



**KARNATAKA ANTIBIOTICS &
PHARMACEUTICALS LIMITED**

(A Government of India Enterprise)

ENQUIRY REF No:	KAPL/QAD/020/2275
DATE	14.03.2026
DUE DATE	20.03.2026 (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	QSPHPL149	HPLC COLUMN 15 CM X 4 MM 3 MIC LI USP	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: puren@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.

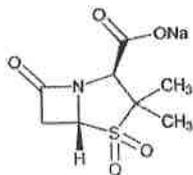
Thanking you,

Yours faithfully,
For KARNATAKA ANTIBIOTICS
& PHARMACEUTICALS LIMITED

YUVARAJA M
DEPUTY MANAGER PURCHASE DEPT

Sulbactam Sodium

Change to read:



$C_8H_{10}NNaO_5S$ 255.22

4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 3,3-dimethyl-7-oxo-, 4,4-dioxide, sodium salt, (2*S*-*cis*)-;

Sodium (2*S*,5*R*)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate 4,4-dioxide CAS RN[®]: 69388-84-7; UNII: DKQ4T82YE6.

▲Sulbactam (free acid)

$C_8H_{11}NO_5S$ 233.24 CAS RN[®]: 68373-14-8; UNII: S4TF6I2330.▲ (USP 1-Dec-2023)

DEFINITION

Sulbactam Sodium contains NLT 886 and NMT 941 µg/mg of sulbactam ($C_8H_{11}NO_5S$), calculated on the anhydrous basis.

IDENTIFICATION

Add the following:

▲• **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K▲ (USP 1-Dec-2023)

Change to read:

• ▲B.▲ (USP 1-Dec-2023) The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Change to read:

• ▲C.▲ (USP 1-Dec-2023) **IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Sodium:** Meets the requirements

ASSAY

• PROCEDURE

Buffer solution: 2.7 g/L of monobasic potassium phosphate, adjusted with dilute phosphoric acid to a pH of 4.0

Solution A: 5.4 g/L of monobasic potassium phosphate, adjusted with dilute phosphoric acid to a pH of 4.0

Solution B: Acetonitrile

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	98	2
7.5	50	50
8.5	50	50
9.0	98	2
12.5	98	2

Standard solution: 0.7 mg/mL of USP Sulbactam RS prepared as follows. Dissolve a suitable amount of USP Sulbactam RS in acetonitrile, using 2% of the final volume, and dilute with *Buffer solution* to volume.

Sample solution: 0.77 mg/mL of Sulbactam Sodium prepared as follows. Dissolve a suitable amount of Sulbactam Sodium in acetonitrile, using 2% of the final volume, and dilute with *Buffer solution* to volume.

Chromatographic system

Chromatography (621), System Suitability.)

Mode: LC

Detector: UV 215 nm

Column: 4-mm × 15-cm; 3-µm packing L1

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: Standard solution

Suitability requirements

Relative standard deviation: NMT 0.73%

Analysis

Samples: Standard solution and Sample solution

Calculate the quantity, in µg, of sulbactam (C₈H₁₁NO₅S) in each mg of Sulbactam Sodium taken:

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

r_U = peak response from the Sample solution

r_S = peak response from the Standard solution

C_S = concentration of USP Sulbactam RS in the Standard solution (mg/mL)

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

P = potency of sulbactam in USP Sulbactam RS (mg/mg)

F = conversion factor, 1000 µg/mg

Acceptance criteria: 886–941 µg/mg on the anhydrous basis

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

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

Diluent: 2 mL of acetonitrile diluted with *Buffer solution* to 100 mL

System suitability solution: 0.7 µg/mL each of USP Sulbactam Related Compound A RS, USP Sulbactam Related Compound D RS, USP Sulbactam Related Compound E RS, and USP Sulbactam Related Compound F RS, prepared as follows. Dissolve suitable amounts of USP Sulbactam Related Compound A RS, USP Sulbactam Related Compound D RS, USP Sulbactam Related Compound E RS, and USP Sulbactam Related Compound F RS in acetonitrile using 10% of the final volume, and sonicate as needed. Dilute with *Diluent* to volume. Protect this solution from light.

Standard stock solution: 0.7 mg/mL of USP Sulbactam RS prepared as follows. Dissolve a suitable amount of USP Sulbactam RS in acetonitrile, using 2% of the final volume, and dilute with *Buffer solution* to volume.

