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Meclizine Hydrochloride Tablets

» Meclizine Hydrochloride Tablets contain not less than 95.0 percent and not more than 110.0 percent of the labeled amount of meclizine hydrochloride ($C_{25}H_{27}ClN_2 \cdot 2HCl$).

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—
USP Meclizine Hydrochloride RS

Identification—

A: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

B: *Thin-Layer Chromatographic Identification Test ⟨201⟩*—

Adsorbent: 0.5-mm layer of chromatographic silica gel mixture.

Test solution—Extract a quantity of finely powdered Tablets, equivalent to about 125 mg of meclizine hydrochloride, by shaking for 15 minutes with 50 mL of methanol.

Standard solution—Prepare a solution of USP Meclizine Hydrochloride RS in methanol, containing 2.5 mg per mL.

Application volume: 50 µL.

Developing solvent system: a mixture of cyclohexane, toluene, and diethylamine (15:3:2).

Procedure—Proceed as directed in the chapter, except to place the plate in a developing chamber that contains and has been equilibrated with *Developing solvent system*.

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

Medium: 0.01 N hydrochloric acid; 900 mL.

Apparatus 1: 100 rpm.

Time: 45 minutes.

Determine the amount of $C_{25}H_{27}ClN_2 \cdot 2HCl$ dissolved by employing the following method.

Mobile phase—Prepare a suitable degassed and filtered mixture of water and methanol (55:45) that contains 0.69 g of monobasic sodium phosphate in each 100 mL and is adjusted with phosphoric acid, if necessary, to a pH of 4.0.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 230-nm detector and a 4.6-mm × 25-cm analytical column that contains packing L9. The flow rate is about 2 mL per minute. Chromatograph replicate injections of the Standard solution, and record the peak responses as directed for *Procedure:* the relative standard deviation is not more than 2.0%.

Procedure—Inject about 100 µL of a filtered portion of the solution under test, suitably diluted with *Mobile phase,* if necessary, into the chromatograph, record the chromatogram, and measure the response for the major peak. Determine the amount of $C_{25}H_{27}ClN_2 \cdot 2HCl$ dissolved from the peak response obtained in comparison with the peak response obtained from a Standard solution having a known concentration of USP Meclizine Hydrochloride RS in a mixture of *Medium* and *Mobile phase* (1:1), similarly chromatographed. An amount of alcohol not to exceed 1% of the total volume of the Standard solution may be used to dissolve USP Meclizine Hydrochloride RS prior to dilution.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{25}H_{27}ClN_2 \cdot 2HCl$ is dissolved in 45 minutes.

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

Procedure for content uniformity—Place 1 Tablet in a 100-mL volumetric flask, add 50 mL of dilute hydrochloric acid (1 in 100), shake by mechanical means for 30 minutes, add the dilute acid to volume, and filter, discarding the first 20 mL of the filtrate. Dilute quantitatively and stepwise with the same acid to obtain a solution having a concentration of about 15 µg of meclizine hydrochloride per mL. Similarly, prepare a Standard solution of USP Meclizine Hydrochloride RS in dilute hydrochloric acid (1 in 100) having a known concentration of about 15 µg per mL. Concomitantly determine the absorbances of the solution from the Tablet and the Standard solution in 1-cm cells at the wavelength of maximum absorbance at about 232 nm, with a suitable spectrophotometer, using dilute hydrochloric acid (1 in 100) as the blank. Calculate

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the quantity, in mg, of meclizine hydrochloride ($C_{25}H_{27}ClN_2 \cdot 2HCl$) in the Tablet taken by the formula:

$$(T/D)C(A_U/A_S)$$

in which T is the quantity, in mg, of meclizine hydrochloride in the Tablet; D is the concentration, in µg per mL, of meclizine hydrochloride in the solution from the Tablet, on the basis of the labeled quantity per Tablet and the extent of dilution; C is the concentration, in µg per mL, of USP Meclizine Hydrochloride RS in the Standard solution; and A_U and A_S are the absorbances of the solution from the Tablet and the Standard solution, respectively.

