

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 L1 HPLC (4µm), 4.6 x 250mm	Pc	0	1	-1	0	1	0	0
2	IMO11476	Kolom Inertsil ODS-3V (5µm) 4.6 x 150mm	Un	0	1	-1	0	1	0	0

Catatan :

1. HPLC Column, C18-Plus, 4µm, 130Å, 4.6 x 250mm, Ex. Hawach, Cat. No : 13021860

- Digunakan untuk memisahkan senyawa dari sampel dengan cara melewati fase gerak (pelarut) melalui kolom.
- Kolom tersebut digunakan untuk pengujian parameter kadar dan cemaran pada produk Levetiracetam KSS 500 mg.
- Estimasi harga : Rp.8.054.848/Pc
- Pemesanan pertama Dept. QC.

2. Inertsil ODS-3V Analytical Column, 5µm, 4.6 x 150mm, Ex. GL Sciences, Part. No : 5020-01801

- Digunakan untuk memisahkan senyawa dari sampel dengan cara melewati fase gerak (pelarut) melalui kolom.
- Kolom tersebut digunakan untuk pengujian parameter disolusi pada produk Levetiracetam KSS 500 mg.
- Estimasi harga : Rp.9.300.000/Un
- Pemesanan pertama Dept. QC.

Latar Belakang Permintaan :

- Sehubungan dengan adanya transfer metode analisa pada produk Levetiracetam KSS 500 mg, maka diperlukan pengadaan kolom tersebut sesuai dengan metode yang telah dikembangkan oleh Dept. R&D, sehingga dapat dilakukan pengujian rutin untuk produk tersebut.

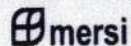
Terlampir metode analisa, rencana kebutuhan dan penawaran harga kolom.

Dibuat


ADA 17/26

Mengetahui


17/26



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**PROTOKOL TRANSFER METODE ANALISIS
IDENTIFIKASI, KADAR, DISOLUSI, DAN CEMARAN
ORGANIK LEVETIRACETAM DALAM PRODUK JADI
LEVETIRACETAM 500 MG KAPLET SALUT SELAPUT
ANALYTICAL METHOD TRANSFER PROTOCOL FOR
THE IDENTIFICATION, ASSAY, DISSOLUTION TEST
AND ORGANIC CONTAMINANTS OF LEVETIRACETAM
IN FINISHED PRODUCT LEVETIRACETAM 500 MG
FILM-COATED TABLETS**

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7.2. PENETAPAN KADAR LEVETIRACETAM SECARA HPLC

ASSAY OF LEVETIRACETAM BY HPLC

7.2.1. Alat, Bahan, dan Metode yang Digunakan

Tools, Materials, and Method Used

7.2.1.1. Alat yang digunakan

Tools Used

No.	Nama Alat Tool Name	Jumlah Amount	No.	Nama Alat Tool Name	Jumlah Amount
1	Labu ukur 100 mL Volumetric Flask 100 mL	2	7	Pipet Volumetrik 1 mL Volumetric pipette 1 mL	1
2	Labu Ukur 10 mL 10 mL Volumetric Flask	6	8	KCKT HPLC	1
3	Gelas piala 1000 mL 1000 mL beaker glass	2	9	Vial HPLC HPLC vials	12
4	Bulb Bulb	1	10	Timbangan Analytical balance	1
5	Botol MPS MPS Bottle	1	11	Saringan Vakum Vacuum Filter	1
6	Sonikator Ultrasonic cleaner	1	12	Syringe filter 0,45 µm PTFE Syringe filter 0,45 µm PTFE	1

7.2.1.2. Bahan yang digunakan

Materials Used

No.	Nama Bahan Material Name	Nomor Katalog Catalog Number	Manufacture
1	Asetonitril Acetonitrile	A998-4	Thermo
2	Purified Water Purified Water	IBC00016A0	PT Mersifarma
3	Kalium Fosfat Monobasa Monobasic potassium phosphate	32379-74S	Kanto
4	Natrium 1 - Heptansulfonat Sodium 1 - Heptanesulphonate	I0345	TCI
5	Asam Fosfat Pekat Phosphoric Acid Concentrated	AR1152	RCI Labscan
6	Levetiracetam WS Levetiracetam WS	2 BE 001 BPS	Zhexiang S
7	Kaplet atau Kaplet Salut Selaput Levetiracetam 500 mg Levetiracetam 500 mg Caplets of Film-Coated Caplets	IPJ00552	PT Mersifarma

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



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7.2.2. Kondisi pengerjaan HPLC

