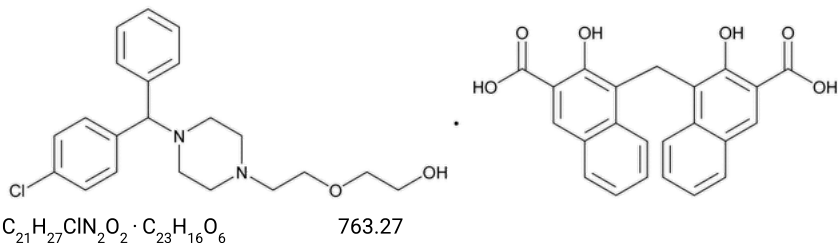


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Hydroxyzine Pamoate



Ethanol, 2-[2-[4-[(4-chlorophenyl)phenylmethyl]-1-piperazinyl]ethoxy]-, (±)-, compd. with 4,4'-methylenebis[3-hydroxy-2-naphthalenecarboxylic acid] (1:1);
(±)-2-[2-[4-(*p*-Chloro- α -phenylbenzyl)-1-piperazinyl]ethoxy]ethanol 4,4'-methylenebis[3-hydroxy-2-naphthoate] (1:1) CAS RN®: 10246-75-0;
UNII: M20215MUFR.

DEFINITION

Hydroxyzine Pamoate contains NLT 97.0% and NMT 102.0% of hydroxyzine pamoate ($C_{21}H_{27}ClN_2O_2 \cdot C_{23}H_{16}O_6$), calculated on the anhydrous basis.

IDENTIFICATION

- A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** [NOTE—Methods described in (197K) or (197A) may be used.]
- B.** The retention time of the hydroxyzine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• **PROCEDURE**

Solution A: To each L of water, add 1.0 mL of [stronger ammonia water](#).

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
6	80	20
20	20	80
25	20	80
26	80	20
30	80	20

Diluent: [Acetonitrile](#) and *Solution A* (80:20)
System suitability solution: 1 µg/mL of [USP Hydroxyzine Pamoate RS](#), 3 µg/mL of [USP Hydroxyzine Related Compound A RS](#), and 1 µg/mL of [USP 4-Chlorobenzophenone RS](#) in *Diluent*
Standard solution: 0.1 mg/mL of [USP Hydroxyzine Pamoate RS](#) in *Diluent*
Sample solution: 0.1 mg/mL of Hydroxyzine Pamoate in *Diluent*
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)
Mode: LC
Detector: UV 230 nm

Column: 4.6-mm × 15-cm; 3.5-μm packing [L1](#)

[NOTE—Rinse the column with a solution of [acetonitrile](#) and water (20:80) and then with a solution of [acetonitrile](#) and water (80:20) after each analysis.]

Column temperature: 45°

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention time for 4-chlorobenzophenone is 1.1. See [Table 2](#) for the relative retention times for other compounds.]

Suitability requirements

Resolution: NLT 1.5 between hydroxyzine and hydroxyzine related compound A; NLT 1.5 between hydroxyzine related compound A and 4-chlorobenzophenone, *System suitability solution*

Tailing factor: NMT 1.5 for hydroxyzine, *Standard solution*

Relative standard deviation: NMT 0.73% for hydroxyzine, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of hydroxyzine pamoate ($C_{21}H_{27}ClN_2O_2 \cdot C_{23}H_{16}O_6$) in the portion of Hydroxyzine Pamoate taken:

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

r_U = peak response of hydroxyzine from the *Sample solution*

r_S = peak response of hydroxyzine from the *Standard solution*

C_S = concentration of [USP Hydroxyzine Pamoate RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Hydroxyzine Pamoate in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–102.0% on the anhydrous basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

Change to read:

- **ORGANIC IMPURITIES**

Mobile phase, Diluent, and Chromatographic system: Proceed as directed in the Assay.

Standard solution: 1 μg/mL of [USP Hydroxyzine Pamoate RS](#), 3 μg/mL of [USP Hydroxyzine Related Compound A RS](#), and 1 μg/mL of [USP 4-Chlorobenzophenone RS](#) in *Diluent*

Sample solution: 1000 μg/mL of Hydroxyzine Pamoate in *Diluent*

System suitability

Sample: *Standard solution*

[NOTE—The relative retention time for 4-chlorobenzophenone is 1.1. See [Table 2](#) for the relative retention times for other compounds.]

Suitability requirements

Resolution: NLT 1.5 between hydroxyzine and hydroxyzine related compound A; NLT 1.5 between hydroxyzine related compound A and ▲4-chlorobenzophenone▲ (ERR 1-Jun-2021)

Relative standard deviation: NMT 5.0% each for hydroxyzine and hydroxyzine related compound A

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of hydroxyzine related compound A in the portion of Hydroxyzine Pamoate taken:

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

r_U = peak response of hydroxyzine related compound A from the *Sample solution*

r_S = peak response of hydroxyzine related compound A from the *Standard solution*

C_S = concentration of [USP Hydroxyzine Related Compound A RS](#) in the *Standard solution* (μg/mL)

C_U = concentration of Hydroxyzine Pamoate in the *Sample solution* (μg/mL)

Calculate the percentage of declozine and each unspecified impurity in the portion of Hydroxyzine Pamoate taken:

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

r_U = peak response of declozine or each unspecified impurity from the *Sample solution*