Status: Currently Official on 17-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-F256D57F-9ABD-4A93-948E-F09F6997F581_2_en-US
DOI: https://doi.org/10.31003/USPNF_M21710_02_01
DOI Ref: 15y4a

Cyproheptadine Hydrochloride Tablets

» Cyproheptadine Hydrochloride Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{21}H_{21}N \cdot HCl$.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Cyproheptadine Hydrochloride RS

Identification—Tablets meet the requirements under *Identification—Organic Nitrogenous Bases* ⟨181⟩.

Dissolution ⟨711⟩—

Medium: 0.1 N hydrochloric acid; 900 mL.

Apparatus 2: 50 rpm.

Time: 30 minutes.

Procedure—Determine the amount of $C_{21}H_{21}N \cdot HCl$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 285 nm on filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Cyproheptadine Hydrochloride RS in the same *Medium*.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{21}H_{21}N \cdot HCl$ is dissolved in 30 minutes.

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

Assay—

Methanesulfonic acid solution—Prepare a solution of methanesulfonic acid in water (3:1000).

Mobile phase—Prepare a filtered and degassed mixture of acetonitrile, isopropyl alcohol, and *Methanesulfonic acid solution* (20:15:65); while mixing adjust with triethylamine to a pH of 4.0 ± 0.05. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Cyproheptadine Hydrochloride RS in *Mobile phase* to obtain a solution having a known concentration of about 0.08 mg per mL.

Assay preparation—Transfer a number of Tablets, accurately weighed, equivalent to 80 mg of cyproheptadine hydrochloride, to a 1-liter volumetric flask, dissolve by sonication in 500 mL of *Mobile phase* for 15 minutes, and agitate for 30 minutes. Dilute with *Mobile phase* to volume, and mix. Pass through a filter having a 0.45-µm or finer porosity.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 285-nm detector and a 3.9-mm × 15-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the tailing factor is not more than 2.5; and the relative standard deviation for replicate injections is not more than 2%.

Procedure—Separately inject equal volumes (about 10 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 $C_{21}H_{21}N \cdot HCl$ in each of the Tablets taken by the formula:

$$1000(C/N)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Cyproheptadine Hydrochloride RS in the *Standard preparation; N* is the number of Tablets taken for the *Assay preparation*; and r_U and r_S are the cyproheptadine 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
CYPROHEPTADINE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 43(1)

Current DocID: GUID-F256D57F-9ABD-4A93-948E-F09F6997F581_2_en-US
Previous DocID: GUID-F256D57F-9ABD-4A93-948E-F09F6997F581_1_en-US
DOI: https://doi.org/10.31003/USPNF_M21710_02_01
DOI ref: 15y4a