HPLC Operating Conditions

7.2.2.1. Kolom
Column

Hawach Scientific C18 250 mm x 4.6 mm, 4µm (L1) Katalog Nomor: 13021860

Hawach Scientific C18 250 mm x 4.6 mm, 4µm (L1) Catalog Number : 13021860

- 7.2.3.2. Aliran pompa** : 1.5 mL / menit
Flow rate : 1.5 mL / minute
- 7.2.3.3. Panjang gelombang detektor** : 220 nm
Detector wavelengths : 220 nm
- 7.2.3.4. Volume penyuntikkan** : 10 µL
Injection volume : 10 µL
- 7.2.3.5. Pelarut** : Asetonitril : Dapar pH 2.8 (8 : 92) digabung
Solvent : Acetonitrile : Buffer pH 2.8 (8:92) combined
- 7.2.3.6. Fase gerak** : Asetonitril : Purified Water (20 : 80)
Mobile Phase : Acetonitrile : Purified Water (20 : 80)
- 7.2.3.7. Waktu Retensi** : 5.6 Menit ± 2 Menit
Retention Time : 5.6 Minutes ± 2 Minutes
- 7.2.3.8. Waktu Berhenti** : 7 Menit ± 2 Menit
End Time : 7 Minutes ± 2 Minutes

7.2.3. Fase gerak

Mobile Phase

7.2.3.1. Pembuatan larutan dapar pH 2.8

Preparation of pH 2.8 buffer solution

- a. Timbang 1,4 gram kalium fosfat monobasa (KH_2PO_4) dan 0,6 gram Natrium 1- Heptansulfonat ($\text{C}_7\text{H}_{15}\text{NaO}_5\text{S}$). Masukkan kedalam gelas piala 1000 mL.
Weigh 1.4 grams of monobasic potassium phosphate (KH_2PO_4) and 0.6 grams of Sodium Heptanesulphonate ($\text{C}_7\text{H}_{15}\text{NaO}_5\text{S}$), put it into a 1000 ml beaker.
- b. Tambahkan Purified water hingga 1000 mL aduk dengan stirrer selama 15 menit
Add purified water up to 1000 mL and stir with a stirrer for 15 minutes.
- c. Atur hingga pH 2.8 ± 0,05 dengan menggunakan Asam fosfat pekat
Adjust to pH 2.8 ± 0,05 using Ortho Concentrated Phosphoric Acid
- d. Saring larutan menggunakan saringan vakum
Filter the solution using a vacuum filter

7.2.3.2. Pembuatan larutan Fase gerak

Preparation of the mobile phase solution

- a. Ukur 920 mL larutan dapar menggunakan gelas ukur, kemudian masukkan ke dalam beaker glass 1 L.
Measure 920 mL of the buffer solution using a graduated cylinder, then transfer it into a 1 L beaker glass
- b. Tambahkan 80 mL asetonitril ke dalam beaker glass, tutup beaker, kemudian aduk menggunakan stirrer selama 15 menit.
Add 80 mL of acetonitrile to the beaker glass, cover the beaker, and stir using a stirrer for 15 minutes.
- c. Pindahkan larutan ke dalam botol MPS, kemudian sonikasi selama 15 menit.
Transfer the solution into the MPS bottle, then sonicate for 15 minutes.



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7.3. UJI DISOLUSI LEVETIRACETAM SECARA HPLC
DISSOLUTION TEST OF LEVETIRACETAM BY HPLC

7.3.1. Alat, Bahan, dan Metode yang Digunakan

Tools, Materials, and Method Used

7.3.1.1. Alat yang digunakan

Tools Used

No.	Nama Alat Tool Name	Jumlah Amount	No.	Nama Alat Tool Name	Jumlah Amount
1	Gelas beaker 1000 mL Beaker glass 1000 mL	1	9	Alat disolusi tipe 2 Dissolution apparatus type 2	1
2	Botol Fase Gerak 1000 mL Mobile Phase Bottle 1000 mL	1	10	Labu disolusi Dissolution flask	6
3	Pipet Volume 1 mL 1 mL Volume Pipette	1	11	Sonikator Ultrasonic cleaner	1
4	Pipet Volume 10 mL 10 mL Volume Pipette	1	12	Vial KCKT HPLC Vial	15
5	Labu ukur 10 mL Volumetric flask 10 mL	6	13	Timbangan Analytical balance	1
6	Gelas Piala 1000 mL 1000 mL Beaker	1	14	Syringe filter 0,45 µm PTFE Syringe filter 0,45 µm PTFE	1
7	Tabung reaksi Reaction tube	6	15	Saringan Vakum Vacuum Filter	1
8	Botol reagen kimia Laboratory reagent bottle	1	16	Botol MPS MPS Bottle	1

