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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), *NF*, and Vehicle for Oral Suspension, *NF*, 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:

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

$r_U$ = peak response from the *Sample solution*

$r_S$ = peak response from the *Standard solution*

$C_S$ = concentration of USP 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<br>Science Program Manager | CMP2020 Compounding 2020 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | CMP2020 Compounding 2020 |

**Chromatographic Database Information:** Chromatographic Database

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