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Melatonin Tablets

DEFINITION

Melatonin Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of melatonin ($C_{13}H_{16}N_2O_2$).

IDENTIFICATION

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

STRENGTH

• PROCEDURE

Buffer: 0.5 g/L of monobasic potassium phosphate in water. Adjust with phosphoric acid to a pH of 3.5, and filter.

Mobile phase: Acetonitrile and *Buffer* (25:75)

System suitability solution: 0.1 mg/mL of [USP Melatonin RS](#) and 0.02 mg/mL of [USP Melatonin Related Compound A RS](#) in *Mobile phase*

Standard solution: 0.1 mg/mL of [USP Melatonin RS](#) in *Mobile phase*

Sample solution: Filtered portion of the solution in *Mobile phase*, equivalent to 0.1 mg/mL of Melatonin from NLT 20 finely powdered Tablets

Chromatographic system

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

Mode: LC

Detector: UV 222 nm

Column: 4.6-mm × 15-cm; 5-μm packing L1

Flow rate: 1.0 mL/min

Injection size: 10 μL

System suitability

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

[NOTE—The relative retention times for melatonin related compound A and melatonin are 0.4 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 4 between melatonin and melatonin related compound A, *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of melatonin ($C_{13}H_{16}N_2O_2$) 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 Melatonin RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- [DISINTEGRATION AND DISSOLUTION OF DIETARY SUPPLEMENTS \(2040\)](#): Meet the requirements for *Dissolution*

Medium: Water; 500 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: Dissolve a suitable amount of [USP Melatonin RS](#) in water to obtain a concentration similar to that expected in the *Sample solution*.

Sample solution: Filtered portion of the solution under test

Analysis: Proceed as directed in *Strength*, making any necessary adjustments.

Calculate the percentage of the labeled amount of melatonin ($C_{13}H_{16}N_2O_2$) dissolved:

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

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

V = volume of *Medium*, 500 mL

L = labeled amount of melatonin (mg/Tablet)

Tolerances: NLT 75% of the labeled amount of melatonin ($C_{13}H_{16}N_2O_2$) is dissolved.

- [WEIGHT VARIATION OF DIETARY SUPPLEMENTS \(2091\)](#): Meet the requirements

IMPURITIES

• RELATED COMPOUNDS

Solution A: Acetonitrile

Solution B: Use *Buffer*, prepared as directed in *Strength*.

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	25	75
7	25	75
15	80	20
18	25	75
25	25	75

Diluent: Mixture of *Solution A* and *Solution B* (25:75)

System suitability solution: 0.1 mg/mL of [USP Melatonin RS](#) and 0.02 mg/mL of [USP Melatonin Related Compound A RS](#) in *Diluent*

Standard solution: 5 µg/mL of [USP Melatonin RS](#) in *Diluent*

Sample solution: Filtered solution in *Diluent*, equivalent to 1 mg/mL of melatonin from NLT 20 finely powdered Tablets

Chromatographic system

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

Mode: LC

Detector: UV 222 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 1.0 mL/min

Injection size: 10 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for melatonin related compound A and melatonin are 0.4 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 4.0 between melatonin and melatonin related compound A

Relative standard deviation: NMT 2.0% for the melatonin peak