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Lamotrigine Compounded Oral Suspension

DEFINITION

Lamotrigine Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of lamotrigine ($C_9H_7Cl_2N_5$).

Prepare Lamotrigine Compounded Oral Suspension 1 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Lamotrigine tablet[a] equivalent to	100 mg
Ora-Blend,[b] a sufficient quantity to make	100 mL

[a] Lamotrigine 100-mg tablet, Torrent Pharmaceuticals LTD, Kalamazoo, MI.

[b] Perrigo, Minneapolis, MN.

Place the required number of tablet(s) in a suitable mortar, and comminute to a fine powder. Add the *Ora-Blend* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Ora-Blend* to make a lamotrigine liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Ora-Blend* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Solution A: Dissolve 2.7 g of monobasic potassium phosphate in 1000 mL of water. Add 6.5 mL of triethylamine, and adjust with phosphoric acid to a pH of 2.0.

Mobile phase: Acetonitrile and *Solution A* (20:80). Filter, and degas.

Diluent: 0.1 M hydrochloric acid

Standard solution: 0.4 mg/mL of USP Lamotrigine RS in *Diluent*

Sample solution: Shake thoroughly each bottle of Oral Suspension. Transfer 4 mL of Oral Suspension into a 10 mL volumetric flask, dilute with *Diluent* 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: 5 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for lamotrigine is about 9.8 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 lamotrigine ($C_9H_7Cl_2N_5$) in the portion of Oral Suspension taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.0–5.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature or 2°–8°.

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

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature or 2°–8°

• **USP Reference Standards** ⟨11⟩

USP Lamotrigine RS

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

Topic/Question	Contact	Expert Committee
LAMOTRIGINE 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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