7.3.1.2. Bahan yang digunakan

Materials Used

No.	Nama Bahan Material Name	Nomor Katalog Catalog Number	Manufacture
1	Asetonitril Acetonitrile	A998-4	Thermo
2	Asam asetat glasial Glacial acetic acid	AR1002	RCI
3	Purified Water Purified Water	IBC00016A0	PT Mersifarma
4	Metanol Methanol	A452-4	Thermo
5	Kalium Fosfat Monobasa Monobasic potassium phosphate	32379-74S	Kanto
6	Natrium 1-heksanasulfonat Sodium 1-hexanesulphonate	I0345	TCI
7	KOH encer KOH in 100 mL of Purified Water	1,050.331.000	Merck
8	Levetiracetam Levetiracetam	2 BE 001 BPS	PT Mersifarma
9	Levetiracetam Kaplet atau Kaplet Salut Selaput Levetiracetam 500 mg Levetiracetam 500 mg Caplets or Film-Coated Caplets	IPJ 00552	PT Mersifarma

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



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7.3.2. Kondisi Pengerjaan Disolusi

Dissolution Working conditions

- 7.3.2.1. Media disolusi : 900 mL, Purified Water
Dissolution medium
900 mL, Purified Water
7.3.2.2. Alat disolusi : Tipe 2 (Dayung)
Aparatus Dissolution
Type 2 (Paddle)
7.3.2.3. Kecepatan putaran : 50 rpm
Rotation speed
50 rpm
7.3.2.4. Waktu pengambilan cuplikan : 15 menit
Time of taking the clip
15 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

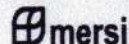
HPLC Operating Conditions

- 7.3.3.1. Kolom : Inertsil ODS-3V GL-Science C18 150 mm x 4,6 mm 5µm (L1)
Column
Katalog Nomor : 5020-01801
Inertsil ODS-3V GL-Science C18 150 mm x 4,6 mm 5µm (L1) Catalog : Number : 5020-01801
7.3.3.2. Aliran pompa : 1,2 mL / menit
Flow rate
1,2 mL / minute
7.3.3.3. Panjang gelombang detektor : 220 nm
Detector wavelengths
220 nm
7.3.3.4. Volume penyuntikkan : 10 µL
Injection volume
10 µL
7.3.3.5. Fase Gerak : Asetonitril : Dapar pH 5,6 (15 : 85)
Mobile Phase
Acetonitrile : Dapar pH 5,6 (15 : 85)
7.3.3.6. Pelarut : Purified Water
Solvent
Purified Water
7.3.3.7. Waktu Retensi : 2,6 Menit ± 1 Menit
Retention Time
2,6 Minutes ± 1 Minutes
7.3.3.8. Waktu Berhenti : 4 Menit
End Time
4 Minutes

7.3.4. Fase Gerak : Larutan Dapar pH 5,6

Mobile Phase : pH 5,6 Buffer Solution

- 7.3.4.1. Timbang 6,8 gram kalium fosfat monobasa, Masukkan kedalam gelas piala 1000
Weigh 6.8 grams of monobasic potassium phosphate, put it into a 1000 ml beaker.
7.3.4.2. Tambahkan Purified water hingga 1000 mL aduk dengan stirrer selama 15 menit
Add purified water up to 1000 mL and stir with a stirrer for 15 minutes.
7.3.4.3. Atur hingga pH 5,6 ± 0,05 dengan menggunakan KOH encer (0,5 gram KOH dalam 100 mL Purified water)
Adjust to pH 5,6 ± 0,05 using dilute KOH (0.5 grams of KOH in 100 mL of purified water)
7.3.4.4. Saring larutan menggunakan saringan vakum
Filter the solution using a vacuum filter
7.3.4.5. Masukkan kedalam botol MPS, sonikasi selama 10 menit
Put into MPS bottle, sonicate for 10 minutes.



