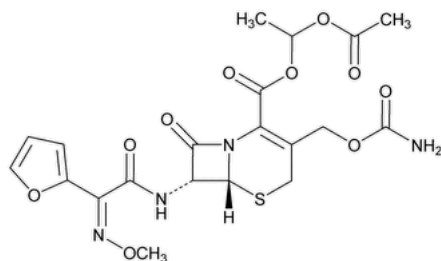


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Cefuroxime Axetil



$C_{20}H_{22}N_4O_{10}S$ 510.47

5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[[[(aminocarbonyl)oxy]methyl]-7-[[2-furanyl(methoxyimino)acetyl]amino]-8-oxo-, 1-(acetyloxy)ethyl ester, [6R-[6 α ,7 β (Z)]]-;

(*RS*)-1-Hydroxyethyl (6*R*,7*R*)-7-[2-(2-furyl)glyoxylamido]-3-(hydroxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate, 7²-(*Z*)-(O-methyloxime), 1-acetate 3-carbamate CAS RN[®]: 64544-07-6; UNII: Z49QDT0J8Z.

DEFINITION

Cefuroxime Axetil is a mixture of the diastereoisomers of cefuroxime axetil ($C_{20}H_{22}N_4O_{10}S$). It contains the equivalent of NLT 745 µg/mg and NMT 875 µg/mg of cefuroxime ($C_{16}H_{16}N_4O_8S$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** **▲ SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 197K ▲** (CN 1-MAY-2020) : Meets the requirements
- **B.** The retention times of cefuroxime axetil diastereoisomers A and B of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Solution A: 23 g/L of monobasic ammonium phosphate

Mobile phase: Methanol and *Solution A* (38:62)

System suitability stock solution: 0.1 mg/mL of [USP Cefuroxime Axetil Delta-3 Isomers RS](#) in methanol

System suitability solution: 10 µg/mL of cefuroxime axetil delta-3 isomers from *System suitability stock solution* and 0.2 mg/mL of [USP Cefuroxime Axetil RS](#) in *Mobile phase*

Standard solution: 0.2 mg/mL of [USP Cefuroxime Axetil RS](#) in *Mobile phase*. Protect the solution from light, refrigerate, and use on the day prepared.

Sample solution: 0.2 mg/mL of Cefuroxime Axetil in *Mobile phase*. Protect the solution from light, refrigerate, and use on the day prepared.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 278 nm

Column: 4.6-mm × 25-cm; 5-µm packing L13

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—See [Table 1](#) for relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between cefuroxime axetil diastereoisomers A and B; NLT 1.5 between cefuroxime axetil diastereoisomer A and cefuroxime axetil delta-3 isomers, *System suitability solution*

Relative standard deviation: NMT 2.0% for the sum of cefuroxime axetil diastereoisomers A and B, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity, in µg/mg, of cefuroxime (C₁₆H₁₆N₄O₈S) in the portion of Cefuroxime Axetil taken:

$$\text{Result} = (r_U/r_T) \times (C_S/C_U) \times P$$

r_U = sum of the peak responses of cefuroxime axetil diastereoisomers A and B from the *Sample solution*

r_T = sum of the peak responses of cefuroxime axetil diastereoisomers A and B from the *Standard solution*

C_S = concentration of [USP Cefuroxime Axetil RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Cefuroxime Axetil in the *Sample solution* (mg/mL)

P = potency of cefuroxime, on the anhydrous basis, in [USP Cefuroxime Axetil RS](#) (µg/mg)

Acceptance criteria: 745–875 µg/mg on the anhydrous basis

IMPURITIES

• ORGANIC IMPURITIES

Solution A, Mobile phase, System suitability solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Peak identification solution: 30 µg/mL of [USP Cefuroxime Axetil E-Isomers RS](#) in *Mobile phase*

Reference solution: 2 µg/mL of [USP Cefuroxime Axetil RS](#) in *Mobile phase*. Protect the solution from light, refrigerate, and use on the day prepared.

System suitability

Samples: *System suitability solution* and *Peak identification solution*

[NOTE—See [Table 1](#) for relative retention times. Use the *Peak identification solution* to identify the locations of the cefuroxime axetil *E*-isomers.]

Suitability requirements

Resolution: NLT 1.5 between cefuroxime axetil diastereoisomers A and B; NLT 1.5 between cefuroxime axetil diastereoisomer A and cefuroxime axetil delta-3 isomers, *System suitability solution*

Analysis

Samples: *Sample solution* and *Reference solution*

Calculate the percentage of each impurity in the portion of Cefuroxime Axetil taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each individual impurity from the *Sample solution*

r_T = sum of the peak responses of cefuroxime axetil diastereoisomers A and B from the *Sample solution*

Acceptance criteria: See [Table 1](#). The reporting threshold is 0.05 times the sum of the responses of the two major peaks from the *Reference solution*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Methoxyiminofuranyl acetic acid ^a	0.24	0.30
Cefuroxime ^b	0.30	0.5
Cefuroxime lactone ^c	0.42	0.30
Cefuroxime axetil diastereoisomer B	0.9	—
Cefuroxime axetil diastereoisomer A	1.0	—
Cefuroxime axetil delta-3 isomers ^{d,e}	1.2	1.20
Cefuroxime axetil <i>E</i> -isomers ^{d,f}	1.7	1.0
	2.1	
Cefuroxime axetil dimer ^{g,h}	2.5	0.5