amount of hydralazine hydrochloride ($C_8H_8N_4$.HCl: 196.64).

**Method of preparation** Prepare as directed under Powder, with Hydralazine Hydrochloride.

**Identification** Weigh a portion of Hydralazine Hydrochloride Powder, equivalent to 0.025 g of Hydralazine Hydrochloride according to the labeled amount, add 100 mL of water, shake well, and filter, if necessary. Add water to 2 mL of the filtrate to make 50 mL and determine the absorption spectrum of this solution as directed under the Ultraviolet-visible Spectrophotometry: it exhibits maxima between 238 nm and 242 nm, between 258 nm and 262 nm, between 301 nm and 305 nm, and between 313 nm and 317 nm.

**Assay** Weigh accurately a portion of Hydralazine Hydrochloride Powder, equivalent to about 0.15 g of Hydralazine Hydrochloride, transfer it to a glass-stoppered flask, add 25 mL of water, shake well, add 25 mL of hydrochloric acid, cool to room temperature, and proceed as directed in the Assay under Hydralazine Hydrochloride.

Each mL of 0.05 mol/L potassium iodate VS
= 9.832 mg of $C_8H_8N_4$.HCl

**Containers and storage** Containers—Tight containers.

# Hydralazine Hydrochloride Tablets

塩酸ヒドララジン錠

Hydralazine Hydrochloride Tablets contain not less than 95% and not more than 105% of the labeled amount of hydralazine hydrochloride ($C_8H_8N_4$.HCl: 196.64).

**Method of preparation** Prepare as directed under Tablets, with Hydralazine Hydrochloride.

**Identification** Weigh a quantity of powdered Hydralazine Hydrochloride Tablets, equivalent to 0.025 g of Hydralazine Hydrochloride according to the labeled amount, add 100 mL of water, mix well, and filter if necessary. To 2 mL of this solution add water to make 50 mL, and determine the absorption spectrum of this solution as directed under the Ultraviolet-visible Spectrophotometry: it exhibits maxima between 238 nm and 242 nm, between 258 nm and 262 nm, between 301 nm and 305 nm and between 313 nm and 317 nm.

**Dissolution test** Perform the test with 1 tablet of Hydralazine Hydrochloride Tablets at 50 revolutions per minute according to Method 2 under the Dissolution Test, using 900 mL of water as the test solution. Take 30 mL or more of the dissolved solution 45 minutes after start of the dissolution test, and filter through a membrane filter with pore size of not more than 0.8 $\mu$m. Discard the first 10 mL of the filtrate, pipet the subsequent $V$ mL, add water to make exactly $V'$ mL so that each mL contains about 11 $\mu$g of hydralazine hydrochloride ($C_8H_8N_4$.HCl) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 0.05 g of hydralazine hydrochloride for assay, previously dried at 105°C for 3 hours, and dissolve in water to make exactly 50 mL. Pipet 1 mL of this solution, add water to make exactly 100 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 260 nm as directed under the Ultraviolet-visible Spectrophotometry.

The dissolution rate of Hydralazine Hydrochloride Tablets in 45 minutes is not less than 80%.

Dissolution rate (%) with respect to the labeled amount of hydralazine hydrochloride ($C_8H_8N_4$.HCl)

$$= W_S \times \frac{A_T}{A_S} \times \frac{V'}{V} \times \frac{1}{C} \times 18$$

$W_S$: Amount (mg) of hydralazine hydrochloride for assay.

$C$: Labeled amount (mg) of hydralazine hydrochloride ($C_8H_8N_4$.HCl) in 1 tablet.

**Assay** Weigh accurately not less than 20 Hydralazine Hydrochloride Tablets, and powder. Weigh accurately a portion of the powder, equivalent to about 0.15 g of hydralazine hydrochloride ($C_8H_8N_4$.HCl), transfer it to a glass-stoppered flask, and proceed as directed in the Assay under Hydralazine Hydrochloride.

Each mL of 0.05 mol/L potassium iodate VS
= 9.832 mg of $C_8H_8N_4$.HCl

**Containers and storage** Containers—Tight containers.

# Hydrochloric Acid

塩酸

Hydrochloric Acid contains not less than 35.0% and not more than 38.0% of hydrogen chloride (HCl: 36.46).

**Description** Hydrochloric Acid is a colorless liquid having a pungent odor.

It is fuming but ceases to fume when it is diluted with 2 volumes of water.

Specific gravity $d_{20}^{20}$: about 1.18

**Identification** **(1)** Allow a glass stick wet with ammonia TS to come near the surface of Hydrochloric Acid: a remarkable white smoke evolves.

**(2)** A solution of Hydrochloric Acid (1 in 100) changes blue litmus paper to red, and responds to the Qualitative Tests for chloride.

**Purity** **(1)** Sulfate—To 15 mL of Hydrochloric Acid add water to make 50 mL, and use this solution as the sample solution. To 3.0 mL of the sample solution add 5 mL of water and 5 drops of barium chloride TS, and allow to stand for 1 hour: no turbidity is produced.

**(2)** Sulfite—To 3.0 mL of the sample solution obtained in (1) add 5 ml of water and 1 drop of iodine TS: the color of iodine TS does not disappear.

**(3)** Bromide or iodide—Place 10 mL of the sample solution obtained in (1) in a glass-stoppered test tube, add 1 mL of chloroform and 1 drop of 0.002 mol/L potassium permanganate VS, and shake well: the chloroform layer remains colorless.

