	0	200	0	0
2	IBS00469	RS Fluphenazine Decanoate Dihydrochloride	mg	0	100	-100	0	100	0	0

Catatan :

- 1. Fluphenazine Hidroklorida Ex. BPFI, No. Kontrol: B0120408 (1 Vial @200 mg)
- 2. Fluphenazine Decanoate Dihydrochloride Ex. USP Cat.no. 1280803 (1 Vial @100 mg)
- Digunakan untuk baku pembanding analisa produk Fluphenazine Decanoate Injeksi 25mg/mL.
- Pemesanan pertama kali Dept.QC

Latar belakang permintaan :

- Sehubungan 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 baku pembanding tersebut, maka diperlukan pengadaan untuk menunjang kegiatan analisa.

Terlampir metode analisa, rencana kebutuhan dan penawaran harga.

Dibuat

 04/26
SOS

Mengetahui

 04/26
DYW

Rencana Kebutuhan Fluphenazine Decanoate Dihydrochloride

No	Nama Produk	Parameter	Validasi Proses (OBM) (Pengujian)	Kebutuhan per Batch (mg)	Kebutuhan Total (mg)
1	Fluphenazine Decanoate Injeksi 25 mg/mL	Kadar dan Cemaran	3	20	60
Total (mg)					60

Kesimpulan : Dibutuhkan sebanyak 60 mg RS Fluphenazine Decanoate Dihydrochloride

In Stock

Ready to ship

uspi

Fluphenazine Decanoate Dihydrochloride (100 mg)

Catalog No : 1280803

CAS RN® 2376-65-0

Molecular Formula: C32H44F3N3 O2S.2HCl

Product Type: Reference Standard

1

+

Add to cart

Add to Favorites

Shipping Information

Related Products

THIS ITEM HAS BEEN IDENTIFIED AS A POTENTIALLY DANGEROUS GOOD. SPECIAL SHIPPING METHODS AND CHARGES MAY APPLY.

\$329.00

Frequently Purchased

Tenivastatin Calcium (2 x 15 mg) (CO LD SHIPMENT REQUIRED) (Calcium (3R,5R)-7-((1S,2S,6R,8S,8aR)-8-((2,2-dimethylbutanoyl)oxy)-2,6-dimethyl-1,2,6,7,8,8a-hexahydronaphthalen-1-yl)-3,5-dihydroxyheptanoate (1:2) monohydrate)

Catalog No : 1612719

CAS RN® 530112-57-3

Molecular Formula: C50H78CaO12.H2O

Product Type: Reference Stand:

1

+

Add to cart

\$904.00

Rencana Kebutuhan Fluphenazine Hydrochloride

No	Nama Produk	Parameter	Validasi Proses (OBM) (Pengujian)	Kebutuhan per Batch (mg)	Kebutuhan Total (mg)
1	Fluphenazine Decanoate Injeksi 25 mg/mL	Kadar dan Cemarkan	3	18	54
Total (mg)					54

Kesimpulan : Dibutuhkan sebanyak 54 mg RS Fluphenazine Hydrochloride

PPOMN EN

BerandaBaku PembandingKultur MikrobaUji ProfisiensiHewan UjiTarif PengujianKalibrasiPelatihanPihak Ke - 3Lot-Release

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Daftar Baku Pembanding Tahun 2026

Berdasarkan Peraturan Menteri Keuangan nomor 73 Tahun 2024, tentang Jenis dan Tarif atas Jenis Penerimaan Negara Bukan Pajak yang Bersifat Volatil yang Berlaku pada Badan Pengawas Obat dan Makanan, harga yang di tetapkan untuk masing-masing jenis baku pembanding adalah Rp. 500.000 (lima ratus ribu) rupiah.

