

Tramadol Hydrochloride Compounded Oral Suspension

DEFINITION
Tramadol Hydrochloride Compounded Oral Suspension 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 5 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Tramadol Hydrochloride tablets ^a equivalent to	500 mg of tramadol hydrochloride
Vehicle: a 1:1 mixture of Ora-Sweet ^b (sugar-free) and Ora-Plus, ^b a sufficient quantity to make	100 mL

- ^a Ultram 50-mg tablets, Ortho-McNeil Pharmaceutical, Inc., Raritan, NJ.
^b Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of *Tramadol Hydrochloride tablets* in a suitable mortar, and comminute to a fine powder. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a tramadol hydrochloride liquid 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**

Solution A: 20 mM of phosphoric acid and 4 g/L of sodium 1-hexane sulfonate
Mobile phase: Acetonitrile and *Solution A* (50:50). Filter and degas.
Diluent: Acetonitrile and water (50:50)
Standard solution: 0.25 mg/mL of [USP Tramadol Hydrochloride RS](#) in *Diluent*
Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Prepare 0.25 mg/mL of tramadol hydrochloride from Oral Suspension and *Diluent*, and centrifuge.
Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)
Mode: LC
Detector: UV 275 nm
Column: 4.6-mm × 25-cm; 5-μm packing L1
Column temperature: 30°
Flow rate: 1.0 mL/min
Injection volume: 5 μL
System suitability
Sample: *Standard solution*
[NOTE—The retention time for tramadol hydrochloride is about 6 min.]
Suitability requirements
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 taken:

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 Tramadol Hydrochloride RS](#) 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 \(791\)](#): 3.8–4.8

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.
- **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded when stored in a refrigerator or controlled room temperature
- **LABELING:** Label it to indicate 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	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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