Acesulphame Potassium

Published on: 07 February, 2024 **Last date for comments:** 22 March, 2024

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

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Document History and Schedule for the Adoption Process

Description	Details
Document version	1.0
First draft published on IPC website for public comments	February 7, 2024
Last date for comments	**March 22, 2024**
Monograph revisions proposed for inclusion in	**IP 2026**
Tentative effective date of monograph revisions	**July, 2026**
Draft revision published on IPC website for public comments	--
Further follow-up action as required.	

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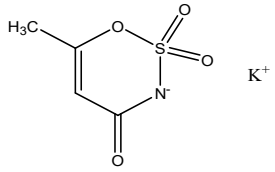

$C_4H_4KNO_4S$ Mol. Wt. 201.2

Acesulphame Potassium is 6-methyl-1, 2, 3-oxathiazine-4(3*H*)-one- 2, 2-dioxide potassium salt.

Acesulphame Potassium contains not less than 99.0 per cent and not more than 101.0 per cent of $C_4H_4KNO_4S$, calculated on the dried basis.

Category. Sweetening agent.

Description. A white or almost white, crystalline powder or colourless crystals.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum obtained with *acesulphame potassium IPRS* or with the reference spectrum of acesulphame potassium.

B. 0.5 ml of solution A (see Tests) gives reaction (A) of potassium salts (2.3.1).

Tests

Solution A. A 20 per cent w/v solution in *carbon dioxide-free water*.

Appearance of solution. Solution A is clear and colourless (2.4.1).

Acidity or alkalinity. To 20 ml of solution A, add 0.1 ml of *bromothymol blue solution*. Not more than 0.2 ml of *0.01 M hydrochloric acid* or *0.01 M sodium hydroxide* is required to change the colour of the indicator.

Chromatographic purity. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 0.1 g of the substance under examination in *water* and dilute to 10.0 ml with *water.*

Reference solution (a). A 0.00002 per cent w/v solution of *acesulphame potassium IPRS* in *water.*

Reference solution (b). A solution containing 0.0002 per cent w/v, each of, *acesulphame potassium IPRS* and *ethylparaben IPRS* in *water*.

Chromatographic system

- a stainless steel column 25 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (Such as Symmetry C18),
- mobile phase: a mixture of 60 volumes of 0.33 per cent w/v solution of *tetrabutylammonium hydrogen sulphate* and 40 volumes of *acetonitrile,*
- flow rate: 1 ml per minute,
- spectrophotometer set at 227 nm,
- injection volume: 20 µl.

Inject reference solution (b). The test is not valid unless the resolution between the peaks due to acesulfame potassium and ethylparaben is not less than 2.0.

Inject reference solution (a) and the test solution. Run the chromatogram 3 times the retention time of the principal peak for test solution. The area of any secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.002 per cent).

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Fluoride. Not more than 3 ppm.

NOTE-Prepare and store all solutions in plastic containers.

Solution A. Dissolve 210 g of *citric acid monohydrate* in 400 ml of *water,* adjusted to pH 7.0 with *ammonia* and dilute to 1000 ml with *water*.

Solution B. 13.2 per cent w/v solution of *diammonium hydrogen orthophosphate* in *water.*

Solution C. Dissolve 292 g of *edetic acid* ((ethylenedinitrilo) tetra-acetic acid) in 500 ml of *water,* add 200 ml of *ammonia*, adjusted to pH between 6 to 7 with *ammonia*, and dilute to 1000 ml with *water*.

Buffer solution. A mixture of equal volumes of solution A, solution B and solution C, adjusted to pH 7.5 with *ammonia*.

Test solution. Dissolve 3.0 g of the substance under examination in *water,* add 15 ml of the buffer solution and dilute to 50.0 ml with *water.*

Reference stock solution (a). Dissolve 0.442 g of *sodium fluoride,* previously dried at300° for 12 hours in *water* and dilute to 1000.0 ml with *water.* Dilute 5.0 ml of the solution to 100.0 ml with *water*, immediately before use.

Reference solutions. Take 0.5 ml, 1.0 ml, 1.5 ml, and 3.0 ml of the reference stock solution separately and mix each with 15 ml of the buffer solution and dilute to 50.0 ml with *water.*

Transfer the solution to 25 ml beaker, introduce the electrode into the solution and allow stirring constantly for 1 to 2 minutes until equilibrium is attained. Determine the end point potentiometrically (2.4.25) for fluoride ion, using a fluoride-selective indicating electrode and silver-silver chloride reference electrode. Rinse, and dry the electrodes between measurements, taking care not to scratch the crystal in the fluoride-selective indicating electrode.

Determine the potential of each reference solution, and plot the fluoride concentration, µg/ml, versus the potential, in Mv, on semi logarithmic graph paper. Using exactly the same condition, determine the potential of the test solution and calculate the content of fluoride from the standard curve, in ppm, in the portion of Acesulfame potassium by using the following formula:

$$\text{Result} = (V \times C/W)$$

Where,

V = volume of the test solution (ml)
C = concentration of fluoride in the test solution, from the standard curve (µg/ml)
W = weight of Acesulphame potassium taken to prepare the test solution (g)

Heavy metals (2.3.13).12 ml of solution A complies with the limit test for heavy metals, Method D (5 ppm), using 10.0 ml of *lead standard solution (1 ppm)*.

Loss on drying (2.4.19). Not more than 1.0 per cent, determined on 1.0 g by drying in an oven at 105° for 3 hours.

Assay. Dissolve 0.15 g in 50 ml of *anhydrous acetic acid*. Titrate with *0.1 M perchloric acid*, determining the end-point potentiometrically (2.4.25). Carry out a blank titration.

1 ml of *0.1 M perchloric acid* is equivalent to 0.02012 g of $C_4H_4KNO_4S$.

Storage. Store protected from light and moisture, at a temperature not exceeding 30°.

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