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Etodolac Capsules

» Etodolac Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of etodolac ($C_{17}H_{21}NO_3$).

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

USP Reference standards ⟨11⟩—

USP Etodolac RS
USP Etodolac Related Compound A RS

(±)-8-Ethyl-1-methyl-1,3,4,9-tetrahydropyrano [3,4-*b*]-indole-1-acetic acid.

$C_{16}H_{19}NO_3$ 273.33

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 ⟨711⟩—

Medium: pH 6.8 phosphate buffer (see *Buffer Solutions* in the section *Reagents, Indicators, and Solutions*); 1000 mL.

Apparatus 1: 100 rpm.

Time: 30 minutes.

Procedure—Determine the amount of $C_{17}H_{21}NO_3$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 274 nm on filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Etodolac RS in the same *Medium*.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{17}H_{21}NO_3$ is dissolved in 30 minutes.

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

Assay—

Mobile phase—Prepare a filtered and degassed mixture of acetonitrile, water, and phosphoric acid (500:500:0.25). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Etodolac RS in *Mobile phase* to obtain a solution having a known concentration of about 0.2 mg per mL. Prepare this solution fresh daily.

System suitability solution—Dissolve suitable quantities of USP Etodolac Related Compound A RS and USP Etodolac RS in *Mobile phase* to obtain a solution containing about 0.01 mg of etodolac related compound A and 0.2 mg of etodolac per mL.

Assay preparation—Weigh not fewer than 20 Capsules, and transfer the contents as completely as possible to a suitable container. Remove any residual powder from the empty capsules with the aid of a current of air, and weigh the capsule shells, determining the weight of the contents by difference. Mix the contents of the Capsules, and transfer an accurately weighed portion of the powder, equivalent to about 1000 mg of etodolac, to a 500-mL volumetric flask, add 300 mL of *Mobile phase*, shake for 15 minutes, sonicate for 5 minutes, cool, dilute with *Mobile phase* to volume, and mix. Allow to settle for 10 minutes. Pipet 10.0 mL of the solution to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Pass the solution through a filter having a 0.45-µm or finer porosity, prior to use.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 274-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.8 for etodolac related compound A and 1.0 for etodolac; the resolution, *R,* between etodolac related compound A and etodolac is not less than 2; the tailing factor is not more than 2; and the relative standard deviation for replicate injections is not more than 2%.

Procedure—Separately inject equal volumes (about 10 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 etodolac ($C_{17}H_{21}NO_3$) in the portion of Capsule contents taken by the formula:

$$5000C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Etodolac RS in the *Standard preparation;* and r_U and r_S are the etodolac peak responses 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
ETODOLAC CAPSULES	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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