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Dyclonine Hydrochloride Topical Solution

» Dyclonine Hydrochloride Topical Solution is a sterile, aqueous solution of Dyclonine Hydrochloride. It contains not less than 92.0 percent and not more than 108.0 percent of the labeled amount of $C_{18}H_{27}NO_2 \cdot HCl$. It may contain suitable stabilizers and antimicrobial agents.

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

USP Reference standards ⟨11⟩—
USP Dyclonine Hydrochloride RS

Identification—To a volume of Topical Solution, equivalent to about 300 mg of dyclonine hydrochloride, add 15 mL of chloroform, shake, and allow the layers to separate. Remove a portion of the chloroform solution, evaporate on a steam bath to dryness, and dry the residue at 105° for 1 hour: the dyclonine hydrochloride so obtained responds to the *Identification* tests under *Dyclonine Hydrochloride*.

Sterility Tests ⟨71⟩: meets the requirements.

pH ⟨791⟩: between 3.0 and 5.0.

Assay—

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

Assay preparation—Transfer an accurately measured volume of Topical Solution, equivalent to about 50 mg of dyclonine hydrochloride, to a 500-mL volumetric flask. Dilute with water 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 each mL of the Topical Solution taken by the formula:

$$500(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Dyclonine Hydrochloride RS in the *Standard preparation*, V is the volume, in mL, of the Topical Solution taken, 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 TOPICAL SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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