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Nabumetone Tablets

DEFINITION

Nabumetone Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of nabumetone ($C_{15}H_{16}O_2$).

IDENTIFICATION

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

Add the following:

▲• **B.**

Diluent: Acetonitrile and water (50:50)

Standard solution: 0.25 mg/mL of USP Nabumetone RS in *Diluent*. Sonicate to dissolve, if necessary.

Sample solution: Nominally 0.25 mg/mL of nabumetone in *Diluent* from NLT 20 finely powdered Tablets. Sonicate to dissolve, if necessary. Pass through a suitable filter of 0.45-µm pore size and discard the first few milliliters.

Acceptance criteria: The UV spectrum of the nabumetone peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Aug-2020)

ASSAY

Change to read:

• **Procedure**

▲**Solution A:** 0.1% (v/v) glacial acetic acid in water

Solution B: Acetonitrile and tetrahydrofuran (70:30)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	60	40
10	60	40
12	10	90
14	10	90
15	60	40
20	60	40

Diluent: Acetonitrile and water (50:50)

Standard solution: 0.5 mg/mL of USP Nabumetone RS in *Diluent*. Sonicate to dissolve, if necessary.

Sample solution: Nominally 0.5 mg/mL of nabumetone in *Diluent* from NLT 20 finely powdered Tablets. Sonicate to dissolve, if necessary. Pass through a suitable filter of 0.45-µm pore size and discard the first few milliliters.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

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

Temperatures

Autosampler: 10°

Column: 30°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of nabumetone ($C_{15}H_{16}O_2$) in the portion of Tablets taken:

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

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

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

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

C_U = nominal concentration of nabumetone in the *Sample solution* (mg/mL)▲ (USP 1-Aug-2020)

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Sodium lauryl sulfate solution (2 in 100); 900 mL

Apparatus 2: 50 rpm

Time: 45 min

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

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

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the labeled amount of nabumetone ($C_{15}H_{16}O_2$) dissolved from the differences between the UV absorbances at the wavelengths of maximum and minimum absorbances at about 270 and 296 nm, respectively.

Tolerances: NLT 75% (*Q*) of the labeled amount of nabumetone ($C_{15}H_{16}O_2$) is dissolved.

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

IMPURITIES

Add the following:

▲• **Organic Impurities**

Solution A and **Solution B:** Prepare as directed in the *Assay*.

Mobile phase: See *Table 2*.

Table 2

Time (min)	Solution A (%)	Solution B (%)
0	65	35
5	65	35
14	55	45
30	20	80
31	65	35
40	65	35

System suitability solution: 1 mg/mL of USP Nabumetone RS and 0.0015 mg/mL of USP Nabumetone Related Compound A RS prepared as follows. Transfer suitable amounts of USP Nabumetone RS and USP Nabumetone Related Compound A RS to a suitable volumetric flask. Add 10% of the flask volume of acetonitrile and dilute with acetonitrile to volume. Sonicate to dissolve, if necessary.

Sensitivity solution: 0.3 µg/mL of USP Nabumetone RS in acetonitrile

Standard solution: 0.01 mg/mL of USP Nabumetone RS in acetonitrile

Sample solution: Nominally 1 mg/mL of nabumetone from NLT 20 finely powdered Tablets in acetonitrile. Sonicate to dissolve, if necessary. Pass through a suitable filter of 0.45-µm pore size and discard the first few milliliters.

Chromatographic system: Proceed as directed in the *Assay*, except for the *Column temperature* and *Flow rate*.

Column temperature: 35°

Flow rate: 1.3 mL/min

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between nabumetone related compound A and nabumetone, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each 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 each degradation product from the *Sample solution*

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

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

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

Acceptance criteria: See *Table 3*.

Table 3

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Nabumetone related compound A[a]	0.95	—
Nabumetone	1.00	—
Any unspecified degradation product	—	0.10
Total degradation products	—	1.0

[a] It is for peak identification only and is not included in the total degradation products.

▲ (USP 1-Aug-2020)

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers, and store at controlled room temperature.

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Nabumetone RS

▲ USP Nabumetone Related Compound A RS

(*E*)-4-(6-Methoxynaphthalen-2-yl)but-3-en-2-one.

$C_{15}H_{14}O_2$ 226.27 ▲ (USP 1-Aug-2020)

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

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

Chromatographic Database Information: Chromatographic Database

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