Standard solution: 0.7 µg/mL of USP Sulbactam RS from the *Standard stock solution*, in *Diluent*

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between sulbactam related compound D and sulbactam related compound E, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of each impurity in the portion of Sulbactam Sodium taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times (1/F) \times 100$$

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

r_S = peak response from the *Standard solution*

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

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

P = potency of sulbactam in USP Sulbactam RS (mg/mg)

F = relative response factor (see [Table 2](#))

Acceptance criteria: See [Table 2](#). The reporting threshold is 0.05%.

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Sulbactam related compound A ^a	0.4	1.7	0.5
▲6-Aminopenicillanic acid▲ (USP 1-Dec-2023) (Amoxicillin related compound A) ^b	0.6	2.0	0.1
Sulbactam	1.0	—	—
6-Bromopenicillanic acid sulfone ^c	1.6	1.0	0.2
Sulbactam related compound D ^d	2.0	2.0	0.1
Sulbactam related compound E ^e	2.1	1.0	0.2
Sulbactam related compound F ^f	2.5	1.7	0.1
Any individual unspecified impurity	—	1.0	0.10
Total impurities	—	—	1.0

^a 3-Sulfinob-valine; (2S)-2-Amino-3-methyl-3-sulfinobutanoic acid.

^b ▲▲ (USP 1-Dec-2023) (2S,5R,6R)-6-Amino-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.

^c (2S,5R,6R)-6-Bromo-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid 4,4-dioxide.

^d 6-Bromopenicillanic acid; (2S,5R,6R)-6-Bromo-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.

^e 6,6-Dibromopenicillanic acid sulfone; also known as (2S,5R)-6,6-Dibromo-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid 4,4-dioxide.

^f 6,6-Dibromopenicillanic acid; also known as (2S,5R)-6,6-Dibromo-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.

SPECIFIC TESTS

• **CRYSTALLINITY (695)**: Meets the requirements

Change to read:

• **BACTERIAL ENDOTOXINS TEST (85)**: Where the label states that Sulbactam Sodium is sterile or must be subjected to further processing during the preparation of injectable dosage forms, ▲the level of bacterial endotoxins is such that the requirement under the relevant dosage form monograph(s) in which Sulbactam Sodium is used can be met.▲ (USP 1-Dec-2023)

Change to read:

• **STERILITY TESTS (71)**: Where the label states that Sulbactam Sodium is sterile, it meets the requirements. ▲▲ (USP 1-Dec-2023)

• **WATER DETERMINATION (921), Method I**: NMT 1.0%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE**: Preserve in tight containers.

• **LABELING**: Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.

Change to read:

• **USP REFERENCE STANDARDS (11)**

Sulbactam RSSulbactam Sodium RS ▲ (USP 1-Dec-2023)USP Sulbactam Related Compound A RS

(2S)-2-Amino-3-methyl-3-sulfinobutanoic acid.

C₅H₁₁NO₄S 181.21USP Sulbactam Related Compound D RS

(2S,5R,6R)-6-Bromo-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, potassium salt.

C₈H₉BrKNO₃S 318.23USP Sulbactam Related Compound E RS

(2S,5R)-6,6-Dibromo-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid 4,4-dioxide.

C₈H₉Br₂NO₅S 391.03USP Sulbactam Related Compound F RS

(2S,5R)-6,6-Dibromo-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.

C₈H₉Br₂NO₃S 359.03**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
SULBACTAM SODIUM	Documentary Standards Support	SM12025 Small Molecules Therapeutic Areas 1
REFERENCE STANDARDS SUPPORT	RS Technical Services RSTECH@usp.org	SM12025 Small Molecules Therapeutic Areas 1

Chromatographic Database Information: [Chromatographic Database](#)**Most Recently Appeared In:**

Pharmacopeial Forum: Volume No. 47(4)

DOI: https://doi.org/10.31003/USPNF_M78709_04_01

OFFICIAL

QUALITY CONTROL DEPARTMENT

KARNATAKA ANTIBIOTICS &
PHARMACEUTICALS LIMITED

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User Requirement specifications**Material Description** : HPLC COLUMN 15 cm x 4 mm, 3 μ m, L1 packing (USP)**URS Number**: QC/URS/002/03/26**1. Description and Quantity:**

Material Description	HPLC COLUMN 15 cm x 4 mm, 3 μ m, L1 packing (USP)
Item code	QSPHPL149
Quantity/ Box	1
Product Name	Sulbactam Sodium USP

2. User Specifications:

#	Requirement	Specification
1.	Specification	HPLC COLUMN 15 cm x 4 mm, 3 μ m, L1 packing (USP)
2.	Particle size	3 μ m
3.	Length	15 cm
4.	Internal Diameter (I.D.)	4 mm
5.	External Construction Materials	Stainless Steel
6.	USP Classification	L1