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Terbutaline Sulfate Compounded Oral Suspension

DEFINITION

Terbutaline Sulfate Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of terbutaline sulfate $[(C_{12}H_{19}NO_3)_2 \cdot H_2SO_4]$. Prepare Terbutaline Sulfate Compounded Oral Suspension 1 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Terbutaline Sulfate	100 mg
Syrup, *NF*,[a] a sufficient quantity to make	100 mL

[a] Syrup, *NF*, containing 0.2% sodium benzoate.

Calculate the required quantity of each ingredient for the total amount to be prepared. If using tablets, place the required number of tablets in a suitable mortar, and comminute the tablets to a fine powder or add *Terbutaline Sulfate* powder. Add the *Syrup*, *NF*, to make a terbutaline sulfate suspension that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Syrup*, *NF*, to bring to final volume, and mix well.

ASSAY

• **Procedure**

Mobile phase: A solution of methanol and 20 mM monobasic potassium phosphate (2:23), adjusted with phosphoric acid to a pH of 3.6. Filter and degas.

Standard stock solution: 5 mg/mL of USP Terbutaline Sulfate RS in methanol

Standard solution: Transfer 0.2 mL of *Standard stock solution* to a 100-mL volumetric flask, dilute with water to volume to obtain a solution containing 10 µg/mL of terbutaline sulfate, and pass through a suitable filter of 0.22-µm pore size.

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Accurately pipet 1.0 mL to a 10-mL volumetric flask. Dilute with *Mobile phase* to volume to obtain a nominal concentration of 100 µg/mL of terbutaline sulfate. Extract terbutaline sulfate from Oral Suspension with methanol. Accurately pipet 1 mL of Oral Suspension and 3 mL of *Mobile phase* in the barrel of a 5-mL plastic syringe. Shake, and pass through a suitable filter of 0.22-µm pore size into a 10-mL volumetric flask. Repeat the process with an additional 2 mL of methanol. Bring to a final volume of 10 mL with *Mobile phase* to obtain a nominal concentration of 10 µg/mL of terbutaline sulfate.

Chromatographic system

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

Mode: LC

Detector: UV 278 nm

Column: 3.9-mm × 30-cm; 10-µm microphenyl packing L11

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for the terbutaline sulfate peak is 5 min.]

Suitability requirements

Relative standard deviation: NMT 2.2% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of terbutaline sulfate $[(C_{12}H_{19}NO_3)_2 \cdot H_2SO_4]$ in the portion of Oral Suspension taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Terbutaline Sulfate RS in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Package in tight, light-resistant containers. Store in a refrigerator.
- **Beyond-Use Date:** NMT 30 days after the date on which it was compounded when stored in a refrigerator
- **Labeling:** Label it to state that it is to be well shaken before use, and to state the *Beyond-Use Date*.
- **USP Reference Standards** ⟨11⟩
  USP Terbutaline Sulfate RS

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

Topic/Question	Contact	Expert Committee
TERBUTALINE SULFATE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

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