Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-Aug-2020
Document Type: USP Monographs
DocId: GUID-619B79CC-372B-4F34-B9A5-677DA54CA330_3_en-US
DOI: https://doi.org/10.31003/USPNF_M34570_03_01
DOI Ref: f1j9w

Furosemide Tablets

» Furosemide Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of furosemide ($C_{12}H_{11}ClN_2O_5S$).

Packaging and storage—Preserve in well-closed, light-resistant containers.

Labeling—The labeling indicates with which *Dissolution* test the product complies. Tablets intended solely for veterinary use are so labeled.

USP Reference standards ⟨11⟩—

USP Furosemide RS

USP Furosemide Related Compound A RS

2-Chloro-4-*N*-furfurylamino-5-sulfamoylbenzoic acid.

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

USP Furosemide Related Compound B RS

4-Chloro-5-sulfamoylanthranilic acid.

$C_7H_7ClN_2O_4S$ 250.66

Identification—Transfer a portion of finely powdered Tablets, equivalent to about 40 mg of furosemide, to a 100-mL volumetric flask. Add 25 mL of 0.1 N sodium hydroxide, and allow to stand for 30 minutes with occasional shaking. Dilute with water to volume, and mix. Filter the solution, discarding the first 10 mL of the filtrate, and transfer 2.0 mL to a second 100-mL volumetric flask. Add 0.02 N sodium hydroxide to volume, and mix. Proceed as directed in the *Identification* test under *Furosemide Injection*, beginning with "Dissolve about 10 mg of USP Furosemide RS."

Dissolution ⟨711⟩—

Test 1: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 1*.

Medium: pH 5.8 phosphate buffer (see *Buffer Solutions* in the section *Reagents, Indicators, and Solutions*); 900 mL.

Apparatus 2: 50 rpm.

Time: 60 minutes.

Procedure—Determine the amount of $C_{12}H_{11}ClN_2O_5S$ dissolved from UV absorbances at the isosbestic point at 274 nm on filtered portions of the solution under test, suitably diluted with pH 5.8 phosphate buffer, in comparison with a Standard solution having a known concentration of USP Furosemide RS in the same *Medium*.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{12}H_{11}ClN_2O_5S$ is dissolved in 60 minutes.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*. Tablets labeled as intended for veterinary use comply with this test.

Apparatus 2: 65 rpm.

Medium, *Time*, and *Procedure*—Proceed as directed under *Test 1*.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{12}H_{11}ClN_2O_5S$ is dissolved in 60 minutes.

Uniformity of dosage units ⟨905⟩**:** meet the requirements.

Change to read:

Limit of furosemide related compound B—[Note—Protect furosemide solutions from exposure to light.]

Mobile phase▲—Prepare a filtered and degassed mixture of water, tetrahydrofuran, and glacial acetic acid (70:30:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Diluting solution—Dilute 22 mL of glacial acetic acid with a mixture of acetonitrile and water (50:50) to 1000 mL, and mix.

System suitability solution—Dissolve suitable quantities of USP Furosemide RS and USP Furosemide Related Compound A RS in *Diluting solution* to obtain a solution containing about 20 µg per mL and 12 µg per mL, respectively.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a detector capable of recording at both 254 nm and 272 nm and a 4.6-mm × 25-cm column that contains packing L1. [Note—The 2,4-dichloro-5-sulfamoylbenzoic acid impurity does not respond at 272 nm and the 2,4-bis(furfurylamino)-5-sulfamoylbenzoic acid impurity has a very intense absorbance at 254 nm.] The flow rate is about 1.0 mL per minute. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure*: the resolution, *R*, between furosemide and furosemide related compound A is not less than 2.5; and the relative standard deviation determined from furosemide is not more than 2.0%. [Note—The response for furosemide is at 254 nm.]▲ (ERR 1-Aug-2020)

Standard solution—Prepare a solution in *Diluting solution* containing 8.0 µg of USP Furosemide Related Compound B RS per mL.

Test solution—Transfer an accurately weighed portion of finely powdered Tablets, equivalent to about 10 mg of furosemide, to a 10-mL volumetric flask, add *Diluting solution* to volume, and mix.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the peak responses. The response at 254 nm obtained for any peak observed in the chromatogram of the *Test solution* at a retention time corresponding to that of the Reference Standard in the *Standard solution* is not greater than the response at 254 nm obtained for the peak in the chromatogram of the *Standard solution*, corresponding to not more than 0.8% of furosemide related compound B.

Change to read:

Assay—[NOTE—Protect furosemide solutions from exposure to light.]

Mobile phase▲—Prepare a filtered and degassed mixture of water, tetrahydrofuran, and glacial acetic acid (70:30:1). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Diluting solution—Dilute 22 mL of glacial acetic acid with a mixture of acetonitrile and water (50:50) to 1000 mL, and mix.

System suitability solution—Dissolve suitable quantities of USP Furosemide RS and USP Furosemide Related Compound A RS in *Diluting solution* to obtain a solution containing about 20 µg per mL and 12 µg per mL, respectively.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a detector capable of recording at both 254 nm and 272 nm and a 4.6-mm × 25-cm column that contains packing L1. [NOTE—The 2,4-dichloro-5-sulfamoylbenzoic acid impurity does not respond at 272 nm and the 2,4-bis(furfurylamino)-5-sulfamoylbenzoic acid impurity has a very intense absorbance at 254 nm.] The flow rate is about 1.0 mL per minute. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure*: the resolution, *R*, between furosemide and furosemide related compound A is not less than 2.5; and the relative standard deviation determined from furosemide is not more than 2.0%. [NOTE—The response for furosemide is at 254 nm.]▲ (ERR 1-Aug-2020)

Standard preparation—Dissolve an accurately weighed quantity of USP Furosemide RS in *Diluting solution* to obtain a solution having a known concentration of about 1.0 mg per mL.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 50 mg of furosemide, to a 50-mL volumetric flask, add 30 mL of *Diluting solution*, and sonicate for 10 minutes. Add *Diluting solution* to volume, mix, and filter, discarding the first 10 mL of the filtrate.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the peak responses. Using the response at 254 nm, calculate the quantity, in mg, of furosemide ($C_{12}H_{11}ClN_2O_5S$) in the portion of Tablets taken by the formula:

$$50C(r_U/r_S)$$

in which *C* is the concentration, in mg per mL, of USP Furosemide RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
FUROSEMIDE 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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-619B79CC-372B-4F34-B9A5-677DA54CA330_3_en-US
DOI: https://doi.org/10.31003/USPNF_M34570_03_01
DOI ref: f1j9w