

metaphosphoric acid (1 in 50), and titrate with 0.05 mol/L iodine VS (indicator: 1 mL of starch TS).

Each mL of 0.05 mol/L iodine VS = 8.806 mg of $C_6H_8O_6$

Containers and storage Containers—Tight containers.
Storage—Light-resistant.

Ascorbic Acid Injection

Vitamin C Injection

アスコルビン酸注射液

Ascorbic Acid Injection is an aqueous solution for injection. It contains not less than 95% and not more than 115% of the labeled amount of L-ascorbic acid ($C_6H_8O_6$; 176.12).

Method of preparation Prepare as directed under Injections, with the sodium salt of Ascorbic Acid.

Description Ascorbic Acid Injection occurs as a clear, colorless liquid.

Identification (1) Measure a volume of Ascorbic Acid Injection, equivalent to 0.5 g of Ascorbic Acid according to the labeled amount, and add water to make 25 mL. Proceed with 5 mL each of the solution as directed in the Identification (1) under Ascorbic Acid.

(2) Measure a volume of Ascorbic Acid Injection, equivalent to 5 mg of Ascorbic Acid according to the labeled amount. Add a solution of metaphosphoric acid (1 in 50) to make 5 mL, and proceed with this solution as directed in the Identification (2) under Ascorbic Acid.

(3) Ascorbic Acid Injection responds to the Qualitative Tests (1) for sodium salt.
pH: 5.6–7.4

Assay Measure exactly a volume of Ascorbic Acid Injection, equivalent to about 0.1 g of L-ascorbic acid ($C_6H_8O_6$), previously diluted with metaphosphoric acid-acetic acid TS, if necessary, and add metaphosphoric acid-acetic acid TS to make exactly 200 mL. Measure exactly 2 mL of the solution, and shake with 8 mL of metaphosphoric acid-acetic acid TS and 2 mL of hydrogen peroxide TS. Titrate with 2,6-dichloroindophenol sodium TS for titration until a light red color persists for 5 seconds. Perform a blank determination, and make any necessary correction.

Each mL of 2, 6-dichlorophenol-indophenol sodium TS for titration
= A mg of $C_6H_8O_6$

A is decided by the following standardization of 2,6-dichloroindophenol sodium TS for titration.

2,6-Dichlorophenol-indophenol sodium TS for titration:

Preparation—Dissolve 0.042 g of sodium hydrogen carbonate in 50 mL of water, add 0.05 g of 2,6-dichloroindophenol sodium dihydrate and water to make 200 mL, and filter. Prepare before use.

Standardization—Weigh accurately about 0.05 g of Ascorbic Acid Reference Standard, previously dried in a desiccator (silica gel) for 24 hours, and dissolve in metaphosphoric acid-acetic acid TS to make exactly 100 mL. Pipet 2 mL of

this solution, shake with 8 mL of metaphosphoric acid-acetic acid TS and 2 mL of hydrogen peroxide TS, and titrate with 2,6-dichloroindophenol sodium TS for titration until a light red color persists for 5 seconds. Perform a blank determination, and make any necessary correction. Calculate the quantity (A mg) of L-ascorbic acid ($C_6H_8O_6$) equivalent to 1 mL of this test solution.

Containers and storage Containers—Hermetic containers.
Storage—Under nitrogen atmosphere.

Ascorbic Acid Powder

Vitamin C Powder

アスコルビン酸散

Ascorbic Acid Powder contains not less than 95% and not more than 120% of the labeled amount of L-ascorbic acid ($C_6H_8O_6$; 176.12).

Method of preparation Prepare as directed under Powders, with Ascorbic Acid.

Identification (1) Weigh a portion of Ascorbic Acid Powder, equivalent to 0.5 g of Ascorbic Acid according to the labeled amount, add 30 mL of water, shake for 1 minute, and filter. Proceed with 5 mL each of the filtrate as directed in the Identification (1) under Ascorbic Acid.

(2) Weigh a portion of Ascorbic Acid Powder, equivalent to about 0.01 g of Ascorbic Acid according to the labeled amount, add 10 mL of a solution of metaphosphoric acid (1 in 50), shake for 1 minute, and filter. Proceed with 5 mL of the filtrate as directed in the Identification (2) under Ascorbic Acid.

Purity Rancidity—Ascorbic Acid Powder is free from any unpleasant or rancid odor and taste.

Assay Weigh accurately a portion of Ascorbic Acid Powder, equivalent to about 0.1 g of L-ascorbic acid ($C_6H_8O_6$) according to the labeled amount, extract with several successive portions of metaphosphoric acid-acetic acid TS, combine the extracts, and filter. Wash the residue with metaphosphoric acid-acetic acid TS. Combine the filtrates and washings, and add metaphosphoric acid-acetic acid to make exactly 200 mL. Pipet 2 mL of the solution, and shake with 8 mL of metaphosphoric acid-acetic acid TS and 2 mL of hydrogen peroxide TS. Titrate with 2,6-dichloroindophenol sodium TS for titration until a light red color persists for 5 seconds. Perform a blank determination, and make any necessary correction.

Each mL of 2,6-dichlorophenol-indophenol sodium TS for titration
= A mg of $C_6H_8O_6$

A is decided by the following standardization of 2,6-dichloroindophenol sodium TS for titration.

