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Clonidine Hydrochloride Injection

DEFINITION

Clonidine Hydrochloride Injection is a sterile solution of Clonidine Hydrochloride in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of clonidine hydrochloride ($C_9H_9Cl_2N_3 \cdot HCl$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#)

Diluent: 9 g/L of [sodium chloride](#) in [water](#)

Standard solution: 0.1 mg/mL of [USP Clonidine Hydrochloride RS](#) in *Diluent*. Sonicate to dissolve, if needed.

Sample solution: Nominally 0.1 mg/mL of clonidine hydrochloride from Injection. Dilute with *Diluent*, if needed.

Acceptance criteria: The UV spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as that of the *Standard solution*.

ASSAY

PROCEDURE

Solution A: Dilute 2.0 mL of [perchloric acid \(70%\)](#) in 4000 mL of [water](#).

Solution B: [Acetonitrile](#) and methanol (95:5)

Mobile phase: *Solution A* and *Solution B* (85:15)

Diluent: 9 g/L of [sodium chloride](#) in [water](#)

Standard solution: 0.01 mg/mL of [USP Clonidine Hydrochloride RS](#) in *Diluent*. Sonicate to dissolve, if needed.

Sample solution: Nominally 0.01 mg/mL of clonidine hydrochloride from the Injection, diluted with *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 3.0-mm × 15-cm; 5-μm packing [L56](#)

Flow rate: 1.2 mL/min

Injection volume: 25 μL

Run time: NLT 2 times the retention time of clonidine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of clonidine hydrochloride ($C_9H_9Cl_2N_3 \cdot HCl$) in the portion of Injection 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 = nominal concentration of clonidine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• ORGANIC IMPURITIES

Solution A, Solution B, and Diluent: Prepare as directed in the Assay.

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	97	3
35	50	50
50	50	50
51	97	3
60	97	3

Sensitivity solution: 0.05 µg/mL of [USP Clonidine Hydrochloride RS](#) in *Diluent*

Standard solution: 0.5 µg/mL of [USP Clonidine Hydrochloride RS](#) in *Diluent*. Sonicate to dissolve, if needed.

Sample solution: Nominally 100 µg/mL of clonidine hydrochloride from the Injection. Dilute with *Diluent*, if needed.

Chromatographic system: Proceed as directed in the Assay, except for the *Flow rate* and the *Run time*.

Flow rate: 1 mL/min

Run time: 60 min

System suitability

Samples: *Sensitivity solution* and *Standard solution*

Suitability requirements

Relative standard deviation: NMT 10.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any unspecified impurity in the portion of Injection taken:

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

r_U = peak response of any unspecified impurity 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* (µg/mL)

C_U = nominal concentration of clonidine hydrochloride in the *Sample solution* (µg/mL)

Acceptance criteria: See [Table 2](#).

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Clonidine	1.0	



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