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7.3.5.4. Perhitungan kadar

Assay Calculation

Hitung kadar (%) Leveteracetam 500 mg dalam kaplet/kaplet salut selaput Leveteracetam 500 mg dengan rumus:

Calculate the assay (%) of Leveteracetam 500 mg in film-coated caplets/caplets using the formula:

$$\% \text{ Leveteracetam} = \frac{R_{\text{spl}} \times W_{\text{std}} \times FP_{\text{spl}}}{R_{\text{std}} \times 500 \times FP_{\text{std}}} \times F$$

Keterangan :

Description :

R_{spl} = 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)

500 = Kandungan Leveteracetam per kaplet atau kaplet salut selaput (mg)
Levetiracetam content per caplets or film-coated caplets (mg)

FP_{spl} = Faktor pengenceran larutan sampel (900)
Dilution factor of sample solution (900)

FP_{std} = Faktor pengenceran larutan standar (100)
Dilution factor of standard solution (100)

F = Kadar Working Standard (%) as is
Working Standard (%) as is

7.4. PEMERIKSAAN CEMARAN ORGANIK

ORGANIC IMPURITIES TEST

7.4.1 Alat, Bahan, dan Metode yang Digunakan

Tools, Materials, and Method Used

7.4.1.1 Alat yang digunakan

Tools Used

No.	Nama Alat Tool Name	Jumlah Amount	No.	Nama Alat Tool Name
1	Gelas beaker 1000 mL <i>Beaker glass 1000 mL</i>	2	8	Botol MPS <i>MPS bottle</i>
2	Labu Ukur 250 mL <i>Volumetric flask 250 mL</i>	1	9	Vial KCKT <i>HPLC Vial</i>
3	Labu Ukur 100 mL <i>Volumetric flask 100 mL</i>	3	10	Sonikator <i>Ultrasonic cleaner</i>
4	Labu Ukur 50 mL <i>Volumetric flask 50 mL</i>	1	11	Timbangan <i>Analytical balance</i>
5	Labu Ukur 25 mL <i>Volumetric flask 25 mL</i>	2	12	Syringe filter 0,45 µm PTFE <i>Syringe filter 0,45 µm PTFE</i>
6	Labu Ukur 10 mL <i>Volumetric flask 10 mL</i>	1	13	Saringan Vakum <i>Vakuum Filter</i>
7	Pipet Volume 1 mL <i>1 mL Volume Pipette</i>	4	14	Botol MPS <i>MPS Bottle</i>



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7.4.1.2 Bahan yang digunakan

Materials Used

No.	Nama Bahan Material Name	Nomor Katalog Catalog Number	Manufacture
1	Asetonitril <i>Acetonitrile</i>	A998-4	Thermo
2	Purified Water <i>Purified Water</i>	IBC00016A0	PT Mersifarma
3	Kalium Fosfat Monobasa <i>Monobasic potassium phosphate</i>	32379-74S	Kanto
4	Natrium Heptansulfonat <i>Sodium Heptansulfonat</i>	I0345	TCI
5	Asam Fosfat Pekat <i>Phosphoric Acid Concentrated</i>	AR1152	RCI Labscan
6	Senyawa Sejenis B Leveteracetam <i>Related Compound B Leveteracetam</i>	1359415	USP
7	Levetiracetam WS <i>Levetiracetam WS</i>	2 BE 001 BPS	Zhexiang S
8	Kaplet atau Kaplet Salut Selaput Levetiracetam 500 mg Levetiracetam 500 mg Caplets of Film- Coated Caplets	IPJ00552	PT Mersifarma

7.4.2 Kondisi pengerjaan HPLC

HPLC Operating Conditions

7.4.2.1. Kolom

Column

Hawach Scientific C18 250 mm x 4.6 mm 4µm (L1) Katalog
Nomor: 13021860

Hawach Scientific C18 250 mm x 4.6 mm 4µm (L1) Catalog Number
: 13021860

7.4.2.2. Aliran pompa

Flow rate

: 1,0 mL / menit

7.4.2.3. Panjang gelombang detektor

Detector wavelengths

: 200 nm

7.4.2.4. Volume penyuntikkan

Injection volume

: 10 µL

7.4.2.5. Fase Gerak

Mobile Phase

: Asetonitrile : Dapar (5 : 95) digabung

7.4.2.6. Pelarut

Solvent

: Fase Gerak

7.4.2.7. Waktu Retensi

Retention Time

: Mobile Phase

a. Senyawa Sejenis Leveteracetam A : 22 menit ± 3 menit
Related Compound A Leveteracetam
22 minutes ± 3 minutes

b. Senyawa Sejenis Leveteracetam B : 7 menit ± 2 menit
Related Compound A Leveteracetam
7 minutes ± 2 minutes

c. Leveteracetam : 13 menit ± 3 menit
Levetiracetam
13 minutes ± 3 minutes

d. Asam Leveteracetam : 27 menit ± 5 menit
Levetiracetam Acid
27 minutes ± 3 minutes

7.4.2.8. Waktu Berhenti

End Time

: 40 menit

40 minutes

Rencana Penggunaan Kolom Hawach C18 250 x 4,6 mm; 4 µm (L1)

