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Valacyclovir Tablets

DEFINITION

Valacyclovir Tablets contain an amount of Valacyclovir Hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of valacyclovir ($C_{13}H_{20}N_6O_4$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** [IDENTIFICATION TESTS—GENERAL, Chloride\(191\)](#): Meet the requirements

ASSAY

PROCEDURE

Diluent: 0.1% (v/v) phosphoric acid in water

Mobile phase: Methanol and *Diluent* (5:95)

Standard solution: 0.1 mg/mL of [USP Valacyclovir Hydrochloride RS](#) in *Diluent*. [NOTE—[USP Valacyclovir Hydrochloride RS](#) contains a detectable quantity of D-valacyclovir.]

Sample solution: Transfer NLT 5 Tablets into a suitable volumetric flask, and add 0.1 M hydrochloric acid (approximately 80% of the volume of the flask). Mechanically shake the sample until the Tablets disintegrate into a fine suspension (60 min), and sonicate for 10 min. Cool to ambient temperature, dilute with 0.1 M hydrochloric acid to volume, and mix to obtain a solution having a concentration of 2.5 mg/mL. Dilute a portion of the sample with *Diluent* to obtain a nominal concentration of 0.1 mg/mL of valacyclovir, and mix. Pass a portion of this solution through a membrane filter of 0.45-μm or finer pore size, and use the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 15-cm; 5-μm packing L66

Column temperature: 10°

Flow rate: 0.75 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 1.3 between the D-valacyclovir and valacyclovir peaks

Tailing factor: NMT 2.0 for the valacyclovir peak

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of valacyclovir ($C_{13}H_{20}N_6O_4$) in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

M_{r1} = molecular weight of valacyclovir, 324.34

M_{r2} = molecular weight of valacyclovir hydrochloride, 360.80

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Test 1

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Diluent: Prepare as directed in the Assay.

Mobile phase: Acetonitrile and *Diluent* (5:95)

Standard solution: Prepare a solution in *Diluent* containing [USP Valacyclovir Hydrochloride RS](#) equivalent to 0.044 mg/mL of valacyclovir free base.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size. Dilute with *Diluent* to obtain a final concentration of about 0.044 mg/mL of valacyclovir free base considering complete dissolution of the Tablet label claim.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 5-cm, 5-μm packing L1

Flow rate: 2.0 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of valacyclovir ($C_{13}H_{20}N_6O_4$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (M_{r1}/M_{r2}) \times (1/L) \times D \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

V = volume of *Medium*, 900 mL

M_{r1} = molecular weight of valacyclovir, 324.34

M_{r2} = molecular weight of valacyclovir hydrochloride, 360.80

L = label claim (mg/Tablet)

D = dilution factor of the *Sample solution*

Tolerances: NLT 75% (Q) of the labeled amount of valacyclovir ($C_{13}H_{20}N_6O_4$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Instrumental conditions

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

Analytical wavelength: 252 nm