2,6-Dichlorophenol-indophenol sodium TS for titration:

Preparation—Dissolve 0.042 g of sodium hydrogen carbonate in 50 mL of water, add 0.05 g of 2,6-dichloroindophenol sodium dihydrate and water to make 200 mL, and filter. Prepare before use.

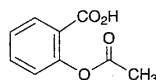
Standardization—Weigh accurately about 0.05 g of Ascorbic Acid Reference Standard, previously dried in a desiccator (silica gel) for 24 hours, and dissolve in metaphosphoric acid-acetic acid TS to make exactly 100 mL. Pipet 2 mL of this solution, shake with 8 mL of metaphosphoric acid-acetic acid TS and 2 mL of hydrogen peroxide TS, and titrate with 2,6-dichloroindophenol sodium TS for titration until a light red color persists for 5 seconds. Perform a blank determination, and make any necessary correction. Calculate the quantity (*A* mg) of L-ascorbic acid ($C_6H_8O_6$) equivalent to 1 mL of this test solution.

Containers and storage Containers—Tight containers.

Aspirin

Acetylsalicylic Acid

アスピリン



$C_9H_8O_4$: 180.16
2-Acetoxybenzoic acid [50-78-2]

Aspirin, when dried, contains not less than 99.5% of $C_9H_8O_4$.

Description Aspirin occurs as white crystals, granules or powder. It is odorless, and has a slight acid taste.

It is freely soluble in ethanol (95) and in acetone, soluble in diethyl ether, and slightly soluble in water.

It dissolves in sodium hydroxide TS and in sodium carbonate TS.

In moist air, it gradually hydrolyzes to salicylic acid and acetic acid.

Melting point: about 136°C (bath fluid is heated at 130°C previously).

Identification (1) Boil 0.1 g of Aspirin in 5 mL of water for 5 to 6 minutes, cool, and add 1 to 2 drops of iron (III) chloride TS: a red-purple color is produced.

(2) Boil 0.5 g of Aspirin in 10 mL of sodium carbonate TS for 5 minutes, and add 10 mL of dilute sulfuric acid: the odor of acetic acid is perceptible, and a white precipitate is produced. Filter the precipitate, add 3 mL of ethanol (95) and 3 mL of sulfuric acid to the filtrate, and heat: the odor of ethyl acetate is perceptible.

Purity (1) Clarity of solution—Dissolve 0.5 g of Aspirin in 10 mL of warm sodium carbonate TS: the solution is clear.

(2) Salicylic acid—Dissolve 2.5 g of Aspirin in 25 mL of ethanol (95), and add 1.0 mL of this solution to a solution which is prepared by transferring 1 mL of a freshly prepared dilute ammonium iron (III) sulfate TS to a Nessler tube and diluting with water to 50 mL. Allow to stand for 30 seconds: the solution has no more color than the following control solution.

Control solution: Dissolve 0.100 g of salicylic acid in water, and add 1 mL of acetic acid (100) and water to make

1000 mL. Add 1.0 mL of this solution to a solution which is prepared by transferring 1 mL of freshly prepared dilute ammonium iron (III) sulfate TS and 1 mL of ethanol (95) to a Nessler tube and diluting with water to 50 mL. Allow to stand for 30 seconds.

(3) Chloride—Boil 1.8 g of Aspirin in 75 mL of water for 5 minutes, cool, add water to make 75 mL, and filter. To 25 mL of the filtrate add 6 mL of dilute nitric acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 0.25 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.015%).

(4) Sulfate—To 25 mL of the filtrate obtained in (3) add 1 mL of dilute hydrochloric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.50 mL of 0.005 mol/L sulfuric acid VS (not more than 0.040%).

(5) Heavy metals—Dissolve 2.5 g of Aspirin in 30 mL of acetone, add 2 mL of dilute acetic acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 2.5 mL of Standard Lead Solution, 30 mL of acetone, 2 mL of dilute acetic acid and water to make 50 mL (not more than 10 ppm).

(6) Readily carbonizable substances—Weigh 0.5 g of Aspirin, and perform the test. The solution has no more color than Matching Fluid Q.

Loss on drying Not more than 0.5% (3 g, silica gel, 5 hours).

Residue on ignition Not more than 0.10% (1 g).

Assay Weigh accurately about 1.5 g of Aspirin, previously dried, add exactly 50 mL of 0.5 mol/L sodium hydroxide VS, and boil gently for 10 minutes under a reflux condenser with a carbon dioxide-absorbing tube (soda lime). Cool, and titrate immediately the excess sodium hydroxide with 0.25 mol/L sulfuric acid VS (indicator: 3 drops of phenolphthalein TS). Perform a blank determination.

Each mL of 0.5 mol/L sodium hydroxide VS
= 45.04 mg of $C_9H_8O_4$

Containers and storage Containers—Well-closed containers.

Aspirin Tablets

Acetylsalicylic Acid Tablets

アスピリン錠

Aspirin Tablets contain not less than 95% and not more than 105% of the labeled amount of aspirin ($C_9H_8O_4$: 180.16).

Method of preparation Prepare as directed under Tablets, with Aspirin.

Identification (1) Weigh a quantity of powdered Aspirin Tablets, equivalent to 0.1 g of Aspirin according to the labeled amount, add 10 mL of water, and boil for 5 to 6 minutes. After cooling, filter, and add 1 to 2 drops of iron (III) chloride TS to the filtrate: a red-violet color develops.