

weight of sodium; 58.44 is the molecular weight of sodium chloride; and R_U and R_S are the sodium emission readings obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Assay for dextrose—Tare a clean, medium-porosity filtering crucible containing several carborundum boiling chips or glass beads. Pipet 50 mL of freshly mixed alkaline cupric tartrate TS into a 400-mL beaker. Add the boiling chips or glass beads from the tared crucible, 45 mL of water, and 5.0 mL of Solution to the beaker. Heat the beaker and contents over a burner that has been adjusted to cause boiling of the solution to start in 3.5 to 4 minutes. Boil the solution for 2 minutes, accurately timed, and filter immediately through the tared crucible, taking care to transfer all of the boiling chips or glass beads to the crucible. Wash the precipitate with hot water and 10 mL of alcohol. Dry the crucible and contents at 110° to constant weight. Perform a blank determination, and make any necessary correction. Each mg of cuprous oxide precipitate obtained is equivalent to 0.496 mg of $C_6H_{12}O_6 \cdot H_2O$.

Assay for adenine—

Mobile phase—Dissolve 3.45 g of ammonium dihydrogen phosphate in 950 mL of water in a 1000-mL volumetric flask, add 10 mL of glacial acetic acid, dilute with water to volume, mix, pass through a membrane filter having a 1- μ m or finer porosity, and degas.

Standard preparations—Dissolve accurately weighed quantities of USP Adenine RS in dilute hydrochloric acid (1 in 120) in three separate volumetric flasks, dilute with the dilute hydrochloric acid solution to volume, and mix to obtain Standard preparations having known concentrations of about 0.25, 0.275, and 0.30 mg of adenine per mL, respectively. Protect from light.

Chromatographic system (see *Chromatography* (621))—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm \times 30-cm stainless steel column that contains packing L9. The flow rate is about 2.0 mL per minute. Prepare a solution containing USP Adenine RS and purine, each at about 0.275 mg per mL, in dilute hydrochloric acid (1 in 120), and chromatograph not less than four injections (about 20 μ L) of this solution: the relative standard deviation of the peak response of adenine is not more than 2.5%, the relative standard deviation of the retention time of adenine is not more than 2.0%, and the resolution of adenine and purine is not less than 3.0.

Procedure—Separately inject equal volumes (about 20 μ L) of the Solution and the *Standard preparations*, record the chromatograms, and measure the responses for the major peaks. Plot the responses against the concentrations, in mg of USP Adenine RS per mL of the *Standard preparations*. Calculate the quantity, in mg, of $C_5H_5N_5$ in each mL of the Solution taken as the value read directly from the Standard curve corresponding to the response obtained from the portion of the Anticoagulant Citrate Phosphate Dextrose Adenine Solution chromatographed.

Anticoagulant Sodium Citrate Solution

» Anticoagulant Sodium Citrate Solution is a sterile solution of Sodium Citrate in Water for Injection. It contains, in each 100 mL, not less than 3.80 g and not more than 4.20 g of $C_6H_5Na_3O_7 \cdot 2H_2O$. It contains no antimicrobial agents.

| | |
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| Sodium Citrate (dihydrate) | 40 g |
| Water for Injection, a sufficient quantity to make | 1000 mL |

NOTE—Anhydrous sodium citrate (35.1 g) may be used instead of the dihydrate.

Dissolve the Sodium Citrate in sufficient Water for Injection to make 1000 mL, and filter until clear. Place the solution in suitable containers, and sterilize.

Packaging and storage—Preserve in single-dose containers, preferably of Type I or Type II glass.

USP Reference standards (11)—

USP Citric Acid RS

USP Endotoxin RS

Identification—When evaporated to a concentration of 1 in 20, it responds to the tests for *Sodium* (191) and for *Citrate* (191).

Bacterial endotoxins (85)—It contains not more than 5.56 USP Endotoxin Units per mL.

pH (791): between 6.4 and 7.5.

