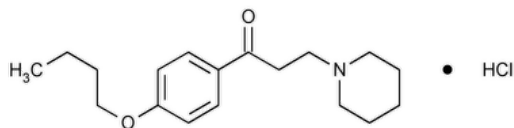


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Dyclonine Hydrochloride



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