Related compounds—

Mobile phase and *Buffer pH 7.5*—Prepare as directed in the *Assay.*

Standard solution—Dissolve an accurately weighed quantity of USP Meclizine Hydrochloride RS in *Mobile phase,* sonicating for about 5 minutes or until the material is dissolved, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.025 mg per mL. [NOTE—This solution is stable for 72 hours when stored at controlled room temperature protected from light.]

Sensitivity solution—Dilute an aliquot of the *Standard solution* with *Diluent* to obtain a solution containing about 1.25 µg per mL. [NOTE—Prepare this solution fresh daily.]

Test solution—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 250 mg of meclizine hydrochloride based on the label claim, to a 100-mL volumetric flask. Add about 50 mL of *Mobile phase* and shake by mechanical means for not less than 30 minutes. Dilute with *Mobile phase* to volume, mix, allow to settle for about 15 minutes, and pass through a 0.45-µm nylon filter, discarding the first 5 mL of the filtrate.

Chromatographic system (see *Chromatography ⟨621⟩*)—Prepare as directed in the *Assay.* Chromatograph the *Standard solution,* and record the peak responses as directed for *Procedure:* the column efficiency, *N,* is not less than 1200 theoretical plates; and the relative standard deviation for replicate injections is not more than 2.0%. Chromatograph the *Sensitivity solution,* and record the peak responses as directed for *Procedure:* the signal-to-noise ratio, S/N, is not less than 10.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard solution* and the *Test solution* into the chromatograph. Allow the *Test solution* to elute for not less than two times the retention time of meclizine hydrochloride. Record the chromatograms and measure all of the peak areas. Calculate the percentage of each impurity relative to the labeled content of meclizine hydrochloride in the portion of the Tablets taken by the formula:

$$100(1/F)(C_S/C_T)(r_i/r_S)$$

in which F is the relative response factor, which is equal to 0.72 for the 4-chlorobenzophenone peak eluting at a relative retention time of about 0.23 and equal to 1.0 for all other peaks; C_T is the concentration, in mg per mL, of meclizine hydrochloride in the *Test solution,* based on the label claim; C_S is the concentration, in mg per mL, of meclizine hydrochloride in the *Standard solution;* r_i is the peak response for each impurity obtained from the *Test solution;* and r_S is the response of the meclizine peak obtained from the *Standard solution:* not more than 0.5% of any individual impurity is found; and not more than 1.0% of total impurities is found. Reporting level for impurities is 0.1%.

Assay—

Buffer pH 7.5—Dissolve 1.32 g of dibasic ammonium phosphate in 1000 mL of water. Adjust with phosphoric acid to a pH of 7.5 ± 0.05.

Mobile phase—Prepare a mixture of *Buffer pH 7.5,* methanol, and acetonitrile (350:325:325). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Meclizine Hydrochloride RS in *Mobile phase,* sonicating for about 5 minutes or until the material is dissolved, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.125 mg per mL. [NOTE—This solution is stable for 72 hours when stored at controlled room temperature protected from light.]

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 12.5 mg of meclizine hydrochloride based on the label claim, to a 100-mL volumetric flask. Add about 50 mL of *Mobile phase*, and shake by mechanical means for not less than 30 minutes. Dilute with *Mobile phase* to volume, mix, and filter through a 0.45-µm nylon filter, discarding the first 5 mL of the filtrate.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 232-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L11. The column temperature is maintained at 30°, and the flow rate is about 2.0 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%.

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 percentage of the labeled amount of meclizine

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hydrochloride ($C_{25}H_{27}ClN_2 \cdot 2HCl$) in each Tablet taken by the formula:

$$100(CV/W)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of meclizine hydrochloride in the *Standard preparation; V* is the volume, in mL, of the *Assay preparation; W* is the quantity, in mg, of meclizine hydrochloride based on the label claim, taken to prepare the *Assay 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
MECLIZINE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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