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Furosemide Oral Solution

DEFINITION

Furosemide Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of furosemide ($C_{12}H_{11}ClN_2O_5S$).

IDENTIFICATION

Delete the following:

▲ **A. SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Ultraviolet-Visible Spectroscopy*: 197U

Standard solution: 6 µg/mL of [USP Furosemide RS](#) in 0.01 N sodium hydroxide

Sample solution: Nominally 6 µg/mL of furosemide from the Oral Solution in 0.01 N sodium hydroxide

Acceptance criteria: Absorptivities are not significantly different.▲ (USP 1-May-2022)

Add the following:

▲ **A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-May-2022)

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

ASSAY

Change to read:

• PROCEDURE

[NOTE—Protect sample specimens, the USP Reference Standards, and solutions containing them by conducting the analysis without delay, under subdued light, or using low-actinic glassware.]

Mobile phase: [Acetonitrile](#), [glacial acetic acid](#), and [water](#) (35:2:165)

Diluent: [Acetonitrile](#), [glacial acetic acid](#), and [water](#) (22:1:22)

System suitability solution: ▲0.1 mg/mL each of [USP Furosemide RS](#) and [USP Furosemide Related Compound A RS](#) in *Diluent*▲ (USP 1-May-2022)

Standard solution: 1 mg/mL of [USP Furosemide RS](#) in *Diluent*

Sample solution: Nominally 1 mg/mL of furosemide from the Oral Solution in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm. ▲For *Identification A*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-May-2022)

Column: 4.6-mm × 25-cm; ▲5-µm▲ (USP 1-May-2022) packing [L10](#)

Flow rate: 2 mL/min

Injection volume: 10 µL

▲**Run time:** NLT 1.9 times the retention time of furosemide▲ (USP 1-May-2022)

System suitability

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

[NOTE—▲The relative retention times for furosemide and furosemide related compound A are about 1.0 and 1.1, respectively.▲ (USP 1-May-2022)]

Suitability requirements

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

Tailing factor: NMT 1.5, ▲*Standard solution*▲ (USP 1-May-2022)

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of furosemide ($C_{12}H_{11}ClN_2O_5S$) in the portion of the Oral Solution taken:

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

r_U = peak response of furosemide in the *Sample solution*

r_S = peak response of furosemide in the *Standard solution*

C_S = concentration of [USP Furosemide RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#)

For Oral Solution packaged in single-unit containers: Meets the requirements

Delete the following:

▲ [MINIMUM FILL \(755\)](#): Meets the requirements ▲ (USP 1-May-2022)

• [DELIVERABLE VOLUME \(698\)](#)

For Oral Solution packaged in multiple-unit containers: Meets the requirements

IMPURITIES

Change to read:

• LIMIT OF FUROSEMIDE RELATED COMPOUND B

[NOTE—Protect sample specimens, the USP Reference Standards, and solutions containing them by conducting the analysis without delay, under subdued light, or using low-actinic glassware.]

Mobile phase, Diluent, System suitability solution, and Chromatographic system: Proceed as directed in the Assay.

Standard solution: ▲ (USP 1-May-2022) 15.0 µg/mL of [USP Furosemide Related Compound B RS](#) in *Diluent*

▲ Sensitivity solution: 1.5 µg/mL of [USP Furosemide Related Compound B RS](#) from the *Standard solution* in *Diluent* ▲ (USP 1-May-2022)

Sample solution: Nominally 1 mg/mL of furosemide from the Oral Solution in *Diluent*

System suitability

Samples: *System suitability solution*, ▲ *Standard solution*, and *Sensitivity solution* ▲ (USP 1-May-2022)

[NOTE—▲ The relative retention times for furosemide and furosemide related compound A are about 1.0 and 1.1, respectively. ▲ (USP 1-May-2022)]

Suitability requirements

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

▲ (USP 1-May-2022)

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

Signal-to-noise-ratio: NLT 10, *Sensitivity solution* ▲ (USP 1-May-2022)

Analysis

Samples: *Standard solution* and *Sample solution*

▲ Calculate the percentage of furosemide related compound B in the portion of the Oral Solution taken:

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

r_U = peak response of furosemide related compound B in the *Sample solution*

r_S = peak response of furosemide related compound B in the *Standard solution*

C_S = concentration of [USP Furosemide Related Compound B RS](#) in the *Standard solution* (mg/mL)

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

▲ (USP 1-May-2022)

Acceptance criteria: ▲ NMT 1.5% ▲ (USP 1-May-2022)

SPECIFIC TESTS

• [pH \(791\)](#): 7.0–10.0

Add the following:

▲ [MICROBIAL ENUMERATION TESTS \(61\)](#) and [TESTS FOR SPECIFIED MICROORGANISMS \(62\)](#): The total aerobic microbial count is NMT 10^2 cfu/mL. The total yeast and mold count is NMT 10^1 cfu/mL. It meets the requirement of the test for absence of *Escherichia coli*. ▲ (USP 1-May-2022)

ADDITIONAL REQUIREMENTS

Change to read: