Status: Currently Official on 14-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-933A5586-17B1-4E50-9E86-5589336C3F6D_2_en-US
DOI: https://doi.org/10.31003/USPNF_M28650_02_01
DOI Ref: soz1c

Dyclonine Hydrochloride Gel

» Dyclonine Hydrochloride Gel contains not less than 90.0 percent and not more than 110.0 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 collapsible, opaque plastic tubes or in tight, light-resistant glass containers. [NOTE—Do not use aluminum or tin tubes.]

USP REFERENCE STANDARDS ⟨11⟩—
USP Dyclonine Hydrochloride RS

Identification—Shake a portion of Gel, equivalent to about 400 mg of dyclonine hydrochloride, with 25 mL of chloroform, and allow the layers to separate. Remove the chloroform layer, 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*.

pH ⟨791⟩: between 2.0 and 4.0.

Assay—

Mobile phase—Dissolve 0.20 g of monobasic potassium phosphate and 0.45 mL of *n*-heptylamine in about 350 mL of water. Adjust with phosphoric acid to a pH of 3.0, dilute with water to 400 mL, add 600 mL of acetonitrile, and mix.

Standard preparation—Dissolve an accurately weighed quantity of USP Dyclonine Hydrochloride RS in 0.001 N phosphoric acid to obtain a solution having a known concentration of about 0.1 mg per mL.

Assay preparation—Transfer an accurately measured portion of Gel, equivalent to about 5.0 mg of dyclonine hydrochloride, to a 50-mL volumetric flask. Add 10 mL of 0.001 N phosphoric acid, and sonicate to dissolve the gel. Dilute with 0.001 N phosphoric acid to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 25-cm column that contains 5-µm diameter packing L13. The flow rate is about 1.2 mL per minute. Adjust the flow rate, if necessary, so that the retention time of dyclonine hydrochloride is not less than 5 minutes. Chromatograph five replicate injections of the *Standard preparation*, and record the peak responses as directed for *Procedure:* the tailing factor is not more than 2.0 and the relative standard deviation is not more than 3.0%.

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 dyclonine hydrochloride ($C_{18}H_{27}NO_2 \cdot HCl$) in the portion of Gel taken by the formula:

$$50C(r_U/r_S)$$

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 GEL	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-933A5586-17B1-4E50-9E86-5589336C3F6D_2_en-US
Previous DocID: GUID-933A5586-17B1-4E50-9E86-5589336C3F6D_1_en-US
DOI: https://doi.org/10.31003/USPNF_M28650_02_01
DOI ref: soz1c