let light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying Not more than 1.0% (0.6 g, in vacuum, 80°C, 3 hours).

Residue on ignition Not more than 0.2% (0.5 g).

Assay Weigh accurately about 0.3 g of Ajmaline, previously dried, dissolve in 50 mL of acetic anhydride and 50 mL of acetone for nonaqueous titration, and titrate with 0.05 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.05 mol/L perchloric acid VS
= 16.322 mg of $C_{20}H_{26}N_2O_2$

Containers and storage Containers—Well-closed containers.

Storage—Light-resistant.

Ajmaline Tablets

アジマリン錠

Ajmaline Tablets contain not less than 90% and not more than 110% of the labeled amount of ajmaline ($C_{20}H_{26}N_2O_2$: 326.43).

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

Identification (1) Shake a quantity of powdered Ajmaline Tablets, equivalent to 0.1 g of Ajmaline according to the labeled amount, with 30 mL of chloroform, and filter. Evaporate the filtrate on a water bath to dryness. With the residue, proceed as directed in the Identification under Ajmaline.

(2) Dissolve 0.01 g of the residue of (1) in 100 mL of ethanol (95). To 10 mL of this solution add ethanol (95) to make 50 mL, and determine the absorption spectrum of the solution as directed under the Ultraviolet-visible Spectrophotometry: it exhibits maxima between 247 nm and 251 nm and between 291 nm and 294 nm, and a minimum between 269 nm and 273 nm.

Dissolution test Perform the test with 1 tablet of Ajmaline Tablets at 100 revolutions per minute according to Method 2 under the Dissolution Test, using 900 mL of diluted phosphate buffer solution, pH 6.8, (1 in 2) as the test solution. Take 20 mL or more of the dissolved solution 60 minutes after start of the test, and filter through a membrane filter with pore size of not more than 0.8 μm. Discard the first 10 mL of the filtrate, and use the subsequent filtrate as the sample solution. Separately, weigh accurately about 0.028 g of ajmaline for assay, previously dried in vacuum at 80°C for 3 hours, dissolve in diluted phosphate buffer solution, pH 6.8, (1 in 2) to make exactly 500 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S, of the sample solution and the standard solution at 288 nm as directed under the Ultraviolet-visible Spectrophotometry.

The dissolution rate of Ajmaline Tablets in 60 minutes is not less than 75%.

Dissolution rate (%) with respect to the labeled amount of ajmaline ($C_{20}H_{26}N_2O_2$)

$$= W_S \times \frac{A_T}{A_S} \times \frac{1}{C} \times 180$$

W_S: Amount (mg) of ajmaline for assay.

C: Labeled amount (mg) of ajmaline ($C_{20}H_{26}N_2O_2$) in 1 tablet.

Assay Weigh accurately and powder not less than 20 Ajmaline Tablets. Weigh accurately a portion of the powder, equivalent to about 0.3 g of ajmaline ($C_{20}H_{26}N_2O_2$), add 15 mL of ammonia solution (28), and extract with four 25-mL portions of chloroform. Combine the chloroform extracts, wash with 10 mL of water, add 5 g of anhydrous sodium sulfate, shake well, and filter. Wash the container and the residue with two 10-mL portions of chloroform, and filter. Evaporate the combined filtrate on a water bath to dryness, dissolve the residue in 50 mL of acetic anhydride and 50 mL of acetone for nonaqueous titration, and titrate with 0.05 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.05 mol/L perchloric acid VS
= 16.322 mg of $C_{20}H_{26}N_2O_2$

Containers and storage Containers—Well-closed containers.

Storage—Light-resistant.

Albumin Tannate

Tannalbin

タンニン酸アルブミン

Albumin Tannate is a compound of tannic acid and a protein.

The label states the origin of the protein of Albumin Tannate.

Description Albumin Tannate occurs as a light brown powder. It is odorless, or has a faint, characteristic odor.

It is practically insoluble in water and in ethanol (95).

It dissolves in sodium hydroxide TS with turbidity.

Identification (1) To 0.1 g of Albumin Tannate add 10 mL of ethanol (95), and heat in a water bath for 3 minutes with shaking. After cooling, filter, and to 5 mL of the filtrate add 1 drop of iron (III) chloride TS: a blue-purple to bluish black color is produced. On standing, a bluish black precipitate is produced.

(2) To 0.1 g of Albumin Tannate add 5 mL of nitric acid: an orange-yellow color develops.

Purity (1) Acid—Shake 1.0 g of Albumin Tannate with 50 mL of water for 5 minutes, and filter. To 25 mL of the filtrate add 1.0 mL of 0.1 mol/L sodium hydroxide VS and 2 drops of phenolphthalein TS: a red color develops.

(2) Fats—To 2.0 g of Albumin Tannate add 20 mL of petroleum benzine, shake vigorously for 15 minutes, and filter. Evaporate 10 mL of the filtrate on a water bath: the mass of the residue is not more than 0.050 g.

Loss on drying Not more than 6.0% (1 g, 105°C, 3 hours).

