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Baclofen Compounded Oral Suspension

DEFINITION

Baclofen Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of baclofen ($C_{10}H_{12}ClNO_2$).

Prepare Baclofen Compounded Oral Suspension 5 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Baclofen	500 mg
Vehicle: a 1:1 mixture of Vehicle for Oral Solution (regular or sugar-free), <i>NF</i> , and Vehicle for Oral Suspension, <i>NF</i> , a sufficient quantity to make	100 mL

If using [Baclofen Tablets](#), place the Tablets in a suitable mortar and comminute to a fine powder, or add *Baclofen* powder. Add 5 mL of the *Vehicle* to wet the powder, and triturate the powder to form a fine paste. Add the *Vehicle* in small portions almost to volume, and mix thoroughly after each addition. Transfer, stepwise and quantitatively, the contents of the mortar to a calibrated bottle. Add sufficient *Vehicle* to bring to final volume, and mix well.

ASSAY

• **PROCEDURE**

Mobile phase: Acetonitrile and 0.05 M monobasic sodium phosphate (20:80). Adjust with phosphoric acid to a pH of 3.5.

Standard solution: 5 µg/mL of [USP Baclofen RS](#) in water

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Pipet 0.5 mL of Oral Suspension from each bottle to a 500-mL volumetric flask, dilute with water to volume to obtain a concentration of 5 µg/mL, and pass through a 0.22-µm polyvinylidene fluoride (PVDF) filter.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

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

Flow rate: 1 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time of baclofen is about 5.5 min.]

Suitability requirements

Relative standard deviation: NMT 2.0% for replicate injections

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 Oral Suspension 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%

SPECIFIC TESTS

• **pH (791):** 4.2–5.2

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store in a refrigerator.
- **BEYOND-USE DATE:** NMT 35 days after the day on which it was compounded when stored in a refrigerator
- **LABELING:** Label it to state that it is to be well shaken, and to state the *Beyond-Use Date*.
- **USP REFERENCE STANDARDS (11).**
[USP Baclofen RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
BACLOFEN COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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