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Labetalol Hydrochloride Compounded Oral Suspension

DEFINITION
Labetalol Hydrochloride Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of labetalol hydrochloride ($C_{19}H_{24}N_2O_3 \cdot HCl$).
Prepare Labetalol Hydrochloride Compounded Oral Suspension 40 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Labetalol Hydrochloride	4 g
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

Place the required number of tablets in a suitable mortar and comminute to a fine powder, or use *Labetalol Hydrochloride* powder. Add 20 mL of the *Vehicle*, and mix to form a uniform paste. Add the *Vehicle* in small portions almost to volume. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add the *Vehicle* in portions to rinse the mortar, then add sufficient *Vehicle* to bring to final volume, and mix well.

ASSAY

• **PROCEDURE**
Mobile phase: Methanol and 0.1 M monobasic sodium phosphate (35:65). Filter, and degas.
Standard solution: 400 µg/mL of [USP Labetalol Hydrochloride RS](#)
Sample solution: Agitate the container of Oral Suspension for 30 min on a rotating mixer, remove a 5-mL sample, and store in a clear glass vial at -70° until analyzed. At the time of analysis, remove the sample from the freezer, allow it to reach room temperature, and mix with a vortex mixer for 30 s. Pipet 1.0 mL of the sample into a 100-mL volumetric flask, and dilute with *Mobile phase* to volume.
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)
Mode: LC
Detector: UV 230 nm
Column: 4.6-mm × 25-cm; 5-µm packing L1
Flow rate: 1.3 mL/min
Injection volume: 20 µL
System suitability
Sample: *Standard solution*
[NOTE—The retention time for labetalol hydrochloride is about 7.5 min.]
Suitability requirements
Relative standard deviation: NMT 1.6% for replicate injections
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of labetalol hydrochloride ($C_{19}H_{24}N_2O_3 \cdot HCl$) in the portion of Oral Suspension taken:

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 Labetalol Hydrochloride RS](#) in the *Standard solution* (µg/mL)

C_u = nominal concentration of labetalol hydrochloride in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH** (791): 4.0–5.0

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at controlled room temperature, or in a refrigerator.
- **BEYOND-USE DATE:** NMT 60 days after the date on which it was compounded when stored at controlled room temperature, or 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 Labetalol Hydrochloride RS](#)

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

Topic/Question	Contact	Expert Committee
LABETALOL HYDROCHLORIDE 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](#)

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