Showing 1 to 1 of 1 entries (filtered from 660 total entries)

Nomor	Nama Baku Uji	Keterangan	No. Kontrol	No. Kontrol Sebelumnya	Bobot	Ket. Pengujian
374	Flufenazin hidroklorida	BPFI	B0120408	-	200 mg	Kuantitatif

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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 Alat Tool Name	Jumlah Amount
11	Labu ukur 10 mL Volumetric flask 10 mL	6
12	Labu ukur 50 mL Volumetric flask 50 mL	2
13	Magnetik Stirer Magnetik Stirer	1

No.	Nama Alat Tool Name	Jumlah Amount
14	Saringan Vakum Vacuum Filter	1
15	Piknometer Piknometer	1
16	Pipet tetes Dropper pipet	1

7.2.1.2. Bahan yang digunakan

Materials Used

No.	Nama Bahan Material Name	Nomor Katalog Catalog Number	Manufature
1	Asetonitril Acetonitrile	A998-4	Thermo
2	Metanol Methanol	A452-4	Thermo
3	Purified Water Purified Water	IBC00016A0	PT Mersifarma
4	Isopropil Alkohol Isopropil Alkohol	A-1087	Smartlab
5	Fluphenazine Hydrochloride RS Fluphenazine Hydrochloride RS	32379-74S	Kanto
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 : 5020-01801
Column : Column Brand Ultisil C18 3.9 x 150 x 5 µm (L1) catalog number : 5020-01801
- 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. Pelarut : Asetonitril : Metanol : 0,05 M Ammonium Acetate (2:2:1)
Solvent : Acetonitrile : Methanol : 0,05 M Ammonium Acetate (2:2:1)
- 7.2.2.6. Fase gerak : Asetonitril : metanol (50 : 50)
Mobile Phase : 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



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- 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

- a. 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.
- b. 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.
- c. Saring larutan menggunakan saringan vakum
Filter the solution using a vacuum filter
- d. Masukkan kedalam botol MPS, sonikasi selama 10 menit.
Put into MPS bottle, sonicate for 10 minutes.

7.2.3.2. Pembuatan Larutan Fase Gerak

Preparation of Mobile Phase

- a. Ukur 400 mL asetonitril menggunakan gelas ukur.
Measure 400 mL of acetonitrile using a graduated cylinder.
- b. Ukur 400 mL metanol menggunakan gelas ukur.
Measure 400 mL of methanol using a graduated cylinder.
- c. 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.
- d. 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.
- e. Homogenkan campuran menggunakan magnetic stirrer selama 10 menit.
Mix the solution using a magnetic stirrer for 10 minutes until homogeneous.
- f. Masukkan kedalam botol MPS, sonikasi selama 10 menit.
Put into MPS bottle, sonicate for 10 minutes.

7.2.4. Pembuatan Larutan Standar

Preparation of Standard Solution

7.2.4.1. Larutan Baku Stok A (Konsentrasi 0,1 mg/mL)

Standard Solution Stock A (Concentration 0,1 mg/mL)

- a. 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.
- b. Tambahkan 20 mL Isopropil Alkohol, Sonikasi selama 10 menit
Add 20 mL Isopropyl Alcohol, Sonicate for 10 minutes
- c. Tambahkan Isopropil Alkohol sampai tanda batas, kocok sampai homogen.
Add Isopropyl Alcohol up to the volume, shake until homogeneous.
- d. Saring larutan menggunakan syringe filter 0.45 µm PTFE.
Filter the solution using PTFE 0.45 µm syringe filter.
- e. Masukkan ke dalam vial HPLC.
Put each into HPLC vial.

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7.2.4.2. Larutan Baku 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 dari larutan baku Stok A, masukkan ke dalam labu ukur 10 mL.
Pipette 2 mL of solution A, put into a 10 mL volumetric flask.
- 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 Isopropil Alcohol 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.

7.2.4.3. Larutan Baku

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 baku Stok B, masukkan ke dalam labu ukur 10 mL.
Pipette 2 mL of 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.

7.2.5. Pembuatan Larutan Uji Kesesuaian Sistem

Preparation of System Suitability Test Solution

7.2.5.1. Larutan Induk UKS Fluphenazine Decanoate Dihydrochloride RS (Konsentrasi : 1 mg/mL

UKS Fluphenazine Decanoate Dihydrochloride RS Main Stock Solution (Concentration: 1 mg/mL)

- Timbang 5 mg Fluphenazine Decanoate Dihydrochloride, masukan kedalam labu ukur 5 mL
Weigh 5 mg of Fluphenazine Decanoate Dihydrochloride, put it into a 5 mL measuring flask.
- Tambahkan 2 mL pelarut, Sonikasi selama 10 menit
Add 2 mL Solvent, Sonicate for 10 minutes
- Tambahkan pelarut sampai tanda batas, kocok sampai homogen.
Add solvent up to the volume, shake until homogeneous.

