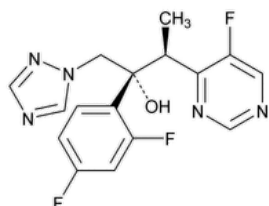


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Voriconazole



$C_{16}H_{14}F_3N_5O$ 349.31

4-Pyrimidineethanol, α -(2,4-difluorophenyl)-5-fluoro- β -methyl- α -(1H-1,2,4-triazol-1-ylmethyl)-, ($\alpha R, \beta S$)-;

($\alpha R, \beta S$)- α -(2,4-Difluorophenyl)-5-fluoro- β -methyl- α -(1H-1,2,4-triazol-1-ylmethyl)-4-pyrimidineethanol CAS RN[®]: 137234-62-9; UNII: JFU09I87TR.

DEFINITION

Voriconazole contains NLT 97.5% and NMT 102.0% of Voriconazole ($C_{16}H_{14}F_3N_5O$), calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy](#): 197K ▲ (ERR 1-Oct-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of *System suitability solution A*, as obtained in the test for *Voriconazole Related Compound B*.

ASSAY

PROCEDURE

Buffer: 1.9 g/L of ammonium formate in water. Adjust with formic acid to a pH of 4.0.

Mobile phase: Acetonitrile, methanol, and *Buffer* (15:30:55)

Standard solution: 25 μ g/mL of [USP Voriconazole RS](#) in *Mobile phase*. [NOTE—Sonicate to dissolve, if necessary.]

Sample solution: 25 μ g/mL of Voriconazole in *Mobile phase*. [NOTE—Sonicate to dissolve, if necessary.]

Chromatographic system

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

Mode: LC

Detector: UV 256 nm

Column: 3.9-mm $\times$ 15-cm; 4- μ m packing L1

Column temperature: 35°

Flow rate: 1 mL/min

Injection size: 20 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Column efficiency: NLT 3500 theoretical plates

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of voriconazole ($C_{16}H_{14}F_3N_5O$) in the portion of Voriconazole 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 Voriconazole RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Voriconazole in the *Sample solution* (µg/mL)

Acceptance criteria: 97.5%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

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

• **VORICONAZOLE RELATED COMPOUNDS C AND D**

Mobile phase and Chromatographic system: Proceed as directed in the Assay.

System suitability solution: 0.25 µg/mL of [USP Voriconazole RS](#) in *Mobile phase*

Standard solution: 2.5 µg/mL each of [USP Voriconazole RS](#), [USP Voriconazole Related Compound C RS](#), and [USP Voriconazole Related Compound D RS](#) in *Mobile phase*. [NOTE—Sonicate to dissolve, if necessary.]

Sample solution: 500 µg/mL of Voriconazole in *Mobile phase*. [NOTE—Sonicate to dissolve, if necessary.]

System suitability

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

Suitability requirements

Tailing factor: NMT 2.0 for the voriconazole peak, *Standard solution*

Column efficiency: NLT 3500 theoretical plates for the voriconazole peak, *Standard solution*

Relative standard deviation: NMT 10.0%, *System suitability solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of voriconazole related compound C and voriconazole related compound D in the portion of Voriconazole taken:

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

r_U = peak response of voriconazole related compound C or voriconazole related compound D from the *Sample solution*

r_S = peak response of voriconazole related compound C or voriconazole related compound D from the *Standard solution*

C_S = concentration of [USP Voriconazole Related Compound C RS](#) or [USP Voriconazole Related Compound D RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Voriconazole in the *Sample solution* (µg/mL)

Calculate the percentage of any unspecified impurity in the portion of Voriconazole taken:

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

r_U = peak response of any individual impurity from the *Sample solution*

r_S = peak response of voriconazole from the *Standard solution*

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

C_U = concentration of Voriconazole in the *Sample solution* (µg/mL)

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

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Voriconazole related compound C ^a	0.26	0.2