

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	IBS00004	Ambroxol HCl	Mg	0	200	-200	0	200	0	0

Catatan :

Baku Pembanding Ambroxol HCl Ex. BPFI No. Kontrol: B0223709

- Digunakan untuk pembuatan / standarisasi baku pembanding sekunder Ambroxol HCl rutin setiap tahun dengan rencana penggunaan untuk satu kali analisa pembakuan adalah 25 mg berdasarkan metode terkini.
- Pemesanan mengikuti MOQ (1 Vial @200 mg)

Latar belakang permintaan:

- Saat ini stok RS Ambroxol HCl sudah habis sehingga diperlukan pengadaan baru untuk memenuhi kebutuhan pembuatan Working Standard (WS) Ambroxol HCl yang nantinya WS tersebut akan digunakan untuk analisa produk antara, ruahan, produk jadi, valpro, stabiita produk dan bahan baku Ambroxol HCl.
- Terlampir European Pharmacopoeia, rencana kebutuhan dan penawaran harga.

Dibuat

 04/26
ADN / 03

Mengetahui

 04/26
WBO / 03

- *disregard limit*: calculate the ratio (R_3) of 0.5 times the area of the peak due to amantadine to the area of the peak due to the internal standard from the chromatogram obtained with the reference solution; from the chromatogram obtained with the test solution, calculate the ratio of the area of any peak, apart from the principal peak and the peak due to the internal standard, to the area of the peak due to the internal standard: disregard any peak with a ratio less than R_3 (0.05 per cent).

Water (2.5.12): maximum 0.5 per cent, determined on 2.00 g.

Sulfated ash (2.4.14): maximum 0.1 per cent, determined on 1.0 g.

ASSAY

Dissolve 0.150 g in a mixture of 5.0 mL of 0.01 M hydrochloric acid and 50 mL of ethanol (96 per cent) R. Carry out a potentiometric titration (2.2.20), using 0.1 M sodium hydroxide. Read the volume added between the 2 points of inflexion.

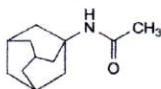
1 mL of 0.1 M sodium hydroxide is equivalent to 18.77 mg of $C_{10}H_{18}ClN$.

IMPURITIES

Other detectable impurities (the following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph. They are limited by the general acceptance criterion for other/unspecified impurities and/or by the general monograph *Substances for pharmaceutical use* (2034). It is therefore not necessary to identify these impurities for demonstration of compliance. See also 5.10. *Control of impurities in substances for pharmaceutical use*): A, B.



A. 1-chlorotricyclo[3.3.1.1^{3,7}]decane,



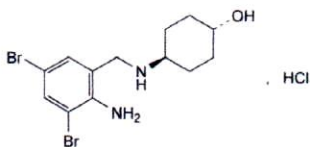
B. N-(tricyclo[3.3.1.1^{3,7}]dec-1-yl)acetamide.



01/2017:1489
corrected 9.2

AMBROXOL HYDROCHLORIDE

Ambroxoli hydrochloridum



$C_{13}H_{19}Br_2ClN_2O$
[23828-92-4]

M_r 414.6

DEFINITION

trans-4-[(2-Amino-3,5-dibromobenzyl)amino]cyclohexanol hydrochloride.

Content: 99.0 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance: white or yellowish, crystalline powder.

Solubility: sparingly soluble in water, soluble in methanol, practically insoluble in methylene chloride.

IDENTIFICATION

First identification: B, D.

Second identification: A, C, D.

A. Ultraviolet and visible absorption spectrophotometry (2.2.25).

Test solution. Dissolve 20.0 mg in dilute sulfuric acid R1 and dilute to 100.0 mL with the same acid. Dilute 2.0 mL of the solution to 10.0 mL with dilute sulfuric acid R1.

Spectral range: 200–350 nm.

Absorption maxima: at 245 nm and 310 nm.

