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Cefuroxime for Injection

General Notices

Cefuroxime Injection

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

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Notes:	REVISED Title and definition revised. TLC Identification test removed. Assay concentrations revised to match Ph. Eur Cefuroxime sodium.

Action and use

Cephalosporin antibacterial.

DEFINITION

Cefuroxime Sodium for Injection is a sterile material consisting of [Cefuroxime Sodium](#) with or without [excipients](#). It is intended to be prepared by dissolving the dry ingredients in the specified volume just before issue for use.

The contents of the sealed container comply with the requirements for Powders for Injections or Infusions stated under [Parenteral Preparations](#) and with the following requirements.

Content of cefuroxime, C₁₆H₁₆N₄O₈S

90.0 to 105.0% of the stated amount.

IDENTIFICATION

A. The [infrared absorption spectrum](#), [Appendix II A](#), is concordant with the *reference spectrum* of cefuroxime sodium ([RS 048](#)).

CONFIRMATION

B. Yield reaction A characteristic [of sodium salts](#), [Appendix VI](#).

TESTS

Acidity or Alkalinity

pH of a solution containing the equivalent of 10.0% w/v of cefuroxime, 5.5 to 8.5, [Appendix V L](#).

Related substances

Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions in [water](#). Prepare the solutions immediately before use.

- (1) Dissolve a quantity of the contents of a sealed container to produce a solution containing the equivalent of 0.1% w/v of cefuroxime.
- (2) Dilute 1 volume of solution (1) to 100 volumes.
- (3) Heat 20 mL of a 0.1% w/v solution of [cefuroxime sodium BPCRS](#) in a water bath at 60° for 10 minutes, cool and inject immediately (generation of descarbamoylcefuroxime).

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (12.5 cm × 4.6 mm) packed with particles of silica the surface of which has been modified with chemically-bonded hexylsilyl groups (5 µm) (Spherisorb S5 C6 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 an ambient column temperature.
- (e) Use an autosampler temperature of 4°.
- (f) Use a detection wavelength of 273 nm.
- (g) Inject 20 µL of each solution.
- (h) For solution (1), allow the chromatography to proceed for at least 3 times the retention time of the principal peak.

MOBILE PHASE

1 volume of [acetonitrile](#) and 99 volumes of [acetate buffer pH 3.4](#).

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the [resolution](#) between the peaks corresponding to cefuroxime and descarbamoylcefuroxime is at least 2.0. If necessary, adjust the concentration of [acetonitrile](#) in the mobile phase.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to descarbamoylcefuroxime (located by comparison with the chromatogram obtained with solution (3)) is not greater than 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 principal peak in the chromatogram obtained with solution (2) (1%);

the sum of the areas of all the secondary peaks is not greater than 3 times the area of the principal peak in the chromatogram obtained with solution (2) (3%).

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

Water

Not more than 3.5% w/w, Appendix IX C. Use 0.4 g.

Bacterial endotoxins

Carry out the test for bacterial endotoxins, Appendix XIV C. Dissolve the contents of the sealed container in water BET to give a solution containing the equivalent of 10 mg of cefuroxime per mL (solution A). The endotoxin limit concentration of solution A is 1.0 IU per mL.

ASSAY

Determine the weight of the contents of 10 containers as described in the test for uniformity of weight, Appendix XII C1, Powders for Parenteral Use.

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

(1) Dissolve a quantity of the mixed contents of the 10 containers to produce a solution containing the equivalent of 0.01% w/v of cefuroxime.

(2) 0.01% w/v of cefuroxime sodium BPCRS.

The chromatographic conditions described under Related Substances should be used, with the exception of (h).

DETERMINATION OF CONTENT

Calculate the content of $C_{16}H_{16}N_4O_8S$ in a container of average content weight from the declared content of $C_{16}H_{15}N_4NaO_8S$ in cefuroxime sodium BPCRS. Each mg of $C_{16}H_{15}N_4NaO_8S$ is equivalent to 0.9508 mg of $C_{16}H_{16}N_4O_8S$.

STORAGE

The sealed container should be protected from light.

LABELLING

The label on the sealed container states the quantity of Cefuroxime Sodium contained in it in terms of the equivalent amount of cefuroxime.

DRAFT MONOGRAPH
SUBJECT TO CHANGE