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Cefuroxime Axetil Tablets

DEFINITION
Cefuroxime Axetil Tablets contain the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of cefuroxime ($C_{16}H_{16}N_4O_8S$).

IDENTIFICATION
• **A.** The retention times of the peaks 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 in water

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

Buffer: 23 g/L of monobasic ammonium phosphate in water, adjusted with phosphoric acid to a pH of 2.4

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 0.3 mg/mL of USP Cefuroxime Axetil RS in *Mobile phase*

Standard solution: 0.3 mg/mL of cefuroxime axetil in *Mobile phase*. Protect the solution from light, refrigerate, and use on the day prepared.

Sample stock solution: Nominally 5 mg/mL of cefuroxime from finely powdered Tablets (NLT 5), prepared as follows. Transfer a suitable portion of the powder to a volumetric flask. Disperse in *Buffer*, using 5% of the final volume. Sonicate if necessary. Add methanol to fill the volumetric flask to about half its capacity and shake by mechanical means for about 10 min. Dilute with methanol to volume, and filter.

Sample solution: Nominally 0.25 mg/mL of cefuroxime from the *Sample stock solution* 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: 1.2 mL/min

Injection volume: 20 µL

System suitability

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

[Note—See *Table 4* 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 percentage of the labeled amount of cefuroxime ($C_{16}H_{16}N_4O_8S$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_T) \times (C_S/C_U) \times P \times F \times 100$$

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 = nominal concentration of cefuroxime in the *Sample solution* (mg/mL)

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

F = conversion factor, 0.001 mg/µg

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Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Test 1

Medium: 0.07 N hydrochloric acid; 900 mL

Apparatus 2: 55 rpm

Times: 15 and 45 min

Standard solution: 10–20 µg/mL of cefuroxime from USP Cefuroxime Axetil RS in *Medium*

Sample solution: Pass portions of the solution under test through a suitable filter and dilute with *Medium*, if necessary, to a concentration similar to that of the *Standard solution*.

Instrumental conditions

Mode: UV-Vis

Analytical wavelength: 278 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentage (Q) of the labeled amount of cefuroxime ($C_{16}H_{16}N_4O_8S$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (1/L) \times P \times F \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

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

F = conversion factor, 0.001 mg/µg

Acceptance criteria

For Tablets labeled to contain nominally 500 mg of cefuroxime: See *Table 1*.

Table 1

Time (min)	Amount Dissolved (%)
15	NLT 50
45	NLT 70

For all other Tablets: See *Table 2*.

Table 2

Time (min)	Amount Dissolved (%)
15	NLT 60
45	NLT 75

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium, Times, and **Analysis:** Proceed as directed in *Test 1*.

Apparatus 2: 100 rpm

Acceptance criteria: See *Table 3*.

Table 3

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Time (min)	Amount Dissolved (%)
15	NLT 60
45	NLT 75

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

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

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

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: 1.2 mL/min

Injection volume: 20 µL

System suitability

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

[Note—See *Table 4* for the relative retention times. The *Peak identification solution* is used to identify the locations of the cefuroxime axetil *E*-isomers.]

Suitability requirements

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

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Tablets 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 4*.

Table 4

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Methoxyiminofuranyl acetic acid[a,b]	0.34	—
Cefuroxime[c]	0.41	0.70
Cefuroxime lactone[d]	0.52	0.30
Cefuroxime axetil diastereoisomer B	0.90	—
Cefuroxime axetil diastereoisomer A	1.0	—
Cefuroxime axetil delta-3 isomers[e,f]	1.1	1.20
Cefuroxime axetil *E*-isomers[e,g]	1.6	1.0
	1.9	
Cefuroxime axetil dimer[a,h,i]	2.6	—
	3.1	

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Name	Relative Retention Time	Acceptance Criteria, NMT (%)
	3.6	
Any other individual impurity	—	0.30
Total impurities	—	3.0

[a] Process impurities are controlled in the drug substance and are not to be reported here. They are not included in total impurities.

[b] (*Z*)-2-(Furan-2-yl)-2-(methoxyimino)acetic acid.

[c] (6*R*,7*R*)-3-[(Carbamoyloxy)methyl]-7-[(*Z*)-2-(furan-2-yl)-2-(methoxyimino)acetamido]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid.

[d] (*Z*)-*N*-((5a*R*,6*R*)-1,7-Dioxo-1,3,4,5a,6,7-hexahydroazeto[2,1-*b*]furo[3,4-*d*][1,3]thiazin-6-yl)-2-(furan-2-yl)-2-(methoxyimino)acetamide.

[e] The system may resolve two isomers. The limit is for the sum of the two isomers.

[f] (1*RS*,6*R*,7*R*)-1-Acetoxyethyl 3-[(carbamoyloxy)methyl]-7-[(*Z*)-2-(furan-2-yl)-2-(methoxyimino)acetamido]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-3-ene-2-carboxylate.

[g] (1*RS*,6*R*,7*R*)-1-Acetoxyethyl 3-[(carbamoyloxy)methyl]-7-[(*E*)-2-(furan-2-yl)-2-(methoxyimino)acetamido]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate.

[h] The system may resolve three isomers.

[i] (6*R*,6'*R*,7*R*,7'*R*,*Z*)-Oxybis(ethane-1,1-diyl)bis{3-[(carbamoyloxy)methyl]-7-[(*Z*)-2-(furan-2-yl)-2-(methoxyimino)acetamido]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate}.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. Store at controlled room temperature.

• **Labeling:** The labeling indicates whether the Tablets contain amorphous or crystalline Cefuroxime Axetil. If Tablets contain a mixture of amorphous and crystalline Cefuroxime Axetil, label to indicate the percentage of each contained therein. When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.

• **USP Reference Standards** (11)

USP Cefuroxime Axetil RS

USP Cefuroxime Axetil Delta-3 Isomers RS

(1*RS*,6*R*,7*R*)-1-Acetoxyethyl 3-[(carbamoyloxy)methyl]-7-[(*Z*)-2-(furan-2-yl)-2-(methoxyimino)acetamido]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-3-ene-2-carboxylate.

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

USP Cefuroxime Axetil E-Isomers RS

(1*RS*,6*R*,7*R*)-1-Acetoxyethyl 3-[(carbamoyloxy)methyl]-7-[(*E*)-2-(furan-2-yl)-2-(methoxyimino)acetamido]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate.

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

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CEFUROXIME AXETIL TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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