Absorbance ratio: $A_{245}/A_{310} = 3.2$ to 3.4.

B. Infrared absorption spectrophotometry (2.2.24).

Comparison: ambroxol hydrochloride CRS.

C. Thin-layer chromatography (2.2.27).

Test solution. Dissolve 50 mg of the substance to be examined in methanol R and dilute to 5 mL with the same solvent.

Reference solution. Dissolve 50 mg of ambroxol hydrochloride CRS in methanol R and dilute to 5 mL with the same solvent.

Plate: TLC silica gel F_{254} plate R.

Mobile phase: concentrated ammonia R, propanol R, ethyl acetate R, hexane R (1:10:20:70 V/V/V/V).

Application: 10 μ L.

Development: over 2/3 of the plate.

Drying: in air.

Detection: examine in ultraviolet light at 254 nm.

Results: the principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution.

D. Dissolve 25 mg in 2.5 mL of water R, mix with 1.0 mL of dilute ammonia R1 and allow to stand for 5 min. Filter and acidify the filtrate with dilute nitric acid R. The filtrate gives reaction (a) of chlorides (2.3.1).

TESTS

Solution S. Dissolve 0.75 g in methanol R and dilute to 15 mL with the same solvent.

Appearance of solution. Solution S is clear (2.2.1) and not more intensely coloured than reference solution Y₆ (2.2.2, Method II).

pH (2.2.3): 4.5 to 6.0.

Dissolve 0.2 g in carbon dioxide-free water R and dilute to 20 mL with the same solvent.

Related substances. Liquid chromatography (2.2.29). Prepare the solutions immediately before use.

Test solution. Dissolve 50 mg of the substance to be examined in water R and dilute to 50.0 mL with the same solvent.

Reference solution (a). Dilute 1.0 mL of the test solution to 100.0 mL with water R. Dilute 1.0 mL of this solution to 10.0 mL with the mobile phase.

Reference solution (b). In order to prepare impurity B *in situ*, dissolve 5 mg of the substance to be examined in 0.2 mL of methanol R, add 0.04 mL of a mixture of 1 volume of formaldehyde solution R and 99 volumes of water R. Heat at 60 °C for 5 min. Evaporate to dryness under a current of nitrogen. Dissolve the residue in 5 mL of water R and dilute to 20.0 mL with the mobile phase.

Column:

- size: $l = 0.25$ m, $\varnothing = 4.0$ mm;
- stationary phase: octadecylsilyl silica gel for chromatography R (5 μ m).

Mobile phase: a mixture of equal volumes of acetonitrile *R* and a solution prepared as follows: dissolve 1.32 g of ammonium phosphate *R* in 900 mL of water *R*, adjust to pH 7.0 with phosphoric acid *R* and dilute to 1000 mL with water *R*.

Flow rate: 1 mL/min.

Detection: spectrophotometer at 248 nm.

Injection: 20 µL.

Run time: 3 times the retention time of amoxol.

Identification of impurities: use the chromatogram obtained with reference solution (b) to identify the peak due to impurity B.

Relative retention with reference to amoxol (retention time = about 9 min): impurity B = about 0.6.

System suitability: reference solution (b):

- **resolution:** minimum 4.0 between the peaks due to impurity B and amoxol.

Limits:

- **unspecified impurities:** for each impurity, not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.10 per cent),
- **total:** not more than 3 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.3 per cent),
- **disregard limit:** 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent).

Loss on drying (2.2.32): maximum 0.5 per cent, determined on 1.000 g by drying in an oven at 105 °C.

Sulfated ash (2.4.14): maximum 0.1 per cent, determined on 1.0 g.

ASSAY

Dissolve 0.300 g in 70 mL of ethanol (96 per cent) *R* and add 5 mL of 0.01 *M* hydrochloric acid. Carry out a potentiometric titration (2.2.20), using 0.1 *M* sodium hydroxide. Read the volume added between the 2 points of inflexion.

