कर्नाटका एन्टिबायोटिक्स एण्ड फार्मास्युटिकल्स लिमिटेड
(भारत सरकार का उद्यम)
KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED
(A Government of India Enterprise)

ENQUIRY REF No:	KAPL/QAD/020/2147
DATE	20.02.2026
DUE DATE	26.02.2026 (13:00HRS)

Dear Sir,

Please submit your lowest and competitive offer in a SEALED ENVELOPE, DULY SUPERSCRIBING OUR ABOVE ENQUIRY REF. NO., DATE and DUE DATE on it/ OR MAIL, with other details of F.O.R terms, Taxes, Credit period, Delivery offered, Name of the Make, Detailed Specification etc., for below mentioned material/s

SL NO.	ITEM CODE	ITEM DESCRIPTION	UOM	QTY
01	QSPDP3001	15 CM X3.9 MM 5 MICRON PACKING L1	NOS	01

1) Please ensure that your offer reaches us on or before Due Date by courier OR speed post Or you can also mail us to our email: purenp@kaplindia.com
2) Please send your quotation mentioning item code

OTHER TERMS:

1. F.O.R TERMS : DOOR DELIVERY TO PEENYA FACTORY
2. GST % : PLEASE SPECIFY
3. PACKING & FORWARDING CHARGES : NOT APPLICABLE
4. CREDIT PERIOD : 30 DAYS
5. DELIVERY OFFERED :
6. ATTACHED PAGES : 05

NOTE: IN CASE YOU ARE NOT QUOTING PLEASE SEND THE REGRET LETTER.

Thanking you,

Yours faithfully,
For KARNATAKA ANTIBIOTICS
& PHARMACEUTICALS LIMITED

YUVARAJA M
DEPUTY MANAGER PURCHASE DEPT

QUALITY CONTROL DEPARTMENT		KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED (A Government of India Enterprise)

User Requirement specifications

Material Description : Stainless steel column 15 cm x 3.9 mm, 5 µm, Packing L1

URS Number: QC/URS/05/02/26

1. Description and Quantity:

Material Description	15 cm x 3.9 mm, 5 µm, Packing L1
Item code	QSPDP3001
Quantity/ Box	1

2. User Specifications:

#	Requirement	Specification
1	Brand Name	Stainless steel column 15 cm x 3.9 mm, 5 µm, Packing L1
5	Matrix active group	Silica
6	Particle size	3.9
7	Length (mm)	15 cm
8	Internal Diameter (I.D.)	3.9 mm
9	Particle Substrate	Silica
10	Particle Shape	Spherical
11	External Construction Materials	Stainless Steel
12	Endcapped	Yes
13	Endfitting Type	-
14	USP Classification	L1
15	Separation Mode	Reverse phase
16	P^H Range	2-12
17	Maximum Pressure	6000 psi (415 Bar)
18	Pore Size	100 °A

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Cefotaxime for Injection

DEFINITION
Cefotaxime for Injection contains an amount of Cefotaxime Sodium equivalent to NLT 90.0% and NMT 115.0% of the labeled amount of cefotaxime ($C_{16}H_{17}N_5O_7S_2$).

IDENTIFICATION
Where the label indicates that there are no added substances:

Change to read:

- **A.** ▲**Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)
- **B. Identification Tests—General,** *Sodium* ⟨191⟩**:** Meets the requirements

Where the label indicates that there are added substances:

- **C.** The retention time of the major peak of the *Sample solution 1*, *2*, *3*, or *4* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

- **Procedure**

Buffer: 7.1 g/L of anhydrous dibasic sodium phosphate in water, adjusted with phosphoric acid to a pH of 6.25

Solution A: Methanol and *Buffer* (14:86). Pass through a filter having a pore size of 0.5 µm or finer, and degas before use.

Solution B: Methanol and *Buffer* (40:60). Pass through a filter having a pore size of 0.5 µm or finer, and degas before use.

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
7	100	0
9	80	20
16	80	20
46	0	100
51	0	100
56	100	0

Standard solution: 0.8 mg/mL of USP Cefotaxime Sodium RS in *Solution A*. Use this solution promptly. It may be used within 24 h if stored in a refrigerator.

