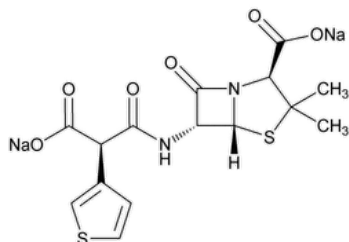


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Ticarcillin Disodium



$C_{15}H_{14}N_2Na_2O_6S_2$ 428.38

4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[(carboxy-3-thienylacetyl)amino]-3,3-dimethyl-7-oxo-, disodium salt, [2S-[2α,5α,6β(S*)]]-;
 N-(2-Carboxy-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]hept-6-yl)-3-thiophenemalonamic acid disodium salt CAS RN®: 4697-14-7.

DEFINITION

Ticarcillin Disodium has a potency equivalent to NLT 800 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)

Solution A: Acetone and water (90:10)

Standard: Dissolve 50 mg of [USP Ticarcillin Monosodium Monohydrate RS](#) in 1 mL of water, add 0.1 mL of hydrochloric acid, swirl, and allow to stand in iced water for 10 min. Pass through a filter. Wash the residue with 2 mL of water and dissolve in *Solution A*. Evaporate almost to dryness, then dry in an oven at 60° for 30 min.

Sample: Dissolve 50 mg of Ticarcillin Disodium in 1 mL of water, add 0.1 mL of hydrochloric acid, swirl, and allow to stand in iced water for 10 min. Pass through a filter. Wash the residue with 2 mL of water and dissolve in *Solution A*. Evaporate almost to dryness, then dry in an oven at 60° for 30 min.

Acceptance criteria: 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 Disodium 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 (C₁₅H₁₆N₂O₆S₂) in the portion of Ticarcillin Disodium 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 Disodium in the *Sample solution* (mg/mL)

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

Acceptance criteria: NLT 800 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 Disodium 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 Disodium taken:

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*

Acceptance criteria: See [Table 2](#).

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).**

Sample solution: 10 mg/mL in water

Acceptance criteria: +172° to +187°

- **pH (791).**

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

Acceptance criteria: 6.0–8.0

- **WATER DETERMINATION, *Method I* (921):** NMT 6.0%
- **STERILITY TESTS (71):** Where the label states that Ticarcillin Disodium is sterile, it meets the requirements in [Test for Sterility of the Product to Be Examined, Membrane Filtration](#).
- **BACTERIAL ENDOTOXINS TEST (85):** Where the label states that Ticarcillin Disodium 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](#) $C_{15}H_{15}N_2NaO_6S_2 \cdot H_2O$ 424.42

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

Topic/Question	Contact	Expert Committee
TICARCILLIN DISODIUM	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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