Table 8

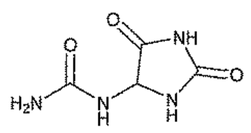
Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Deacylated alfuzosin[a]	0.46	0.40
N-Formyl analog[b]	0.50	0.30
Alfuzosin	1.0	—
Furamide analog[c]	1.18	—[d]
Any individual unspecified impurity	—	0.20
Total impurities	—	0.80

[a] N^2-(3-Aminopropyl)-6,7-dimethoxy-N^2-methylquinazoline-2,4-diamine.
[b] *N*-[3-[(4-Amino-6,7-dimethoxyquinazolin-2-yl)(methyl)amino]propyl]formamide.
[c] *N*-{3-[(4-Amino-6,7-dimethoxyquinazolin-2-yl)(methyl)amino]propyl}furan-2-carboxamide.
[d] Furamide analog, a component of USP Alfuzosin System Suitability Mixture A RS, is not a specified impurity.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Protect from light and moisture. Store at controlled room temperature.
- **LABELING:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.
- **USP REFERENCE STANDARDS** ⟨11⟩
  USP Alfuzosin Hydrochloride RS
  USP Alfuzosin System Suitability Mixture A RS
  Furamide analog: *N*-{3-[(4-Amino-6,7-dimethoxyquinazolin-2-yl)(methyl)amino]propyl}furan-2-carboxamide.
  $C_{19}H_{23}N_5O_4$ 385.42
  Deacylated alfuzosin: N^2-(3-Aminopropyl)-6,7-dimethoxy-N^2-methylquinazoline-2,4-diamine.
  $C_{14}H_{21}N_5O_2$ 291.35
  N-Formyl analog: *N*-[3-[(4-Amino-6,7-dimethoxyquinazolin-2-yl)(methyl)amino]propyl]formamide.
  $C_{15}H_{21}N_5O_3$ 319.36

Allantoin



$C_4H_6N_4O_3$ 158.12
Urea, (2,5-dioxo-4-imidazolidinyl)-;
Allantoin [97-59-6].

DEFINITION

Allantoin contains NLT 98.5% and NMT 101.0% of $C_4H_6N_4O_3$.

IDENTIFICATION

- **A. INFRARED ABSORPTION** ⟨197K⟩
- **B. THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST** ⟨201⟩: The R_F value of the principal spot from *Sample solution B* corresponds to that from *Standard solution A*, as described in the test for *Organic Impurities*.

ASSAY

- **PROCEDURE**
  Sample: 120 mg
  Analysis: Transfer the *Sample* to a 100-mL beaker, dissolve by stirring in 40 mL of water, and titrate with 0.1 M sodium hydroxide. Use a suitable electrode system (see *Titrimetry* ⟨541⟩). Each mL of 0.1 M sodium hydroxide is equivalent to 15.81 mg of $C_4H_6N_4O_3$.
  Acceptance criteria: 98.5%–101.0%

IMPURITIES

- **RESIDUE ON IGNITION** ⟨281⟩: NMT 0.1%
- **ORGANIC IMPURITIES**
  Adsorbent: Cellulose
  Diluent: Methanol and water (1:1)
  Urea stock solution: 1 mg/mL of USP Urea RS in water
  Standard solution A: 1 mg/mL of USP Allantoin RS in *Diluent*
  Standard solution B: 0.1 mg/mL of USP Urea RS in methanol, from *Urea stock solution*
  Standard solution C: *Standard solution A* and *Standard solution B* (1:1)
  Sample solution A: Transfer 0.10 g of Allantoin to a 10-mL volumetric flask, add 5 mL of water, dissolve by heating, and allow to cool. Dilute with methanol to volume. [NOTE—Use immediately after preparation.]
  Sample solution B: Transfer 1 mL of *Sample solution A* to a 10-mL volumetric flask, and dilute with *Diluent* to volume.
  Spray reagent: 5 mg/mL of *p*-dimethylaminobenzaldehyde in a mixture of methanol and hydrochloric acid (3:1)
  Application volume
  Standard solution A: 5 µL
  Standard solution B: 5 µL
  Standard solution C: 5 µL
  Sample solution A: 10 µL
  Sample solution B: 5 µL
  Developing solvent system: Butyl alcohol, glacial acetic acid, and water (60:15:25)
  Analysis: Proceed as directed for *Chromatography* ⟨621⟩, *Thin-Layer Chromatography*. Develop the chromatogram until the solvent front has moved about 10 cm. Spray the plate with *Spray reagent*, dry in a current of hot air, and after 30 min examine under visible light.
  Acceptance criteria: Any spot from *Sample solution A*, except for the principal spot, is not more intense than the spot from *Standard solution B* (NMT 0.5%). The test is not valid unless the principal spots from *Standard solution C* are clearly separated.

SPECIFIC TESTS

- **ACIDITY OR ALKALINITY**
  Sample solution: 5 mg/mL in carbon dioxide-free water
  Analysis: To 5 mL of the *Sample solution* add 5 mL of water, 0.1 mL of methyl red TS, and 0.2 mL of 0.01 M sodium hydroxide.
  Acceptance criteria: A yellow color is observed. The solution turns red upon the addition of 0.4 mL of 0.01 M hydrochloric acid.
- **LOSS ON DRYING** ⟨731⟩: Dry a sample at 105° to constant weight: it loses NMT 0.1% of its weight.
- **REDUCING SUBSTANCES**
  Sample solution: 1.0 g of Allantoin in 10 mL of water. Shake for 2 min, and filter.
  Analysis: To the *Sample solution* add 1.5 mL of 0.02 M potassium permanganate.
  Acceptance criteria: The solution remains violet for at least 10 min.

ADDITIONAL REQUIREMENTS

- **USP REFERENCE STANDARDS** ⟨11⟩
  USP Allantoin RS
  USP Urea RS