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Diclofenac Sodium Extended-Release Tablets

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DEFINITION

Diclofenac Sodium Extended-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of diclofenac sodium ($C_{14}H_{10}Cl_2NNaO_2$).

IDENTIFICATION

- **A.** The retention time of the diclofenac peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The UV (190–400 nm) spectrum of the diclofenac peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• **PROCEDURE**

Solution A: 0.7708 g/L of [ammonium acetate](#) in [water](#). Adjust with [acetic acid](#) to a pH of 5.3. Pass through a suitable filter of 0.2-µm pore size.

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.00	70	30
0.50	70	30
8.50	5	95
10.00	5	95
10.01	70	30
14.00	70	30

Diluent: [Acetonitrile](#) and [water](#) (50:50)

Standard solution: 0.2 mg/mL of [USP Diclofenac Sodium RS](#) in *Diluent*

Sample solution: Nominally 0.2 mg/mL of diclofenac sodium in *Diluent* prepared as follows. Transfer a suitable portion of diclofenac sodium to a suitable volumetric flask from NLT 20 finely powdered Tablets. Add *Diluent* equivalent to 70% of the flask volume. Dissolve with the aid of sonication for 25 min at 45° and fill with *Diluent* to volume. Pass the solution through a suitable filter of 0.22-µm pore size.

[NOTE—Protect the *Standard solution* and *Sample solution* from light.]

Chromatographic system

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

Mode: LC

Detector: UV 280 nm. For *Identification test B*, use a photo-diode array detector.

Column: 10-cm × 2.0-mm; 1.9-µm packing [L1](#)

Column temperature: 35°

Flow rate: 0.3 mL/min

Injection volume: 1 µL

System suitability

Sample: *Standard solution*

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements**Tailing factor:** NMT 1.2**Relative standard deviation:** NMT 2.8%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of diclofenac sodium ($C_{14}H_{10}Cl_2NNaO_2$) in the portion of Tablets taken:

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

 r_U = peak response of diclofenac from the *Sample solution* r_S = peak response of diclofenac from the *Standard solution* C_S = concentration of [USP Diclofenac Sodium RS](#) in the *Standard solution* (mg/mL) C_U = nominal concentration of diclofenac sodium in the *Sample solution* (mg/mL)**Acceptance criteria:** 90.0%–110.0%**PERFORMANCE TESTS****Change to read:**

- [DISSOLUTION \(711\)](#).

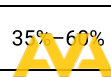
Test 1**Medium:** 0.05 M phosphate buffer, pH 7.5; 900 mL**Apparatus 2:** 50 rpm; use wire sinkers.**Times:** 1, 5, 10, 16, and 24 h**Detector:** UV 276 nm**Standard solution:** [USP Diclofenac Sodium RS](#) in *Medium***Analysis:** Pass portions of the solution under test through a suitable filter. Dilute with *Medium*, if necessary, to a concentration similar to that of the *Standard solution*.**Tolerances:** See [Table 2](#).**Table 2**

Time (h)	Amount Dissolved
1	15%–35%
5	45%–65%
10	65%–85%
16	75%–95%
24	NLT 80%

The percentages of the labeled amount of diclofenac sodium ($C_{14}H_{10}Cl_2NNaO_2$) dissolved at the times specified conform to [Acceptance Table 2](#) in [\(711\)](#).

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.**Medium, Apparatus 2, and Analysis:** Proceed as directed for *Dissolution Test 1*.**Times:** 1, 2, 4, 6, and 10 h**Tolerances:** See [Table 3](#).**Table 3**

Time (h)	Amount Dissolved
1	NMT 28%
2	20%–40%
4	35%–60%

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