Edition: BP 2025 (Ph. Eur. 11.6 update)

Hyoscine Butylbromide Injection

General Notices

Action and use

Anticholinergic.

DEFINITION

Hyoscine Butylbromide Injection is a sterile solution of Hyoscine Butylbromide in Water for Injections.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of hyoscine butylbromide, $C_{21}H_{30}BrNO_4$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Evaporate to dryness a volume containing 0.1 g of Hyoscine Butylbromide, shake the residue with *chloroform*, filter, evaporate the filtrate to dryness and triturate the residue with 5 mL of *acetonitrile*. Evaporate to dryness and dry the residue at 50° at a pressure not exceeding 0.7 kPa for 1 hour. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of hyoscine butylbromide *(RS 185)*.
B. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the principal peak in the chromatogram obtained with solution (2).

TESTS

Acidity

pH, 3.7 to 5.5, Appendix V L.

Related substances

Carry out the method for *liquid chromatography*, *Appendix III D*, using the following solutions.

(1) Dilute a quantity of the injection containing 100 mg of Hyoscine Butylbromide to 20 mL with 0.001M *hydrochloric acid*.
(2) Dilute 1 volume of solution (1) to 50 volumes with 0.001M *hydrochloric acid*, further dilute 1 volume of this solution to 10 volumes with the same solvent.
(3) 0.006% w/v of *tropic acid* (impurity B) in 0.001M *hydrochloric acid*.
(4) 0.5% w/v of *hyoscine butylbromide BPCRS* and 0.003% w/v of *tropic acid* in 0.001M *hydrochloric acid*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (12.5 cm × 4 mm) packed with *base-deactivated end-capped octylsilyl silica gel for chromatography* (5 µm) (LiChrospher 60 RP-select B is suitable).

(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.5 mL per minute.
(d) Use a column temperature of 45°.
(e) Use a detection wavelength of 220 nm.
(f) Inject 10 µL of each solution.

MOBILE PHASE

Solution A a mixture containing 1.265% w/v of *sodium dihydrogen orthophosphate monohydrate* and 0.34% w/v of *tetrabutylammonium hydrogen sulfate*, adjust the pH to 5.5 with 0.5M *sodium hydroxide* as necessary.

125 volumes of *methanol* and 875 volumes of solution A.

When the chromatograms are recorded under the prescribed conditions, the relative retentions with reference to hyoscine butylbromide (retention time about 5 minutes) are: tropic acid (impurity B), about 1.3 and impurity G, about 2.6.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (4), the *resolution* between the peaks due to hyoscine butylbromide and tropic acid is at least 1.5.

LIMITS

In the chromatogram obtained with solution (1):

Identify any peak due to impurity G using the specified retention time and multiply the area of the peak by the correction factor of 0.41;

the area of any peak corresponding to tropic acid is not greater than the area of the principal peak in the chromatogram obtained with solution (3) (1.2%);

the area of any peak corresponding to impurity G is not greater than 5 times the area of the principal peak in the chromatogram obtained with solution (2) (1%);

the area of any other *secondary peak* is not greater than the area of the principle peak in the chromatogram obtained with solution (2) (0.2%);

the sum of the impurities is not greater than 2.5%.

Disregard any peak with an area less than half the area of the principal peak in the chromatogram obtained with solution (2) (0.1%).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Dilute a quantity of the injection containing 100 mg of Hyoscine Butylbromide to 20 mL with 0.001M *hydrochloric acid*.
(2) 0.5% w/v of *hyoscine butylbromide BPCRS* in 0.001M *hydrochloric acid*.
(3) 0.5% w/v of *hyoscine butylbromide BPCRS* and 0.003% w/v of *tropic acid* in 0.001M *hydrochloric acid*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

DETERMINATION OF CONTENT

Calculate the content of $C_{21}H_{30}BrNO_4$ in the injection using the declared content of $C_{21}H_{30}BrNO_4$ in *hyoscine butylbromide BPCRS*.

STORAGE

Hyoscine Butylbromide Injection should be protected from light.

IMPURITIES

The impurities limited by the requirements of this monograph include impurities A, B and G listed under Hyoscine Butylbromide.