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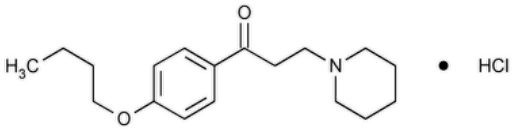
# Dyclonine Hydrochloride




$C_{18}H_{27}NO_2 \cdot HCl$ 325.87

1-Propanone, 1-(4-butoxyphenyl)-3-(1-piperidinyl)-hydro chloride.

4'-Butoxy-3-piperidinopropiophenone hydrochloride CAS RN®: 536-43-6; UNII: ZEC193879Q.

» Dyclonine Hydrochloride contains not less than 98.0 percent and not more than 102.0 percent of $C_{18}H_{27}NO_2 \cdot HCl$, calculated on the dried basis.

**Packaging and storage**—Preserve in tight, light-resistant containers.

**USP Reference standards** ⟨11⟩—

USP Dyclonine Hydrochloride RS

**Identification**—

***Change to read:***

**A:** ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197M*▲ (CN 1-May-2020) ·

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

**C:** Add 2 mL of silver nitrate TS to 10 mL of Dyclonine Hydrochloride solution (1 in 100): a white precipitate is formed. Add 2 mL of nitric acid, centrifuge, and discard the supernatant. Wash the precipitate twice by adding 10 mL of 2 N nitric acid, centrifuging, and discarding the supernatant: the precipitate so obtained is soluble in 6 N ammonium hydroxide.

**Melting range** ⟨741⟩**:** between 173° and 178°.

**pH** ⟨791⟩**:** between 4.0 and 7.0, in a solution (1 in 100).

**Loss on drying** ⟨731⟩—Dry it at 105° for 1 hour: it loses not more than 1.0% of its weight.

**Residue on ignition** ⟨281⟩**:** not more than 0.2%.

**Assay**—

*Mobile phase, Standard preparation,* and *Chromatographic system*—Proceed as directed in the *Assay* under *Dyclonine Hydrochloride Gel*.

*Assay preparation*—Transfer about 50 mg of Dyclonine Hydrochloride, accurately weighed, to a 500-mL volumetric flask, dissolve in 0.001 N phosphoric acid, dilute with 0.001 N phosphoric acid to volume, and mix.

*Procedure*—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{18}H_{27}NO_2 \cdot HCl$ in the portion of Dyclonine Hydrochloride taken by the formula:

$$500C(r_U/r_S)$$

in which $C$ is the concentration, in mg per mL, of USP Dyclonine Hydrochloride RS in the *Standard preparation;* and $r_U$ and $r_S$ are the peak 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 |
|---|---|---|
| DYCLONINE HYDROCHLORIDE | Documentary Standards Support | SM52020 Small Molecules 5 |

**Chromatographic Database Information:** Chromatographic Database

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