volumetric flask. Dilute with water to volume, mix, and filter, discarding the first 2 mL of the filtrate.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 280-nm detector, a 0.5-µm precolumn, and a 6.2-mm × 8-cm column that contains 3-µm packing L7. The column temperature is maintained at 40°. The flow rate is about 1.5 mL per minute. Chromatograph the *Resolution solution*, and record the peak responses as directed for *Procedure:* the relative retention times are about 1.0 and 0.83 for terbutaline and terbutaline related compound A, respectively; and the resolution, *R,* between terbutaline sulfate and terbutaline related compound A is not less than 1.6. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of terbutaline sulfate $[(C_{12}H_{19}NO_3)_2 \cdot H_2SO_4]$ in each container taken by the formula:

$$250C(r_U / r_S)$$

in which *C* is the concentration, in mg per mL, of USP Terbutaline Sulfate RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Terbutaline Sulfate Injection

» Terbutaline Sulfate Injection is a sterile solution of Terbutaline Sulfate in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $(C_{12}H_{19}NO_3)_2 \cdot H_2SO_4$.
NOTE—Do not use the Injection if it is discolored.

Packaging and storage—Preserve in single-dose containers, preferably of Type I glass, protected from light, at controlled room temperature.

USP Reference standards ⟨11⟩**—**
USP Endotoxin RS
USP Terbutaline Sulfate RS
USP Terbutaline Related Compound A RS
3,5-Dihydroxy-ω-*t*-butylaminoacetophenone sulfate.

Identification—

A: Apply 2 µL of Injection and 2 µL of a solution of USP Terbutaline Sulfate RS in sodium chloride solution (0.9 in 100) containing 1 mg per mL to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel. Develop the chromatogram in a solvent system consisting of a mixture of isopropyl alcohol, cyclohexane, and formic acid (13:5:1) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and dry with a current of air. Spray the plate with a 1 in 50 solution of 4-aminoantipyrine in methanol, allow to air-dry, and spray with a 2 in 25 solution of potassium ferricyanide in a solvent prepared by mixing ammonium hydroxide with water (4:1): the R_F value of the principal spot obtained from the Injection corresponds to that obtained from the Standard solution.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation* as obtained in the *Assay*.

Bacterial endotoxins ⟨85⟩**—**It contains not more than 1250.0 USP Endotoxin Units per mg of terbutaline sulfate.

pH ⟨791⟩: between 3.0 and 5.0.

Other requirements—It meets the requirements under *Injections* ⟨1⟩.

Assay—

Mobile phase, Standard preparation, Resolution solution, and *Chromatographic system*—Prepare as directed in the *Assay* under *Terbutaline Sulfate.*

Assay preparation—Use Injection. If necessary, quantitatively dilute an accurately measured volume of Injection with water to obtain a solution having a concentration of about 1 mg per mL.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $(C_{12}H_{19}NO_3)_2 \cdot H_2SO_4$ in each mL of the Injection taken by the formula:

$$(LC / D)(r_U / r_S)$$

in which *L* is the labeled quantity, in mg per mL, of terbutaline sulfate in the Injection, *C* is the concentration, in mg per mL, of USP Terbutaline Sulfate RS in the *Standard preparation, D* is the concentration, in mg per mL, of terbutaline sulfate in the *Assay preparation,* based upon the labeled quantity, in mg per mL, of terbutaline sulfate in the Injection and the extent of dilution, and r_U and r_S are the terbutaline peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Terbutaline Sulfate Tablets

» Terbutaline Sulfate Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $(C_{12}H_{19}NO_3)_2 \cdot H_2SO_4$.

Packaging and storage—Preserve in tight containers, at controlled room temperature.

USP Reference standards ⟨11⟩**—**
USP Terbutaline Sulfate RS
USP Terbutaline Related Compound A RS
3,5-Dihydroxy-ω-*t*-butylaminoacetophenone sulfate.

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

Dissolution, *Procedure for a Pooled Sample* ⟨711⟩**—**
Medium: water; 900 mL.
Apparatus 1: 100 rpm.
Time: 45 minutes.

Procedure—Determine the amount of $(C_{12}H_{19}NO_3)_2 \cdot H_2SO_4$ dissolved, employing the procedure set forth in the *Assay*, making any necessary modifications.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $(C_{12}H_{19}NO_3)_2 \cdot H_2SO_4$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Ion-pair solution, Mobile phase, System suitability solution, and *Chromatographic system*—Proceed as directed in the *Assay* under *Terbutaline Sulfate.*

Standard preparation—Dissolve an accurately weighed quantity of USP Terbutaline Sulfate RS in *Mobile phase,* and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 1 mg per mL. Transfer 10.0 mL of the solution so obtained to a 100-mL volumetric flask, add 10 mL of 0.05 N sulfuric acid, dilute with water to volume, and mix.