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Tiagabine Hydrochloride Compounded Oral Suspension

DEFINITION

Tiagabine Hydrochloride Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of tiagabine hydrochloride ($C_{20}H_{25}NO_2S_2 \cdot HCl$). Prepare Tiagabine Hydrochloride Compounded Oral Suspension 1 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Tiagabine Hydrochloride	100 mg
Vehicle: a 1:1 mixture of Vehicle for Oral Solution, *NF*, and Vehicle for Oral Suspension, *NF*, a sufficient quantity to make	100 mL

Calculate the required quantity of each ingredient for the total amount to be prepared. If using tablets, place the required number of tablets in a suitable mortar, and comminute the tablets to a fine powder or add *Tiagabine Hydrochloride* powder. Add the *Vehicle* in small portions and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a tiagabine hydrochloride suspension that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and 5 mM octanesulfonic acid (50:50). Pass through a suitable filter of 0.45-µm pore size and degas.

Standard stock solution: 1.0 mg/mL of USP Tiagabine Hydrochloride RS in methanol

Standard solution: Transfer 0.2 mL of *Standard stock solution* to a 10-mL volumetric flask, and dilute with *Mobile phase* to volume to obtain a solution containing 20 µg/mL of tiagabine hydrochloride. Centrifuge, and pass through a suitable filter of 0.22-µm pore size.

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Centrifuge, and pass through a suitable filter of 0.22-µm pore size. Accurately pipet 0.2 mL of the Oral Suspension to a 10-mL volumetric flask, and dilute with *Mobile phase* to volume to obtain a nominal concentration of 20 µg/mL of tiagabine hydrochloride.

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Flow rate: 0.4 mL/min

Column: 3.0-mm × 15-cm; 5-µm packing L10

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time of the tiagabine hydrochloride peak is 3.2 min.]

Suitability requirements

Relative standard deviation: NMT 1.7%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of tiagabine hydrochloride ($C_{20}H_{25}NO_2S_2 \cdot HCl$) in the volume of Oral Suspension 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 Tiagabine Hydrochloride RS in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.0–4.5

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded, when stored in a refrigerator; NMT 60 days after the date it was compounded, when stored at controlled room temperature

• **Labeling:** Label it to state that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩
USP Tiagabine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
TIAGABINE HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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