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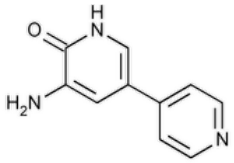
Inamrinone



$C_{10}H_9N_3O$ 187.20

[3,4'-Bipyridin]-6(1*H*)-one, 5-amino-.

5-Amino[3,4'-bipyridin]-6(1*H*)-one CAS RN®: 60719-84-8; UNII: JUT23379TN.

» Inamrinone contains not less than 98.0 percent and not more than 102.0 percent of $C_{10}H_9N_3O$, calculated on the anhydrous basis.

[**Caution—**Inamrinone is a cardiotonic agent.]

Packaging and storage—Preserve in well-closed containers, protected from light. Store at 25°, excursions permitted between 15° and 30°.

USP Reference standards ⟨11⟩—

USP Inamrinone RS

USP Inamrinone Related Compound A RS

5-Carboxamide[3,4'-bipyridin]-6(1*H*)-one.

$C_{11}H_9N_3O_2$ 215.21

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) ·

Change to read:

B: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020) —

pH 8.9 Buffer—Dissolve 107 g of dibasic sodium phosphate in water, adjust, if necessary, with 0.1 M sodium hydroxide or 0.1 M phosphoric acid to a pH of 8.9 ± 0.1, dilute with water to 1000 mL, and mix.

Solution: 6 µg per mL, prepared as follows. Dissolve 100 mg in 20 mL of water and 1.0 mL of 1 N hydrochloric acid in a 100-mL volumetric flask, dilute with water to volume, and mix. Dilute 5.0 mL of this solution to 50.0 mL with 0.01 N hydrochloric acid, mix, and transfer 3.0 mL to a 50-mL volumetric flask. Dilute with *pH 8.9 Buffer* to volume, and mix.

Ratio: A_{237}/A_{318} do not differ by more than 3.0%.

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

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

Chromatographic purity—

Solution A—Dissolve 6.8 g of monobasic potassium phosphate in 1000 mL of water, add 2 mL of triethylamine, and adjust with phosphoric acid to a pH of 2.5. Filter and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Solution B—Prepare a mixture of *Solution A* and acetonitrile (85:15).

Mobile phase—Use variable mixtures of *Solution A* and *Solution B* as directed for *Chromatographic system.*

Diluting solution—Dissolve 0.25 g of sodium metabisulfite in 1000 mL of *Solution A.*

Standard stock solution—Dissolve an accurately weighed quantity of USP Inamrinone RS in *Diluting solution* to obtain a solution having a known concentration of about 2 mg per mL.

Standard solution—Dilute a suitable volume of *Standard stock solution* quantitatively, and stepwise if necessary, with *Diluting solution* to obtain a solution having a known concentration of 4 µg of USP Inamrinone RS per mL.

System suitability solution—Prepare a solution of USP Inamrinone Related Compound A RS in *Diluting solution* having a concentration of 2 mg per mL. Transfer 5.0 mL of this solution and 5.0 mL of the *Standard stock solution* to a 50-mL volumetric flask, dilute with *Diluting solution* to

volume, and mix.

Test solution—Transfer about 100 mg of Inamrinone, accurately weighed, to a 50-mL volumetric flask, dissolve in and dilute with *Diluting solution* to volume, and mix. [NOTE—Use this solution within 1 hour after preparation.]

Chromatographic system (see *CHROMATOGRAPHY ⟨621⟩*)—The liquid chromatograph is equipped with a 315-nm detector and a 4.0-mm × 25-cm analytical column that contains packing L1 and is fitted with a guard column that contains packing L1. The flow rate is about 1.0 mL per minute. The chromatograph is programmed as follows.

Time (minutes)	*Solution A* (%)	*Solution B* (%)	Elution
0	87	13	equilibration
0–1	87	13	isocratic
1–29	87→0	13→100	linear gradient
29–30	0	100	isocratic

Allow the system to equilibrate at the original conditions before making subsequent injections. Chromatograph 15 µL of the *System suitability solution,* record the chromatograms, and measure the peak responses as described for *Procedure:* the relative retention times are 0.6 for inamrinone and 1.0 for inamrinone related compound A; and the resolution, *R,* between inamrinone and inamrinone related compound A is not less than 4.0. Chromatograph about 15 µL of the *Standard solution,* and record the peak responses for inamrinone as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 5.0%.

Procedure—Separately inject equal volumes (about 15 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms allowing the *Test solution* to elute for not less than five times the retention times of inamrinone, and measure the areas of all the peaks observed in the chromatogram of the *Test solution.* Calculate the percentage of each impurity in the portion of Inamrinone taken by the formula:

$$5000(C/W)(r_i/r_S)$$

in which C is the concentration, in mg per mL, of USP Inamrinone RS in the *Standard solution; W* is the weight, in mg, of inamrinone taken for the *Test solution;* r_i is the response of each impurity peak; and r_S is the mean response for the *Standard solution:* not more than 0.2% of any individual impurity is found; and the sum of all impurities is not more than 1.0%.

Assay—Weigh accurately about 500 mg of Inamrinone, and proceed as directed under *Nitrite Titration ⟨451⟩*. Each mL of 0.1 M sodium nitrite is equivalent to 18.72 mg of $C_{10}H_9N_3O$.

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

Topic/Question	Contact	Expert Committee
INAMRINONE	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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