System suitability solution: Mix 1 mL of *Standard solution*, 7.0 mL of water, and 2.0 mL of methanol. Add 25 mg of sodium carbonate, mix, and allow to stand at room temperature for 10 min, with occasional swirling. Add 3 drops of glacial acetic acid and 1 mL of *Standard solution*.

Sensitivity solution: 1.6 µg/mL of USP Cefotaxime Sodium RS in *Solution A*

Sample solution 1 (for use where the *Weight Variation* test is to be performed)**:** 0.8 mg/mL of Cefotaxime for Injection in *Solution A*. Use this solution promptly. It may be used within 24 h if stored in a refrigerator.

Sample solution 2 (for use in assaying vials and infusion bottles packaged for dispensing)**:** Nominally 0.8 mg/mL of cefotaxime, prepared as follows. Constitute one container of Cefotaxime for Injection with the smallest volume of diluent specified in the labeling. Invert the container, and withdraw all of the withdrawable contents of the container with a hypodermic needle and syringe. Transfer the contents of

the syringe to a 100-mL volumetric flask, dilute with *Solution A* to volume, and mix. Do not rinse the syringe or container. Dilute a suitable aliquot of this solution with *Solution A*. Use this solution promptly. It may be used within 24 h if stored in a refrigerator.

Sample solution 3 (for use in assaying piggyback infusion bottles)**:** Nominally 0.8 mg/mL of cefotaxime, prepared as follows. Constitute one container of Cefotaxime for Injection with the smallest volume of diluent recommended in the labeling, using the directions specified in the labeling. Invert the container, and withdraw all of the withdrawable contents of the container with a hypodermic needle and syringe. Transfer the contents of the syringe to a 100-mL volumetric flask, dilute with *Solution A* to volume, and mix. Do not rinse the syringe or container. Dilute a suitable aliquot of this solution with *Solution A*. Use this solution promptly. It may be used within 24 h if stored in a refrigerator.

Sample stock solution 4 (for use in assaying pharmacy bulk packages where the label states the quantity of cefotaxime in a given volume of constituted solution)**:** Nominally 10 mg/mL of cefotaxime, prepared as follows. Constitute one container of Cefotaxime for Injection with the volume of diluent specified in the labeling. With a hypodermic needle and syringe, withdraw a suitable aliquot of the reconstituted product, transfer to a suitable volumetric flask, dilute with *Solution A* to volume, and mix. Do not rinse the syringe or container.

Sample solution 4: Nominally 0.8 mg/mL of cefotaxime from *Sample stock solution 4* in *Solution A*. Use this solution promptly. It may be used within 24 h if stored in a refrigerator.

Chromatographic system

(See Chromatography ⟨621⟩, System Suitability.)

Mode: LC

Detector: UV 235 nm

Column: 3.9-mm × 15-cm; 5-µm packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Samples: *Standard solution, System suitability solution*, and *Sensitivity solution*. [NOTE—The retention times for desacetylcefotaxime and cefotaxime in the *System suitability solution* are 3.5 min and 14 min, respectively. The retention time for cefotaxime in the *Standard solution* is 12–15 min.]

Suitability requirements

Sensitivity: The response of the cefotaxime peak from the *Sensitivity solution* is between 0.18% and 0.22% of the response of the cefotaxime peak of the *Standard solution*.

Resolution: NLT 20 between desacetylcefotaxime and cefotaxime, *System suitability solution*

Tailing factor: NMT 2, *Standard solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Sample solution 1*, or *Sample solution 2*, or *Sample solution 3*, or *Sample solution 4*, and *Standard solution*

Calculate the percentage of the labeled amount of cefotaxime ($C_{16}H_{17}N_5O_7S_2$) withdrawn from the container, or in the portion of Cefotaxime for Injection taken:

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

r_U = peak area of the *Sample solution*

r_S = peak area of the *Standard solution*

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

C_U = nominal concentration of cefotaxime in *Sample solution 1*, *2*, *3*, or *4* (mg/mL)

P = potency of cefotaxime in USP Cefotaxime Sodium RS (µg/mg)

Acceptance criteria: 90.0%–115.0%. Where the test for *Uniformity of Dosage Units* has been peformed using the *Procedure for Content Uniformity*, use the average of these determinations as the *Assay* value.

