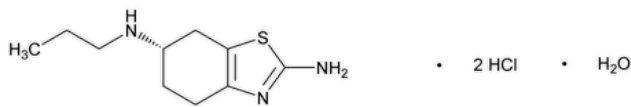


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Pramipexole Dihydrochloride



$C_{10}H_{17}N_3S \cdot 2HCl \cdot H_2O$ 302.26
Benzothiazole-2,6-diamine, 4,5,6,7-tetrahydro-*N*⁶-propyl-, dihydrochloride, monohydrate, (S)-;
(S)-2-Amino-4,5,6,7-tetrahydro-6-(propylamino)benzothiazole dihydrochloride monohydrate CAS RN[®]: 191217-81-9; UNII: 3D867NP06J.

Change to read:

DEFINITION

Pramipexole Dihydrochloride is a monohydrate and contains NLT 98.0% and NMT 102.0% of pramipexole dihydrochloride ($\blacktriangle C_{10}H_{17}N_3S \cdot 2HCl \blacktriangle$ (USP 1-Dec-2022)), calculated on the anhydrous basis.

IDENTIFICATION

- **A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#):** 197A or 197M
Wavelength ranges
For 197A: 3800 cm⁻¹ to 650 cm⁻¹
For 197M: 4000 cm⁻¹ to 600 cm⁻¹
Acceptance criteria: Meets the requirements
- **B.** The retention time of the major peak of the *Sample solution* corresponds to the pramipexole (S-enantiomer) peak of the *System suitability solution* in the test for *Limit of Pramipexole Related Compound D*.
- **C. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Chloride](#)**
Sample: 1 mg/mL of Pramipexole Dihydrochloride in [water](#)
Acceptance criteria: Meets the requirements of test A

ASSAY

Change to read:

- **PROCEDURE**
Solution A: Dissolve 9.1 g of [potassium dihydrogen phosphate](#) and 5.0 g of [sodium 1-octanesulfonate monohydrate](#) in 1 L of [water](#). Adjust with [phosphoric acid](#) to a pH of 3.0.
Solution B: [Acetonitrile](#) and *Solution A* (50:50)
Diluent: [Acetonitrile](#) and *Solution A* (20:80)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	60	40
15	20	80
15.1	60	40

Time (min)	Solution A (%)	Solution B (%)
20	60	40

System suitability solution: 1.5 mg/mL of [USP Pramipexole Dihydrochloride RS](#) and 0.8 mg/mL of [USP Pramipexole Related Compound A RS](#) in *Diluent*

Standard solution: 1.5 mg/mL of [USP Pramipexole Dihydrochloride RS](#) in *Diluent*

Sample solution: 1.5 mg/mL of Pramipexole Dihydrochloride in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 264 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Column temperature: 40 ± 5°

Flow rate: 1.5 mL/min

Injection volume: 5 μL

System suitability

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

[NOTE—The relative retention times for pramipexole related compound A and pramipexole are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 6.0 between pramipexole related compound A and pramipexole, *System suitability solution*

Tailing factor: NMT 2.0 for pramipexole, *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pramipexole dihydrochloride ($\text{C}_{10}\text{H}_{17}\text{N}_3 \cdot 2\text{HCl}$) (USP 1-Dec-2022) in the portion of Pramipexole Dihydrochloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of the *Sample solution*

r_S = peak response of the *Standard solution*

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

C_U = concentration of Pramipexole Dihydrochloride (as monohydrate) in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of pramipexole dihydrochloride, 284.24

M_{r2} = molecular weight of pramipexole dihydrochloride monohydrate, 302.26

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.10%

Change to read:

• **LIMIT OF PRAMIPEXOLE RELATED COMPOUND D**

Mobile phase: *n*-Hexane, [dehydrated alcohol](#), and [diethylamine](#) (850:150:1)

System suitability stock solution: 1 mg/mL $\blacktriangle$ (USP 1-Dec-2022) of [USP Pramipexole Dihydrochloride RS](#) and $\blacktriangle$ 1.3 mg/mL of $\blacktriangle$ (USP 1-Dec-2022) [USP Pramipexole Related Compound D RS](#) in [dehydrated alcohol](#)

System suitability solution: 0.01 mg/mL $\blacktriangle$ (USP 1-Dec-2022) of [USP Pramipexole Dihydrochloride RS](#) and $\blacktriangle$ 0.013 mg/mL of $\blacktriangle$ (USP 1-Dec-2022) [USP Pramipexole Related Compound D RS](#) from the *System suitability stock solution* in *Mobile phase*

Standard stock solution: $\blacktriangle$ 2.7 $\blacktriangle$ (USP 1-Dec-2022) mg/mL of [USP Pramipexole Related Compound D RS](#) in [dehydrated alcohol](#)