(4) Bromine or chlorine—Place 10 mL of the sample solution obtained in (1) in a glass-stoppered test tube, add 5 drops of potassium iodide TS and 1 mL of chloroform, and shake for 1 minute: the chloroform layer remains free from a purple color.

(5) Heavy metals—Evaporate 5 mL of Hydrochloric Acid on a water bath to dryness, and add 2 mL of dilute acetic acid and water to the residue to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution as follons: to 3.0 mL of Standard Lead Solution add 2 mL of dilute acetic acid and water to make 50 mL (not more than 5 ppm).

(6) Arsenic—Prepare the test solution with 1.7 mL of Hydrochloric Acid according to Method 1, and perform the test using Apparatus B (not more than 1 ppm).

(7) Mercury—Dilute 20 mL of Hydrochloric Acid with water to make exactly 100 mL, and use the solution as the sample solution. Perform the test with this sample solution as directed under the Atomic Absorption Spectrophotometry (cold vapor type). Place the sample solution in a sample bottle of the atomic absorption spectrophotometer, add 10 mL of tin (II) chloride-sulfuric acid TS, connect the bottle immediately to the spectrophotometer, circulate air, and determine the absorbance $A_T$ of the sample solution after the recorder reading has risen rapidly, and becomes constant at a wavelength of 253.7 nm. On the other hand, to 8 mL of Standard Mercury Solution add water to make exactly 100 mL, and determine the absorbance $A_S$ of the solution obtained by the same procedure as used for the sample solution: $A_T$ is smaller than $A_S$ (not more than 0.04 ppm).

**Residue on ignition** Pipet 10 mL of Hydrochloric Acid, add 2 drops of sulfuric acid, evaporate to dryness, and ignite: not more than 1.0 mg of residue remains.

**Assay** Weigh accurately a glass-stoppered flask containing 20 mL of water, add about 3 mL of Hydrochloric Acid, and weigh accurately again. Dilute with 25 mL of water, and titrate with 1 mol/L sodium hydroxide VS (indicator: 2 to 3 drops of methyl red TS).

Each mL of 1 mol/L sodium hydroxide VS
= 36.461 mg of HCl

**Containers and storage** Containers—Tight containers.

# Dilute Hydrochloric Acid

希塩酸

Dilute Hydrochloric Acid contains not less than 9.5 w/v% and not more than 10.5 w/v% of hydrogen chloride (HCl: 36.46).

**Description** Dilute Hydrochloric Acid is a colorless liquid. It is odorless and has a strong acid taste.

Specific gravity $d_{20}^{20}$: about 1.05

**Identification** A solution of Dilute Hydrochloric Acid (1 in 30) changes blue litmus paper to red and responds to the Qualitative Tests for chloride.

**Purity** (1) Sulfate—To 3.0 mL of Dilute Hydrochloric Acid add 5 mL of water and 5 drops of barium chloride TS, and allow to stand for 1 hour: no turbidity is produced.

(2) Sulfite—To 3.0 mL of Dilute Hydrochloric Acid add 5 mL of water and 1 drop of iodine TS: the color of iodine TS does not disappear.

(3) Bromide or iodide—Place 10 mL of Dilute Hydrochloric Acid in a glass-stoppered test tube, add 1 mL of chloroform and 1 drop of 0.002 mol/L potassium permanganate VS, and shake well: the chloroform layer remains colorless.

(4) Bromine or chlorine—Place 10 mL of Dilute Hydrochloric Acid in a glass-stoppered test tube, add 5 drops of potassium iodide TS and 1 mL of chloroform, and shake for 1 minute: the chloroform layer remains free from a purple color.

(5) Heavy metals—Evaporate 9.5 mL of Dilute Hydrochloric Acid on a water bath to dryness, 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 as follows: to 3.0 mL of Standard Lead Solution add 2 mL of dilute acetic acid and water to make 50 mL (not more than 3 ppm).

(6) Arsenic—Prepare the test solution with 4.0 mL of Dilute Hydrochloric Acid according to Method 1, and perform the test using Apparatus B (not more than 0.5 ppm).

(7) Mercury—Dilute 80 mL of Dilute Hydrochloric Acid with water to make exactly 100 mL, and use this solution as the sample solution. Perform the test with this solution according to the Atomic Absorption Spectrophotometry (cold vapor type). Place the sample solution in a sample bottle of the atomic absorption spectrophotometer, add 10 mL of tin (II) chloride-sulfuric acid TS, connect the bottle immediately to the spectrophotometer, circulate air, and read the absorbance $A_T$ of the sample solution after the recorder reading has risen rapidly and become constant at a wavelength of 253.7 nm. On the other hand, to 8 mL of Standard Mercury Solution add water to make exactly 100 mL, and read the absorbance $A_S$ of the solution obtained by the same procedure as used for the sample solution: $A_T$ is smaller than $A_S$ (not more than 0.01 ppm).

**Residue on ignition** Pipet 10 mL of Dilute Hydrochloric Acid, add 2 drops of sulfuric acid, evaporate to dryness, and ignite: the mass of the residue is not more than 1.0 mg.

**Assay** Measure exactly 10 mL of Dilute Hydrochloric Acid, and dilute with 20 mL of water. Titrate with 1 mol/L sodium hydroxide VS (indicator: 2 to 3 drops of methyl red TS).

Each mL of 1 mol/L sodium hydroxide VS
= 36.461 mg of HCl

**Containers and storage** Containers—Tight containers.

# Hydrochlorothiazide

ヒドロクロロチアジド