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# Labetalol Hydrochloride Tablets

» Labetalol Hydrochloride Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of labetalol hydrochloride ($C_{19}H_{24}N_2O_3 \cdot HCl$).

**Packaging and storage**—Preserve in tight, light-resistant containers, at a temperature between 2° and 30°.

**USP Reference standards ⟨11⟩**—
USP Labetalol Hydrochloride RS

**Identification**—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation,* as obtained in the *Assay*.

**Dissolution ⟨711⟩**—
*Medium:* water; 900 mL.
*Apparatus 2:* 50 rpm.
*Time:* 45 minutes.
*Procedure*—Determine the amount of $C_{19}H_{24}N_2O_3 \cdot HCl$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 302 nm of filtered portions of the solution under test, suitably diluted with water, if necessary, in comparison with a Standard solution having a known concentration of USP Labetalol Hydrochloride RS in the same *Medium*.
*Tolerances*—Not less than 80% *(Q)* of the labeled amount of $C_{19}H_{24}N_2O_3 \cdot HCl$ is dissolved in 45 minutes.

**Uniformity of dosage units ⟨905⟩:** meet the requirements.

**Assay**—
*Mobile phase*, *Standard preparation,* and *Chromatographic system*—Proceed as directed in the *Assay* under *Labetalol Hydrochloride*.
*Assay preparation*—Transfer an accurately counted number of Tablets, equivalent to about 2000 mg of labetalol hydrochloride, to a 500-mL volumetric flask, add 200 mL of water, and shake by mechanical means for 60 minutes. Dilute with water to volume, and mix. Filter the solution through a filter of 0.5 µm or finer porosity, discarding the first few mL of the filtrate. Transfer 10.0 mL of the filtrate to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.
*Procedure*—Separately inject equal volumes (about 5 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the area responses for the major peaks. Calculate the quantity, in mg, of labetalol hydrochloride ($C_{19}H_{24}N_2O_3 \cdot HCl$) in each Tablet taken by the formula:

$$5000(C/N)(r_U/r_S)$$

in which $C$ is the concentration, in mg per mL, of USP Labetalol Hydrochloride RS in the *Standard preparation;* N is the number of Tablets taken; and $r_U$ and $r_S$ are the peak area responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.



**Auxiliary Information** - Please check for your question in the FAQs before contacting USP.

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| LABETALOL HYDROCHLORIDE TABLETS | Documentary Standards Support | SM22020 Small Molecules 2 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM22020 Small Molecules 2 |

**Chromatographic Database Information:** Chromatographic Database

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