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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:

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

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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:

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• **Packaging and Storage:** Preserve in tight, light-resistant containers. ▲Store at controlled room temperature.▲ (USP 1-May-2022)

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Furosemide RS

USP Furosemide Related Compound A RS

▲2-Chloro-4-[(furan-2-ylmethyl)amino]-5-sulfamoylbenzoic acid.▲ (USP 1-May-2022)

$C_{12}H_{11}ClN_2O_5S$ 330.74

USP Furosemide Related Compound B RS

▲2-Amino-4-chloro-5-sulfamoylbenzoic acid.▲ (USP 1-May-2022)

$C_7H_7ClN_2O_4S$ 250.65

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

Topic/Question	Contact	Expert Committee
FUROSEMIDE ORAL SOLUTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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