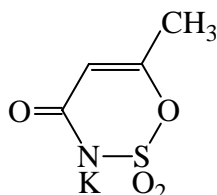


## D. MONOGRAPHS

### Acesulfame Potassium

Acesulfame K



$C_4H_4KNO_4S$

Mol. Wt. 201.24

Potassium salt of 6-methyl-1,2,3-oxathiazin-4(3H)-one-2,2-dioxide [ 55589-62-3 ]

**Content** Acesulfame Potassium, when calculated on the dried basis, contains 99.0-101.0% of acesulfame potassium ( $C_4H_4KNO_4$ ).

**Description** Acesulfame Potassium occurs as a white crystalline powder. It is odorless and has a strong sweet taste.

**Identification** (1) Dissolve 10 mg of Acesulfame Potassium in 1,000 ml of water. The solution exhibits an absorption maximum at a wavelength of 225 - 229 nm.

(2) Acesulfame Potassium responds to all tests for Potassium Salt as described in the Quantitative Tests.

(3) Dissolve 0.2 g of Acesulfame Potassium in 2 ml of diluted acetic acid (3 100) and 2 ml of water. Add a few drops of sodium cobaltinitrite TS to the solution. A yellow precipitate is formed.

**Purity** (1) Clarity and color of solution Colorless and clear (1.0 g, water 5 ml).

(2) pH 5.5 - 7.5 (1.0 g, water 100 ml).

(3) Heavy metals Not more than 10  $\mu\text{g/g}$  as Pb (2.0 g, Method 2, Control solution Lead Standard Solution 2.0 ml).

(4) Lead Not more than 1.0  $\mu\text{g/g}$  as Pb (10.0 g, Method 1).

(5) Arsenic Not more than 4.0  $\mu\text{g/g}$  as  $\text{As}_2\text{O}_3$  (0.50 g, Method 1, Apparatus B).

(6) Fluoride Not more than 3.0  $\mu\text{g/g}$  as F.

**Test Solution** Weigh 2.0 g of Acesulfame Potassium, transfer into a polyethylene beaker, add 10 ml of water, and mix for a while. Add 20 ml of diluted hydrochloric acid (1 2) gradually and dissolve. Heat the solution, boil for 1 minute, transfer into a polyethylene beaker, and immediately cool with ice. Add 15 ml of sodium citrate solution (25 100) and 10 ml of disodium ethylenediaminetetraacetate solution (2.5 100), and mix it. Adjust the pH of the solution to 5.4 - 5.6 with diluted hydrochloric acid (1 10) or sodium hydroxide solution (4 10). Transfer

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the solution into a 100-ml volumetric flask and add water to make 100 ml. Place about 50 ml of the solution in a polyethylene beaker and use as the test solution.

*Control Stock solution* Weigh accurately 2.210 g of sodium fluoride, previously dried at 110 °C for 2 hours, transfer into a polyethylene beaker, add 200 ml of water, and dissolve while stirring. Transfer the solution into a 1,000-ml volumetric flask, add water to make 1,000 ml, and transfer into a polyethylene bottle.

*Control solution* Prepare the control solution freshly before use. Transfer 3.0 ml of the stock solution into a 1,000-ml volumetric flask and add water to make 1,000 ml. Transfer 2.0 ml of the solution into a polyethylene beaker, add 15 ml of sodium citrate solution (25 mg/100) and 10 ml of disodium ethylenediaminetetraacetate solution (2.5 mg/100), and mix. Adjust the pH of the solution to 5.4 - 5.6 with diluted hydrochloric acid (1 mg/10) or sodium hydroxide solution (4 mg/10). Transfer the solution into a 100- ml volumetric flask, and add water to make 100 ml. Place about 50 ml of the solution into a polyethylene beaker and use as the control solution.

*Procedure* Measure the electric potentials of both solutions using a potentiometer connected to a reference electrode and a fluorine ion electrode. The electric potential of the test solution is not lower than that of the control solution.

(7) UV active components (Organic impurities) Not more than 20 µg/g as acesulfame potassium.

*Test solution* Weigh accurately about 1 g of Acesulfame Potassium, dissolve in water to make exactly 100 ml.

*Procedure* Measure 20 µl of the solution and perform Liquid Chromatography under the conditions given below.

If any other peak appears besides the main peak of Acesulfame Potassium within three times the retention time (3Rt) of Acesulfame Potassium, carry out a second run with 20 µl of a 50,000-fold dilution of the test solution in water. The total area of all peaks that appear within 3Rt in the first run, except the main peak of Acesulfame Potassium, does not exceed the main Acesulfame Potassium peak area in the second run.

### *Operating conditions*

Detector: UV detector (determination wavelength: 227nm).

Column packing material: 3- to 5-µm octadecylsilanized silica gel.

Column tube: Stainless steel 25 cm in length and 4.6 mm in internal diameter.

Column temperature: 40 °C.

Mobil phase: Acetonitrile - 0.01 mol/l tetrabutyl ammonium hydrogen sulfate mixture (40 : 60).

Flow rate: 1 ml/min.

The column should be capable of separating each of the peaks of Acesulfame

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Potassium and Ethyl *p*-Hydroxybenzoate, when the following test is conducted:  
Weigh 10 mg of Acesulfame Potassium and 10 mg of Ethyl *p*-Hydroxybenzoate, dissolve in water to make a mixture, and add water to make 1,000 ml. Measure 20  $\mu$ l of the solution, and perform Liquid Chromatography under the above conditions.

**Loss on Drying** Not more than 1.0 % (105 °C, 2 hours).

**Assay** Weigh accurately about 0.15g of Acesulfame Potassium, previously dried, dissolve in 50 ml of acetic acid, and titrate with 0.1 mol/l perchloric acid solution. The end point is usually confirmed using a potentiometer. When crystal violet - acetic acid TS is used as an indicator (2 drops), the end point is the time when the green color produced through blue color persists for at least 30 seconds. Separately, perform a blank test.

1 ml of 0.1 mol/l perchloric acid solution = 20.124 mg of  $C_4H_4KNO_4S$