

Status: Currently Official on 13-Feb-2025
 Official Date: Official as of 01-Aug-2022
 Document Type: USP Monographs
 DocId: GUID-80AB9C5B-A4D9-4E9D-BC62-A79872610DC9_5_en-US
 DOI: https://doi.org/10.31003/USPNF_M6945_05_01
 DOI Ref: 9z24n

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Baclofen Injection

DEFINITION

Baclofen Injection is a sterile solution of Baclofen in Water for Injection. It contains NLT 95.0% and NMT 105.0% 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 baclofen in the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Mobile phase: 5.0 g/L of [sodium dodecyl sulfate](#) prepared as follows. Transfer a suitable portion of [sodium dodecyl sulfate](#) to an appropriate volumetric flask. Add 50% of the flask volume of [water](#) and then 0.5% of the flask volume of [phosphoric acid](#). Add 40% of the flask volume of [acetonitrile](#). Dilute with [water](#) to volume.

System suitability stock solution 1: 200 µg/mL of [USP Baclofen Related Compound A RS](#) prepared as follows. Transfer a suitable portion of [USP Baclofen Related Compound A RS](#) to an appropriate volumetric flask. Dissolve in 10% of the flask volume of [acetonitrile](#). Dilute with [water](#) to volume.

System suitability stock solution 2: 20 µg/mL of [USP Baclofen Related Compound A RS](#) from *System suitability stock solution 1*, in [water](#)

Standard stock solution: 500 µg/mL of [USP Baclofen RS](#) in [water](#)

System suitability solution: 0.5 µg/mL of [USP Baclofen Related Compound A RS](#) from *System suitability stock solution 2* and 50 µg/mL of [USP Baclofen RS](#) from *Standard stock solution* in [water](#)

Standard solution: 50 µg/mL of [USP Baclofen RS](#) in [water](#)

Sample solution: Nominally 50 µg/mL of baclofen from Injection. Use a portion of Injection. Dilute with [water](#), if necessary.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 218 nm. For *Identification B*, use a diode array detector in the range of 210–400 nm.

Column: 4.6-mm × 25-cm; 10-µm packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 50 µL

Run time: NLT 1.6 times the retention time of baclofen

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—See [Table 1](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 4.0 between baclofen related compound A and baclofen, *System suitability solution*

Tailing factor: NMT 1.5 for baclofen, *System suitability solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

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 Injection 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: 95.0%–105.0%

IMPURITIES• **ORGANIC IMPURITIES**

Mobile phase, System suitability stock solution 1, System suitability stock solution 2, Standard stock solution, System suitability solution,

Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Sensitivity solution: 0.05 µg/mL of [USP Baclofen RS](#) in [water](#)

Standard solution: 0.5 µg/mL of [USP Baclofen Related Compound A RS](#) from *System suitability stock solution 2* and 0.25 µg/mL of [USP Baclofen RS](#) from *Standard stock solution* in [water](#)

System suitability

Samples: *System suitability solution, Sensitivity solution, and Standard solution*

[NOTE—See [Table 1](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 4.0 between baclofen related compound A and baclofen, *System suitability solution*

Relative standard deviation: NMT 5.0% each for baclofen related compound A and baclofen, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Sample solution and Standard solution*

Calculate the percentage of baclofen related compound A in the portion of Injection 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 other impurity in the portion of Injection taken:

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

r_U = peak response of any other 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* (µg/mL)

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

Acceptance criteria: See [Table 1](#). The reporting threshold is 0.1%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Baclofen related compound A	0.5	1.0
Baclofen	1.0	—
Any other impurity	—	0.5
Total impurities	—	1.5

SPECIFIC TESTS

- [pH \(791\)](#): 5.0–7.5
- [PARTICULATE MATTER IN INJECTIONS \(788\)](#): Meets the requirements for small-volume injections
- [STERILITY TESTS \(71\)](#): Meets the requirements

Change to read:

- [▲ OSMOLALITY AND OSMOLARITY \(785\)](#)

Osmolality: 270–320 mOsm/kg▲ (ERR 1-Aug-2022)

- [BACTERIAL ENDOTOXINS TEST \(85\)](#): Meets the requirements
- **OTHER REQUIREMENTS:** Meets the requirements in [Injections and Implanted Drug Products \(1\)](#).