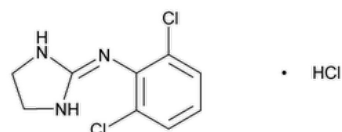


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Clonidine Hydrochloride



$C_9H_9Cl_2N_3 \cdot HCl$ 266.55

Benzenamine, 2,6-dichloro-*N*-2-imidazolidinylidene-, monohydrochloride;

2-[(2,6-Dichlorophenyl)imino]imidazolidine monohydrochloride CAS RN®: 4205-91-8; UNII: W7616XXF06.

DEFINITION

Change to read:

Clonidine Hydrochloride contains NLT $\blacktriangle$ 98.0% $\blacktriangle$ (USP 1-May-2020) and NMT $\blacktriangle$ 102.0% $\blacktriangle$ (USP 1-May-2020) of clonidine hydrochloride ($C_9H_9Cl_2N_3 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** $\blacktriangle$ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: [197A](#) or [197K](#) $\blacktriangle$ (CN 1-May-2020)

Change to read:

- **B.** $\blacktriangle$ The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. $\blacktriangle$ (USP 1-May-2020)
- **C.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), *Chemical Identification Tests, Chloride*: Meets the requirements

ASSAY

Change to read:

• PROCEDURE

Solution A: 1.0 mL/L of [triethylamine](#) in [water](#)

Mobile phase: [Acetonitrile](#) and *Solution A* (32:68). Adjust with [phosphoric acid](#) to a pH of 6.9.

$\blacktriangle$ $\blacktriangle$ (USP 1-May-2020)

Standard solution: 0.05 mg/mL of [USP Clonidine Hydrochloride RS](#) in *Mobile phase* $\blacktriangle$ $\blacktriangle$ (USP 1-May-2020)

Sample solution: 0.05 mg/mL of Clonidine Hydrochloride in *Mobile phase* $\blacktriangle$ $\blacktriangle$ (USP 1-May-2020)

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: LC

Detector: UV 220 nm

Column: 3.9-mm × 30-cm; 10- μ m packing [L1](#)

Flow rate: 2 mL/min

Injection volume: 50 μ L

$\blacktriangle$ **Run time:** NLT 3 times the retention time of clonidine $\blacktriangle$ (USP 1-May-2020)

System suitability

Sample: $\blacktriangle$ $\blacktriangle$ (USP 1-May-2020) *Standard solution*

Suitability requirements

$\blacktriangle$ $\blacktriangle$ (USP 1-May-2020)

Tailing factor: NMT 2.0

Relative standard deviation: NMT $\blacktriangle$ 0.73% $\blacktriangle$ (USP 1-May-2020)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of clonidine hydrochloride ($C_9H_9Cl_2N_3 \cdot HCl$) in the portion of Clonidine Hydrochloride taken:

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

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

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

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

C_U = concentration of Clonidine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: $\blacktriangle$ 98.0%–102.0% $\blacktriangle$ (USP 1-May-2020) on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Change to read:

• **ORGANIC IMPURITIES**

Solution A and Mobile phase: Prepare as directed in the Assay.

Standard stock solution: 0.06 mg/mL each of [USP Clonidine Hydrochloride RS](#), [USP Clonidine Related Compound A RS](#), and [2,6-dichloroaniline](#) in acetonitrile $\blacktriangle$ (USP 1-May-2020)

Standard solution: 0.6 μ g/mL each of [USP Clonidine Hydrochloride RS](#), $\blacktriangle$ [USP Clonidine Related Compound A RS](#), and [2,6-dichloroaniline](#) (USP 1-May-2020) in *Mobile phase* from the *Standard stock solution*

$\blacktriangle$ **Sensitivity solution:** 0.06 μ g/mL each of [USP Clonidine Hydrochloride RS](#), [USP Clonidine Related Compound A RS](#), and [2,6-dichloroaniline](#) in *Mobile phase* from the *Standard solution*

Sample stock solution: 1.5 mg/mL of Clonidine Hydrochloride in *Mobile phase* prepared as follows. Transfer 150 mg of Clonidine Hydrochloride to a 100-mL volumetric flask. Add *Mobile phase* to about 60% of the volume of the flask, sonicate for 5 min, and then dilute with *Mobile phase* to volume. $\blacktriangle$ (USP 1-May-2020)

Sample solution: 150 μ g/mL of Clonidine Hydrochloride in *Mobile phase* $\blacktriangle$ from the *Sample stock solution* $\blacktriangle$ (USP 1-May-2020)

Chromatographic system: $\blacktriangle$ Proceed as directed in the Assay, except for the *Run time*. $\blacktriangle$ (USP 1-May-2020)

Run time: $\blacktriangle$ NLT 6 $\blacktriangle$ (USP 1-May-2020) times the retention time of clonidine

System suitability

Samples: *Standard solution* $\blacktriangle$ and *Sensitivity solution*

[NOTE—See [Table 1](#) for the relative retention times.] $\blacktriangle$ (USP 1-May-2020)

Suitability requirements

Resolution: NLT 2.0 between clonidine related compound A and 2,6-dichloroaniline, *Standard solution* $\blacktriangle$ (USP 1-May-2020)

Relative standard deviation: NMT 5% for $\blacktriangle$ clonidine, clonidine related compound A, and 2,6-dichloroaniline. $\blacktriangle$ (USP 1-May-2020) *Standard solution*

$\blacktriangle$ **Signal-to-noise ratio:** NLT 10 for clonidine, clonidine related compound A, and 2,6-dichloroaniline, *Sensitivity solution* $\blacktriangle$ (USP 1-May-2020)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of clonidine related compound A and 2,6-dichloroaniline in the portion of Clonidine Hydrochloride taken:

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

r_U = peak response of clonidine related compound A or 2,6-dichloroaniline from the *Sample solution*

r_S = peak response of clonidine related compound A or 2,6-dichloroaniline from the *Standard solution*



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