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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.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 10 mg of terbutaline sulfate, to a 100-mL volumetric flask. Add 10 mL of 0.05 N sulfuric acid and 20 mL of water, and shake for 15 minutes. Dilute with water to volume, mix, and filter.

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 the portion of Tablets taken by the formula:

$$100C(r_U/r_S)$$

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 terbutaline peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Chromatographic Database Information: Chromatographic Database

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