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Procyclidine Hydrochloride Tablets

» Procyclidine Hydrochloride Tablets contain not less than 93.0 percent and not more than 107.0 percent of the labeled amount of $C_{19}H_{29}NO \cdot HCl$.

Packaging and storage—Preserve in tight containers, and store in a dry place.

USP Reference standards ⟨11⟩—
USP Procyclidine Hydrochloride RS

Identification—

A: Triturate a portion of finely powdered Tablets, equivalent to about 10 mg of procyclidine hydrochloride, with 20 mL of chloroform, filter, evaporate the filtrate on a steam bath to dryness, and dry the residue at 105° for 1 hour: the IR absorption spectrum of a potassium bromide dispersion of the procyclidine hydrochloride so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Procyclidine Hydrochloride RS.

B: A portion of finely powdered Tablets, equivalent to about 50 mg of procyclidine hydrochloride, responds to *Identification* test *B* under *Procyclidine Hydrochloride*.

Dissolution, *Procedure for a Pooled Sample* ⟨711⟩—

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_{19}H_{29}NO \cdot HCl$ dissolved, employing the procedure set forth in the *Assay*, making any necessary modifications.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{19}H_{29}NO \cdot HCl$ is dissolved in 45 minutes.

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

Related compounds—Using a portion of powdered Tablets, equivalent to 200 mg of procyclidine hydrochloride, proceed as directed in the test for *Related compounds* under *Procyclidine Hydrochloride*.

Assay—

Bromocresol purple solution—Dissolve 250 mg of bromocresol purple in dilute glacial acetic acid (1 in 50) to make 1000 mL.

Standard preparation—Transfer about 25 mg of USP Procyclidine Hydrochloride RS, accurately weighed, to a 100-mL volumetric flask, add water to volume, and mix. Transfer 10.0 mL of this solution to a second 100-mL volumetric flask, dilute with *Bromocresol purple solution* to volume, and mix. The concentration of the *Standard preparation* is about 25 µg per mL.

Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 2.5 mg of procyclidine hydrochloride, to a 100-mL volumetric flask, add 10.0 mL of water, and mix. Dilute with *Bromocresol purple solution* to volume, mix, and allow the undissolved particles to settle. Use the supernatant as directed in the *Procedure*.

Procedure—Transfer 5.0 mL each of the *Standard preparation* and the *Assay preparation* to individual 60-mL separators. Transfer 0.5 mL of water and 4.5 mL of *Bromocresol purple solution* to a third separator to provide the blank. Extract each solution with 20.0 mL of chloroform, and filter each extract, discarding the first 5 mL of the filtrate. Concomitantly determine the absorbance of each subsequent filtrate in a 1-cm cell at the wavelength of maximum absorbance at about 405 nm, with a suitable spectrophotometer, against the blank. Calculate the quantity, in mg, of $C_{19}H_{29}NO \cdot HCl$ in the portion of Tablets taken by the formula:

$$0.1C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Procyclidine Hydrochloride RS in the *Standard preparation*, and A_U and A_S are the absorbances of the solutions from the *Assay preparation* and the *Standard preparation*, respectively.

Topic/Question	Contact	Expert Committee
PROCYCLIDINE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

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