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Tacrolimus Compounded Oral Suspension

DEFINITION

Tacrolimus Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of tacrolimus ($C_{44}H_{69}NO_{12}$).

Prepare Tacrolimus Compounded Oral Suspension 0.5 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Tacrolimus capsules[a] equivalent to	50 mg of tacrolimus
Vehicle: a 1:1 mixture of Ora-Plus[b] and Syrup, *NF*, a sufficient quantity to make	100 mL

[a] Prograf 5-mg capsules, Astellas Pharma US, Inc., Deerfield, IL.

[b] Paddock Laboratories, Minneapolis, MN.

Calculate the quantity of each ingredient required for the total amount to be prepared. Empty the required number of *Tacrolimus capsules* in a suitable mortar. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a tacrolimus liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well. Tacrolimus powder is not interchangeable with *Tacrolimus capsules* and should not be used.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and deionized distilled water (65:35). Filter and degas.

Standard stock solution: 0.5 mg/mL of USP Tacrolimus RS in acetonitrile

Standard solution: Pipet 1.0 mL of *Standard stock solution* into a 10-mL volumetric flask, and dilute with *Mobile phase* to volume to obtain a solution having a nominal concentration of 50 µg/mL of tacrolimus. [Note—The *Standard solution* is relatively unstable, and the *Assay* should proceed immediately.]

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Pipet 1.0 mL of Oral Suspension to a 10-mL volumetric flask, and dilute with *Mobile phase* to volume to obtain a solution with a nominal concentration of 50 µg/mL of tacrolimus. [Note—The *Sample solution* is relatively unstable, and the *Assay* should proceed immediately.]

Chromatographic system

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

Mode: LC

Detector: UV 214 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 70°

Flow rate: 1.7 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for tacrolimus is about 6.4 min.]

Suitability requirements

Column efficiency: NLT 2500 theoretical plates

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 tacrolimus ($C_{44}H_{69}NO_{12}$) in the portion of Oral Suspension 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 Tacrolimus RS in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.1–5.1

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature

• **Labeling:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Tacrolimus RS

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

Topic/Question	Contact	Expert Committee
TACROLIMUS COMPOUNDED ORAL SUSPENSION	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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