



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

Furosemide Injection

[General Notices](#)

Furosemide Infusion

Action and use

Loop diuretic.

DEFINITION

Furosemide Injection is a sterile solution of furosemide sodium, prepared by the interaction of Furosemide with Sodium Hydroxide, in Water for Injections.

The injection complies with the requirements stated under [Parenteral Preparations](#) and with the following requirements.

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

95.0 to 105.0% of the stated amount.

CHARACTERISTICS

A colourless or almost colourless solution.

IDENTIFICATION

A. To a volume containing the equivalent of 20 mg of Furosemide add sufficient [water](#) to produce 100 mL. Dilute 5 mL to 100 mL with 0.1M [sodium hydroxide](#). The [light absorption](#), [Appendix II B](#), in the range 220 to 320 nm exhibits two maxima, at 228 nm and 271 nm.

B. In the Assay, the principal peak in the chromatogram obtained with solution (1) has the same retention time as the principal peak in the chromatogram obtained with solution (2).

TESTS

Alkalinity

pH, 8.0 to 9.3, [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 volume of the injection to produce a solution containing 0.1% w/v of Furosemide.

- (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) 0.1% 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 1.0 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

0.286% w/v of [potassium dihydrogen phosphate](#) and 0.357% w/v of [cetrimide](#) in [water](#), adjusted to pH 7.0 using 6M [ammonia](#) (solution A).

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

When the chromatograms are recorded under the prescribed conditions, the relative retentions with reference to furosemide (retention time about 9 minutes) are: impurity C, about 0.5; impurity A, about 0.8 and impurity D, about 1.5.

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.

LIMITS

Identify any peak due to impurity C and impurity D using solution (4) and multiply the area of the peak by a correction factor of 1.4 and 2 respectively.

In the chromatogram obtained with solution (1):

the area of any peak corresponding to impurity C is not greater than twice the area of the peak in the chromatogram obtained with solution (2) (1.0%);

the area of any peak corresponding to impurity D is not greater than 1.5 times area of the principal peak in the chromatogram obtained with solution (5) (0.15%);

the area of any other [secondary peak](#) is not greater than 1.3 times the area of the principal peak in the chromatogram obtained with solution (5) (0.13%);

the sum of the areas of any [secondary peaks](#) excluding impurity C is not greater than the area of the peak in the chromatogram obtained with solution (2) (0.5%).

Disregard any peak with an area less than 0.5 times the area of the principal peak in the chromatogram obtained with solution (5) (0.05%).

Bacterial endotoxins

Carry out the [test for bacterial endotoxins, Appendix XIV C](#). Dilute the injection with [water BET](#), if necessary, to contain the equivalent of 10 mg of furosemide per mL (solution A). The endotoxin limit concentration of this solution is 35 IU of endotoxin per mL.

ASSAY

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 injection to produce a solution containing 0.01% w/v of Furosemide.

(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 under Related substances may be used.

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.

DETERMINATION OF CONTENT

Calculate the content of furosemide, $C_{12}H_{11}ClN_2O_5S$, in the injection from the chromatograms obtained and using the declared content of $C_{12}H_{11}ClN_2O_5S$ in [furosemide BPCRS](#).

STORAGE

Furosemide Injection should be protected from light.

LABELLING

The strength is stated in terms of the equivalent amount of furosemide in a suitable dose-volume.

IMPURITIES

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