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# Terbutaline Sulfate Injection

## DEFINITION

Terbutaline Sulfate Injection is a sterile solution of Terbutaline Sulfate in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of terbutaline sulfate  $[(C_{12}H_{19}NO_3)_2 \cdot H_2SO_4]$ .

[CAUTION—Do not use the Injection if it is discolored.]

## IDENTIFICATION

Delete the following:

▲ **A. THIN LAYER CHROMATOGRAPHY** ▲ (USP 1-Dec-2023)

Add the following:

▲ **A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲ (USP 1-Dec-2023)

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

## ASSAY

Change to read:

### PROCEDURE

**Buffer:** 3.15 g/L of [ammonium formate](#) and 5.49 g/L of [sodium 1-hexanesulfonate](#) in [water](#) prepared as follows. Transfer 3.15 g of [ammonium formate](#) to a 1000-mL volumetric flask, dissolve in 900 mL of [water](#), adjust the solution with [formic acid](#) to a pH of 3.0, add 5.49 g of [sodium 1-hexanesulfonate](#), and dilute with [water](#) to volume.

**Mobile phase:** [Methanol](#) and *Buffer* (23:77)

**System suitability solution:** 1.0 mg/mL of [USP Terbutaline Sulfate RS](#) and 0.4 mg/mL of [USP Terbutaline Related Compound A RS](#) in *Mobile phase*

**Standard solution:** 1.0 mg/mL of [USP Terbutaline Sulfate RS](#) in *Mobile phase*

**Sample solution:** Nominally 1.0 mg/mL from a volume of Injection. If necessary, dilute with [water](#).

### Chromatographic system

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

**Mode:** LC

**Detector:** UV 276 nm. ▲ For *Identification A*, use a diode array detector in the range of 240–400 nm. ▲ (USP 1-Dec-2023)

**Column:** 4.6-mm × 15-cm; 5-μm packing [L1](#)

**Flow rate:** 1 mL/min

**Injection volume:** 20 μL

▲ **Run time:** NLT 1.6 times the retention time of terbutaline ▲ (USP 1-Dec-2023)

### System suitability

**Sample:** *System suitability solution*

[NOTE—The relative retention times for terbutaline related compound A and terbutaline are 0.9 and 1.0, respectively.]

### Suitability requirements

**Resolution:** NLT 2.0 between terbutaline related compound A and terbutaline

▲ ▲ (USP 1-Dec-2023)

**Tailing factor:** NMT 2.0 for terbutaline

**Relative standard deviation:** NMT ▲ 1.0% ▲ (USP 1-Dec-2023) for terbutaline

### 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 Injection taken:

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

$r_U$  = peak response of terbutaline from the *Sample solution*

$r_s$  = peak response of terbutaline from the *Standard solution*

$C_s$  = concentration of [USP Terbutaline Sulfate RS](#) in the *Standard solution* (mg/mL)

$C_u$  = nominal concentration of terbutaline sulfate in the *Sample solution* (mg/mL)

**Acceptance criteria:** 90.0%–110.0%

Add the following:

#### ▲IMPURITIES

##### • ORGANIC IMPURITIES

**Buffer:** 3.15 g/L of [ammonium formate](#) and 5.49 g/L of [sodium 1-hexanesulfonate](#) in [water](#) prepared as follows. Transfer 3.15 g of [ammonium formate](#) to a 1000-mL volumetric flask, dissolve in 900 mL of [water](#), adjust the solution with [formic acid](#) to a pH of 3.0, add 5.49 g of [sodium 1-hexanesulfonate](#), and dilute with [water](#) to volume.

**Solution A:** [Methanol](#) and *Buffer* (23:77)

**Solution B:** [Methanol](#)

**Mobile phase:** See [Table 1](#).

**Table 1**

| Time<br>(min) | Solution A<br>(%) | Solution B<br>(%) |
|---------------|-------------------|-------------------|
| 0             | 100               | 0                 |
| 15            | 100               | 0                 |
| 35            | 80                | 20                |
| 40            | 80                | 20                |
| 42            | 100               | 0                 |
| 45            | 100               | 0                 |

**System suitability solution:** 0.2 mg/mL of [USP Terbutaline Sulfate RS](#) and 0.08 mg/mL of [USP Terbutaline Related Compound A RS](#) in *Solution A*

**Sensitivity solution:** 0.0003 mg/mL of [USP Terbutaline Sulfate RS](#) in *Solution A*

**Standard solution:** 0.0006 mg/mL each of [USP Terbutaline Sulfate RS](#) and [USP Terbutaline Related Compound A RS](#) in *Solution A*

**Sample solution:** Nominally 0.3 mg/mL of terbutaline sulfate, from the pooled content of Injection from vials (NLT 5), in *Solution A*

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 276 nm

**Column:** 4.6-mm × 15-cm; 5-μm packing [L1](#)

**Flow rate:** 1 mL/min

**Injection volume:** 100 μL

#### System suitability

**Samples:** *System suitability solution*, *Sensitivity solution*, and *Standard solution*

[NOTE—See [Table 2](#) for the relative retention times.]

#### Suitability requirements

**Resolution:** NLT 1.5 between terbutaline related compound A and terbutaline, *System suitability solution*

**Relative standard deviation:** NMT 5.0% from terbutaline and terbutaline related compound A, *Standard solution*

**Signal-to-noise ratio:** NLT 10, *Sensitivity solution*

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of terbutaline related compound A in the portion of Injection taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times 100$$

$r_u$  = peak response of terbutaline related compound A from the *Sample solution*

$r_s$  = peak response of terbutaline related compound A from the *Standard solution*