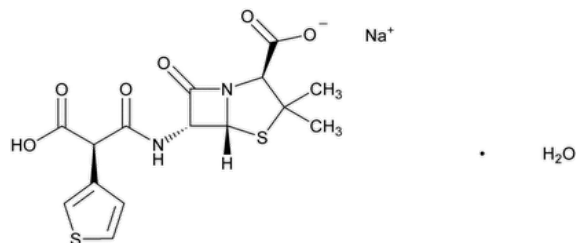


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Ticarcillin Monosodium



$C_{15}H_{15}N_2NaO_6S_2 \cdot H_2O$ 424.42

4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[(carboxy-3-thienylacetyl)amino]-3,3-dimethyl-7-oxo, monosodium salt, [2S-[2 α ,5 α ,6 β (S*)]]-, monohydrate;

(R)-N-[(2S,5R,6R)-2-Carboxy-3,4-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]hept-6-yl]-3-thiophenemalonamic acid monosodium salt.
 Anhydrous

$C_{15}H_{15}N_2NaO_6S_2$ 406.40 CAS RN®: 74682-62-5.

DEFINITION

Ticarcillin Monosodium contains the equivalent of NLT 890 µg/mg of ticarcillin ($C_{15}H_{16}N_2O_6S_2$), 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.** Meets the requirements of the test for *Optical Rotation, Specific Rotation*.
- **C.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the Assay.
- **D.** [IDENTIFICATION TESTS—GENERAL, Sodium \(191\)](#).

Sample solution: 50 mg/mL

Acceptance criteria: Meets the requirements

ASSAY

PROCEDURE

Buffer: 1.3 g/L of dibasic ammonium phosphate in water adjusted with phosphoric acid to a pH of 7.0

Mobile phase: Methanol and *Buffer* (20:80)

Standard solution: 0.1 mg/mL of [USP Ticarcillin Monosodium Monohydrate RS](#) in *Mobile phase*

Sample solution: 0.1 mg/mL of Ticarcillin Monosodium in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between the two ticarcillin peaks

Relative standard deviation: NMT 1.0% for the sum of the ticarcillin peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity, in µg/mg, of ticarcillin ($C_{15}H_{16}N_2O_6S_2$) in the portion of Ticarcillin Monosodium taken:

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

r_U = sum of the responses of the two ticarcillin peaks from the *Sample solution*

r_S = sum of the responses of the two ticarcillin peaks from the *Standard solution*

C_S = concentration of [USP Ticarcillin Monosodium Monohydrate RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Ticarcillin Monosodium in the *Sample solution* (mg/mL)

P = potency of ticarcillin in [USP Ticarcillin Monosodium Monohydrate RS](#) (µg/mg)

Acceptance criteria: NLT 890 µg/mg on the anhydrous basis

IMPURITIES

• [DIMETHYLANILINE \(223\)](#): Meets the requirements

• **ORGANIC IMPURITIES**

Solution A: 1.3 g/L of dibasic ammonium phosphate in water adjusted with phosphoric acid to a pH of 7.0

Solution B: Methanol and *Solution A* (50:50)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
30	30	70
40	30	70

System suitability solution: 0.02 mg/mL of [USP Ticarcillin Monosodium Monohydrate RS](#) in *Solution A*

Sample solution: 1 mg/mL of Ticarcillin Monosodium in *Solution A*

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 2.0 between the two ticarcillin peaks

Relative standard deviation: NMT 5.0% for the sum of the ticarcillin peaks

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Ticarcillin Monosodium taken:

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

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

r_T = sum of the responses of the two ticarcillin peaks from the *Sample solution*

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Ticarcillin	0.95	—
	1.0	
Ticarcillin related compound A ^a	2.1	4
Any individual unspecified impurity	—	2.5

^a Decarboxy ticarcillin; (2S,5R,6R)-3,3-Dimethyl-7-oxo-6-[[[(thiophen-3-yl)acetyl]amino]-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.

SPECIFIC TESTS

- **OPTICAL ROTATION, Specific Rotation (781S).**

Buffer: 6.9 g/L of monobasic sodium phosphate adjusted with 10 N sodium hydroxide to a pH of 6.4 ± 0.1 before final dilution

Sample solution: 10 mg/mL in Buffer

Acceptance criteria: +181° to +197°

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

- **pH (791).**

Sample solution: 10 mg/mL of ticarcillin from Ticarcillin Monosodium in water

Acceptance criteria: 2.5–4.0

- **WATER DETERMINATION, Method I (921):** 4.0%–6.0%
- **STERILITY TESTS (71):** Where the label states that Ticarcillin Monosodium is sterile, it meets the requirements when tested as directed for [Test for Sterility of the Product to Be Examined, Membrane Filtration](#).
- **BACTERIAL ENDOTOXINS TEST (85):** Where the label states that Ticarcillin Monosodium is sterile, or must be subjected to further processing during the preparation of injectable dosage forms, it contains NMT 0.05 USP Endotoxin Units/mg of ticarcillin.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers and store in a refrigerator.
- **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.
- **USP REFERENCE STANDARDS (11).**

[USP Ticarcillin Monosodium Monohydrate RS](#)

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

Topic/Question	Contact	Expert Committee
TICARCILLIN MONOSODIUM	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

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