

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	IMO11467	Kolom HPLC L3	Un	0	1	-1	0	1	0	0

Catatan :

HPLC Column Analytical, Silica, 10µm, 4.60mm x 250 mm (Cat. No: HICH4216-001)

- Digunakan untuk memisahkan senyawa dari sampel dengan cara melewatkan sampel menggunakan fase gerak melalui kolom. Kolom tersebut digunakan untuk pengujian penetapan kadar Mertisal Tablet menggunakan instrumen High Performance Liquid Chromatography (HPLC)
- Estimasi harga : Rp.18.105.000
- Pemesanan pertama Dept. QC

Latar belakang pemesanan :

- Sehubungan dengan adanya pengujian penetapan kadar pada produk Mertisal tablet maka diperlukan pengadaan kolom tersebut sesuai dengan rekomendasi USP.
- Terlampir USP terkini, penawaran harga dan rencana kebutuhan.

Dibuat

 08/26
ADA 05

Mengetahui

 09/26
H 03

Triprolidine and Pseudoephedrine Hydrochlorides Tablets

» Triprolidine and Pseudoephedrine Hydrochlorides Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of triprolidine hydrochloride ($C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$) and pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$).

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards (11)—
USP Triprolidine Hydrochloride RS
USP Pseudoephedrine Hydrochloride RS

Identification—

A: The retention times of the major peaks in the chromatogram of the *Assay preparation* correspond to those of the *Standard preparation* as obtained in the *Assay*.

B: Transfer 1 Tablet to a suitable glass-stoppered tube, add 10 mL of water, shake for 5 minutes, and allow the solids to settle. Prepare a Standard solution in water of USP Pseudoephedrine Hydrochloride RS and USP Triprolidine Hydrochloride RS having known concentrations of 6 mg per mL and 250 µg per mL, respectively. Separately apply 10-µL portions of the test solution and the Standard solution to a suitable thin-layer chromatographic plate (see *Chromatography* (621)) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of butyl alcohol, glacial acetic acid, and water (8:2:2) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate, mark the solvent front, allow the solvent to evaporate, and examine the plate under short- and long-wavelength UV light: the R_f values of the principal spots obtained from the test solution correspond to those obtained from the Standard solution.

Dissolution, Procedure for a Pooled Sample (711)—

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Time: 45 minutes.

Determine the amounts of pseudoephedrine hydrochloride and triprolidine hydrochloride dissolved using the following method.

Mobile phase and Chromatographic system—Proceed as directed in the *Assay under Triprolidine and Pseudoephedrine Hydrochlorides Oral Solution*.

Procedure—Inject an accurately measured volume (about 200 µL) of a filtered portion of the solution under test into the chromatograph by means of a microsyringe or a sampling

valve, record the chromatogram, and measure the responses for the major peaks. Calculate the quantities of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) and triprolidine hydrochloride ($C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$) dissolved in comparison with a Standard solution having known concentrations of USP Pseudoephedrine Hydrochloride RS and USP Triprolidine Hydrochloride RS in the same medium and similarly chromatographed.

Tolerances—Not less than 75% (Q) of the labeled amounts of $C_{10}H_{15}NO \cdot HCl$ and $C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$ is dissolved in 45 minutes.

Uniformity of dosage units (905): meet the requirements for *Content Uniformity* with respect to triprolidine hydrochloride and to pseudoephedrine hydrochloride.

Assay—

Mobile phase and Standard preparation—Prepare as directed in the *Assay under Triprolidine and Pseudoephedrine Hydrochlorides Oral Solution*.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 120 mg of pseudoephedrine hydrochloride, to a 100-mL volumetric flask. Add about 10 mL of 0.01 N hydrochloric acid, and sonicate for 10 minutes. Cool to room temperature. Dilute with 0.01 N hydrochloric acid to volume, mix, and filter.

