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Ethotoin Tablets

» Ethotoin Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{11}H_{12}N_2O_2$.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Ethotoin RS
USP Ethylparaben RS

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

Dissolution ⟨711⟩—

Medium: 0.1 N hydrochloric acid; 900 mL.

Apparatus 2: 100 rpm.

Time: 60 minutes.

Standard solution—Transfer about 100 mg of USP Ethotoin RS, accurately weighed, to a 25-mL volumetric flask. Dissolve in methanol, dilute with methanol to volume, and mix. Transfer 4.0 mL of this solution to a 50-mL volumetric flask, add *Dissolution Medium* to volume, and mix.

Procedure—Determine the amount of $C_{11}H_{12}N_2O_2$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 257 nm on filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with the *Standard solution*.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{11}H_{12}N_2O_2$ is dissolved in 60 minutes.

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

Assay—

Diluent—Prepare a mixture of water, acetonitrile, and phosphoric acid (750:250:1).

Mobile phase—Prepare a filtered and degassed mixture of water and acetonitrile (3:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Internal standard solution—Prepare a solution of USP Ethylparaben RS in *Diluent* having a concentration of 0.02 mg per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Ethotoin RS in *Mobile phase*, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 1.0 mg per mL. Immediately transfer 5 mL of this solution and 5 mL of the *Internal standard solution* to a suitable container, and mix well.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 100 mg of ethotoin, to a 100-mL volumetric flask. Add 75 mL of *Mobile phase*, shake vigorously for 60 minutes, dilute with *Mobile phase* to volume, mix, and immediately filter. Without delay, transfer 5 mL of the filtrate and 5 mL of the *Internal standard solution* to a suitable container, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between the analyte and internal standard peaks is not less than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 50 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. [Note—For the purpose of identification, the relative retention times are about 0.5 for ethotoin and 1.0 for ethylparaben.] Calculate the quantity, in mg, of ethotoin ($C_{11}H_{12}N_2O_2$) in the portion of Tablets taken by the formula:

$$200C(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Ethotoin RS in the *Standard preparation;* and R_U and R_S are the peak response ratios obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
ETHOTOIN TABLETS	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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