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 μm. 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 μg 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.