

Bagian : QC

**ANALISA PERMINTAAN BARANG**

Due date : 11 April 2026

Tanggal : 09 Maret 2026

| 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  | IMO11041    | Kolom L11   | Un     | 0                 | 1                     | -1                    | 0                      | 1      | 0                   | 0                    |

Catatan :

**Kolom ZORBAX Eclipse XDB 80Å Phenyl, 3.0 x 150mm, 3.5µm Part. No: 963954-312**

- Digunakan untuk memisahkan senyawa dari sampel dengan cara melewati sampel menggunakan fase gerak melalui kolom. Kolom tersebut dapat digunakan untuk pengujian penetapan kadar bahan baku pseudoephedrine menggunakan instrumen High Performance Liquid Chromatography (HPLC)

- Estimasi harga : Rp.18.105.000

- Pemesanan pertama Dept. QC

**Latar belakang pemesanan :**

- Sehubungan dengan adanya update metode analisa sesuai dengan kompendial terkini maka dibutuhkan pengadaan kolom tersebut untuk pengujian penetapan kadar pada bahan baku Pseudoephedrine Hydrochloride.

- Terlampir USP terkini, penawaran harga dan rencana kebutuhan.

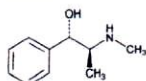
Dibuat

  
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Mengetahui

  
.....

## Pseudoephedrine Hydrochloride



$C_{10}H_{15}NO \cdot HCl$  201.69  
Benzenemethanol,  $\alpha$ -[1-(methylamino)ethyl]-, [S-(R\*,R\*)]-, hydrochloride;  
(+)-Pseudoephedrine hydrochloride CAS RN®: 345-78-8;  
UNII: 6V9V2RYJ8N.

### DEFINITION

Pseudoephedrine Hydrochloride contains NLT 98.0% and NMT 102.0% of pseudoephedrine hydrochloride ( $C_{10}H_{15}NO \cdot HCl$ ), calculated on the dried basis.

### IDENTIFICATION

#### Change to read:

- **A. <sup>Δ</sup>SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: **197K<sub>Δ</sub>** (CN 1-May-2020)
- **B. IDENTIFICATION TESTS—GENERAL**, *Chloride* (191): Meets the requirements

### ASSAY

#### • PROCEDURE

**Triethylamine–phosphoric acid solution:** Mix 5 mL of triethylamine with 1 L of water. Adjust with phosphoric acid to a pH of 6.8.

**Mobile phase:** Methanol and *Triethylamine–phosphoric acid solution* (10:90)

**System suitability solution:** 0.1 mg/mL of USP Pseudoephedrine Hydrochloride RS and 0.002 mg/mL of USP Ephedrine Sulfate RS in water

**Standard solution:** 0.1 mg/mL of USP Pseudoephedrine Hydrochloride RS in water

**Sample solution:** 0.1 mg/mL of pseudoephedrine hydrochloride in water

#### Chromatographic system

(See *Chromatography* (621), *System Suitability*.)

**Mode:** LC

**Detector:** UV 206 nm

**Column:** 3.0-mm × 15-cm; packing L11

**Flow rate:** 0.6 mL/min

**Injection volume:** 10  $\mu$ L

#### System suitability

**Sample:** *System suitability solution*

[NOTE—The relative retention times for ephedrine and pseudoephedrine are approximately 0.9 and 1.0, respectively.]

#### Suitability requirements

**Resolution:** NLT 2 between the pseudoephedrine and ephedrine peaks

**Tailing factor:** NMT 2.0 for the pseudoephedrine peak  
**Relative standard deviation:** NMT 2.0%

### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of pseudoephedrine hydrochloride ( $C_{10}H_{15}NO \cdot HCl$ ) in the portion of Pseudoephedrine Hydrochloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

$r_U$  = peak response from the *Sample solution*

$r_S$  = peak response from the *Standard solution*

$C_S$  = concentration of USP Pseudoephedrine Hydrochloride RS in the *Standard solution* (mg/mL)

$C_U$  = concentration of Pseudoephedrine Hydrochloride in the *Sample solution* (mg/mL)

**Acceptance criteria:** 98.0%–102.0% on the dried basis

### IMPURITIES

- **RESIDUE ON IGNITION** (281): NMT 0.1%

- **ORGANIC IMPURITIES**

**Sample solution:** Proceed as directed in the *Assay*.

**Analysis:** Using the chromatogram of the *Sample solution*, calculate the percentage of each impurity in the portion of Pseudoephedrine Hydrochloride taken:

$$\text{Result} = (r_U/r_T) \times 100$$

$r_U$  = peak response for each impurity

$r_T$  = sum of all the peak responses

**Acceptance criteria:** NMT 2.0%, total impurities

### SPECIFIC TESTS

- **MELTING RANGE OR TEMPERATURE**, *Class I* (741): 182°–186°. The range between beginning and end of melting does not exceed 2°.

