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Furosemide Tablets

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. **Dissolution** Addition of secondary test to accommodate strengths 100 mg and above. **Related substances** Quantitative limits introduced. Impurity D included in total impurities limit.

Action and use

Loop diuretic.

DEFINITION

Furosemide Tablets contain Furosemide.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of furosemide, $C_{12}H_{11}ClN_2O_5S$

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

Dissolution

For tablets containing less than 100 mg of Furosemide.

Comply with the *dissolution test for tablets and capsules*, Appendix XII B1.

TEST CONDITIONS

(a) Use Apparatus 2, rotating the paddle at 50 revolutions per minute.
(b) Use 900 mL of *phosphate buffer pH 5.8*, at a temperature of 37°, as the medium.

PROCEDURE

(1) After 45 minutes withdraw a sample of the medium and measure the *absorbance* of the filtered sample, suitably diluted with the dissolution medium if necessary, to produce a solution expected to contain 0.001% w/v of Furosemide at the maximum at 277 nm, Appendix II B, using dissolution medium in the reference cell.
(2) Measure the *absorbance* of a 0.001% w/v solution of *furosemide BPCRS* in the dissolution medium using dissolution medium in the reference cell.

DETERMINATION OF CONTENT

Calculate the total content of furosemide, $C_{12}H_{11}ClN_2O_5S$, in the medium from the absorbances obtained and using the declared content of $C_{12}H_{11}ClN_2O_5S$ in *furosemide BPCRS*.

LIMITS

The amount of furosemide released is not less than 75% (Q) of the stated amount.

For tablets containing 100 mg or more of Furosemide.

Comply with the *dissolution test for tablets and capsules*, Appendix XII B1.

TEST CONDITIONS

(a) Use Apparatus 1, rotating the basket at 100 revolutions per minute.
(b) Use 1000 mL of *phosphate buffer pH 6.8*, at a temperature of 37°, as the medium.

PROCEDURE

(1) After 45 minutes withdraw a sample of the medium and measure the *absorbance* of the filtered sample, suitably diluted with the dissolution medium if necessary, to produce a solution expected to contain 0.001% w/v of Furosemide at the maximum at 278 nm, Appendix II B, using dissolution medium in the reference cell.
(2) Measure the *absorbance* of a 0.001% w/v solution of *furosemide BPCRS* in the dissolution medium using dissolution medium in the reference cell.

DETERMINATION OF CONTENT

Calculate the total content of furosemide, $C_{12}H_{11}ClN_2O_5S$, in the medium from the absorbances obtained and using the declared content of $C_{12}H_{11}ClN_2O_5S$ in *furosemide BPCRS*.

LIMITS

The amount of furosemide released is not less than 75% (Q) of the stated amount.

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) Shake a quantity of the powdered tablets containing 20 mg of Furosemide in sufficient mobile phase to produce 50 mL and mix with the aid of ultrasound.
(2) Dilute 1 volume of solution (1) to 200 volumes.
(3) 0.00008% 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 *octylsilyl silica gel for chromatography* (5 µm) (Symmetry C8 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1 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 a solution containing 0.286% w/v *potassium dihydrogen phosphate* and 0.357% w/v of *cetrimide* in *water* and adjust the pH of the solution to 7.0 using 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 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 retention(s): 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 0.8%;

— unspecified impurities: for each impurity, not more than 0.2%;

— total impurities, excluding impurity C: not more than 0.7%;

— reporting threshold: 0.1%.

ASSAY

Weigh and powder 20 tablets. 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) Shake a quantity of the powdered tablets containing 20 mg of Furosemide in sufficient mobile phase to produce 20 mL, mix with the aid of ultrasound for and filter. Dilute 1 volume of the filtrate to 10 volumes.
(2) 0.01% w/v of *furosemide BPCRS*.
(3) 0.00025% w/v each of *furosemide BPCRS* and *furosemide impurity A EPCRS*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions stated under Related substances may be used, using an injection volume of 20 µL.

SYSTEM SUITABILITY

The test is not valid unless the *resolution* between the peaks due to impurity A and furosemide is at least 4.0.

DETERMINATION OF CONTENT

Calculate the content of furosemide, $C_{12}H_{11}ClN_2O_5S$, in the tablets from the chromatograms obtained and using the declared content of $C_{12}H_{11}ClN_2O_5S$ in *furosemide BPCRS*.

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Furosemide.