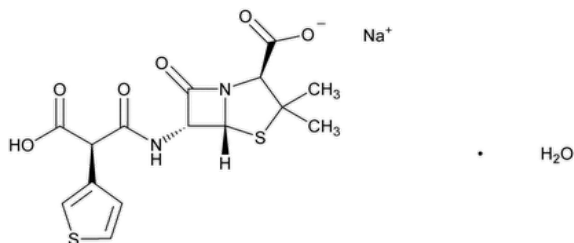


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Ticarcillin Monosodium



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