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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, <i>NF</i> , 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:

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