

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	IBS00112	Levetiracetam CRS	mg	0	120	-120	0	120	0	0
2	IBS00243	Levetiracetam RC B	mg	0	40	-40	0	40	0	0

Catatan :

1. Levetiracetam CRS, Ex. EDQM, Cat. Code : Y0001253, CAS No : 102767-28-2

- Digunakan sebagai baku internal dalam analisa penetapan kadar dan cemaran pada produk Levetiracetam KSS 500 mg.
- Rencana kebutuhan sebanyak 70 mg. Pemesanan mengikuti MOQ 1 vial @120 mg.
- Estimasi harga : Rp.1.835.244 / vial.
- Pemesanan pertama Dept. QC.

2. Levetiracetam Related Compound B, Ex. USP, Cat. No : 1359437, CAS. No : 7682-20-4

- Digunakan sebagai standar dalam analisa cemaran organik pada produk Levetiracetam KSS 500 mg.
- Rencana kebutuhan sebanyak 27 mg. Pemesanan mengikuti MOQ 1 vial @20 mg.
- Estimasi harga : Rp.15.960.977 / vial.
- Pemesanan pertama Dept. QC.

Latar Belakang Permintaan :

- Sehubung dengan adanya transfer metode analisa pada produk Levetiracetam KSS 500 mg, maka diperlukan pengadaan reference standar 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 ~~kelem~~ Reference Standard

Atada 17/09/26

Dibuat

Mengetahui

Atada 17/09/26

Atada 17/09/26

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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:

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

Keterangan

Description

R_{api} = 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)

Leveteracetam content per caplets or film-coated caplets (mg)

FP_{api} = 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 Beaker glass 1000 mL	2	8	Botol MPS MPS bottle
2	Labu Ukur 250 mL Volumetric flask 250 mL	1	9	Vial KCKT HPLC Vial
3	Labu Ukur 100 mL Volumetric flask 100 mL	3	10	Sonikator Ultrasonic cleaner
4	Labu Ukur 50 mL Volumetric flask 50 mL	1	11	Timbangan Analytical balance
5	Labu Ukur 25 mL Volumetric flask 25 mL	2	12	Syringe filter 0.45 µm PTFE Syringe filter 0.45 µm PTFE
6	Labu Ukur 10 mL Volumetric flask 10 mL	1	13	Saringan Vakum Vacuum Filter
7	Pipet Volume 1 mL 1 mL Volume Pipette	4	14	Botol MPS MPS Bottle

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7.4.1.2 Bahan yang digunakan

Materials Used

No.	Nama Bahan Material Name	Nomor Katalog Catalog Number	Manufature
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	Natrum Heptansulfonat Sodium Heptansulfonat	10345	TCI
5	Asam Fosfat Pekat Phosphoric Acid Concentrated	AR1152	RCI Labscan
6	Senyawa Sejenis B Leveteracetam Related Compound B Leveteracetam	1359415	USP
7	Leveteracetam WS Leveteracetam WS	2 BE 001 BPS	Zhexiang S
8	Kaplet atau Kaplet Salut Selaput Leveteracetam 500 mg Leveteracetam 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

1.0 mL / minutes

7.4.2.3 Panjang gelombang detektor

Detector wavelengths

200 nm

200 nm

7.4.2.4 Volume penyuntikkan

Injection volume

10 µL

10 µL

7.4.2.5 Fase Gerak

Mobile Phase

Asetonitril : Dapar (5 : 95) digabung

Acetonitrile : Buffer (5 : 95) combined

7.4.2.6 Pelarut

Solvent

Fase Gerak

Mobile Phase

7.4.2.7 Waktu Retensi

Retention Time

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 B Leveteracetam : 7 minutes ± 2 minutes

c. Leveteracetam : 13 menit ± 3 menit

Leveteracetam : 13 minutes ± 3 minutes

d. Asam Leveteracetam : 27 menit ± 5 menit

Leveteracetam Acid : 27 minutes ± 5 minutes

7.4.2.8 Waktu Berhenti

End Time

40 menit

40 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	Manufaktur
1	Asetonitril Acetonitrile	A898-4	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	Type 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