7.2.5.2. Larutan Induk UKS Fluphenazine Hydrochloride RS (Konsentrasi : 0,8 mg/mL

UKS Fluphenazine Hydrochloride RS Main Stock Solution (Concentration: 0,8 mg/mL)

- Timbang 4 mg Fluphenazine Hydrochloride, masukan kedalam labu ukur 5 mL
Weigh 4 mg of Fluphenazine Hydrochloride, put it into a 5 mL measuring flask.
- Tambahkan 2 mL pelarut, Sonikasi selama 10 menit
Add 2 mL Solvent, Sonicate for 10 minutes
- Tambahkan pelarut sampai tanda batas, kocok sampai homogen.
Add solvent up to the volume, shake until homogeneous.

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591,87 = Berat molekul Fluphenazine Decanoate

Molecular weight of Fluphenazine Decanoate

664,69 = Berat molekul Fluphenazine Decanoate Dihydrochloride

Molecular weight of Fluphenazine Decanoate Dihydrochloride

7.3. BATAS FLUPHENAZINE DAN BATAS CEMARAN YANG TERELUSI LAMBAT FLUPHENAZINE LIMITS AND SLOWLY ELUTERATING IMPURITIES LIMITS

7.3.1. Persyaratan : Sesuai dengan spesifikasi produk yang berlaku.
Requirement In accordance with applicable product specifications.

7.3.2. Alat, Bahan, dan Metode yang Digunakan
Tools, Materials, and Method Used

Seluruh prosedur pada Pengujian ini tidak memerlukan preparasi ulang. Analisis dilakukan menggunakan kondisi KCKT, kolom, preparasi larutan baku, preparasi larutan kesesuaian sistem (UKS), dan preparasi larutan sampel yang sama seperti pada pengujian kadar. Perhitungan persentase kadar fluphenazine dalam sampel injeksi dilakukan menggunakan kromatogram yang diperoleh dari pengujian kadar.

This test does not require re-preparation of the solutions. The analysis is performed using the same HPLC conditions, column, standard solution preparation, system suitability solution preparation, and sample solution preparation as described in the Assay. The percentage of fluphenazine in the Injection is calculated using the chromatograms obtained from the Assay.

7.3.3. Perhitungan kadar Batas Fluphenazine

Limit of Fluphenazine Calculation

Hitung perolehan kembali (%) batas Fluphenazine dalam larutan Fluphenazine Decanoate 25 mg/mL injeksi dengan rumus :

Calculate the recovery (%) limit of Fluphenazine in Fluphenazine Decanoate 25 mg/mL injection solution using the formula:

$$\% \text{ Fluphenazine} = \frac{R_{std} \times W_{std} \times F \times FP_{spi} \times 473,53}{R_{spi} \times V_{spi} \times \text{content} \times FP_{std} \times 510,44}$$

Keterangan :

Description :

R_{spi} = Respons puncak larutan sampel

Peak response of sample solution

R_{std} = Respons puncak larutan standar

Peak response of standard solution

W_{std} = Bobot standar yang ditimbang (mg)

Standard weight weighed (mg)

25 = Kandungan Fluphenazine Decanoat per Injeksi (mg)

Fluphenazine Decanoat content per Injection (mg)

FP_{spi} = Faktor pengenceran larutan sampel (250)

Dilution factor of sample solution (250)

FP_{std} = Faktor pengenceran larutan standar (1250)

Dilution factor of standard solution (1250)

F = Kadar Reference Standard (%) sebagai as is

Reference Standard Level (%) as is

473,53 = Berat molekul Fluphenazine

Molecular weight of Fluphenazine

510,44 = Berat molekul Fluphenazine Hydrochloride

Molecular weight of Fluphenazine Hydrochloride