# Verapamil Hydrochloride Injection

ベラパミル塩酸塩注射液

Verapamil Hydrochloride Injection is an aqueous injection.

It contains not less than 93.0% and not more than 107.0% of the labeled amount of verapamil hydrochloride ($C_{27}H_{38}N_2O_4$.HCl: 491.06).

**Method of preparation** Prepare as directed under Injections, with Verapamil Hydrochloride.

**Description** Verapamil Hydrochloride Injection is a clear, colorless liquid.

**Identification** To 1 mL of the sample solution obtained in the Assay, add 0.02 mol/L hydrochloric acid TS to make 50 mL, and determine the absorption spectrum of this solution as directed under Ultraviolet-visible Spectrophotometry *<2.24>*: it exhibits maxima between 227 nm and 231 nm, and between 276 nm and 280 nm.

**pH** Being specified separately when the drug is granted approval based on the Law.

**Bacterial endotoxins** *<4.01>* Less than 12 EU/mg.

**Extractable volume** *<6.05>* It meets the requirement.

**Foreign insoluble matter** *<6.06>* Perform the test according to Method 1: it meets the requirement.

**Insoluble particulate matter** *<6.07>* It meets the requirement.

**Sterility** *<4.06>* Perform the test according to the Membrane filtration method: it meets the requirement.

**Assay** Pipet a volume of Verapamil Hydrochloride Injection, equivalent to about 10 mg of verapamil hydrochloride ($C_{27}H_{38}N_2O_4$.HCl), add 0.02 mol/L hydrochloric acid TS to make exactly 10 mL, and use this solution as the sample solution. Separately, weigh accurately about 50 mg of verapamil hydrochloride for assay, previously dried at 105℃ for 2 hours, dissolve in 0.02 mol/L hydrochloric acid TS to make exactly 50 mL, and use this solution as the standard solution. Perform the test with exactly 10 $\mu$L each of the sample solution and standard solution as directed under Liquid Chromatography *<2.01>* according to the following conditions, and determine the peak areas, $A_T$ and $A_S$, of verapamil in each solution.

Amount (mg) of verapamil hydrochloride ($C_{27}H_{38}N_2O_4$.HCl)
$= M_S \times A_T / A_S \times 1/5$

$M_S$: Amount (mg) of verapamil hydrochloride for assay taken

*Operating conditions*—

Detector: An ultraviolet absorption photometer (wavelength: 279 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 $\mu$m in particle diameter).

Column temperature: A constant temperature of about 40℃.

Mobile phase: A mixture of methanol, water and perchloric acid (550:450:1).

Flow rate: Adjust so that the retention time of verapamil is about 5 minutes.

*System Suitability*—

System performance: When the procedure is run with 10 $\mu$L of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of verapamil are not less than 2000 and not more than 2.0, respectively.

System repeatability: When the test is repeated 6 times with 10 $\mu$L of the standard solution under the above operating conditions, the relative standard deviation of the peak area of verapamil is not more than 1.0%.

**Containers and storage** Containers—Hermetic containers, and colored containers may be used.

Storage—Light-resistant.