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Dicloxacillin Sodium Capsules

DEFINITION

Dicloxacillin Sodium Capsules contain NLT 90.0% and NMT 120.0% of the labeled amount of dicloxacillin ($C_{19}H_{17}Cl_2N_3O_5S$).

IDENTIFICATION

• **A.** The retention time of the dicloxacillin peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Buffer: 2.72 g/L of monobasic potassium phosphate in water, adjusted with 8 N potassium hydroxide to a pH of 5.0 ± 0.1

Mobile phase: Acetonitrile and *Buffer* (50:150)

Standard solution: 1.1 mg/mL of USP Dicloxacillin Sodium RS in *Buffer*. Use the *Standard solution* promptly, or refrigerate and use on the day prepared.

Sample solution: Nominally 1 mg/mL of dicloxacillin in *Buffer*, prepared as follows. Remove, as completely as possible, the contents of NLT 10 Capsules. Transfer a suitable portion of the powder to a volumetric flask, dilute with *Buffer* to volume, and mix for 10 min with the aid of a magnetic stirrer. Pass a portion of the solution through a suitable filter, discarding the first 5 mL of the filtrate. Use the clear filtrate. Use the *Sample solution* promptly, or refrigerate and use on the day prepared.

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 700 theoretical plates

Tailing factor: NMT 2.0

Capacity factor: 4–11

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dicloxacillin ($C_{19}H_{17}Cl_2N_3O_5S$) 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 area from the *Sample solution*

r_S = peak area from the *Standard solution*

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

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

P = potency of dicloxacillin in USP Dicloxacillin Sodium RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

Change to read:

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Time: 30 min

Standard solution: USP Dicloxacillin Sodium RS in *Medium*

Sample solution: Sample per the chapter. ▲Pass a portion of the solution under test through a suitable filter.▲ (ERR 1-Mar-2020) Dilute with *Medium* to a concentration that is similar to the *Standard solution*.

▲Instrumental conditions

Mode: UV-Vis▲ (ERR 1-Mar-2020)

Tolerances: NLT 75% (*Q*) of the labeled amount of dicloxacillin ($C_{19}H_{17}Cl_2N_3O_5S$) 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 Dicloxacillin Sodium RS

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

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

Chromatographic Database Information: Chromatographic Database

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