Status: Currently Official on 14-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-77E6EBD1-229F-4678-A3CE-4C2B7C2A65EC_1_en-US
DOI: https://doi.org/10.31003/USPNF_M16490_01_01
DOI Ref: 3mq1x

Chlorpheniramine Maleate Tablets

» Chlorpheniramine Maleate Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—
USP Chlorpheniramine Maleate RS

Identification—Disperse a portion of powdered Tablets, equivalent to about 25 mg of chlorpheniramine maleate, in about 20 mL of dilute hydrochloric acid (1 in 100). Dissolve about 25 mg of USP Chlorpheniramine Maleate RS in 20 mL of dilute hydrochloric acid (1 in 100). Treat each solution as follows. Render alkaline, to a pH of about 11, with sodium hydroxide solution (1 in 10). Extract with two 50-mL portions of solvent hexane, collect the extracts in a beaker, and evaporate to dryness. Prepare a mineral oil dispersion of the residue so obtained and determine the IR absorption spectrum of the preparation in the region between 2 µm and 12 µm: the spectrum of the test preparation exhibits maxima only at the same wavelengths as that of the Standard preparation.

Dissolution ⟨711⟩—
Medium: 0.01 N hydrochloric acid; 500 mL
Apparatus 2: 50 rpm.
Time: 30 minutes.
Procedure—Determine the amount of $C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 265 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 Chlorpheniramine Maleate RS in the same *Medium*.
Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$ is dissolved in 30 minutes.

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

Assay—Using a portion of powdered Tablets equivalent to 4 mg of chlorpheniramine maleate, proceed as directed under *Salts of Organic Nitrogenous Bases ⟨501⟩*, but using dilute hydrochloric acid (1 in 100) instead of the dilute sulfuric acid (1 in 350), and dilute sulfuric acid (1 in 70), and using solvent hexane instead of the ether, and diluting 10 mL of the *Assay preparation* with dilute hydrochloric acid (1 in 100) to 25.0 mL to prepare the solution employed for the determination of the absorbance, A_U, at 264 nm. For the determination of A_S, prepare a solution containing about 40 mg of USP Chlorpheniramine Maleate RS, accurately weighed, in 200.0 mL of dilute hydrochloric acid (1 in 100), and treat 20.0 mL of this solution the same as the solution in dilute hydrochloric acid (1 in 100) of the portion of Tablets taken. Calculate the quantity, in mg, of $C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$ in the portion of Tablets taken by the formula:

$$C(A_U/A_S)$$

in which C is the weight, in mg, of USP Chlorpheniramine Maleate RS in the 20.0-mL portion of the *Standard preparation*.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CHLORPHENIRAMINE MALEATE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 41(1)

Current DocID: GUID-77E6EBD1-229F-4678-A3CE-4C2B7C2A65EC_1_en-US

DOI: https://doi.org/10.31003/USPNF_M16490_01_01

DOI ref: 3mq1x