No	Nama Produk	Parameter	Validasi Proses (OBM) (Pengujian) (a)	Pengujian Stabilita (Interval) (b)	Total Injekan (kali) (c)	Kebutuhan Total (Injekan) (a + b) x c
1	Levetiracetam Kaplet Salut Selaput 500 mg	Kadar dan Cemaran	3	27	18	540
Total (mg)						540

Kesimpulan : Dibutuhkan sebanyak 540 / 500 injekan = 1 ~ 1 Kolom Hawach C18 250 x 4,6 mm; 4 µm (L1)



Hawach Scientific Co., Ltd

Tel: 0086-29-89284429

Email: sales7@hawach.com

Quotation

Quote#Q202609100008

Customer

Company PT. MERSIFARMA TM

Date 10-Sep-26

Contact Dea Anggraeni

Email Dea_Anggraeni@mersifarma.co.id

Order No ***

Address Jln. Raya Pelabuhan Km. 18, Cikembar, Cikembar, Kab. Sukabumi,
Jawa Barat, 43157, Indonesia

Rep Caroline Dong

Phone +62 21 38834021

EXW Xi'an, China

No.	Cat#	Description	Unit Price	Qty	Total
1	13021860	HPLC Column,C18-Plus,4µm,130 A,4.6x250mm,1pc/pk HS CODE: 9027.90	¥3,059.00	2 packs	¥6,118.00
Subtotal					¥6,118.00
Freight Cost to door by UPS					¥298.00
TOTAL					¥6,416.00

NOTE

LEAD TIME: 6-8 Workdays after Receiving the Payment.

DELIVERY: 6-7 Workdays.

PAYMENT: 100% Paid in Advance.

BANK INFORMATION:

Bank Name: CHINA MERCHANTS BANK

Bank Account #: 1299 0556 8210 402

Beneficiary Name: HAWACH SCIENTIFIC CO., LTD

Beneficiary Address: Room 2408, Building A1, No.32 JinYE Rd, Xi'an, Shaanxi Province, P.R.China.

SWIFT Code: CMBCCNBS 231

Bank Branch Address: NO.1 Zhangbayilu, High-tech Development zone, Yanta District Xi'an, Shaanxi Province, China.

PS: Please strictly use the complete Beneficiary Name 'Hawach Scientific Co., Ltd' when making payment.
Any incomplete name may cause failure in receiving your payment.

Hawach Scientific Co., Ltd

www.hawach.com

Tel: +86-29-89284429

Email: info@hawach.com

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Rencana Penggunaan Kolom Inertsil ODS-3V C18 150 x 4,6 mm; 5 µm (L1)

No	Nama Produk	Parameter	Validasi Proses (OBM) (Pengujian) (a)	Pengujian Stabilita (Interval) (b)	Total Injeksi (kali) (c)	Kebutuhan Total (Injeksi) (a + b) x c
1	Levetiracetam Kaplet Salut Selaput 500 mg	Disolusi	3	27	12	360
Total (mg)						360

Kesimpulan : Dibutuhkan sebanyak 360 / 500 injeksi = 0,7 ~ 1 Kolom Inertsil ODS-3V C18 150 x 4,6 mm; 5 µm (L1)



PT MASS SAINTIFIKA INDONESIA
Jl. Pangeran Sogiri Blok H 3 No 10, Tanah Baru, Bogor Utara, Bogor 16154

QUOTATION

Email : Sales@masssaintifikaIndonesia.com
Website : www.masssaintifikaIndonesia.com

To : R&D CENTER PT MERSIFARMA TM
Jl. Raya Bogor No.52, Cisalak, Kec. Sukmajaya, Kota Depok, Jawa Barat 16416

Quotation Number: 0347/QUO/MSI/RA/II/2026

Phone: 0856-9513-6988

Quotation Date: 25/02/2026

Attention: Ibu Dea

Validity: 1 month

Email: Dea_anggraeni@mersifarma.com

Revision: 0

Item No.	Description	Part Number	Quantity	Unit	Price	Discount	Final Price	Total Price
1	GL Sciences Inertsil ODS-3V Analytical Column 5µm 150mm x 4.6mm	5020-01801	1	EA	Rp 9.300.000	10%	Rp 8.370.000	Rp 8.370.000
TOTAL								Rp 8.370.000
PPN 11%								Rp 920.700
GRAND TOTAL								Rp 9.290.700

Notes :

- Franco Depok
- Ready Stock Before Sold
- Term of payment 100% before delivery

Best Regards,
PT Mass Saintifika Indonesia

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