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Etodolac Tablets

DEFINITION

Etodolac Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of etodolac ($C_{17}H_{21}NO_3$).

IDENTIFICATION

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

Add the following:

▲• **B.** 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-May-2024)

ASSAY

Change to read:

• PROCEDURE

Mobile phase: [Acetonitrile](#), [phosphoric acid](#), and [water](#) (50: 0.025: 50)

System suitability solution: 0.01 mg/mL of [USP Etodolac Related Compound A RS](#) and 0.2 mg/mL of [USP Etodolac RS](#) in *Mobile phase*

Standard solution: 0.2 mg/mL of [USP Etodolac RS](#) in *Mobile phase*. Prepare this solution fresh daily.

Sample stock solution: Nominally 2 mg/mL of etodolac prepared as follows. Transfer a portion of finely powdered Tablets (NLT 20), equivalent to about 1000 mg of etodolac, to a 500-mL volumetric flask, add 300 mL of *Mobile phase*, shake for 15 min, and sonicate for 5 min. Cool, and dilute with *Mobile phase* to volume. Allow to settle for 10 min.

Sample solution: Nominally 0.2 mg/mL of etodolac in *Mobile phase*, from *Sample stock solution*. Pass the solution through a suitable filter of 0.45-μm or finer pore size.

Chromatographic system

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

Mode: LC

Detector: UV 274 nm. ▲For *Identification B*, use a diode array detector in the range of 190–400 nm.▲ (USP 1-May-2024)

Column: 4.6-mm × 25-cm; ▲10-μm▲ (USP 1-May-2024) packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 10 μL

System suitability

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

[NOTE—The relative retention times for etodolac related compound A and etodolac are 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2 between etodolac related compound A and etodolac, *System suitability solution*

Tailing factor: NMT 2, *Standard solution*

Relative standard deviation: NMT 2%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of etodolac ($C_{17}H_{21}NO_3$) in the portion of Tablets taken:

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

r_U = peak response of etodolac from the *Sample solution*

r_S = peak response of etodolac from the *Standard solution*

C_S = concentration of [USP Etodolac RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of etodolac in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#).

Medium: [pH 6.8 phosphate buffer](#); 1000 mL

Apparatus 1: 100 rpm

Time: 30 min

Standard solution: A known concentration of [USP Etodolac RS](#) in *Medium*

Sample solution: Pass the solution under test through a suitable filter. Dilute with *Medium*, if necessary, to a suitable concentration that is similar to that of the *Standard solution*.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum at about 274 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of etodolac ($C_{17}H_{21}NO_3$) dissolved:

▲Result = $(A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of [USP Etodolac RS](#) in the *Standard solution* (mg/mL)

V = volume of the *Medium*, 1000 mL

D = dilution factor of the *Sample solution*

L = label claim (mg/Tablet)

▲ (USP 1-May-2024)

Tolerances: NLT 80% (Q) of the labeled amount of etodolac ($C_{17}H_{21}NO_3$) is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

Add the following:

▲IMPURITIES

• **ORGANIC IMPURITIES**

Protect the solutions containing etodolac from light.

Solution A: 0.77 g/L of [ammonium acetate](#) in [water](#)

Solution B: [Acetonitrile](#) and *Solution A* (90:10)

Mobile phase: See [Table 1](#). Return to original conditions and re-equilibrate the system. [NOTE—A re-equilibration time of 15 min may be used.]

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
25	50	50
50	50	50

System suitability solution: 1.0 mg/mL of [USP Etodolac RS](#) and 0.002 mg/mL of [USP Etodolac Related Compound H RS](#) in [acetonitrile](#). Sonicate to dissolve as needed.

Standard solution: 0.002 mg/mL each of [USP Etodolac RS](#) and [USP Etodolac Related Compound H RS](#) in [acetonitrile](#). Sonicate to dissolve as needed.

Sensitivity solution: 1.0 µg/mL each of [USP Etodolac RS](#) and [USP Etodolac Related Compound H RS](#) in [acetonitrile](#), from the *Standard solution*

Sample solution: Nominally 1.0 mg/mL of etodolac prepared as follows. Transfer a portion of finely powdered Tablets (NLT 20), equivalent to about 50 mg of etodolac, to a 50-mL volumetric flask. Add about 30 mL of [acetonitrile](#), sonicate, and dilute with [acetonitrile](#) to volume. [NOTE—A sonication time of 15 min may be used.]

Chromatographic system

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