- **OPTICAL ROTATION**, *Specific Rotation* (781S)

**Sample solution:** 50 mg/mL

**Acceptance criteria:** +61.0° to +62.5°

- **PH** (791): 4.6–6.0, in a 50-mg/mL solution

- **LOSS ON DRYING** (731)

**Analysis:** Dry a sample at 105° for 3 h.

**Acceptance criteria:** NMT 0.5%

### ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

- **USP REFERENCE STANDARDS** (11)

USP Ephedrine Sulfate RS

USP Pseudoephedrine Hydrochloride RS



# Chromatographic Columns

[Resources](#)[Contact Us](#)[Logout](#)

Monograph Name or General Chapter &lt;###&gt;

[SEARCH](#)

Packing, GC Phase or Support

[SEARCH](#)**PSEUDOEPHEDRINE HYDROCHLORIDE**

| PF    | LGS#                | Column Brand         | Type Of Test                 | Comments                                                        |
|-------|---------------------|----------------------|------------------------------|-----------------------------------------------------------------|
| 34(2) | <a href="#">L11</a> | Eclipse XDB Phenyl   | Assay and Organic Impurities | 3.0 mm x 15 cm, 3.5 $\mu$ m. Manufacturer: Agilent Technologies |
| 44(4) | <a href="#">L11</a> | Pinnacle DB Biphenyl | Assay and Organic Impurities | 2.1 mm x 10 cm, 1.9 $\mu$ m. Manufacturer: Restek Corp.         |
| 18(3) | <a href="#">G43</a> | None Cited           | Organic volatile impurities  | See Method V <467>. Manufacturer: n/a                           |
| 16(3) | <a href="#">G27</a> | None Cited           | Organic volatile impurities  | See Method I <467>. Manufacturer: n/a                           |

**PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE CAPSULES**

| PF    | LGS#               | Column Brand       | Type Of Test | Comments                              |
|-------|--------------------|--------------------|--------------|---------------------------------------|
| 23(6) | <a href="#">L3</a> | Partisil 10 Silica | Assay        | 4.6 mm x 25 cm. Manufacturer: Avantor |
| 25(2) | <a href="#">L3</a> | Partisil 10 Silica | Dissolution  | 4.6 mm x 25 cm. Manufacturer: Avantor |

**PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE TABLETS**

| PF    | LGS#                | Column Brand         | Type Of Test                 | Comments                                                                 |
|-------|---------------------|----------------------|------------------------------|--------------------------------------------------------------------------|
| 23(6) | <a href="#">L3</a>  | Partisil Silica      | Assay                        | 4.2 mm x 25 cm. Manufacturer: Avantor                                    |
| 24(3) | <a href="#">L3</a>  | Partisil Silica      | Assay                        | 4.6 mm x 15 cm, 5 $\mu$ m. Manufacturer: Avantor                         |
| 44(4) | <a href="#">L11</a> | Pinnacle DB Biphenyl | Assay and Organic Impurities | 2.1 mm x 10 cm, 1.9 $\mu$ m. Manufacturer: Restek Corp.                  |
| 29(1) | <a href="#">L1</a>  | Hypersil-ODS         | Dissolution                  | Dissolution Test 2. 4.6 mm x 5 cm. Manufacturer: Thermo Scientific       |
| 0(0)  | <a href="#">L1</a>  | Inertsil ODS-3V      | Dissolution                  | Dissolution Test 4. 4.6 mm x 15 cm, 5 $\mu$ m. Manufacturer: GL Sciences |