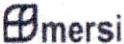
7.3.3.1. Kolom	Inertsil ODS-3V GL Science C18 150 mm x 4.6 mm 5µm (L1)
Column	Katalog Nomor : 5020-01801
	Inertsil ODS-3V GL Science C18 150 mm x 4.6 mm 5µm (L1) Catalog Number : 5020-01801
7.3.3.2. Aliran pompa	1.2 mL / menit
Flow rate	1.2 mL / minute
7.3.3.3. Panjang gelombang detektor	220 nm
Detector wavelengths	220 nm
7.3.3.4. Volume penyuntikkan	10 µL
Injection volume	10 µL
7.3.3.5. Fase Gerak	Acetonitrile : 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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7.2 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	Manufature
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	10345	TCI
5	Asam Fosfat Pekat Phosphate 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

Method Used

 PT. MERSIFARMA TM SUKABUMI-INDONESIA	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	Halaman : 9 dari 22
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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

7.2.2.2 Aliran pompa

Flow rate

1.5 mL / menit

1.5 mL / minute

7.2.2.3 Panjang gelombang detektor

Detector wavelengths

220 nm

220 nm

7.2.2.4 Volume penyuntikkan

Injection volume

10 µL

10 µL

7.2.2.5 Pelarut

Solvent

Acetonitrile : Dapar pH 2.8 (8 : 92) digabung

Acetonitrile : Buffer pH 2.8 (8, 92) combined

7.2.2.6 Fase gerak

Mobile Phase

Acetonitrile : Purified Water (20 : 80)

Acetonitrile : Purified Water (20 : 80)

7.2.2.7 Waktu Retensi

Retention Time

5.6 Menit ± 2 Menit

5.6 Minutes ± 2 Minutes

7.2.2.8 Waktu Berhenti

End Time

7 Menit ± 2 Menit

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 ($\text{C}_7\text{H}_{15}\text{NaO}_2\text{S}$). Masukkan kedalam gelas piala 1000 mL

Weight 1.4 grams of monobasic potassium phosphate (KH_2PO_4) and 0.6 grams of Sodium Heptanesulphonate ($\text{C}_7\text{H}_{15}\text{NaO}_2\text{S}$); 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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Rencana Kebutuhan Levetiracetam CRS

No	Nama Produk	Keperluan	Pembakuan (kali) (a)	Kebutuhan per Pembakuan (mg) (b)	Kebutuhan Total (mg) (a x b)
1	Levetiracetam Kaplet Salut Selaput 500 mg	Pembakuan <i>Working</i> <i>Standar</i>	2	35	70
Total (mg)					70

Kesimpulan : Dibutuhkan sebanyak 70 mg RS Levetiracetam CRS, Quantity 1 Vial @ 120 mg sehingga dibutuhkan **1 vial**

Catalogue Code	Y0001253
Name	LEVETIRACETAM CRS
Current batch number	4
Unit quantity per vial	120 MG
Number of vials per sales unit	1
Used in monograph(s)	2535
Additional information	
Leaflet	click to download the leaflet
Chemical hazard	Click to download Safety Data Sheet
Biological hazard	none identified
SDS Product Code	201600519
CAS Registry Number	102767-28-2
Origin	click to download Origin Of Goods.pdf
Proposed Import HS code	293379
EDQM long term storage conditions	+5°C+/-3°C
Dispatching conditions	Ambient temp.
UN Code	Not classified
Shipping group	A1A
Price	90 EUR
Availability	Available
Sales restriction	No

Batches

batch 4 is valid at this date ▼



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Rencana Kebutuhan Levetiracetam Related Compound B

No	Nama Produk	Keperluan	Validasi Proses (OBM) (Pengujian) (a)	Kebutuhan per Pengujian (mg) (b)	Kebutuhan Total (mg) (a x b)
1	Levetiracetam Kaplet Salut Selaput 500 mg	Cemaran Organik	3	9	27
					27

Kesimpulan : Dibutuhkan sebanyak 27 mg RS Levetiracetam Related Compound B, Qty 1 Vial @ 20 mg sehingga dibutuhkan **2 vial**

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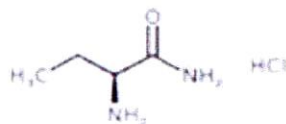
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USP



Catalog no. 1359437 CAS RN[®] 7683-20-4



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