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Cloxacillin Sodium Capsules

DEFINITION
Cloxacillin Sodium Capsules contain the equivalent of NLT 90.0% and NMT 120.0% of the labeled amount of cloxacillin ($C_{19}H_{18}ClN_3O_5S$).

ASSAY

• **Procedure**

Buffer: 0.02 M monobasic potassium phosphate in water, adjusted with 2 N sodium hydroxide to a pH of 6.8

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

Standard solution: 0.55 mg/mL of USP Cloxacillin Sodium RS in *Buffer*

Sample solution: Nominally 0.5 mg/mL of cloxacillin in *Buffer*, prepared as follows. Mix the contents of NLT 10 Capsules. Transfer a suitable portion of the powder to a volumetric flask, dilute with *Buffer* to volume, and stir for 10 min. Pass a portion of the solution through a suitable filter, discarding the first 5 mL of the filtrate. Use the clear filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.8

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cloxacillin ($C_{19}H_{18}ClN_3O_5S$) in the portion of Capsules taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = nominal concentration of cloxacillin in the *Sample solution* (mg/mL)

P = potency of cloxacillin in USP Cloxacillin Sodium RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.05 M pH 6.8 potassium phosphate buffer; 900 mL

Apparatus 1: 100 rpm

Time: 30 min

Buffer, Mobile phase, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Standard solution: USP Cloxacillin Sodium RS in *Medium*

Sample solution: Sample per the chapter.

Tolerances: NLT 80% (*Q*) of the labeled amount of cloxacillin ($C_{19}H_{18}ClN_3O_5S$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

SPECIFIC TESTS

• **Water Determination ⟨921⟩, *Method I*:** NMT 5.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards ⟨11⟩**
USP Cloxacillin Sodium RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CLOXACILLIN SODIUM CAPSULES	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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