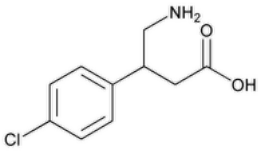
Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-01B40006-3842-4FF8-A971-07AAEA2AA26B_4_en-US
DOI: https://doi.org/10.31003/USPNF_M6940_04_01
DOI Ref: e5j21

Baclofen



$C_{10}H_{12}ClNO_2$ 213.66

Butanoic acid, 4-amino-3-(4-chlorophenyl)-;

β-(Aminomethyl)-*p*-chlorohydrocinnamic acid CAS RN®: 1134-47-0; UNII: H789N3FKE8.

DEFINITION

Baclofen contains NLT 98.0% and NMT 102.0% of baclofen ($C_{10}H_{12}ClNO_2$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197M**▲ (CN 1-May-2020)

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

ASSAY

• **Procedure**

Solution A: Dissolve 1.38 g of potassium dihydrogen phosphate and 1.74 g of sodium-1-pentanesulfonate in 1 L of water. Adjust with dilute phosphoric acid to a pH of 3.0.

Solution B: Acetonitrile and methanol (1:1)

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

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
30	65	35

Standard solution: 0.2 mg/mL of USP Baclofen RS in *Diluent*

Sample solution: 0.2 mg/mL of Baclofen in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 25.0-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 1.5

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of baclofen ($C_{10}H_{12}ClNO_2$) in the portion of the Baclofen 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* (mg/mL)

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

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.3%
- **Organic Impurities**

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

Standard solution: 0.0015 mg/mL of USP Baclofen RS and 0.003 mg/mL of USP Baclofen Related Compound A RS in *Diluent*

Sample solution: 0.3 mg/mL of Baclofen in *Diluent*

System suitability

Sample: *Standard solution*

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

Suitability requirements

Tailing factor: NMT 1.5 for baclofen

Relative standard deviation: NMT 5.0% for both 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 the Baclofen 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* (mg/mL)

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

Calculate the percentage of any unspecified impurity in the portion of the Baclofen taken:

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

r_U = peak response of any unspecified impurity 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* (mg/mL)

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

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Baclofen	1.0	—
Baclofen related compound A	2.3	1.0
Any individual unspecified impurity	—	0.10
Total impurities	—	2.0

SPECIFIC TESTS

• **Water Determination, *Method I* ⟨921⟩:** NMT 3.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers. Store at 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	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 38(2)

Current DocID: GUID-01B40006-3842-4FF8-A971-07AAEA2AA26B_4_en-US

DOI: https://doi.org/10.31003/USPNF_M6940_04_01

DOI ref: e5j21