

Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Aug-2015
Document Type: USP Monographs
DocId: GUID-242B07E7-6615-486A-8D60-D7CC4250EA6A_1_en-US
DOI: https://doi.org/10.31003/USPNF_M8849_01_01
DOI Ref: 7w8sn

© 2025 USPC
Do not distribute

Tadalafil Compounded Oral Suspension

DEFINITION
Tadalafil Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of tadalafil ($C_{22}H_{19}N_3O_4$).
Prepare Tadalafil Compounded Oral Suspension 5 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Tadalafil tablets ^a equivalent to	500 mg
Vehicle: A 1:1 mixture of Ora-Plus ^b and Ora-Sweet ^b , a sufficient quantity to make	100 mL

- ^a Adcirca 20-mg tablets, Eli Lilly and Company, Indianapolis, IN.
^b Perrigo Pharmaceuticals, Allegan, MI.

Place the required number of tablets in a suitable mortar, and comminute to a fine powder. Wet the powder with a small amount of the *Vehicle*, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a tadalafil 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.

ASSAY

• **PROCEDURE**

Solution A: 10 mM sodium phosphate adjusted with phosphoric acid to a pH of 3.0. Pass through a nylon filter of 0.45-µm pore size.

Solution B: Water adjusted with phosphoric acid to a pH of 3.0

Mobile phase: Acetonitrile and *Solution A* (60:40)

Diluent: Acetonitrile and *Solution B* (50:50)

Standard stock solution: 5 mg/mL of tadalafil prepared from [USP Tadalafil RS](#) in acetonitrile. Mix well, and store at 2°–8°.

Standard solution: Transfer 2.0 mL of the *Standard stock solution* into a 500-mL volumetric flask, and dilute with *Diluent* to volume. Mix well. Centrifuge an aliquot for 5 min at 14,000 rpm. Protect from light, and store at 2°–8°.

Sample solution: Transfer 2.0 mL of Oral Suspension into a 500-mL volumetric flask, and dilute with *Diluent* to volume. Mix well. Centrifuge an aliquot for 5 min at 14,000 rpm. Protect from light, and store at 2°–8°.

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

Mode: LC

Detector: UV 220 nm

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

Temperatures

Autosampler: 5°

Column: 30°

Flow rate: 0.8 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for tadalafil is about 4.5 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 tadalafil ($C_{22}H_{19}N_3O_4$) in the portion of Oral Suspension taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH** (791): 4.3–5.3

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at 2°–8° or controlled room temperature.
- **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded when stored at 2°–8° or 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 Tadalafil RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
TADALAFIL 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](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 40(2)

Current DocID: GUID-242B07E7-6615-486A-8D60-D7CC4250EA6A_1_en-US

DOI: https://doi.org/10.31003/USPNF_M8849_01_01

DOI ref: [7w8sn](#)