

Status: Currently Official on 14-Feb-2025  
Official Date: Official as of 01-May-2018  
Document Type: USP Monographs  
DocId: GUID-778672E5-E9D5-45E4-8F98-686C05673C5B\_3\_en-US  
DOI: [https://doi.org/10.31003/USPNF\\_M9795\\_03\\_01](https://doi.org/10.31003/USPNF_M9795_03_01)  
DOI Ref: nb1q0

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# Clomipramine Hydrochloride Compounded Oral Suspension, Veterinary

**DEFINITION**  
Clomipramine Hydrochloride Compounded Oral Suspension, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of clomipramine hydrochloride ( $C_{19}H_{23}ClN_2 \cdot HCl$ ). Prepare Clomipramine Hydrochloride Compounded Oral Suspension, Veterinary 1 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Clomipramine Hydrochloride tablets <sup>a</sup> equivalent to	100 mg of clomipramine hydrochloride
Vehicle: a 1:1 mixture of Ora-Plus <sup>b</sup> and Ora-Sweet SF <sup>b</sup> , a sufficient quantity to make	100 mL

- <sup>a</sup> Clomicalm 20-mg tablets, Novartis Animal Health, Greensboro, NC.  
<sup>b</sup> Perrigo, Allegan, MI.

Place the *Clomipramine Hydrochloride tablets* in a suitable container and comminute to a fine powder. Wet the powder with a small amount of *Vehicle* and triturate to make a smooth paste. Add the *Vehicle* to make the mortar contents pourable. Transfer contents stepwise and quantitatively to a calibrated container using the remainder of the *Vehicle*. Add sufficient *Vehicle* to bring to final volume. Shake to mix well.

**ASSAY**

- PROCEDURE**  
**Solution A:** Methanol and acetonitrile (50:50)  
**Solution B:** 25 mM monobasic potassium phosphate adjusted with phosphoric acid to a pH of 3.2  
**Mobile phase:** See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	40	60
4	50	50
10	50	50
10.5	40	60
20	40	60

**Standard solution:** 0.1 mg/mL of clomipramine hydrochloride prepared from [USP Clomipramine Hydrochloride RS](#) and methanol. Vortex for about 30 s until dissolved.  
**Sample solution:** Transfer 1.0 mL of Oral Suspension, Veterinary to a 10-mL volumetric flask, and rinse the pipette with about 2 mL of methanol. Vortex for 30 s and dilute with methanol to volume.  
**Chromatographic system**  
(See [Chromatography \(621\)](#), [System Suitability](#).)

**Mode:** LC

**Detector:** UV 254 nm

**Column:** 2.0-mm × 10-cm; 2.5-µm packing L1

**Column temperature:** 50°

**Flow rate:** 0.275 mL/min

**Injection volume:** 5 µL

#### System suitability

**Sample:** *Standard solution*

[NOTE—The retention time for clomipramine hydrochloride is about 8.4 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 clomipramine hydrochloride ( $C_{19}H_{23}ClN_2 \cdot HCl$ ) 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 clomipramine hydrochloride from the *Sample solution*

$r_S$  = peak response of clomipramine hydrochloride from the *Standard solution*

$C_S$  = concentration of [USP Clomipramine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

$C_U$  = nominal concentration of clomipramine 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 day on which it was compounded when stored in a refrigerator or at controlled room temperature
- **LABELING:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*. Label it to state that it is for veterinary use.
- **USP REFERENCE STANDARDS** (11).  
[USP Clomipramine Hydrochloride RS](#)

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
CLOMIPRAMINE COMPOUNDED ORAL SUSPENSION, VETERINARY	<a href="#">Brian Serumaga</a> Science Program Manager	CMP2020 Compounding 2020

**Chromatographic Database Information:** [Chromatographic Database](#)

#### Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 41(2)

**Current DocID:** GUID-778672E5-E9D5-45E4-8F98-686C05673C5B\_3\_en-US

**Previous DocID:** GUID-778672E5-E9D5-45E4-8F98-686C05673C5B\_1\_en-US

**DOI:** [https://doi.org/10.31003/USPNF\\_M9795\\_03\\_01](https://doi.org/10.31003/USPNF_M9795_03_01)

**DOI ref:** [nb1q0](#)