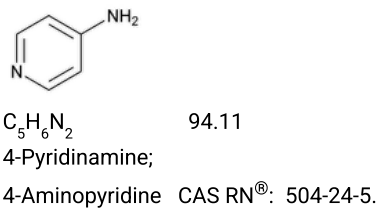


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Dalfampridine



DEFINITION
Dalfampridine contains NLT 98.0% and NMT 102.0% of dalfampridine ($C_5H_6N_2$).

IDENTIFICATION
Change to read:

- **A.**  **SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K or 197A  (ERR 1-Oct-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

- **PROCEDURE**
Solution A: 3.03 g/L of [sodium 1-heptanesulfonate](#), 1.36 g/L of [monobasic potassium phosphate](#), and 1.15 g/L of [phosphoric acid](#) in [water](#)
Solution B: Acetonitrile
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	90	10
5.0	90	10
15.0	80	20
20.0	80	20
20.1	90	10
25.0	90	10

Diluent: *Solution A* and *Solution B* (90:10)
System suitability stock solution: 0.04 mg/mL of [USP Dalfampridine Related Compound A RS](#) prepared as follows. Transfer a suitable quantity of [USP Dalfampridine Related Compound A RS](#) to an appropriate volumetric flask and add 20% of the total flask volume of *Diluent*. Sonicate for about 5 min. Allow to cool to room temperature and dilute with *Diluent* to volume. Use within 24 h.
System suitability solution: 0.0002 mg/mL of [USP Dalfampridine Related Compound A RS](#) from *System suitability stock solution* and 0.2 mg/mL of [USP Dalfampridine RS](#) in *Diluent* prepared as follows. Transfer a suitable quantity of [USP Dalfampridine RS](#) to an appropriate volumetric flask, add an appropriate volume of *System suitability stock solution*, and add 25% of the total flask volume of *Diluent*. Sonicate.

for NLT 5 min. Allow to cool to room temperature and dilute with *Diluent* to volume. Pass the resulting solution through a suitable filter, discard NLT the first 2 mL, and use the filtrate.

Standard solution: 0.2 mg/mL of [USP Dalfampridine RS](#) in *Diluent* prepared as follows. Transfer a suitable quantity of [USP Dalfampridine RS](#) to an appropriate volumetric flask and add 25% of the total flask volume of *Diluent*. Sonicate for NLT 5 min. Allow to cool to room temperature and dilute with *Diluent* to volume. Pass the resulting solution through a suitable filter and use the filtrate.

Sample solution: 0.2 mg/mL of Dalfampridine in *Diluent* prepared as follows. Transfer a suitable quantity of Dalfampridine to an appropriate volumetric flask and add 25% of the total flask volume of *Diluent*. Sonicate for NLT 5 min. Allow to cool to room temperature and dilute with *Diluent* to volume. Pass the resulting solution through a suitable filter and use the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 275 nm

Column: 4.6-mm × 10.0-cm; 3.5-μm packing [L1](#)

Column temperature: 30°

Flow rate: 2 mL/min

Injection volume: 10 μL

System suitability

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

[NOTE—See [Table 2](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 2.0 between dalfampridine and dalfampridine related compound A, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dalfampridine ($C_5H_6N_2$) in the portion of Dalfampridine 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 Dalfampridine RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0%

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#)

Ignition temperature: 800°

Acceptance criteria: NMT 0.3%

• LIMIT OF DALFAMPRIDINE RELATED COMPOUND B AND DALFAMPRIDINE RELATED COMPOUND C

[NOTE—This test should be conducted if dalfampridine related compound B and dalfampridine related compound C are possible from the manufacturing process.]

Solution A, Solution B, Mobile phase, and Diluent: Prepare as directed in the Assay.

Standard solution: 2 μg/mL each of [USP Dalfampridine Related Compound B RS](#) and [USP Dalfampridine Related Compound C RS](#) in *Diluent*

Sensitivity solution: 0.1 μg/mL each of [USP Dalfampridine Related Compound B RS](#) and [USP Dalfampridine Related Compound C RS](#) from *Standard solution* in *Diluent*

Sample solution: 2000 μg/mL of Dalfampridine in *Diluent* prepared as follows. Transfer a suitable quantity of Dalfampridine to an appropriate volumetric flask and add 25% of the total flask volume of *Diluent*. Sonicate for NLT 5 min. Allow to cool to room temperature and dilute with *Diluent* to volume.

Chromatographic system: Proceed as directed in the Assay, except use an *Injection volume* of 30 μL.

System suitability

Samples: *Standard solution* and *Sensitivity solution*

[NOTE—See [Table 2](#) for the relative retention times.]