Other requirements—It meets the requirements under *Injections* (1).

Assay—

Mobile Phase, Standard Preparation 1, and Chromatographic System—Proceed as directed under *Assay for Citric Acid/Citrate and Phosphate* (345).

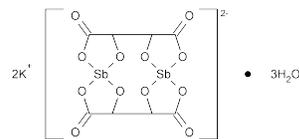
Assay preparation—Pipet 10 mL of Solution into a suitable volumetric flask, and proceed as directed for *Assay Preparation for Citric Acid/Citrate Assay* under general chapter (345).

Procedure—Proceed as directed for *Procedure* under general chapter (345), and calculate the quantity, in mg, of sodium citrate dihydrate ($C_6H_5Na_3O_7 \cdot 2H_2O$) in the volume of Solution taken by the formula:

$$0.001(294.10/189.10)C_5 D(r_U / r_S)$$

in which 294.10 is the molecular weight of sodium citrate dihydrate; 189.10 is the molecular weight of citrate ($C_6H_5O_7$); C_5 is the concentration, in μ g per mL, of citrate in *Standard Preparation 1*; D is the dilution factor; and r_U and r_S are the citrate peak areas obtained from the *Assay preparation* and *Standard Preparation 1*, respectively.

Antimony Potassium Tartrate



$C_8H_4K_2O_{12}Sb_2 \cdot 3H_2O$ 667.87

Antimonate(2-), bis[μ -[2,3-dihydroxybutanedioato(4-)- $O^1, O^2:O^3, O^4$]-di-, dipotassium, trihydrate, stereoisomer.

Dipotassium bis[μ -[L-(+)-tartrato(4-)]diantimonate(2-) trihydrate [28300-74-5].

Anhydrous 613.82 [11071-15-1].

» Antimony Potassium Tartrate contains not less than 99.0 percent and not more than 103.0 percent of $C_8H_4K_2O_{12}Sb_2 \cdot 3H_2O$.

Packaging and storage—Preserve in well-closed containers.

Completeness of solution (641): meets the requirements, using a 750-mg specimen and water as the solvent.

Identification—

A: When heated to redness, it chars, emits an odor resembling that of burning sugar, and leaves a blackened residue. This residue has an alkaline reaction, and when a small fragment of it is held in a nonluminous flame, the flame is tinted violet.

B: In a solution (1 in 20), acidified with hydrochloric acid, hydrogen sulfide TS produces an orange-red precipitate, which is soluble in ammonium sulfide TS and in 1 N sodium hydroxide.

C: It responds to the test for *Tartrate* (191).

Acidity or alkalinity—Dissolve 1.0 g in 50 mL of carbon dioxide-free water, and titrate with 0.010 N hydrochloric acid or 0.010 N sodium hydroxide to a pH of 4.5: not more than 2.0 mL is required.

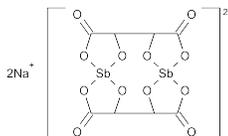
Loss on drying (731)—Dry it at 105° to constant weight: it loses not more than 2.7% of its weight.

Arsenic—Dissolve 100 mg in 5 mL of hydrochloric acid. Add 10 mL of a recently prepared solution of 20 g of stannous chloride in 30 mL of hydrochloric acid. Mix, transfer to a color-comparison tube, and allow to stand for 30 minutes. Viewed downward over a white surface, the color of the solution appears no deeper than that of a blank to which has been added 15 µg of arsenic (0.015%).

Lead (251): not more than 0.002%.

Assay—Dissolve about 500 mg of Antimony Potassium Tartrate, accurately weighed, in 50 mL of water, add 5 g of potassium sodium tartrate, 2 g of sodium borate, and 3 mL of starch TS, and immediately titrate with 0.1 N iodine VS to the production of a persistent blue color. Each mL of 0.1 N iodine is equivalent to 16.70 mg of $C_8H_4K_2O_{12}Sb_2 \cdot 3H_2O$.

