Monographs

Acesulfame Potassium

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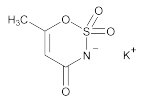
Acesulfame K
6-Methyl-1,2,3-oxathiazine-4(3*H*)-one-2,2 Dioxide Potassium Salt



$C_4H_4KNO_4S$ Formula wt 201.24
INS: 950 CAS: [55589-62-3]
UNII: 23OV73Q5G9 [acesulfame potassium]

DESCRIPTION

Acesulfame Potassium occurs as a white, free-flowing crystalline powder. It is freely soluble in water and very slightly soluble in ethanol.

Function: Non-nutritive sweetener; flavor enhancer

Packaging and Storage: Store in well-closed containers in a cool, dry place.

IDENTIFICATION

- **A. Procedure**
  Sample solution: 0.3 g in 1 mL of glacial acetic acid and 5 mL of water
  Analysis: Add a few drops of sodium cobaltinitrite TS to the *Sample solution*.
  Acceptance criteria: A yellow precipitate forms.
- **B. Ultraviolet Absorption**
  Sample solution: 0.01 mg/mL
  Acceptance criteria: The *Sample solution* shows an absorption maximum at 227 ± 2 nm.
- **C. Infrared Absorption**, *Spectrophotometric Identification Tests,* Appendix IIIC
  Reference standard: USP Acesulfame Potassium RS
  Sample and standard preparation: *K*
  Acceptance criteria: The spectrum of the sample exhibits maxima at the same wavelengths as those in the spectrum of the *Reference standard*.

ASSAY

- **Procedure**
  Sample: 200–300 mg, previously dried at 105° for 2 h
  Analysis: Dissolve the *Sample* in 50 mL of glacial acetic acid in a 250-mL flask. [Note—Dissolution may be slow.] Add 2 or 3 drops of crystal violet TS, and titrate with 0.1 N perchloric acid to a blue-green endpoint that persists for at least 30 s. [**Caution—**Handle perchloric acid in an appropriate fume hood.] Perform a blank determination (see *General Provisions*), and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 20.12 mg of $C_4H_4KNO_4S$.
  Acceptance criteria: 99.0%–101.0% of $C_4H_4KNO_4S$, on the dried basis

IMPURITIES

Inorganic Impurities

- **Fluoride**, *Fluoride Limit Test, Method III,* Appendix IIIB
  Sample: 4 g
  Acceptance criteria: NMT 3 mg/kg
- **Lead**, *Lead Limit Test,* Appendix IIIB
  Sample solution: 2 g in 20 mL of water
  Control: 2 µg Pb (2 mL of *Diluted Standard Lead Solution*)
  Acceptance criteria: NMT 1 mg/kg

Organic Impurities

- **Organic Impurities**
  Mobile phase: Acetonitrile and 0.01 M tetrabutyl ammonium hydrogen sulfate (40:60, v/v)
  Standard: 4-hydroxybenzoic acid ethyl ester
  Sample solution: 10 mg/mL
  Dilute sample solution: 0.2 mg/L
  Chromatographic system, Appendix IIA
  Mode: High-performance liquid chromatography
  Detector: UV or diode array (227 nm)
  Column: 25-cm × 4.6-mm (id) stainless steel, or equivalent, packed with 3- to 5-µm reversed phase C18 silica gel, or equivalent
  Flow rate: About 1 mL/min
  Injection volume: 20 µL
  Elution: Isocratic
  System suitability
  Suitability requirements: The resolution, R, between acesulfame potassium and 4-hydroxybenzoic acid ethyl ester is NLT 2.
  Analysis: Inject the *Sample solution* into the chromatograph and obtain the chromatogram. If peaks other than that caused by acesulfame potassium appear within three times the elution time of acesulfame potassium, carry out a second analysis using the *Dilute sample solution*.
  Acceptance criteria: The sum of the areas of all peaks eluted in the analysis of the *Sample solution* within three times the elution time of acesulfame potassium, except for the acesulfame potassium peak, does not exceed the peak area of acesulfame potassium in the analysis of the *Dilute sample solution* (NMT 20 µg/g of UV-active compounds).

SPECIFIC TESTS

- **Loss on Drying**, Appendix IIC**:** 105° for 2 h
  Acceptance criteria: NMT 1.0%
- **pH**, *pH Determination,* Appendix IIB
  Sample solution: 10 mg/mL
  Acceptance criteria: Between 5.5 and 7.5