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Furosemide Oral Solution

General Notices

Details for the public consultation of this monograph are as follows:

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Notes	Revised monograph If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required. Identification HPLC-DAD method introduced, harmonised with Assay. Related substances Quantitative limits introduced. Impurity C limit widened from NMT 0.5% to NMT 1.5%.

Action and use

Loop diuretic.

DEFINITION

Furosemide Oral Solution is a solution of [Furosemide](#) in a suitable vehicle.

The oral solution complies with the requirements stated under [Oral Liquids](#) and with the following requirements.

Content of furosemide, C₁₂H₁₁ClN₂O₅S

95.0 to 105.0% of the stated amount.

IDENTIFICATION

In the Assay, record the UV spectrum of the principal peak in the chromatograms obtained with solutions (1) and (2) with a diode array detector in the range of 210 to 400 nm.

The UV spectrum of the principal peak in the chromatogram obtained with solution (1) is concordant with that of the peak in the chromatogram obtained with solution (2);

the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the peak in the chromatogram obtained with solution (2).

TESTS

Acidity or alkalinity

pH, 7.0 to 9.0, [Appendix V L](#).

Related substances

Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions prepared in the mobile phase. Prepare the solutions immediately before use and protect from light.

- (1) Dilute a quantity of the oral solution containing 20 mg of Furosemide to 50 mL.
- (2) Dilute 1 volume of solution (1) to 200 volumes.
- (3) 0.00025% w/v of each of [furosemide BPCRS](#) and [furosemide impurity A EPCRS](#).
- (4) 0.04% w/v of [furosemide for peak identification EPCRS](#).
- (5) Dilute 1 volume of solution (2) to 5 volumes.

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (25 cm × 4.6 mm) packed with [end-capped octylsilyl silica gel for chromatography](#) (5 µm) (Luna C8 is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 1.0 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 238 nm.
- (f) Inject 100 µL of each solution.
- (g) Allow the chromatography to proceed for three times the retention time of furosemide.

MOBILE PHASE

30 volumes of [propan-1-ol](#) and 70 volumes of solution A.

Solution A 0.286% w/v of [potassium dihydrogen orthophosphate](#) and 0.357% w/v of [cetrimide](#) in [water](#). Adjust the pH of the mixture to 7.0 with 6M [ammonia](#).

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the [resolution](#) between the peaks due to impurity A and furosemide is at least 4.0;

in the chromatogram obtained with solution (4), the [signal-to-noise ratio](#) of the peak due to impurity D and impurity C is at least 20.

CALCULATION OF IMPURITIES

For each impurity, use the concentration of furosemide in solution (2).

For the reporting threshold, use the concentration of furosemide in solution (5).

For peak identification, use solution (3) and (4).

Furosemide retention time: about 9 minutes.

Relative retentions: impurity C, about 0.5; impurity A, about 0.8 and impurity D, about 1.5.

Correction factors: impurity C, multiply by 1.4; impurity D, multiply by 2.0.

LIMITS

- impurity C: not more than 1.5%;
- unspecified impurities: for each impurity, not more than 0.2%;
- total impurities, excluding impurity C: not more than 0.5%;
- reporting threshold: 0.1%.

ASSAY

Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions in the mobile phase.

(1) To a weighed quantity of the oral solution containing 20 mg of Furosemide, add 20 mL of 1M [sodium hydroxide](#) and dilute to 100 mL with the mobile phase. Further dilute 1 volume of this solution to 5 volumes.

(2) 0.004% w/v of [furosemide BPCRS](#).

CHROMATOGRAPHIC CONDITIONS

- Use a stainless steel column (10 cm × 4.6 mm) packed with [octadecylsilyl silica gel for chromatography](#) (3.5 µm) (Symmetry C18 is suitable).
- Use isocratic elution and the mobile phase described below.
- Use a flow rate of 1.2 mL per minute.
- Use an ambient column temperature.
- Use a detection wavelength of 228 nm.
- Inject 20 µL of each solution.

MOBILE PHASE

30 volumes of [acetonitrile](#) and 70 volumes of a solution of 0.012% w/v of [sodium dihydrogen orthophosphate](#), previously adjusted to pH 4.2 with [orthophosphoric acid](#).

When the chromatograms are recorded under the prescribed conditions the retention time of furosemide is about 3 minutes.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (2), the [symmetry factor](#) of the peak due to furosemide is between 0.8 and 2.0.

DETERMINATION OF CONTENT

Determine the [weight per mL](#) of the oral solution, [Appendix V G](#), and calculate the content of $C_{12}H_{11}ClN_2O_5S$, weight in volume, using the declared content of $C_{12}H_{11}ClN_2O_5S$ in [furosemide BPCRS](#).

STORAGE

Furosemide Oral Solution should be protected from light.

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under [Furosemide](#).