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Baclofen Tablets

DEFINITION

Baclofen Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of baclofen ($C_{10}H_{12}ClNO_2$).

IDENTIFICATION

- **A.** The retention time of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

- **Procedure**

Solution A: 1.4 g/L of monobasic sodium phosphate and 1.7 g/L of sodium 1-pentanesulfonate in water. Adjust with 1.5 M phosphoric acid TS to a pH of 3.0.

Solution B: Acetonitrile and methanol (50:50)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	65	35
5	65	35
15	45	55
25	45	55
27	65	35
35	65	35

Diluent: *Solution A* and *Solution B* (65:35)

Standard solution: 200 µg/mL of USP Baclofen RS in *Diluent*

Sample solution: Nominally 200 µg/mL of baclofen prepared as follows. Finely powder NLT 20 Tablets and transfer a portion of the powder to an appropriate volumetric flask. Add *Diluent* to about 80% of the flask volume, sonicate for 10 min, and shake by mechanical means for 30 min. Dilute with *Diluent* to volume. Centrifuge a portion of this solution and use the supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 225 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 35°

Flow rate: 0.8 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of baclofen ($C_{10}H_{12}ClNO_2$) in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Baclofen RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of baclofen in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩, *Procedure*, *Apparatus 1 and Apparatus 2*, *Immediate-Release Dosage Forms*, *Procedure for a pooled sample for immediate-release dosage forms*

Medium: 0.01 N hydrochloric acid; 500 mL for Tablets containing NMT 10 mg of baclofen; 1000 mL for Tablets containing more than 10 mg of baclofen

Apparatus 2: 50 rpm

Time: 30 min

Solution A: 62.7 g/L of sodium 1-pentanesulfonate in water

Mobile phase: Methanol, 0.3 N acetic acid, and *Solution A* (44:55:2)

Standard solution: USP Baclofen RS in *Medium*

Sample solution: Use a portion of the solution under test.

Chromatographic system

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

Mode: LC

Detector: UV 265 nm

Column: 3.9-mm × 30-cm; 10-µm packing L1

Flow rate: 0.6 mL/min

Injection volume: 190 µL

Run time: NLT 2 times the retention time of the baclofen peak

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of baclofen ($C_{10}H_{12}ClNO_2$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

V = volume of *Medium*; 500 or 1000 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (*Q*) of the labeled amount of baclofen ($C_{10}H_{12}ClNO_2$) is dissolved.

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

IMPURITIES

• **Organic Impurities**

Solution A, Solution B, Mobile phase, Diluent, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.4 µg/mL of USP Baclofen RS and 8 µg/mL of USP Baclofen Related Compound A RS in *Diluent*

System suitability

Sample: *Standard solution*

[Note—See *Table 2* for the relative retention times.]

Suitability requirements

Tailing factor: NMT 1.5 for baclofen

Relative standard deviation: NMT 5.0% each for baclofen and baclofen related compound A

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of baclofen related compound A in the portion of Tablets taken:

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

r_U = peak response of baclofen related compound A from the *Sample solution*

r_S = peak response of baclofen related compound A from the *Standard solution*

C_S = concentration of USP Baclofen Related Compound A RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of baclofen in the *Sample solution* (µg/mL)

Calculate the percentage of any individual degradation product in the portion of Tablets taken:

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

r_U = peak response of any individual degradation product from the *Sample solution*

r_S = peak response of baclofen from the *Standard solution*

C_S = concentration of USP Baclofen RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of baclofen in the *Sample solution* (µg/mL)

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Baclofen	1.0	—
Baclofen related compound A	3.0	4.0
Any individual degradation product	—	0.2
Total degradation products	—	1.0[a]

[a] Baclofen related compound A is not included in the total degradation products.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers. Store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩

USP Baclofen RS

USP Baclofen Related Compound A RS

4-(4-Chlorophenyl)-2-pyrrolidinone.
$C_{10}H_{10}ClNO$ 195.65

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

Topic/Question	Contact	Expert Committee
BACLOFEN TABLETS	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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