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Voriconazole Compounded Ophthalmic Solution, Veterinary

DEFINITION

Voriconazole Compounded Ophthalmic Solution, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of voriconazole ($C_{16}H_{14}F_3N_5O$).

Prepare Voriconazole Compounded Ophthalmic Solution, Veterinary 10 mg/mL as follows (see *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩*).

Voriconazole for Injection[a] equivalent to	200 mg
Sodium Chloride Injection (0.9%), a sufficient quantity to make	20 mL

[a] V-Fend 200-mg injection, Pfizer, Inc., Groton, CT.

Reconstitute *Voriconazole for Injection* with *Sodium Chloride Injection (0.9%)* to bring to a final volume of 20 mL. [Note—May reconstitute according to package insert to achieve a 10-mg/mL solution.] Shake well until a clear solution is achieved. Aseptically draw up into sterile unit-dose 1-mL syringes.

ASSAY

• **Procedure**

Solution A: 30 mM monobasic sodium phosphate adjusted with phosphoric acid to a pH of 4.0

Mobile phase: Methanol, acetonitrile, and *Solution A* (30:15:55). Pass through a PTFE filter of 0.45-µm pore size.

Standard solution: 0.25 mg/mL of voriconazole prepared from USP Voriconazole RS in *Mobile phase*. Sonicate for about 5 min to dissolve.

Sample solution: Transfer 250 µL of Ophthalmic Solution, Veterinary into a 10-mL volumetric flask, dilute with *Mobile phase* to volume, and mix well to dissolve. Protect from light.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 256 nm

Column: 3.9-mm × 15-cm; 5-µm packing L1

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for voriconazole is about 4.2 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of voriconazole ($C_{16}H_{14}F_3N_5O$) in the portion of Ophthalmic Solution, Veterinary taken:

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

r_U = peak response of voriconazole from the *Sample solution*

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

C_S = concentration of voriconazole in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 5.7–6.7

• **Sterility Tests** ⟨71⟩**:** It meets the requirements when tested as directed in *Test for Sterility of the Product to be Examined, Membrane Filtration*.

Change to read:

• ▲**Subvisible Particulate Matter in Intraocular Solutions** ⟨789⟩▲ (CN 1-May-2024) **:** It meets the requirements.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in sterile unit-dose 1-mL syringes. Store at 2°–8°.

• **Beyond-Use Date:** In the absence of performing and completing a sterility test, the storage conditions in *Pharmaceutical Compounding – Sterile Preparations* ⟨797⟩*, 14.3 Establishing a BUD for a CSP* apply.

• **Labeling:** Label it to indicate that it is for veterinary use only. Label it to state that this is a single-dose container intended for use in the eye and to not use if a precipitate is present. Label it with a warning that it is not for injection. Label it to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Voriconazole RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
VORICONAZOLE COMPOUNDED OPHTHALMIC SOLUTION, VETERINARY	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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