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Add the following:

^Lamotrigine Orally Disintegrating Tablets

DEFINITION

Lamotrigine Orally Disintegrating Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of lamotrigine ($C_9H_7Cl_2N_5$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Buffer: 3.4 g/L of [monobasic potassium phosphate](#) in [water](#)

Mobile phase: [Methanol](#) and *Buffer* (60:40)

Standard stock solution: 1.0 mg/mL of [USP Lamotrigine RS](#) in *Mobile phase*. Sonication may be used to aid dissolution.

Standard solution: 0.05 mg/mL of [USP Lamotrigine RS](#) from the *Standard stock solution* in *Mobile phase*

Sample stock solution: Nominally 2 mg/mL of lamotrigine prepared as follows. Finely powder Tablets (NLT 30) and transfer a portion of the powder equivalent to 500 mg of lamotrigine to a suitable volumetric flask. Dissolve the contents in about 55% of the flask volume of *Mobile phase*, sonicate for NLT 20 min with intermittent shaking, and dilute with *Mobile phase* to volume. Centrifuge a portion of the solution and use the supernatant. [NOTE—Centrifuging at a speed of NLT 3500 rpm for 10 min may be suitable.]

Sample solution: Nominally 0.05 mg/mL of lamotrigine prepared from the *Sample stock solution* in *Mobile phase*. Pass a portion of the solution through a suitable filter of 0.45- μ m pore size, and use a portion of the filtrate after discarding the first 4 mL.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 210 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L1](#)

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 10 μ L

Run time: NLT 3.5 times the retention time of lamotrigine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 1.0%

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 Tablets 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 [USP Lamotrigine RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISINTEGRATION \(701\)](#): NMT 30 s

• [DISSOLUTION \(711\)](#)

Medium: 0.01 N hydrochloric acid; 900 mL

Apparatus 2: 75 rpm

Time: 15 min

Buffer: 3.4 g/L of [monobasic potassium phosphate](#) in [water](#)

Mobile phase: [Acetonitrile](#) and *Buffer* (25:75)

Standard stock solution: 1 mg/mL of [USP Lamotrigine RS](#) in [methanol](#)

Standard solution: (L/900) mg/mL of lamotrigine from *Standard stock solution* in *Medium*, where L is the label claim in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.22-μm pore size, and use a portion of the filtrate after discarding the first 4 mL of the solution.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 310 nm

Column: 2.1-mm × 5-cm; 1.7-μm packing [L1](#)

Column temperature: 30°

Flow rate: 0.3 mL/min

Injection volume: 2.0 μL

Run time: NLT 1.5 times the retention time of lamotrigine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of lamotrigine ($C_9H_7Cl_2N_3$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times 100$$

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

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

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of lamotrigine ($C_9H_7Cl_2N_3$) is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

• **ORGANIC IMPURITIES**

Buffer: 2.7 g/L of [monobasic potassium phosphate](#) in [water](#)

Solution A: To 1500 mL of *Buffer* add 10 mL of [triethylamine](#) and adjust with [phosphoric acid](#) to a pH 2.0.

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1