PERFORMANCE TESTS

• **UNIFORMITY OF DOSAGE UNITS** ⟨905⟩**:** Meets the requirements

IMPURITIES

• **ORGANIC IMPURITIES**

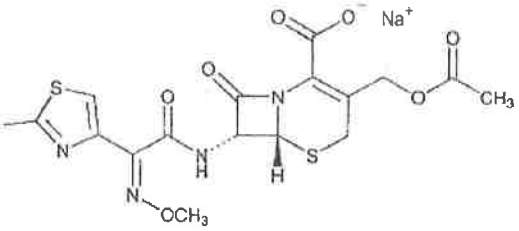
Mobile phase; Standard solution; System suitability solution; Sample solutions 1, 2, 3 or **4; Chromatographic system;** and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Calculate the percentage of each impurity in the portion of Cefotaxime for Injection taken:

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

efotaxime Sodium



$C_{16}H_{16}N_5NaO_7S_2$ 477.45

ia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[(acetyloxy)methyl]-7-[[(2-amino-4-thiazolyl)(methoxyimino)acetyl]amino]-8-oxo-, osodium salt, [6*R*-[6α,7β (*Z*)]]-;

um (6*R*,7*R*)-7-[2-(2-amino-4-thiazolyl)glyoxylamido]-3-(hydroxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate 7^2-(*Z*)-(*O*-nyloxime), acetate (ester) CAS RN®: 64485-93-4; UNII: 258J72S7TZ.

INITION

taxime Sodium contains the equivalent of NLT 916 µg/mg and NMT 964 µg/mg of cefotaxime ($C_{16}H_{17}N_5O_7S_2$), calculated on the dried basis.

ITIFICATION

ge to read:

▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

Identification Tests—General, *Sodium* ⟨191⟩: It meets the requirements.

AY

CEDURE

ffe 7.1 g/L of anhydrous dibasic sodium phosphate in water. Adjust with phosphoric acid to a pH of 6.25.

lution A: Methanol and *Buffer* (14:86)

lution B: Methanol and *Buffer* (40:60)

bile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
7	100	0
9	80	20
16	80	20
45	0	100
50	0	100

Time (min)	Solution A (%)	Solution B (%)
55	100	0
65	100	0

System suitability stock solution: 0.08 mg/mL each of USP Cefetamet RS and USP Cefotaxime Related Compound E RS prepared as follows. Dissolve USP Cefetamet RS and USP Cefotaxime Related Compound E RS in the minimum volume of methanol. Sonicate, if necessary, and dilute with *Solution A* to volume.

System suitability solution: 8 µg/mL each of cefetamet and cefotaxime related compound E from *System suitability stock solution* in *Solution A*. Store refrigerated, and use within 24 h.

Standard solution: 0.8 mg/mL of USP Cefotaxime Sodium RS in *Solution A*. Store refrigerated, and use within 24 h.

Sensitivity solution: 1.6 µg/mL of USP Cefotaxime Sodium RS from the *Standard solution* in *Solution A*. Store refrigerated, and use within 24 h.

Sample solution: 0.8 mg/mL of Cefotaxime Sodium in *Solution A*. Store refrigerated, and use within 24 h.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 235 nm

Column: 3.9-mm × 15-cm; 5-µm packing L1

Temperatures

Column: 30°

Autosampler: 4°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

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

[NOTE—See *Table 2* for relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between cefetamet and cefotaxime related compound E, *System suitability solution*

Tailing factor: NMT 2, *Standard solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Sensitivity: Calculate the peak response ratio:

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

r_U = peak response from the *Sensitivity solution*

r_S = peak response from the *Standard solution*

Acceptance criteria: 0.18%–0.22%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity, in µg/mg, of cefotaxime ($C_{16}H_{17}N_5O_7S_2$) in the portion of Cefotaxime Sodium taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = concentration of Cefotaxime Sodium in the *Sample solution* (mg/mL)

P = potency of cefotaxime in USP Cefotaxime Sodium RS (µg/mg)