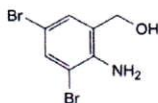
1 mL of 0.1 *M* sodium hydroxide is equivalent to 41.46 mg of C₁₃H₁₉Br₂ClN₂O.

STORAGE

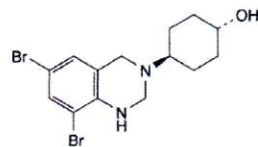
Protected from light.

IMPURITIES

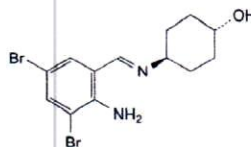
Other detectable impurities (the following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph. They are limited by the general acceptance criterion for other/unspecified impurities and/or by the general monograph *Substances for pharmaceutical use* (2034). It is therefore not necessary to identify these impurities for demonstration of compliance. See also 5.10. *Control of impurities in substances for pharmaceutical use*): A, B, C, D, E.



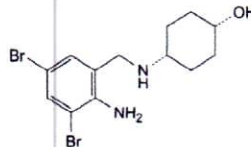
A. (2-amino-3,5-dibromophenyl)methanol,



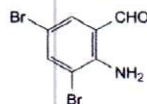
B. *trans*-4-(6,8-dibromo-1,4-dihydroquinazolin-3(2H)-yl)-cyclohexanol,



C. *trans*-4-([(E)-2-amino-3,5-dibromobenzylidene]amino)-cyclohexanol,



D. *cis*-4-[(2-amino-3,5-dibromobenzyl)amino]cyclohexanol,



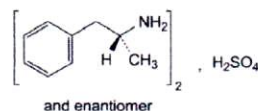
E. 2-amino-3,5-dibromobenzaldehyde.



04/2019:0368

AMFETAMINE SULFATE

Amfetamini sulfas



C₁₀H₁₅N, O₄S
[60-13-9]

M_r 368.5

DEFINITION

Bis[(2*RS*)-1-phenylpropan-2-amine] sulfate.

Content: 99.0 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance: white or almost white powder.

Solubility: freely soluble in water, very slightly soluble in ethanol (96 per cent), practically insoluble in methylene chloride.

IDENTIFICATION

First identification: A, B, D.

Second identification: C, D.

A. Optical rotation (see Tests).

B. Infrared absorption spectrophotometry (2.2.24).

Comparison: amphetamine sulfate CRS.

C. To 50 mL of solution S add 5 mL of strong sodium hydroxide solution *R* and 0.5 mL of benzoyl chloride *R* and shake. Continue to add benzoyl chloride *R* in portions of 0.5 mL, shaking after each addition, until no further precipitate is formed. Filter, wash the precipitate with water *R*, recrystallise twice from a mixture of equal volumes of ethanol (96 per cent) *R* and water *R*, then dry at 100–105 °C. The crystals melt (2.2.14) at 131 °C to 135 °C.

D. Solution S (see Tests) gives reaction (a) of sulfates (2.3.1).

TESTS

Solution S. Dissolve 2.0 g in carbon dioxide-free water *R* and dilute to 100 mL with the same solvent.

RENCANA KEBUTUHAN REFERENCE STANDARD UNTUK PENGUJIAN RUTIN

Ambroxol HCl

No.	Penggunaan	Kebutuhan/Batch	Jumlah Analisa	Kebutuhan/Tahun	Kebutuhan/Tahun
	1 Pembakuan WS Ambroxol HCl	25 mg	4	100 mg	0.50 vial

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.

Show 10 entries

Search B0223709

Nomor	Nama Baku Uji	Keterangan	No. Kontrol	No. Kontrol Sebelumnya	Bobot	Ket. Pengujian	Ketersediaan
798	Ambroksol Hidroklorida	BPL	B0223709	-	200 mg	Kuantitatif	Tersedia

Showing 1 to 1 of 1 entries (filtered from 945 total entries)

Previous1Next