Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-Aug-2015
Document Type: USP Monographs
DocId: GUID-E99F206A-4A95-493E-B198-E7A5C25C97B0_1_en-US
DOI: https://doi.org/10.31003/USPNF_M8850_01_01
DOI Ref: sz9me

Tramadol Hydrochloride Compounded Oral Suspension, Veterinary

DEFINITION

Tramadol Hydrochloride Compounded Oral Suspension, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of tramadol hydrochloride ($C_{16}H_{25}NO_2 \cdot HCl$).

Prepare Tramadol Hydrochloride Compounded Oral Suspension, Veterinary 20 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Tramadol Hydrochloride	2.0 g
Sodium Chloride	0.5 g
Ora-Blend[a], a sufficient quantity to make	100 mL

[a] Perrigo Pharmaceuticals, Allegan, MI.

Add *Tramadol Hydrochloride* and *Sodium Chloride* to a suitable mortar, and triturate to a fine powder. Add a small amount of *Ora-Blend*, and triturate to make a smooth paste. Add increasing volumes of *Ora-Blend* to make a tramadol hydrochloride liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough *Ora-Blend* to bring to final volume, and mix well. [Note—*Sodium Chloride* is used to mask bitterness.]

ASSAY

• **Procedure**

Solution A: Dissolve 6.8 g of monobasic potassium phosphate in 1000 mL of water. Add 2.0 g of sodium 1-octanesulfonate, and stir until dissolved. Adjust with phosphoric acid to a pH of 2.0.

Mobile phase: Methanol, acetonitrile, tetrahydrofuran, and *Solution A* (5:5:15:75)

Standard solution: 0.4 mg/mL of tramadol hydrochloride prepared from USP Tramadol Hydrochloride RS in *Solution A*

Sample solution: Transfer 1 mL of Oral Suspension, Veterinary into a 50-mL volumetric flask, dilute with *Solution A* to volume, and mix well.

Chromatographic system

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

Mode: LC

Detector: UV 270 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for tramadol hydrochloride is about 13.4 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of tramadol hydrochloride ($C_{16}H_{25}NO_2 \cdot HCl$) in the portion of Oral Suspension, Veterinary taken:

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

r_U = peak response of tramadol hydrochloride from the *Sample solution*

r_S = peak response of tramadol hydrochloride from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.4–4.4

ADDITIONAL REQUIREMENTS

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

• **Beyond-Use Date:** NMT 180 days after the day on which it was compounded when stored at controlled room temperature

• **Labeling:** Label it to indicate that it is for veterinary use only. 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 Tramadol Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
TRAMADOL HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION, VETERINARY	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(2)

Current DocID: GUID-E99F206A-4A95-493E-B198-E7A5C25C97B0_1_en-US

DOI: https://doi.org/10.31003/USPNF_M8850_01_01

DOI ref: sz9me