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Ibuprofen Tablets

DEFINITION
Ibuprofen Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of ibuprofen ($C_{13}H_{18}O_2$).

IDENTIFICATION
• **A.** The UV absorption spectra of the ibuprofen peak of the *Sample solution* exhibit maxima and minima at the same wavelengths as those of the *Standard solution*, as obtained in the *Assay*.
• **B.** The retention time of the ibuprofen peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY
• **Procedure**

Mobile phase: Dissolve 4.0 g of chloroacetic acid in 400 mL of water, adjust with ammonium hydroxide to a pH of 3.0 if necessary, add 600 mL of acetonitrile, and mix.

Standard solution: 10.0 mg/mL of USP Ibuprofen RS in *Mobile phase*

Sample solution: Nominally 10.0 mg/mL of ibuprofen prepared as follows. Transfer NLT 10 Tablets to a suitable volumetric flask and add about 50% final volume of *Mobile phase*. Shake on a mechanical shaker for at least 60 min or until the Tablets are disintegrated. Dilute with *Mobile phase* to volume. Centrifuge a portion of the solution at about 3000 rpm for about 10 min or until a clear supernatant is obtained. Use the supernatant for analysis.

Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability*.)
[Note—It is suggested to use the mixture of methanol and water (90:10) for needle wash.]
Mode: LC
Detectors
Assay: UV 254 nm
Identification test A: Diode array UV 200–400 nm
Column: 4.6-mm × 25-cm; 5-µm packing L1
Flow rate: 2.0 mL/min
Injection volume: 10 µL

System suitability
Sample: *Standard solution*
Suitability requirements
Tailing factor: NMT 2.5
Relative standard deviation: NMT 2.0%

Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of ibuprofen ($C_{13}H_{18}O_2$) in the portion of Tablets taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS
• **Dissolution ⟨711⟩**
Medium: pH 7.2 phosphate buffer (see *Reagents, Indicators, and Solutions—Buffers*); 900 mL
Apparatus 2: 50 rpm
Time: 60 min

Standard solution: A known concentration of USP Ibuprofen RS in *Medium*

Sample solution: Filter a portion of the solution under test, and suitably dilute with *Medium* if necessary.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 221 nm

Analysis: Determine the amount of ibuprofen ($C_{13}H_{18}O_2$) dissolved by comparing the UV absorbance of the *Sample solution* with that of the *Standard solution*. [NOTE—Where the Tablets are labeled as gelatin-coated, determine the amount of ibuprofen ($C_{13}H_{18}O_2$) dissolved from the UV absorbance at the wavelength of maximum absorbance at about 266 nm, from which is subtracted the absorbance at 280 nm, in comparison with the *Standard solution*, similarly measured.]

Tolerances: NLT 80% (*Q*) of the labeled amount of ibuprofen ($C_{13}H_{18}O_2$) is dissolved.

• **UNIFORMITY OF DOSAGE UNITS ⟨905⟩:** Meet the requirements

IMPURITIES

• **ORGANIC IMPURITIES**

Mobile phase, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Sensitivity solution: 0.005 mg/mL of USP Ibuprofen RS in *Mobile phase*

System suitability solution: 10.0 mg/mL of USP Ibuprofen RS and 0.01 mg/mL each of USP Ibuprofen Related Compound C RS and USP Ibuprofen Related Compound J RS in *Mobile phase*

Standard solution: 0.02 mg/mL of USP Ibuprofen RS and 0.01 mg/mL each of USP Ibuprofen Related Compound C RS and USP Ibuprofen Related Compound J RS in *Mobile phase*

System suitability

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

Suitability requirements

Resolution: NLT 2.5 between ibuprofen related compound J and ibuprofen; NLT 2.5 between ibuprofen and ibuprofen related compound C, *System suitability solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Relative standard deviation: NMT 6.0% for ibuprofen related compound J, ibuprofen, and ibuprofen related compound C, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ibuprofen related compound J and ibuprofen related compound C in the portion of Tablets taken:

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

r_U = peak response of ibuprofen related compound J or ibuprofen related compound C from the *Sample solution*

r_S = peak response of ibuprofen related compound J or ibuprofen related compound C from the *Standard solution*

C_S = concentration of USP Ibuprofen Related Compound J RS or USP Ibuprofen Related Compound C RS in the *Standard solution* (mg/mL)

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

Calculate the percentage of any unspecified degradation product in the portion of Tablets taken:

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

r_U = peak response of any individual unspecified degradation product from the *Sample solution*

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

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

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

Acceptance criteria: See *Table 1*. Disregard any peaks less than 0.05%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Ibuprofen related compound J	0.47	0.2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Ibuprofen	1.00	—
Ibuprofen related compound C	1.62	0.25
Any unspecified degradation product	—	0.2
Total degradation products	—	1.5

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **Labeling:** Where the Tablets are gelatin-coated, the label so states.
- **USP Reference Standards** (11)

USP Ibuprofen RS

USP Ibuprofen Related Compound C RS

4-Isobutylacetophenone.

$C_{12}H_{16}O$ 176.25

USP Ibuprofen Related Compound J RS

2-(4-Isobutyrylphenyl)propanoic acid.

$C_{13}H_{16}O_3$ 220.26

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

Topic/Question	Contact	Expert Committee
IBUPROFEN TABLETS	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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