**PSEUDOEPHEDRINE HYDROCHLORIDE ORAL SOLUTION**

| PF    | LGS#               | Column Brand            | Type Of Test                 | Comments                                         |
|-------|--------------------|-------------------------|------------------------------|--------------------------------------------------|
| 8(6)  | <a href="#">L3</a> | Partisil Silica         | Assay                        | Manufacturer: Avantor                            |
| 45(1) | <a href="#">L1</a> | Zorbax Eclipse Plus C18 | Assay and Organic Impurities | 3 mm x 10 cm, 1.8 $\mu$ m. Manufacturer: Agilent |

**PSEUDOEPHEDRINE HYDROCHLORIDE TABLETS**

| PF    | LGS#               | Column Brand    | Type Of Test          | Comments                                                    |
|-------|--------------------|-----------------|-----------------------|-------------------------------------------------------------|
| 8(6)  | <a href="#">L3</a> | Partisil Silica | Assay and Dissolution | Manufacturer: Avantor                                       |
| 43(5) | <a href="#">L1</a> | Hypersil ODS-2  | Organic Impurities    | 4.6 mm x 5.0 cm, 5 $\mu$ m. Manufacturer: Thermo Scientific |



## PT. VISION SCIENTIFIC

TOTAL Building 6<sup>th</sup> floor  
Jl. Let. Jend. S Parman Kav. 106 A  
Jakarta 11440 - INDONESIA  
Tel. (+62 ).21. 5695 1538  
F. (+62).21. 5695 1539  
Email: info@vision-scientific.com  
Website: www.vision-scientific.com

### QUOTATION

**PT. Mersifarma Tirmaku Mercusana**

Jl. Raya Pelabuhan Km. 18, Cikembar, Cikembar, Sukabumi  
Sukabumi 43161  
Jawa Barat  
Indonesia

Attn: Mr. Oktoni

Date : February 27, 2026  
Number : VSC 260348  
Payment Term : Upon receipt  
Delivery Term : Franco Sukabumi  
Shipment : Indent 4-6 Weeks  
Expiration Date : March 06, 2026  
No. BPPB :

| No                               | Part Number | Description                                                     | Qty | Unit Price<br>(IDR) | Total Price<br>(IDR) |
|----------------------------------|-------------|-----------------------------------------------------------------|-----|---------------------|----------------------|
| <b><u>Agilent Consumable</u></b> |             |                                                                 |     |                     |                      |
| 1,                               | 963954-312  | ZORBAX Eclipse XDB 80Å Phenyl, 3.0 x 150 mm, 3.5 µm HPLC column | 1   | 24.140.000,00       | 24.140.000,00        |
| <b>SUB TOTAL (IDR)</b>           |             |                                                                 |     |                     | <b>24.140.000,00</b> |
| <b>DISCOUNT (25%)</b>            |             |                                                                 |     |                     | <b>6.035.000,00</b>  |
| <b>GRAND TOTAL (IDR)</b>         |             |                                                                 |     |                     | <b>18.105.000,00</b> |

**Notes :**

- Price are Franco Sukabumi and Excluding 11% VAT
- Price could be Change without announcement (please contact us before PO release for further information)
- Items that have been purchased cannot be exchanged or returned.
- Price valid with Exchange rate 1 USD ≈ Rp 16.500 ±3%

*Your Sincerely.*

**Irma Febriyani**

Sales Engineer

081295253855

[irma.febriyani@vision-scientific.com](mailto:irma.febriyani@vision-scientific.com)

| Rencana Pengujian Bahan Baku Pseudoefedrin 2026 |                 |                                                     |            |                 |                              |               |
|-------------------------------------------------|-----------------|-----------------------------------------------------|------------|-----------------|------------------------------|---------------|
| No                                              | Nama Bahan Baku | Kolom                                               | Kedatangan | Parameter       | Total injekan per kedatangan | Total injekan |
| 1                                               | Pseudoefedrin   | Zorbax Eclipse XDB 80A Phenyl, 3.0 x 150 mm, 3.5 um | 1          | Penetapan Kadar | 15                           | 15            |
| Total                                           |                 |                                                     |            |                 |                              | 15            |
| (+ ) worstcase 30%                              |                 |                                                     |            |                 |                              | 19.5          |

Total injekan 2026

Estimasi ketahanan 1 kolom

Kebutuhan kolom 2026

20 injekan

500 injekan

$20/500 = 0.04$  dibulatkan menjadi 1 kolom