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Sildenafil Compounded Oral Suspension

DEFINITION
Sildenafil Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of sildenafil ($C_{22}H_{30}N_6O_4S$).

Prepare Sildenafil Compounded Oral Suspension containing 2.5 mg/mL of sildenafil as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Sildenafil Citrate tablets[a] equivalent to	250 mg of sildenafil
Vehicle: a 1:1 mixture of Ora-Sweet[b] and Ora-Plus,[b] a sufficient quantity to make	100 mL

[a] Viagra 25-mg tablets, Pfizer Inc., New York, NY.

[b] Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of *Sildenafil Citrate tablets* in a suitable mortar, and comminute to a fine powder with a pestle. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a sildenafil 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**

Mobile phase: Acetonitrile and 0.2 M ammonium acetate (50:50). Pass through a nylon 66 filter of 0.45-µm pore size, and degas.

Standard stock solution: 2.5 mg/mL of sildenafil prepared from USP Sildenafil Citrate RS in *Mobile phase*

Standard solution: 0.25 mg/mL of sildenafil prepared from *Standard stock solution* and *Mobile phase*

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Prepare 0.25 mg/mL of sildenafil from Oral Suspension and *Mobile phase*, and centrifuge.

Chromatographic system

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

Mode: LC

Detector: UV 245 nm

Column: 3.0-mm × 15-cm; 5-µm packing L1

Column temperature: 25°

Flow rate: 0.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for sildenafil is about 7.1 min.]

Suitability requirements

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sildenafil ($C_{22}H_{30}N_6O_4S$) 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 sildenafil in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.9–4.9

ADDITIONAL REQUIREMENTS

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

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded, when stored in a refrigerator or 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 Sildenafil Citrate RS

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

Topic/Question	Contact	Expert Committee
SILDENAFIL 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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