Status: Currently Official on 14-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-8FB50DE7-F41A-4106-8E81-F8EA0F2F4080_1_en-US
DOI: https://doi.org/10.31003/USPNF_M19030_01_01
DOI Ref: 60wjt

Cloxacillin Sodium for Oral Solution

DEFINITION

Cloxacillin Sodium for Oral Solution is a dry mixture of Cloxacillin Sodium and one or more suitable buffers, colors, flavors, and preservatives. It contains 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 of 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. Constitute Cloxacillin Sodium for Oral Solution as directed in the labeling. Transfer a suitable portion of the resulting solution to a volumetric flask, dilute with *Buffer* to volume, mix, and stir for 15 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 Cloxacillin Sodium for Oral Solution 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

• **Deliverable Volume ⟨698⟩:** Meets the requirements

• **Uniformity of Dosage Units ⟨905⟩**

For solids packaged in single-unit containers

Acceptance criteria: Meets the requirements

SPECIFIC TESTS

- **pH** ⟨791⟩

  Sample solution: Constitute as directed in the labeling.

  Acceptance criteria: 5.0–7.5

- **Water Determination** ⟨921⟩, *Method I*: NMT 1.0%

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 FOR ORAL SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 28(4)

Current DocID: GUID-8FB50DE7-F41A-4106-8E81-F8EA0F2F4080_1_en-US

DOI: https://doi.org/10.31003/USPNF_M19030_01_01

DOI ref: 60wjt