Residue on ignition Not more than 1.0% (0.5 g).

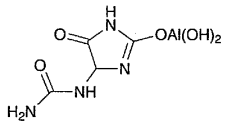
Digestion test To 1.00 g of Albumin Tannate add 0.25 g of saccharated pepsin and 100 mL of water, shake well, and allow to stand for 20 minutes at 40 ± 1°C in a water bath. Add 1.0 mL of dilute hydrochloric acid, shake, and allow to stand for 3 hours at 40 ± 1°C. Cool rapidly to ordinary temperature, and filter. Wash the residue with three 10-mL portions of water, dry in a desiccator (silica gel) for 18 hours, and dry at 105°C for 5 hours: the mass of the residue is 0.50 to 0.58 g.

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

Aldioxa

Dihydroxyaluminum Allantoinate

アルジオキサ



$C_4H_7AlN_4O_5$: 218.10
Dihydroxo(4,5-dihydro-5-oxo-4-ureido-1*H*-imidazol-2-yl)-oxoaluminium [*5579-81-7*]

Aldioxa is a condensation product of allantoin and aluminum hydroxide.

When dried, it contains not less than 65.3% and not more than 74.3% of allantoin ($C_4H_6N_4O_3$: 158.12), and not less than 11.1% and not more than 13.0% of aluminum (Al: 26.98).

Description Aldioxa occurs as a white powder. It is odorless and tasteless.

It is practically insoluble in water, in ethanol (95) and in diethyl ether.

It dissolves in dilute hydrochloric acid and in dilute nitric acid.

Melting point: about 230°C (with decomposition).

Identification (1) To 0.2 g of Aldioxa add 10 mL of dilute hydrochloric acid, boil for 5 minutes, and add 10 mL of a solution of phenylhydrazinium chloride (1 in 100). After cooling, mix well with 0.5 mL of potassium hexacyanoferrate (III) TS, and shake with 1 mL of hydrochloric acid: a red color develops.

(2) To 0.2 g of Aldioxa add 10 mL of dilute hydrochloric acid, dissolve by warming, and cool: the solution responds to the Qualitative Tests for aluminum salt.

Purity (1) Chloride—To 0.10 g of Aldioxa add 6 mL of dilute nitric acid, boil to dissolve with shaking for 5 minutes, cool, and add water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.40 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.142%).

(2) Sulfate—To 0.20 g of Aldioxa add 6 mL of dilute hydrochloric acid, boil to dissolve with shaking for 5 minutes, cool, and add water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 1.0 mL of 0.005 mol/L sulfuric acid VS (not more than 0.240%).

(3) Nitrate—To 0.10 g of Aldioxa add carefully 5 mL of water and 5 mL of sulfuric acid, dissolve by shaking, cool, and superimpose 2 mL of iron (II) sulfate TS: no brown ring is produced at the zone of contact.

(4) Heavy metals—To 1.0 g of Aldioxa add 3 mL of hydrochloric acid and 3 mL of water, heat gently to boil with shaking, and evaporate on a water bath to dryness. To the residue add 30 mL of water, shake under warming, cool, filter, and to the filtrate add 2 mL of dilute acetic acid (31) and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution as follows: to 3 mL of hydrochloric acid add 3 mL of water, evaporate on a water bath to dryness, and add 2.0 mL of Standard Lead Solution, 2 mL of dilute acetic acid (31) and water to make 50 mL (not more than 20 ppm).

(5) Arsenic—Prepare the test solution with 1.0 g of Aldioxa according to Method 2, and perform the test using Apparatus B (not more than 2 ppm).

Loss on drying Not more than 4.0% (1 g, 105°C, 2 hours).

Assay (1) Allantoin—Weigh accurately about 0.1 g of Aldioxa, previously dried, dissolve in 50 mL of dilute sulfuric acid by heating, cool, and add water to make exactly 100 mL. Pipet 10 mL of this solution, and perform the test as directed under the Nitrogen Determination.

Each mL of 0.005 mol/L sulfuric acid VS
= 0.39529 mg of $C_4H_6N_4O_3$

(2) Aluminum—Weigh accurately about 0.2 g of Aldioxa, previously dried, dissolve carefully in 50 mL of dilute hydrochloric acid by heating, cool, and add dilute hydrochloric acid to make exactly 100 mL. Pipet 4 mL of this solution, add water to make exactly 25 mL, and use this solution as the sample solution. Separately, pipet a suitable quantity of Standard Aluminum Stock Solution, dilute with water so that each mL of the solution contains not less than 16.0 μg and not more than 64.0 μg of aluminum (Al: 26.98), and use this solution as the standard solution. Perform the test with the sample solution and the standard solution as directed under the Atomic Absorption Spectrophotometry according to the following conditions, and calculate the aluminum content of the sample solution from the calibration curve obtained from the absorbance of the standard solution.

Gas: Combustible gas—Acetylene
Supporting gas—Nitrous oxide
Lamp: An aluminum hollow cathode lamp
Wavelength: 309.2 nm

Containers and storage Containers—Well-closed containers.