Atropine Ophthalmic Solution

Atropine Sulphate Ophthalmic Solution

Atropine Ophthalmic Solution is a sterile, aqueous solution of Atropine Sulphate. It may contain suitable stabilizer and antimicrobial agents.

Atropine Ophthalmic Solution contains not less than 93.0 per cent and not more than 107.0 per cent of the stated amount of atropine sulphate monohydrate, $(C_{17}H_{23}NO_3)_2,H_2SO_4,H_2O$.

Usual strength. 1.0 per cent w/v.

Identification

A. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (a).

B. Evaporate a quantity of ophthalmic solution to dryness. A 5 per cent w/v solution gives the reactions of sulphates (2.3.1).

Tests

pH (2.4.24). 3.5 to 6.0.

Related substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. A mixture of 85 volumes of a buffer solution prepared by dissolving 6.8 g of *sodium acetate* in 600 ml of *water*. Add 4 ml of *glacial acetic acid* and dilute to 1000 ml with *water*, adjusted to pH 4.5 with *glacial acetic acid* and 15 volumes of *methanol*.

Test solution. Dilute a suitable volume of the ophthalmic solution with the solvent mixture to obtain a solution having 0.05 per cent w/v of Atropine sulphate monohydrate.

Reference solution (a). A 0.05 per cent w/v solution of *atropine sulphate IPRS* in the solvent mixture.

Reference solution (b). A solution containing 0.0005 per cent w/v of *atropic acid* and 0.05 per cent w/v of *atropine sulphate IPRS* in the solvent mixture.

Chromatographic system

- a stainless steel column 15 cm x 4.6 mm, packed with nitrile groups bonded to porous silica (5µm),
- column temperature: 40º,
- mobile phase: a mixture of 85 volumes of a buffer solution prepared by dissolving 6.8 g of *sodium acetate,* in 600 ml of *water*. Add 3.5 ml of *triethylamine* and 6.6 ml of *glacial acetic acid* and dilute to1000 ml with *water,* adjusted to pH 4.5 with *glacial acetic acid* and 15 volumes of *methanol,*
- flow rate: 1.2 ml per minute,
- spectrophotometer set at 225 nm,
- injection volume: 20 µl.

Name	Relative retention time	Correction factor
Tropic acid[1]	0.69	0.5
Atropic acid[2]	0.87	0.082
Atropine	1.0	—
Apoatropine[3]	2.1	0.23

[1]3-Hydroxy-2-phenylpropanoic acid.
[2]2-Phenylacrylic acid.
[3](1*R*,3*r*,5*S*)-8-Methyl-8-azabicyclo[3.2.1]octan-3-yl2-phenylacrylate.

Inject reference solution (a) and (b). The test is not valid unless the resolution between the peaks due to atropic acid and atropine is not less than 1.5 in the chromatogram obtained with reference solution (b) and the relative standard

deviation for replicate injections is not more than 5.0 per cent in the chromatogram obtained with reference solution (a).

Inject reference solutions (a) and the test solution. Run the chromatogram 3 times the retention time of the principal peak for test solution. The area of any peak corresponding to tropic acid is not more than 0.07 times the area of the principal peak in the chromatogram obtained with reference solution (a) (7.0 per cent), the area of any peak corresponding to atropic acid and apoatropine, each of, is not more than 0.01 times the area of the principal peak in the chromatogram obtained with reference solution (a) (1.0 per cent), the area of any other secondary peak is not more than 0.01 times the area of the principal peak in the chromatogram obtained with reference solution (a) (1.0 per cent) and the sum of areas of all the secondary peaks is not more than 0.07 times the area of the principal peak in the chromatogram obtained with reference solution (a) (7.0 per cent).

Other tests. Comply with the tests stated under Eye Drops.

Sterility (2.2.11). Complies with the test for sterility.

Assay. Determine by liquid chromatography (2.4.14), as described under Related substances.

Inject reference solution (a). The test is not valid unless the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 1.0 per cent.

Inject reference solution (a) and the test solution.

Calculate the content of $(C_{17}H_{23}NO_3)_2$, H_2SO_4, H_2O in the ophthalmic solution.

Storage. Store protected from moisture, at a temperature not exceeding 30°.