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Ticlopidine Hydrochloride Tablets

DEFINITION
Ticlopidine Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of ticlopidine hydrochloride $C_{14}H_{14}ClNS \cdot HCl$.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests** ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: **197U**.▲ (CN 1-May-2020) Place a portion of powdered Tablets, equivalent to 100 mg of ticlopidine hydrochloride, in a suitable flask. Add 1 mL of water, and allow to stand for 15 min with occasional shaking. Add about 60 mL of *Mobile phase*, sonicate for 15 min, and shake by mechanical means for an additional 15 min. Dilute with *Mobile phase* to volume, and mix. Dilute a portion of this solution with *Mobile phase* to prepare 0.1 mg/mL of ticlopidine hydrochloride.

Acceptance criteria: The UV absorption spectra of the solution exhibits maxima at the same wavelength (232 nm) as that of a similar solution prepared from USP Ticlopidine Hydrochloride RS, concomitantly measured.

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Buffer: 3.55 g/L of dibasic sodium phosphate

Mobile phase: Acetonitrile and *Buffer* (3:2). Adjust with phosphoric acid to a pH of 7.0 ± 0.1.

Standard solution: 0.1 mg/mL of USP Ticlopidine Hydrochloride RS in *Mobile phase*

Sample solution: Weigh and finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to about 250 mg of ticlopidine hydrochloride to a 250-mL volumetric flask, add 150 mL of *Mobile phase*, sonicate for about 5 min, and shake mechanically for 10 additional min. Dilute with *Mobile phase* to volume, and mix. Pass a portion of this solution through a suitable 0.45-µm filter, and use the filtrate after discarding the first few mL. Transfer 5 mL of the filtrate into a 50-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 228 nm

Column: 3.9-mm × 30-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection size: 15 µL

Run time: Twice the retention time of the ticlopidine peak

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{14}H_{14}ClNS \cdot HCl$ in the portion of Tablets taken:

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

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

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

C_S = concentration of USP Ticlopidine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of ticlopidine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution**

Medium: Water; 900 mL, deaerated

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: 0.278 mg/mL of USP Ticlopidine Hydrochloride RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter.

Detection: UV 232 nm

Path length: 0.1 cm

Blank: *Medium*

Calculate the percentage of $C_{14}H_{14}ClNS \cdot HCl$ dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

L = Tablet label claim (mg)

V = volume of *Medium*, 900 mL

Tolerances: NLT 75% (Q) of the labeled amount of $C_{14}H_{14}ClNS \cdot HCl$ is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers and stored at controlled room temperature.

• **USP Reference Standards ⟨11⟩**

USP Ticlopidine Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
TICLOPIDINE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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