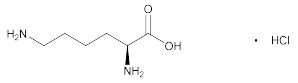
System suitability
Suitability requirements: The chromatogram of the *System suitability solution* exhibits two clearly separated spots.
Analysis
Samples: *Standard solution*, *System suitability solution*, and *Sample solution*
Dry the plate between 100° and 105° until the ammonia completely disappears. Spray with *Spray reagent*, and heat between 100° and 105° for 15 min. Examine the plate under white light.
Acceptance criteria: Any secondary spot of the *Sample solution* is not larger or more intense than the principal spot of the *Standard solution*.
Individual impurities: NMT 0.5%
Total impurities: NMT 2.0%

SPECIFIC TESTS
- **Optical Rotation,** *Specific Rotation* ⟨**781S**⟩
Sample solution: 100 mg/mL in water
Acceptance criteria: +8.4° to +9.9°
- **Loss on Drying** ⟨**731**⟩**:** Dry a sample at 80° for 3 h: it loses NMT 0.2% of its weight.

ADDITIONAL REQUIREMENTS
- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨**11**⟩
USP Arginine Hydrochloride RS
USP L-Lysine Acetate RS

Lysine Hydrochloride



$C_6H_{14}N_2O_2 \cdot HCl$ 182.65
L-Lysine hydrochloride [657-27-2].

DEFINITION
Lysine Hydrochloride contains NLT 98.5% and NMT 101.5% of L-lysine hydrochloride ($C_6H_{14}N_2O_2 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION
- **A. Infrared Absorption** ⟨**197K**⟩

ASSAY
- **Procedure**
Sample: 90 mg of Lysine Hydrochloride
Blank: Mix 3 mL of formic acid and 50 mL of glacial acetic acid.
Titrimetric system
(See *Titrimetry* ⟨541⟩.)
Mode: Direct titration
Titrant: 0.1 N perchloric acid VS
Endpoint detection: Potentiometric
Analysis: Dissolve the *Sample* in 3 mL of formic acid and 50 mL of glacial acetic acid. Add 10 mL of mercuric acetate TS, and titrate with the *Titrant*. Perform the *Blank* determination.
Calculate the percentage of lysine hydrochloride ($C_6H_{14}N_2O_2 \cdot HCl$) in the *Sample* taken:

$$\text{Result} = \{[(V_S - V_B) \times N \times F]/W\} \times 100$$

V_S = *Titrant* volume consumed by the *Sample* (mL)
V_B = *Titrant* volume consumed by the *Blank* (mL)
N = actual normality of the *Titrant* (mEq/mL)
F = equivalency factor, 91.33 mg/mEq
W = *Sample* weight (mg)
Acceptance criteria: 98.5%–101.5% on the dried basis

OTHER COMPONENTS
- **Content of Chloride**
Sample: 350 mg of Lysine Hydrochloride
Blank: 140 mL of water
Titrimetric system
(See *Titrimetry* ⟨541⟩.)
Mode: Direct titration
Titrant: 0.1 N silver nitrate VS
Endpoint detection: Visual
Analysis: Transfer the *Sample* to a porcelain casserole, and add 140 mL of water and 1 mL of dichlorofluorescein TS. Titrate with the *Titrant* until the silver chloride flocculates and the mixture acquires a faint pink color. Perform the *Blank* determination.
Calculate the percentage of chloride (Cl) in the *Sample* taken:

$$\text{Result} = \{[(V_S - V_B) \times N \times F]/W\} \times 100$$

V_S = *Titrant* volume consumed by the *Sample* (mL)
V_B = *Titrant* volume consumed by the *Blank* (mL)
N = actual normality of the *Titrant* (mEq/mL)
F = equivalency factor, 35.45 mg/mEq
W = *Sample* weight (mg)
Acceptance criteria: 19.0%–19.6%

