Adenine

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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.

Document History and Schedule for the Adoption Process

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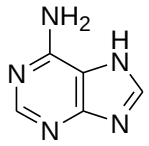
Adenine



$C_5H_5N_5$ Mol. Wt. 135.1

Adenine is 9H-Purin-6-amine; 1,6-Dihydro-6-iminopurine.

Adenine contains not less than 98.0 per cent and not more than 102.0 per cent of $C_5H_5N_5$, calculated on the dried basis.

Category. Nutritional supplement.

Description. A white crystals or crystalline powder.

Identification

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

B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the principal peak in the chromatogram obtained with reference solution (a).

Tests

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 25 mg of the substances under examination in 15 ml of boiling *water*, cool and dilute to 25.0 ml with *water*.

Reference solution (a). A 0.01 per cent w/v solution of *adenine IPRS* in *water*. *(NOTE- If necessary sonicate the solution at 30° until the substance is completely dissolved).*

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 10.0 ml with *water*.

Reference solution (c). A solution containing 0.005 per cent w/v, each of, *adenine IPRS* and *7-methyladenine* in *water*.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with both reversed-phase (an alkyl chain longer than C8) and weak cation-exchange (carboxyl groups) functional groups bonded to porous silica, (5 µm) (Such as Acclaim Mixed-Mode WCX-1),
- mobile phase: A. a buffer solution prepared by dissolving 6.9 g of *ammonium dihydrogen orthophosphate* in 1000 ml of *water*, adjusted to pH 6.2 with *ammonium hydroxide*,
  B. *acetonitrile*,
  C. *water*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 240 nm,
- injection volume: 20 µl.

Time	Mobile phase A	Mobile phase B	Mobile phase C

(in min.)	(per cent v/v)	(per cent v/v)	(per cent v/v)
0	5	5	90
20	5	5	90
20.1	10	10	80
30	10	10	80
30.1	5	5	90
40	5	5	90

The relative retention time with reference to adenine for 7-methyladenine is about 0.88.

Inject reference solution (c). The test is not valid unless the resolution between the peaks due to 7-methyladenine and adenine is not less than 2.0.

Inject reference solution (b) and the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than 0.1 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.1 per cent) and the sum of the areas of all the secondary peaks is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (b) (2.0 per cent).

Sulphated ash (2.3.18). Not more than 0.1 per cent.

Loss on drying (2.4.19). Not more than 1.0 per cent, determined on 1.0 g by drying in an oven at 110° for 4 hours.

Assay. Determine by liquid chromatography (2.4.14), as described under Related substances with the following modifications.

Test solution. Dissolve 25 mg of the substances under examination in 200 ml of *water*, with the aid of ultrasound at a temperature 30° and dilute to 250.0 ml with *water*.

Chromatographic system
- spectrophotometer set at 260 nm,
- injection volume: 10 µl.

Inject reference solution (a). The test is not valid unless the column efficiency is not less than 2000 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject reference solution (a) and the test solution.

Calculate the content of $C_5H_5N_5$.

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

Solubility.

Adenine. Sparingly soluble in boiling *water;* slightly soluble in *ethanol (95 per cent)*; very slightly soluble in *water*; practically insoluble in *ether* and in *chloroform.*