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Diclofenac Potassium Tablets

DEFINITION
Diclofenac Potassium Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of diclofenac potassium ($C_{14}H_{10}Cl_2KNO_2$).

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 Potassium RS in *Diluent*

Sample solution: Nominally 0.2 mg/mL of diclofenac potassium in *Diluent* prepared as follows. Transfer a suitable portion of diclofenac potassium to a suitable volumetric flask from NLT 20 finely powdered Tablets. Add *Diluent* equivalent to 80% of the flask volume. Dissolve 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 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of diclofenac potassium ($C_{14}H_{10}Cl_2KNO_2$) 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 Potassium RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Simulated intestinal fluid (without enzyme); 900 mL

Apparatus 2: 50 rpm

Time: 60 min

Standard solution: A known concentration of USP Diclofenac Potassium RS in *Medium*. Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size. Dilute with *Medium* if necessary.

Sample solution: Sample as per *Dissolution ⟨711⟩*. Dilute with *Medium* to a concentration that is similar to the *Standard solution*.

Instrumental conditions

Mode: UV-Vis

Analytical wavelength: Maximum absorbance at about UV 276 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of diclofenac potassium ($C_{14}H_{10}Cl_2KNO_2$) dissolved:

$$\frac{A_U \times C_S \times V \times 100}{A_S \times L}$$

A_U = absorbance of the *Sample solution*

C_S = concentration of the *Standard solution* (mg/mL)

V = volume of *Medium*, 900 mL

A_S = absorbance of the *Standard solution*

L = label claim of diclofenac potassium (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of diclofenac potassium ($C_{14}H_{10}Cl_2KNO_2$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Mobile phase and **Diluent:** Proceed as directed in the *Assay*.

Standard solution: 0.001 mg/mL each of USP Diclofenac Potassium RS and USP Diclofenac Related Compound A RS in *Diluent*

Sample solution: Nominally 1.0 mg/mL of diclofenac potassium in *Diluent* prepared as follows. Transfer a suitable portion of diclofenac potassium to a suitable volumetric flask from NLT 20 finely powdered Tablets. Add *Diluent* equivalent to 80% of the flask volume. Dissolve and fill with *Diluent* to volume. Pass the solution through a suitable filter of 0.22-µm pore size.

Chromatographic system: Proceed as directed in the *Assay* except for the *Detector*.

Detector: UV 254 nm

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 5%

Signal-to-noise ratio: NLT 10

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of diclofenac related compound A 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 related compound A from the *Sample solution*

r_S = peak response of diclofenac related compound A from the *Standard solution*

C_S = concentration of USP Diclofenac Related Compound A RS in the *Standard solution* (mg/mL)

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

Calculate the percentage of any other impurity in the portion of Tablets taken:

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

r_U = peak response of each individual impurity from the *Sample solution*

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

C_S = concentration of USP Diclofenac Potassium RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: See *Table 2*. Disregard any impurity peak less than 0.05%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Oxindole[a,b]	0.4	—
Diclofenac	1.0	—
Diclofenac related compound D (diclofenac bromo analog)[c,b]	1.04	—
Diclofenac related compound A	1.48	0.5
Diclofenac alcohol analog[d,b]	1.55	—
Diclofenac benzaldehyde analog[e,b]	1.81	—
Any individual unspecified impurity	—	0.5
Total impurities[b]	—	1.5

[a] 1,3-Dihydro-2*H*-indol-2-one.

[b] Process-related impurities, not to be counted in total impurities.

[c] 2-{2-[(2-Bromo-6-chlorophenyl)amino]phenyl}acetic acid.

[d] {2-[(2,6-Dichlorophenyl)amino]phenyl}methanol.

[e] 2-[(2,6-Dichlorophenyl)amino]benzaldehyde.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers, and store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩

USP Diclofenac Potassium RS

USP Diclofenac Related Compound A RS

1-(2,6-Dichlorophenyl)indolin-2-one (diclofenac lactam).

$C_{14}H_9Cl_2NO$ 278.13

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

Topic/Question	Contact	Expert Committee
DICLOFENAC POTASSIUM TABLETS	Documentary Standards Support	SM22020 Small Molecules 2

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