IMPURITIES
- **Residue on Ignition** ⟨**281**⟩**:** NMT 0.1%
- **Chloride and Sulfate,** *Sulfate* ⟨**221**⟩
Standard solution: 0.10 mL of 0.020 N sulfuric acid
Sample: 0.33 g of Lysine Hydrochloride
Acceptance criteria: NMT 0.03%
- **Iron** ⟨**241**⟩**:** NMT 30 ppm
- **Heavy Metals,** *Method I* ⟨**231**⟩**:** NMT 15 ppm
- **Related Compounds**
Standard solution: 0.05 mg/mL of USP L-Lysine Hydrochloride RS in water. [NOTE—This solution has a concentration equivalent to 0.5% of that of the *Sample solution*.]
Sample solution: 10 mg/mL of Lysine Hydrochloride in water
System suitability solution: 0.4 mg/mL each of USP L-Lysine Hydrochloride RS and USP Arginine Hydrochloride RS
Chromatographic system
(See *Chromatography* ⟨621⟩, *Thin-Layer Chromatography*.)
Mode: TLC
Adsorbent: 0.25-mm layer of chromatographic silica gel mixture
Application volume: 5 µL
Developing solvent system: Isopropyl alcohol and ammonium hydroxide (7:3)
Spray reagent: 0.2 g of ninhydrin in a mixture of butyl alcohol and 2 N acetic acid (95:5)
System suitability
Suitability requirements: The chromatogram of the *System suitability solution* exhibits two clearly separated spots.
Analysis
Samples: *Standard solution*, *System suitability solution*, and *Sample solution*
Dry the plate between 100° and 105° until the ammonia completely disappears. Spray with *Spray reagent*, and heat between 100° and 105° for 15 min. Examine the plate under white light.
Acceptance criteria: Any secondary spot of the *Sample solution* is not larger or more intense than the principal spot of the *Standard solution*.

Individual impurities: NMT 0.5%
Total impurities: NMT 2.0%

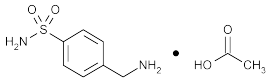
SPECIFIC TESTS

- **Optical Rotation,** *Specific Rotation* ⟨**781S**⟩
  Sample solution: 80 mg/mL in 6 N hydrochloric acid
  Acceptance criteria: +20.4° to +21.4°
- **Loss on Drying** ⟨**731**⟩**:** Dry a sample at 105° for 3 h: it loses NMT 0.4% of its weight.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨**11**⟩
  USP Arginine Hydrochloride RS
  USP L-Lysine Hydrochloride RS

Mafenide Acetate



$C_7H_{10}N_2O_2S \cdot C_2H_4O_2$ 246.28
Benzenesulfonamide, 4-(aminomethyl)-, monoacetate.
α-Amino-*p*-toluenesulfonamide monoacetate [13009-99-9].

» Mafenide Acetate contains not less than 98.0 percent and not more than 102.0 percent of $C_7H_{10}N_2O_2S \cdot C_2H_4O_2$, calculated on the anhydrous basis.

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

USP Reference standards ⟨11⟩**—**
USP Mafenide Acetate RS
USP Mafenide Related Compound A RS
4-Formylbenzenesulfonamide.
$C_7H_7NO_3S$ 185.20

Identification—

A: *Infrared Absorption* ⟨197K⟩.

B: The R_F value of the principal spot in the chromatogram of the *Identification solution* corresponds to that in the chromatogram of *Standard solution A,* as obtained in the test for *Chromatographic purity*.

Melting range ⟨741⟩**:** between 162° and 171°, but the range between beginning and end of melting does not exceed 4°.

pH ⟨791⟩**:** between 6.4 and 6.8, in a solution (1 in 10).

Water, *Method I* ⟨921⟩**:** not more than 1.0%.

Residue on ignition ⟨281⟩**:** not more than 0.2%.

Selenium ⟨291⟩**:** 0.003%, a 200-mg test specimen being used.

Heavy metals, *Method II* ⟨231⟩**:** 0.002%.

