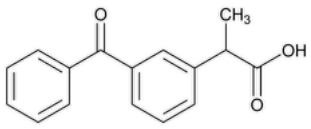
Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-A6EA10A7-26DB-482D-953A-F577D3B0EE38_4_en-US
DOI: https://doi.org/10.31003/USPNF_M44002_04_01
DOI Ref: ojv3a

Ketoprofen



$C_{16}H_{14}O_3$ 254.28

Benzeneacetic acid, 3-benzoyl-α-methyl-, (±)-;

(±)-*m*-Benzoylhydratropic acid CAS RN®: 22071-15-4; UNII: 90Y4QC304K.

DEFINITION

Ketoprofen contains NLT 98.5% and NMT 101.0% of $C_{16}H_{14}O_3$, calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

Change to read:

• **B.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U**▲ (CN 1-May-2020)

Analytical wavelength: 258 nm

Medium: Methanol and water (3:1)

Blank: *Medium*

Sample solution: 10 µg/mL in *Medium*

Acceptance criteria: Absorptivities, calculated on the dried basis, do not differ by more than 3.0%.

ASSAY

• **Procedure**

Sample: 450 mg

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Direct titration

Titrant: 0.1 N sodium hydroxide VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in 25 mL of alcohol. Add 25 mL of water and several drops of phenol red TS. Perform a blank determination. Each mL of *Titrant* is equivalent to 25.43 mg of $C_{16}H_{14}O_3$. [Note—Standardize the 0.1 N sodium hydroxide by a similar titration of primary standard benzoic acid.]

Acceptance criteria: 98.5%–101.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.2%

• **Organic Impurities**

[Note—Protect the solutions from light.]

Buffer: 68 g/L of monobasic potassium phosphate in water, and adjust with phosphoric acid to a pH of 3.5 ± 0.05

Mobile phase: Acetonitrile, water, and *Buffer* (43:55:2)

System suitability solution: 5 µg/mL of USP Ketoprofen RS and 1.5 µg/mL of USP Ketoprofen Related Compound D RS in *Mobile phase*

Standard solution: 0.002 mg/mL of USP Ketoprofen RS in *Mobile phase*

Sample solution: 1 mg/mL of Ketoprofen in *Mobile phase*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 233 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection size: 20 µL

Run time: Seven times the retention time for Ketoprofen

System suitability

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

[NOTE—The relative retention times for ketoprofen and ketoprofen related compound D (3-acetylbenzophenone) are about 1.0 and 1.6, respectively.]

Suitability requirements

Resolution: NLT 7.0 between ketoprofen related compound D and ketoprofen, *System suitability solution*

Column efficiency: NLT 2250 theoretical plates from ketoprofen, *System suitability solution*

Tailing factor: NMT 2.0 for ketoprofen, *System suitability solution*

Relative standard deviation: NMT 5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Ketoprofen taken:

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

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

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

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

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

Acceptance criteria

Any individual impurity: NMT 0.2%

Total impurities: NMT 1.0%

SPECIFIC TESTS

- **MELTING RANGE OR TEMPERATURE,** *Procedure for Class I*⟨741⟩**:** 92.0°–97.0°
- **OPTICAL ROTATION,** *Specific Rotation*⟨781S⟩

Sample solution: 10 mg/mL, in dehydrated alcohol

Acceptance criteria: +1° to −1°

- **LOSS ON DRYING** ⟨731⟩**:** Dry a sample in a vacuum at 60° for 4 h: it loses NMT 0.5% of its weight.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **USP REFERENCE STANDARDS** ⟨11⟩

USP Ketoprofen RS

USP Ketoprofen Related Compound D RS

3-Acetylbenzophenone.

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

Topic/Question	Contact	Expert Committee
KETOPROFEN	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 34(3)

Current DocID: GUID-A6EA10A7-26DB-482D-953A-F577D3B0EE38_4_en-US

DOI: https://doi.org/10.31003/USPNF_M44002_04_01

DOI ref: ojv3a