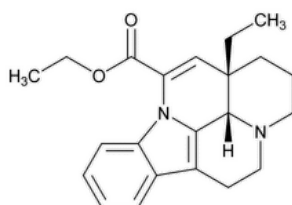


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# Vinpocetine

## Change to read:



$C_{22}H_{26}N_2O_2$  350.45

Eburnamenine-14-carboxylic acid, ethyl ester, (3 $\alpha$ ,16 $\alpha$ )-;

Ethyl apovincamin-22-oate CAS RN<sup>®</sup>: 42971-09-5; ▲UNII: 543512OBTC.▲ (USP 1-Aug-2021)

## DEFINITION

Vinpocetine contains NLT 98.0% and NMT 102.0% of vinpocetine ( $C_{22}H_{26}N_2O_2$ ), calculated on the dried basis.

## IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K
- **B.** The retention time of the main peak of the *Sample solution* corresponds to that of the main peak of *Standard solution 4*, as obtained in the Assay.

## ASSAY

### Change to read:

#### PROCEDURE

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

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

**Standard solution 1:** 0.02 mg/mL of [USP Vinpocetine RS](#) in *Mobile phase*

**Standard solution 2:** 0.12 mg/mL of [USP Vinpocetine Related Compound A RS](#) and 0.10 mg/mL each of [USP Vinpocetine Related Compound B RS](#), [USP Vinpocetine Related Compound C RS](#), and [USP Vinpocetine Related Compound D RS](#) in *Mobile phase*

**Standard solution 3:** Dilute 1.0 mL of *Standard solution 1* and 1.0 mL of *Standard solution 2* with *Mobile phase* to 20.0 mL.

**Standard solution 4:** 0.2 mg/mL of [USP Vinpocetine RS](#) in *Mobile phase*

**Sample solution:** 0.2 mg/mL of Vinpocetine in *Mobile phase*

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 280 nm

**Column:** 4.6-mm × 25-cm; 5- $\mu$ m packing [L1](#)

**Flow rate:** 1.0 mL/min

**Injection volume:** 15  $\mu$ L

#### System suitability

**Samples:** *Standard solution 3* ▲ and *Standard solution 4* ▲ (USP 1-Aug-2021)

[NOTE—See [Table 1](#) for the relative retention times.]

#### Suitability requirements

**Resolution:** NLT 2.0 between vinpocetine related compound B and vinpocetine related compound D, ▲*Standard solution 3* ▲ (USP 1-Aug-2021)

**Relative standard deviation:** NMT 2.0%, *Standard solution 4*

#### Analysis

**Samples:** *Standard solution 4* and *Sample solution*

Calculate the percentage of vinpocetine ( $C_{22}H_{26}N_2O_2$ ) in the portion of Vinpocetine 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 *Standard solution 4*

$C_S$  = concentration of [USP Vinpocetine RS](#) in *Standard solution 4* (mg/mL)

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

**Acceptance criteria:** 98.0%–102.0% on the dried basis

## IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• **ORGANIC IMPURITIES**

**Solution A, Mobile phase, Standard solution 1, Standard solution 2, Standard solution 3, Chromatographic system, and System suitability:** Proceed as directed in the Assay.

**Sample solution:** 1 mg/mL of Vinpocetine in *Mobile phase*

## Analysis

**Samples:** *Standard solution 3* and *Sample solution*

Record the chromatograms for NLT 3 times the retention time of vinpocetine. Disregard any peak with an area less than 0.5 times the area of the peak due to vinpocetine in *Standard solution 3*.

Separately calculate the percentages of vinpocetine related compounds A, B, C, and D in the portion of Vinpocetine taken:

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

$r_U$  = peak response of each of the related compounds from the *Sample solution*

$r_S$  = peak response of each corresponding related compound from *Standard solution 3*

$C_S$  = concentration of the corresponding Reference Standard in *Standard solution 3* (mg/mL)

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

Calculate the percentage of any unspecified individual impurity in the portion of Vinpocetine taken:

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

$r_U$  = peak response of each of the unspecified impurities from the *Sample solution*

$r_S$  = peak response of vinpocetine from *Standard solution 3*

$C_S$  = concentration of [USP Vinpocetine RS](#) in *Standard solution 3* (mg/mL)

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

**Acceptance criteria:** See [Table 1](#).

**Table 1**

| Name                                        | Relative Retention Time | Acceptance Criteria, NMT (%) |
|---------------------------------------------|-------------------------|------------------------------|
| Vinpocetine                                 | 1.00                    | —                            |
| Vinpocetine related compound A <sup>a</sup> | 0.40                    | 0.6                          |