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# Hydroxyzine Hydrochloride Tablets

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**DEFINITION**

Hydroxyzine Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of hydroxyzine hydrochloride ( $C_{21}H_{27}ClN_2O_2 \cdot 2HCl$ ).

**IDENTIFICATION**

- **A.** The retention time of the main peak of the *Sample solution* corresponds to that of the hydroxyzine peak of the *Standard solution*, as obtained in the Assay.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

**ASSAY**

• **PROCEDURE**

**Solution A:** [Trifluoroacetic acid](#) and [water](#) (0.1: 99.9)  
**Solution B:** [Trifluoroacetic acid](#) and [acetonitrile](#) (0.05: 99.95)  
**Mobile phase:** See [Table 1](#).

Table 1

| Time (min) | Solution A (%) | Solution B (%) |
|------------|----------------|----------------|
| 0          | 90             | 10             |
| 4          | 90             | 10             |
| 12         | 55             | 45             |
| 16         | 55             | 45             |
| 21         | 20             | 80             |
| 25         | 20             | 80             |
| 26         | 90             | 10             |
| 30         | 90             | 10             |

**Diluent:** [Acetonitrile](#) and [water](#) (30:70)  
**Standard solution:** 0.05 mg/mL of [USP Hydroxyzine Hydrochloride RS](#) in *Diluent*  
**Sample stock solution:** Nominally 0.5 mg/mL of hydroxyzine hydrochloride from Tablets in *Diluent* prepared as follows. Transfer a portion of finely powdered Tablets (NLT 10), equivalent to 50 mg of hydroxyzine hydrochloride, to a 100-mL volumetric flask and add 80 mL of *Diluent*. Sonicate for 30 min to dissolve and dilute with *Diluent* to volume. Centrifuge the solution and use the supernatant. [NOTE—The use of a centrifuge speed of 3000 rpm for 10 min may be suitable.]  
**Sample solution:** Nominally 0.05 mg/mL of hydroxyzine hydrochloride from the *Sample stock solution* in *Diluent*  
**Chromatographic system**  
(See [Chromatography \(621\), System Suitability](#).)  
**Mode:** LC  
**Detector:** UV 230 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.  
**Column:** 2.1-mm × 15-cm; 1.8-μm packing [L1](#)  
**Flow rate:** 0.3 mL/min  
**Injection volume:** 2 μL

**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 2.0**Relative standard deviation:** NMT 1.0%**Analysis****Samples:** *Standard solution and Sample solution*Calculate the percentage of the labeled amount of hydroxyzine hydrochloride ( $C_{21}H_{27}ClN_2O_2 \cdot 2HCl$ ) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

 $r_U$  = peak response from the *Sample solution* $r_S$  = peak response from the *Standard solution* $C_S$  = concentration of [USP Hydroxyzine Hydrochloride RS](#) in the *Standard solution* (mg/mL) $C_U$  = nominal concentration of hydroxyzine hydrochloride in the *Sample solution* (mg/mL)**Acceptance criteria:** 90.0%–110.0%**PERFORMANCE TESTS****Change to read:**

- [DISSOLUTION \(711\)](#).

**Test 1****Medium:** [Water](#); 900 mL**Apparatus 2:** 50 rpm**Time:** 45 min**Standard solution:** [USP Hydroxyzine Hydrochloride RS](#) in *Medium***Sample solution:** Use a filtered portion of the solution under test. Dilute with *Medium*, if necessary.**Instrumental conditions****Mode:** UV**Analytical wavelength:** Maximum absorbance at about 230 nm**Analysis****Samples:** *Standard solution and Sample solution*Determine the percentage of the labeled amount of hydroxyzine hydrochloride ( $C_{21}H_{27}ClN_2O_2 \cdot 2HCl$ ) dissolved from the UV absorbances.**Tolerances:** NLT 75% (Q) of the labeled amount of hydroxyzine hydrochloride ( $C_{21}H_{27}ClN_2O_2 \cdot 2HCl$ ) is dissolved.**Test 2:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.**Medium:** [Water](#); 250 mL**Apparatus 3:** 30 dips/min**Time:** 45 min**Standard solution:** [USP Hydroxyzine Hydrochloride RS](#) in *Medium***Sample solution:** Use a filtered portion of the solution under test. Dilute with *Medium*, if necessary.**Instrumental conditions****Mode:** UV**Analytical wavelength:** Maximum absorbance at about 230 nm**Analysis****Samples:** *Standard solution and Sample solution*Determine the percentage of the labeled amount of hydroxyzine hydrochloride ( $C_{21}H_{27}ClN_2O_2 \cdot 2HCl$ ) dissolved from the UV absorbances.**Tolerances:** NLT 75% (Q) of the labeled amount of hydroxyzine hydrochloride ( $C_{21}H_{27}ClN_2O_2 \cdot 2HCl$ ) is dissolved.**▲Test 3:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.**Medium:** 0.1 N [hydrochloric acid](#); 500 mL**Apparatus 2:** 50 rpm**Time:** 30 min**Buffer:** Dissolve 1.38 g of [potassium phosphate, monobasic](#) in 1 L of [water](#). Adjust with [phosphoric acid](#) to a pH of 2.5.**Mobile phase:** [Acetonitrile](#) and *Buffer* (40:60)**Standard solution:** 0.02 mg/mL of [USP Hydroxyzine Hydrochloride RS](#) in *Medium*. Sonicate to dissolve, if necessary.**Sample solution:** Pass a portion of the solution under test through a suitable filter of 10-μm pore size. Dilute with *Medium* to a concentration similar to that of the *Standard solution*, if necessary. Pass through a suitable filter of 0.4-μm pore size, discarding an appropriate volume of filtrate so that a consistent result can be obtained.