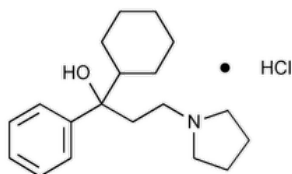


Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-FD2B6ACE-2FD0-4771-8327-DC17575BCE80_2_en-US
DOI: https://doi.org/10.31003/USPNF_M69790_02_01
DOI Ref: 0d6th

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Procyclidine Hydrochloride



$C_{19}H_{29}NO \cdot HCl$ 323.90

1-Pyrrolidinepropanol, α -cyclohexyl- α -phenyl-, hydrochloride.

α -Cyclohexyl- α -phenyl-1-pyrrolidinepropanol hydrochloride CAS RN®: 1508-76-5; UNII: CQC932Z7YW.

» Procyclidine Hydrochloride contains not less than 99.0 percent and not more than 101.0 percent of $C_{19}H_{29}NO \cdot HCl$, calculated on the dried basis.

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

USP REFERENCE STANDARDS (11)—

[USP Procyclidine Hydrochloride RS](#)

Identification—

Change to read:

A: ▲ [Spectroscopic Identification Tests \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-May-2020) ·

B: Dissolve about 250 mg in 10 mL of water in a separator, render alkaline with 6 N ammonium hydroxide, and extract with three 10-mL portions of ether. Filter the ether extracts slowly through a layer of about 2 g of anhydrous granular sodium sulfate supported on glass wool, evaporate the ether with a current of warm air, and scratch the surface of the container to induce crystallization of the residue: the procyclidine so obtained melts between 83° and 87°, the procedure for *Class I* being used (see [Melting Range or Temperature \(741\)](#)).

C: A solution (1 in 100) responds to the tests for [Chloride \(191\)](#).

pH (791): between 5.0 and 6.5, in a solution (1 in 100).

LOSS ON DRYING (731)—Dry it in vacuum at 105° for 4 hours: it loses not more than 0.5% of its weight.

RESIDUE ON IGNITION (281): not more than 0.1%.

Related compounds—Dissolve approximately 200 mg of Procyclidine Hydrochloride in 20 mL of water, and render the solution alkaline by adding 1.5 mL of 6 N ammonium hydroxide. Extract with three 15-mL portions of chloroform, wash the combined extracts with 20 mL of water, discard the water washing, and filter the chloroform solution through a layer of 3 to 4 g of anhydrous granular sodium sulfate supported on glass wool. Reduce the volume to 5 mL by evaporating with the aid of gentle heat and a current of air. Inject 2 μ L of this solution into a suitable gas chromatograph (see [Chromatography \(621\)](#)) equipped with a flame-ionization detector, and record the chromatogram to 2.5 relative to the retention time of the principal (procyclidine) peak. Under typical conditions, the instrument contains a 1-m $\times$ 2-mm glass column packed with 10% polyethylene glycol 20,000 and 2% potassium hydroxide on packing S1A. The column is maintained at a temperature of about 180°, the injection port is maintained at 210°, the detector block is maintained at about 220°, and dry helium is used as the carrier gas at a flow rate of about 60 mL per minute. From the total area under the curve, excluding the solvent peak, calculate the percentage of total impurities by area normalization: not more than 4.0% is found.

Assay—Dissolve about 700 mg of Procyclidine Hydrochloride, accurately weighed, in 75 mL of glacial acetic acid in a 250-mL beaker, warming, if necessary, to effect solution. Cool, add 10 mL of mercuric acetate TS, and titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 32.39 mg of $C_{19}H_{29}NO \cdot HCl$.

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. 46(5)

Current DocID: GUID-FD2B6ACE-2FD0-4771-8327-DC17575BCE80_2_en-US

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