Chromatographic system (see *Chromatography* (621)) and **Procedure**—Proceed as directed in the *Assay under Triprolidine and Pseudoephedrine Hydrochlorides Oral Solution*, except to calculate the quantity, in mg, of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) in the portion of Tablets taken by the formula:

$$100C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Pseudoephedrine Hydrochloride RS in the *Standard preparation*; and r_U and r_S are the peak responses for pseudoephedrine hydrochloride obtained from the *Assay preparation* and the *Standard preparation*, respectively. Calculate the quantity, in mg, of triprolidine hydrochloride ($C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$) in the portion of Tablets taken by the formula:

$$(332.88/314.86)(100C)(r_U/r_S)$$

in which 332.88 and 314.86 are the molecular weights of triprolidine hydrochloride monohydrate and anhydrous triprolidine hydrochloride, respectively; C is the concentration, in mg per mL, calculated on the anhydrous basis, of USP Triprolidine Hydrochloride RS in the *Standard preparation*; and r_U and r_S are the peak responses for triprolidine hydrochloride obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Triprolidine and Pseudoephedrine Hydrochlorides Oral Solution

» Triprolidine and Pseudoephedrine Hydrochlorides Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of triprolidine hydrochloride ($C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$) and pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$).

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards (11)—

USP Triprolidine Hydrochloride RS

USP Pseudoephedrine Hydrochloride RS

Identification—

A: The retention times of the major peaks in the chromatogram of the *Assay preparation* correspond to those in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

B: Transfer 10 mL of Oral Solution to a suitable glass-stoppered tube, add 10 mL of ether and 2 mL of 1 N sodium hydroxide, shake for 5 minutes, and allow the layers to separate. The ether layer is the test solution. Prepare a Standard solution in water of USP Pseudoephedrine Hydrochloride RS and USP Triprolidine Hydrochloride RS having known concentrations of 6 mg per mL and 250 µg per mL, respectively. Separately apply 10-µL portions of the test solution and the Standard solution to a suitable thin-layer chromatographic plate (see *Chromatography* (621)) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of butyl alcohol, glacial acetic acid, and water (8:2:2) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate, mark the solvent front, allow the solvent to evaporate, and examine the plate under short-wavelength and long-wavelength UV light: the R_f values of the principal spots obtained from the test solution correspond to those obtained from the Standard solution.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of alcohol and 0.40% ammonium acetate solution (17:3). Make adjustments if necessary (see *System Suitability* under *Chromatography* (621)).

Standard preparation—Dissolve accurately weighed quantities of USP Pseudoephedrine Hydrochloride RS and USP

Triprolidine Hydrochloride RS in 0.01 N hydrochloric acid, and dilute quantitatively and stepwise with 0.01 N hydrochloric acid to obtain a solution having known concentrations of about 1.2 mg of USP Pseudoephedrine Hydrochloride RS per mL and about 0.05 mg of anhydrous USP Triprolidine Hydrochloride RS per mL, and filter.

Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 60 mg of pseudoephedrine hydrochloride, to a 50-mL volumetric flask, dilute with 0.01 N hydrochloric acid to volume, and mix.

Chromatographic system (see *Chromatography* (621))—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains packing L3. The flow rate is about 1.5 mL per minute. Chromatograph replicate injections of the *Standard preparation*, and record the peak responses as directed for *Procedure*: the relative standard deviation is not more than 2.0%; and the resolution factor between triprolidine and pseudoephedrine is not less than 2.0. The tailing factor for the triprolidine peak is not more than 2.0, and the pseudoephedrine peak is not more than 2.0.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The relative retention times are about 0.68 for pseudoephedrine hydrochloride and 1.0 for triprolidine hydrochloride. Calculate the quantity, in mg, of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) in the portion of Oral Solution taken by the formula:

$$50C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Pseudoephedrine Hydrochloride RS in the *Standard preparation*; and r_U and r_S are the peak responses for pseudoephedrine hydrochloride obtained from the *Assay preparation* and the *Standard preparation*, respectively. Calculate the quantity, in mg, of triprolidine hydrochloride ($C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$) in the portion of Oral Solution taken by the formula:

$$(332.88/314.86)(50C)(r_U/r_S)$$

in which 332.88 and 314.86 are the molecular weights of triprolidine hydrochloride monohydrate and anhydrous triprolidine hydrochloride, respectively; C is the concentration, in mg per mL, calculated on the anhydrous basis, of USP Triprolidine Hydrochloride RS in the *Standard preparation*; and r_U and r_S are the peak responses for triprolidine hydrochloride obtained from the *Assay preparation* and the *Standard preparation*, respectively.



