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Rufinamide Tablets

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DEFINITION

Rufinamide Tablets contain an amount of Rufinamide equivalent to NLT 95.0% and NMT 105.0% of the labeled amount of rufinamide ($C_{10}H_8F_2N_4O$).

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

Diluent: [Acetonitrile](#), [methanol](#), and [water](#) (40:50:10)

Mobile phase: [Methanol](#), [tetrahydrofuran](#), and *Buffer* (15:5:80)

System suitability stock solution: 0.8 mg/mL of [USP Rufinamide RS](#), and 0.02 mg/mL each of [USP Rufinamide Related Compound A RS](#) and [USP Rufinamide Related Compound B RS](#) in *Diluent*. [NOTE—[USP Rufinamide Related Compound B RS](#) is used for identification purposes only.]

System suitability solution: 0.08 mg/mL of [USP Rufinamide RS](#), and 2 µg/mL each of [USP Rufinamide Related Compound A RS](#) and [USP Rufinamide Related Compound B RS](#), in *Buffer* from the *System suitability stock solution*

Standard stock solution: 0.8 mg/mL of [USP Rufinamide RS](#) in *Diluent*

Standard solution: 0.08 mg/mL of [USP Rufinamide RS](#) in *Buffer* from the *Standard stock solution*

Sample stock solution: Nominally 0.8 mg/mL of rufinamide in *Diluent* from a portion of NLT 20 finely powdered Tablets. Sonicate for 10 min, and shake for 15 min. Centrifuge a portion of the suspension.

Sample solution: Nominally 0.08 mg/mL of rufinamide in *Buffer*, from a portion of suspension obtained from the *Sample stock solution*

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 190–400 nm.

Column: 4.6-mm × 12.5-cm; 5-µm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 25 µL

Run time: NLT 2.3 times the retention time of rufinamide

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—See [Table 9](#) for relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between rufinamide and rufinamide related compound A, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of rufinamide ($C_{10}H_8F_2N_4O$) in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

Medium 1: [0.1 N hydrochloric acid](#)

Medium 2: [pH 6.8 phosphate buffer](#)

Apparatus 4: With 22.6-mm cell, glass beads in the cone, with Tablet laying on the beads. Insert 320–350 mg of glass wool in the filter insert and then a glass microfiber filter of 2.7-μm pore size and a glass microfiber filter of 0.7-μm pore size.

Times: 5 and 12 h for the 200-mg Tablets; 6 and 16 h for the 400-mg Tablets

Flow rate: 16 mL/min, pulsating

Test intervals, media, and sample solutions for the 200-mg Tablets: See [Table 1](#).

Table 1

Samples	Interval (min)	Volume (mL)	Medium
1	60	50	1
2	120	50	2
1	60	50	2
3	120	50	2

Test intervals (I_p): See [Table 2](#).

Table 2

Interval	Time (min)
I_1	0–60
I_2	60–180
I_3	180–300
I_4	300–360
I_5	360–480
I_6	480–600
I_7	600–720



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Sample solutions (V_i): See [Table 3](#).

Table 3

V_1	eluate of test interval I_1 ; volume = 960 mL
V_2 to V_3	eluate of test interval I_2 to I_3 ; volume = 1920 mL, each
V_4	eluate of test interval I_4 ; volume 960 mL
V_5 to V_7	eluate of test interval I_5 to I_7 ; volume = 1920 mL, each

Test intervals, media, and sample solutions for the 400-mg Tablets: See [Table 4](#).

Table 4

Samples	Interval (min)	Volume (mL)	Medium
1	60	50	1
1	60	50	2
3	120	50	2
1	120	50	2
2	180	50	2

Test intervals (I_i): See [Table 5](#).

Table 5

Interval	Time (min)
I_1	0–60
I_2	60–120
I_3	120–240
I_4	240–360
I_5	360–480
I_6	480–600
I_7	600–780
I_8	780–960

Sample solutions (V_i): See [Table 6](#).

Table 6