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Vinpocetine Tablets

DEFINITION

Vinpocetine Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of vinpocetine ($C_{22}H_{26}N_2O_2$).

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), *Ultraviolet-Visible Spectroscopy*:** 197U

Medium: [Alcohol](#)

Standard solution: 15 µg/mL of [USP Vinpocetine RS](#) in *Medium*

Sample solution: Equivalent to 15 µg/mL of vinpocetine from finely powdered Tablets in *Medium*

Acceptance criteria: The spectra of the *Sample solution* and *Standard solution* exhibit maxima and minima at the same wavelengths.

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

STRENGTH

PROCEDURE

Solution A: 15.4 g/L of [ammonium acetate](#) in [water](#)

Mobile phase: [Acetonitrile](#) and *Solution A* (55:45)

Standard solution: 0.2 mg/mL of [USP Vinpocetine RS](#) in *Mobile phase*

Sample solution: Dissolve a portion from NLT 20 finely powdered Tablets in [acetonitrile](#) by shaking thoroughly and sonicating for 5 min. Allow the solution to cool to room temperature, dilute with [acetonitrile](#) to get a solution nominally equivalent to 0.2 mg/mL of vinpocetine, and filter.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Flow rate: 1.0 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of vinpocetine ($C_{22}H_{26}N_2O_2$) 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 Vinpocetine RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- **DISINTEGRATION AND DISSOLUTION (2040), Dissolution:** Meet the requirements

Medium: 0.1 N [hydrochloric acid](#); 900 mL

Apparatus 1: 100 rpm

Time: 30 min

Sample solution: Withdraw a portion of the solution under test, pass through a suitable filter, and use the pooled sample as the test specimen.

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

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelength: 268 nm

Blank: *Medium*

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of the labeled amount of vinpocetine ($C_{22}H_{26}N_2O_2$) dissolved:

$$\text{Result} = (A_U/A_S) \times [C_S \times (V/L)] \times 100$$

A_U = absorbance of vinpocetine from the *Sample solution*

A_S = absorbance of vinpocetine from the *Standard solution*

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

V = volume of *Medium*, 900 mL

L = label claim of vinpocetine (mg/Tablet)

Tolerances: NLT 75% of the labeled amount of vinpocetine ($C_{22}H_{26}N_2O_2$) is dissolved.

- **WEIGHT VARIATION (2091):** Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

Add the following:

- ▲ **LABELING:** Label to include the following statement: "Do not use if you are pregnant, planning to become pregnant, or breastfeeding." ▲ (USP 1-Aug-2021)

- **USP REFERENCE STANDARDS (11).**
[USP Vinpocetine RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
VINPOCETINE TABLETS	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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