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Vinpocetine Capsules

DEFINITION

Vinpocetine Capsules 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 Capsule contents 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: Weigh NLT 20 Capsules in a tared weighing bottle. Open the Capsules, without the loss of shell material, and transfer the contents to a suitable beaker. Remove any contents adhering to the empty shells by washing, if necessary, with several portions of ether. Discard the washings, and dry the Capsule shells with the aid of a current of dry air until the odor of ether is no longer perceptible. Weigh the empty Capsule shells in the tared weighing bottle, and calculate the average net weight per Capsule. Dissolve a portion of the Capsule contents in [acetonitrile](#) with sonication for 5 min. Allow the solution to cool to room temperature, dilute with [acetonitrile](#) to get a solution with a nominal concentration of 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 Capsules 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 \(2040\)](#), [Disintegration](#): Meet the requirements
- [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 CAPSULES	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](#)

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