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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⟩

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers. Do not freeze. 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 INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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