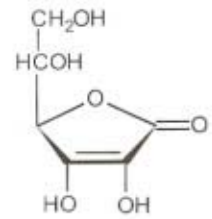
Ascorbic Acid



$C_6H_8O_6$ 176.1 *50-81-7*

Ascorbic Acid complies with the requirements of the 3rd edition of the European Pharmacopoeia [0253]. These requirements are reproduced after the heading 'Definition' below.

Action and use Used in the treatment of vitamin C deficiency.

Preparations
Ascorbic Acid Injection
Ascorbic Acid Tablets
Vitamins B and C Injection

When vitamin C is prescribed or demanded, Ascorbic Acid shall be dispensed or supplied.

Ph Eur

DEFINITION

Ascorbic acid contains not less than 99.0 per cent and not more than the equivalent of 100.5 per cent of (*R*)-5-[(*S*)-1,2-dihydroxyethyl]-3,4-dihydroxy-5*H*-furan-2-one.

CHARACTERS

A white or almost white, crystalline powder or colourless crystals, becoming discolored on exposure to air and moisture, freely soluble in water, soluble in alcohol, practically insoluble in ether.

It melts at about 190°C, with decomposition.

IDENTIFICATION

First identification: B, C.
Second identification: A, C, D.

A. Dissolve 0.10 g in *water R* and dilute immediately to 100.0 ml with the same solvent. To 10 ml of *0.1M hydrochloric acid*, add 1.0 ml of the solution and dilute to 100.0 ml with *water R*. Measure the absorbance (*2.2.25*) at the maximum at 243 nm immediately after dissolution. The specific absorbance at the maximum is 545 to 585.

B. Examine by infrared absorption spectrophotometry (*2.2.24*), comparing with the spectrum obtained with *ascorbic acid CRS*. Examine the substance prepared as discs containing 1 mg.

C. The pH (*2.2.3*) of solution S (see Tests) is 2.1 to 2.6.

D. To 1 ml of solution S add 0.2 ml of *dilute nitric acid R* and 0.2 ml of *silver nitrate solution R2*. A grey precipitate is formed.

TESTS

Solution S. Dissolve 1.0 g in *carbon dioxide-free water R* and dilute to 20 ml with the same solvent.

Appearance of solution Solution S is clear (*2.2.1*) and not more intensely coloured than reference solution BY_7 (*Method II, 2.2.2*).

Specific optical rotation (*2.2.7*). Dissolve 2.50 g in *water R* and dilute to 25.0 ml with the same solvent. The specific optical rotation is +20.5° to +21.5°.

Oxalic acid Dissolve 0.25 g in 5 ml of *water R*. Neutralise to *red litmus paper R* using *dilute sodium hydroxide solution R* and add 1 ml of *dilute acetic acid R* and 0.5 ml of *calcium chloride solution R* (test solution). Prepare a reference solution as follows: dissolve 70 mg of *oxalic acid R* in *water R* and dilute to 500 ml with the same solvent; to 5 ml of this solution add 1 ml of *dilute acetic acid R* and 0.5 ml of *calcium chloride solution R* (reference solution). Allow the solutions to stand for 1 h. Any opalescence in the test solution is not more intense than that in the reference solution (0.2 per cent).

Copper Not more than 5 ppm of Cu, determined by atomic absorption spectrophotometry (*Method I, 2.2.23*).

Test solution. Dissolve 2.0 g of the substance to be examined in *0.1M nitric acid* and dilute to 25.0 ml

with the same acid.

Reference solutions. Prepare reference solutions containing 0.2 ppm, 0.4 ppm and 0.6 ppm of Cu by diluting *copper standard solution (10 ppm Cu) R* with *0.1M nitric acid*.

Measure the absorbance at 324.8 nm using a copper hollow-cathode lamp as a source of radiation and an air-acetylene flame. Adjust the zero of the apparatus using *0.1M nitric acid*.

Iron. Not more than 2 ppm of Fe, determined by atomic absorption spectrophotometry (*Method I, 2.2.23*).

Test solution. Dissolve 5.0 g of the substance to be examined in *0.1M nitric acid* and dilute to 25.0 ml with the same acid.

Reference solutions. Prepare reference solutions containing 0.2 ppm, 0.4 ppm and 0.6 ppm of Fe by diluting *iron standard solution (20 ppm Fe) R* with *0.1M nitric acid*.

Measure the absorbance at 248.3 nm using an iron hollow-cathode lamp as a source of radiation and an air-acetylene flame. Adjust the zero of the apparatus using *0.1M nitric acid*.

Heavy metals (*2.4.8*). Dissolve 1.5 g in *water R* and dilute to 15 ml with the same solvent. 12 ml of the solution complies with limit test A for heavy metals (10 ppm). Prepare the standard using *lead standard solution (1 ppm Pb) R*.

Sulphated ash (*2.4.14*). Not more than 0.1 per cent, determined on 1.0 g

ASSAY

Dissolve 0.150 g in a mixture of 10 ml of *dilute sulphuric acid R* and 80 ml of *carbon dioxide-free water R*. Add 1 ml of *starch solution R*. Titrate with *0.05M iodine* until a persistent violet-blue colour is obtained.

1 ml of *0.05M iodine* is equivalent to 8.81 mg of $C_6H_8O_6$.

STORAGE

Store in a well-closed, non-metallic container, protected from light.