Chromatographic purity—

Standard solutions—Dissolve USP Mafenide Acetate RS in methanol, mix to obtain *Standard solution A* having a known concentration of 500 µg per mL, dissolve USP Mafenide Related Compound A RS in methanol, and mix to obtain *Standard solution D* having a known concentration of 500 µg per mL. [NOTE—USP Mafenide Related Compound A RS is 4-formylbenzenesulfonamide.] Quantitatively dilute portions of these solutions with methanol to obtain *Standard solutions* having the following compositions:

Standard solution	Dilution	Concentration (µg RS per mL)	Percentage (%, for comparison with test specimen)
A	(undiluted)	500	1.0
B	5 in 10	250	0.5
C	1 in 5	100	0.2
D	(undiluted)	500	1.0
E	5 in 10	250	0.5
F	1 in 5	100	0.2

Test solution—Dissolve an accurately weighed quantity of Mafenide Acetate in methanol to obtain a solution containing 50 mg per mL.

Identification solution—Quantitatively dilute a portion of the *Test solution* with methanol to obtain a solution containing 500 µg per mL.

Ninhydrin solution—Dissolve 300 mg of ninhydrin in 100 mL of butyl alcohol, add 3 mL of glacial acetic acid, and mix.

Procedure—Apply separately 5 µL of the *Test solution,* 5 µL of the *Identification solution*, and 5 µL of each *Standard solution* to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Position the plate in a chromatographic chamber, and develop the chromatograms in a solvent system consisting of a mixture of ethyl acetate, methanol, and isopropylamine (77:20:3) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate in warm, circulating air. Examine the plate under short-wavelength UV light, and compare the intensities of any secondary spots observed in the chromatogram of the *Test solution* at the R_F value corresponding to those of the principal spots in the chromatograms of *Standard solutions D, E,* and *F*. Spray the plate with the *Ninhydrin solution,* heat the plate at 105° for 5 minutes, and examine the plate. Compare the intensities of any secondary spots observed in the chromatogram of the *Test solution* to those of the principal spots in the chromatograms of *Standard solutions A, B,* and *C*. No secondary spot, observed by both visualizations, from the chromatogram of the *Test solution* is larger or more intense than the principal spots obtained from *Standard solution B* (0.5%) and *Standard solution E* (0.5%), and the sum of the intensities of all secondary spots obtained from the *Test solution* corresponds to not more than 1.0%.

Assay—Transfer about 100 mg of Mafenide Acetate, accurately weighed, to a 50-mL volumetric flask, dissolve in about 20 mL of water, dilute with water to volume, and mix. Pipet 10 mL of this solution into a 100-mL volumetric flask containing 1 mL of 1 N hydrochloric acid, dilute with water to volume, and mix. Dissolve an accurately weighed quantity of USP Mafenide Acetate RS in 0.01 N hydrochloric acid, and dilute quantitatively and stepwise with the same solvent to obtain a Standard solution having a known concentration of about 200 µg per mL. Concomitantly determine the absorbance of both solutions in 1-cm cells at the wavelength of maximum absorbance at about 267 nm, with a suitable spectrophotometer, using 0.01 N hydrochloric acid as the blank. Calculate the quantity, in mg, of $C_7H_{10}N_2O_2S \cdot C_2H_4O_2$ in the portion of Mafenide Acetate taken by the formula:

$$0.5C(A_U / A_S)$$

in which C is the concentration, in µg per mL, of USP Mafenide Acetate RS in the Standard solution; and A_U and A_S are the absorbances of the solution of Mafenide Acetate and the Standard solution, respectively.

Mafenide Acetate Cream

» Mafenide Acetate Cream is Mafenide Acetate in a water-miscible, oil-in-water cream base, containing suitable preservatives. It contains not less than 90.0 percent and not more than 110.0 percent of mafenide acetate ($C_7H_{10}N_2O_2S \cdot C_2H_4O_2$) in terms of the labeled amount of mafenide ($C_7H_{10}N_2O_2S$).

Packaging and storage—Preserve in tight, light-resistant containers, and avoid exposure to excessive heat.

USP Reference standards ⟨11⟩**—**
USP Mafenide Acetate RS

Identification—

A: *Ultraviolet Absorption* ⟨197U⟩—

Solution: Assay preparation.

B: Place about 1 g in a 60-mL separatory funnel, and add 20 mL of chloroform to dissolve it. Add 20 mL of water, shake for 2 minutes, allow the layers to separate completely, and discard