Chromatographic Columns

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Monograph Name or General Chapter <###>

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Packing, GC Phase or Support

[SEARCH](#)**TRIPROLIDINE AND PSEUDOEPHEDRINE HYDROCHLORIDES ORAL SOLUTION**

PF	LGS#	Column Brand	Type Of Test	Comments
8(6)	L3	Partisil 10 Silica	Assay and Identification	Manufacturer: Avantor

TRIPROLIDINE AND PSEUDOEPHEDRINE HYDROCHLORIDES TABLETS

PF	LGS#	Column Brand	Type Of Test	Comments
8(6)	L3	Partisil 10 Silica	Assay, Identification, Dissolution, Uniformity of dosage units	Manufacturer: Avantor

TRIPROLIDINE HYDROCHLORIDE

PF	LGS#	Column Brand	Type Of Test	Comments
41(1)	L1	Inertsil ODS-3V	Assay and Organic Impurities	4.6 mm x 25 cm, 5 µm. Manufacturer: GL Sciences
16(5)	G27	None Cited	Organic volatile impurities	See Method I <467>. Manufacturer: n/a
18(2)	G43	None Cited	Organic volatile impurities	See Method V <467>. Manufacturer: n/a

TRIPROLIDINE HYDROCHLORIDE ORAL SOLUTION

PF	LGS#	Column Brand	Type Of Test	Comments
8(6)	L3	Partisil 10 Silica	Assay and Identification	Manufacturer: Avantor

TRIPROLIDINE HYDROCHLORIDE TABLETS

PF	LGS#	Column Brand	Type Of Test	Comments
8(6)	L3	Partisil 10 Silica	Assay and Identification	Manufacturer: Avantor

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**QUOTATION
PENAWARAN****Customer :**
*Pelanggan***PT MERSIFARMA TIRMAKU MERCUSANA****Our Ref :**
*No. Ref***0926/QTN-DPL/0002****Attn. :**
*Up***Pak Okto****Date :**
*Tanggal***27 Feb 26**

<u>No</u>	<u>Cat. No.</u>	<u>Description</u>	<u>Product</u>	<u>Pack</u>	<u>Price/unit</u>	<u>Disc</u>	<u>Total price/unit</u>	<u>Status stok</u>
	<i>No. Kat.</i>	<i>Nama Produk</i>	<i>Produk</i>	<i>Kemasan</i>	<i>Harga/sat</i>	<i>Diskon</i>		
1	HICH4216-001	Avantor® Partisil Avantor® Partisphere, HPLC Columns Analytical, Silica, 10 µm, 4,60 mm x 250 mm	VWR Singapore	SET	25,436,000	15%	21,620,600	*Indent 1-2 Bulan

NB: Harga diatas belum termasuk Ppn 11%

Payment
*Pembayaran***: Net 60 Days****Best Regards****Delivery Time**
*Penyerahan barang***: *Indent 1-2 Bulan****Validity**
*Masa berlaku***: 1 bulan****Tuti Nursafitri**
Product Specialist

Rencana Pengujian Produk Jadi Mertisal 2026						
No	Nama Produk	Kolom	Parameter	Proses	Total batch 2026	Total injekan
1	Mertisal	Partisil Avantor, Partisphere, HPLC Columns Analytical, Silica, 10 um 4.6 x 250 mm	Penetapan Kadar	Granul	1	12
				Core	1	12
Total						24
(+) worstcase 30%						31.2

Produk mertisal direncanakan akan diproduksi sebanyak 1 batch pada tahun 2026

Total injekan 2026

32 injekan

Estimasi ketahanan 1 kolom

500 injekan

Kebutuhan kolom 2026

$32/500 = 0.064$ dibulatkan menjadi 1 kolom