Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2024
Document Type: USP Monographs
DocId: GUID-69F44524-80A9-4FC3-83AC-FD07F7EBD9D5_4_en-US
DOI: https://doi.org/10.31003/USPNF_M9261_04_01
DOI Ref: gjmxt

Cyclosporine Compounded Ophthalmic Solution, Veterinary

DEFINITION

Cyclosporine Compounded Ophthalmic Solution, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of cyclosporine ($C_{62}H_{111}N_{11}O_{12}$).

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

Cyclosporine Oral Solution[a] equivalent to	100 mg of cyclosporine
Corn Oil, *NF*, a sufficient quantity to make	10 mL

[a] Sandimmune Oral Solution 100 mg/mL, Novartis Pharmaceuticals Corporation, East Hanover, NJ.

Mix the *Cyclosporine Oral Solution* with sufficient *Corn Oil* to bring to final volume and mix thoroughly. Pass the solution through a compatible sterile membrane filter of 0.22-µm pore size into a sterile ophthalmic container. Replace the tip and cap, and mix well. [Note—Cyclosporine Oral Solution Modified is not interchangeable and should not be used.]

ASSAY

• **Procedure**

Mobile phase: See *Table 1*.

Table 1

Time (min)	Acetonitrile (%)	Water (%)
0	60	40
40	90	10
45	90	10
45.05	60	40
55	60	40

Standard solution: 0.5 mg/mL of cyclosporine prepared from USP Cyclosporine RS in acetonitrile. Mix well to dissolve.

Sample solution: Transfer 0.5 mL of Ophthalmic Solution, Veterinary into a 10-mL volumetric flask, dilute with acetonitrile to volume, and mix well. Allow the oil to separate from the solution. Once the top layer appears clear, transfer about 1 mL of the top layer into an amber HPLC vial.

Chromatographic system

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

Mode: LC

Detector: UV-Vis 208 nm

Column: 4.6-mm × 10-cm; 2.6-µm packing L1

Column temperature: 60°

Flow rate: 0.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for cyclosporine is about 34.0 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 cyclosporine ($C_{62}H_{111}N_{11}O_{12}$) 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 cyclosporine from the *Sample solution*

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

C_S = concentration of USP Cyclosporine RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **STERILITY TESTS ⟨71⟩:** It meets the requirements.

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 ophthalmic dropper bottles, protected from light. Store at controlled room temperature.

• **BEYOND-USE DATE:** In the absence of performing and completing a sterility test, the storage conditions for High-Risk Level CSPs in *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩* apply. After successful completion of sterility testing, NMT 180 days after the date on which it was compounded when stored at controlled room temperature.

• **LABELING:** Label it to indicate that it is for veterinary use only. State that it is intended for use in the eye and to not use if a precipitate is present. State the *Beyond-Use Date*.

• **USP REFERENCE STANDARDS ⟨11⟩**

USP Cyclosporine RS

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

Topic/Question	Contact	Expert Committee
CYCLOSPORINE COMPOUNDED OPHTHALMIC SOLUTION, VETERINARY	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(5)

Current DocID: GUID-69F44524-80A9-4FC3-83AC-FD07F7EBD9D5_4_en-US

DOI: https://doi.org/10.31003/USPNF_M9261_04_01

DOI ref: gjmxt