Antimony Sodium Tartrate



$C_8H_4Na_2O_{12}Sb_2$ 581.61
Antimonate(2-), bis[μ -[2,3-dihydroxybutanedioato(4-)-O¹, O²:O³,O⁴]]di-, disodium, stereoisomer.
Disodium bis[μ -[L-(+)-tartrato(4-)]diantimonate(2-)
[34521-09-0].

» Antimony Sodium Tartrate contains not less than 98.0 percent and not more than 101.0 percent of $C_8H_4Na_2O_{12}Sb_2$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

Identification—It responds to the tests for *Antimony* (191), for *Sodium* (191), and for *Tartrate* (191).

Acidity or alkalinity—Dissolve 1.0 g in 50 mL of carbon dioxide-free water, and titrate with 0.010 N hydrochloric acid or 0.010 N sodium hydroxide to a pH of 4.5: not more than 2.0 mL is required.

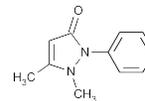
Loss on drying (731)—Dry it at 105° to constant weight: it loses not more than 6.0% of its weight.

Arsenic, Method II (211): 8 ppm.

Lead (251): not more than 0.002%.

Assay—Dissolve about 500 mg of Antimony Sodium Tartrate, accurately weighed, in 50 mL of water, add 5 g of potassium sodium tartrate, 2 g of sodium borate, and 3 mL of starch TS, and immediately titrate with 0.1 N iodine VS to the production of a persistent blue color. Each mL of 0.1 N iodine is equivalent to 14.54 mg of $C_8H_4Na_2O_{12}Sb_2$.

Antipyrine



$C_{11}H_{12}N_2O$ 188.23

1,2-Dihydro-1,5-dimethyl-2-phenyl-3H-pyrazol-3-one.
2,3-Dimethyl-1-phenyl-3-pyrazolin-5-one [60-80-0].

» Antipyrine contains not less than 99.0 percent and not more than 100.5 percent of $C_{11}H_{12}N_2O$, calculated on the dried basis.

Packaging and storage—Preserve in tight containers.

USP Reference standards (11)—

USP Antipyrine RS

Completeness and color of solution—It is completely soluble in its own weight of cold water, the solution being colorless or not more than slightly yellow when viewed transversely in a tube having a diameter of about 20 mm.

Identification—

A: *Infrared Absorption* (197K).

B: *Ultraviolet Absorption* (197U)—

Solution: 20 µg per mL.

Medium: methanol.

Absorptivities at 266 nm, calculated on the dried basis, do not differ by more than 3.0%.

C: Add tannic acid TS to a solution of it: a white precipitate is formed.

Melting range (741): between 110° and 112.5°.

Loss on drying (731)—Dry it at 60° for 2 hours: it loses not more than 1.0% of its weight.

Residue on ignition (281): not more than 0.15%.

Heavy metals (231)—Dissolve 1 g in 2 mL of 1 N acetic acid, and add water to make 25 mL: the limit is 0.002%.

Ordinary impurities (466)—

Test solution: chloroform.

Standard solution: chloroform.

Eluant: a mixture of chloroform, acetone, butyl alcohol, and formic acid (60:15:15:15).

Visualization: 1.

Assay—Transfer about 150 mg of Antipyrine, accurately weighed, to a 250-mL iodine flask, and dissolve in 25 mL of water. Add 2 g of sodium acetate, 1 mL of diluted acetic acid, and 20.0 mL of 0.1 N iodine VS, mix, and allow to stand in a cool, dark place for 20 minutes. Add 25 mL of alcohol to dissolve the precipitate, and titrate the excess iodine with 0.1 N sodium thiosulfate VS, using starch TS as the indicator. Each mL of 0.1 N iodine is equivalent to 9.412 mg of $C_{11}H_{12}N_2O$.