

Loss on drying Not more than 1.0% (1 g, in vacuum, silica gel, 18 hours).

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

Assay Weigh accurately about 0.3 g of Norepinephrine, previously dried, dissolve in 50 mL of acetic acid for nonaqueous titration by warming, if necessary, and titrate with 0.1 mol/L perchloric acid VS until the color of the solution changes from blue-purple through blue to blue-green (indicator: 2 drops of crystal violet TS). Perform a blank determination, and make any necessary correction.

$$\begin{aligned} \text{Each mL of 0.1 mol/L perchloric acid VS} \\ = 16.918 \text{ mg of } C_8H_{11}NO_3 \end{aligned}$$

Containers and storage Containers—Tight containers.

Storage—Light-resistant, under nitrogen atmosphere, and in a cold place.

Norepinephrine Injection

Noradrenaline Hydrochloride Injection

Noreprenamine Hydrochloride Injection

ノルエピネフリン注射液

Norepinephrine Injection is an aqueous solution for injection. It contains not less than 90% and not more than 110% of the labeled amount of *dl*-norepinephrine ($C_8H_{11}NO_3$; 169.18).

Method of preparation Dissolve Norepinephrine in 0.01 mol/L hydrochloric acid TS, and prepare as directed under Injections.

Description Norepinephrine Injection is a clear, colorless liquid.

It gradually becomes a pale red color by light and by air.
pH: 2.3 – 5.0

Identification (1) Measure a volume of Norepinephrine Injection, equivalent to 1 mg of Norepinephrine according to the labeled amount, and proceed as directed in the Identification (1) under Norepinephrine.

(2) Transfer a volume of Norepinephrine Injection, equivalent to 1 mg of Norepinephrine according to the labeled amount, to each of two test tubes A and B, and proceed as directed in the Identification (2) under Norepinephrine.

Purity (1) Arterenone—Measure a volume of Norepinephrine Injection, equivalent to 0.010 g of Norepinephrine according to the labeled amount, add water to make exactly 20 mL, and determine the absorbance of this solution at 310 nm: the absorbance is not more than 0.10.

(2) Epinephrine—Measure a volume of Norepinephrine Injection, equivalent to 5 mg of Norepinephrine according to the labeled amount, add 1 mL of diluted acetic acid (100) (1 in 2) and water to make exactly 10 mL, and proceed as directed in the Purity (3) under Norepinephrine.

Assay Pipet a volume of Norepinephrine Injection, equivalent to about 5 mg of *dl*-norepinephrine ($C_8H_{11}NO_3$), add

water to make exactly 25 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.01 g of Norepinephrine Bitartrate Reference Standard, previously dried in a desiccator (in vacuum, silica gel) for 24 hours, dissolve in water to make exactly 25 mL, and use this solution as the standard solution. Pipet 5 mL each of the sample solution and the standard solution, add 0.2 mL each of starch TS, then add iodine TS dropwise with swirling until a persistent blue color is produced. Add 2 mL of iodine TS, and shake. Adjust the pH of the solution to 6.5 with 0.05 mol/L disodium hydrogenphosphate TS, add 10 mL of phosphate buffer solution, pH 6.5, and shake. Immediately after allowing to stand for 3 minutes, add sodium thiosulfate TS dropwise until a red-purple color develops, then add water to make exactly 50 mL. Determine the absorbances, A_T and A_S , of the subsequent solutions of the sample solution and the standard solution at 515 nm within 5 minutes as directed under the Ultraviolet-visible Spectrophotometry.

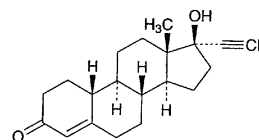
$$\begin{aligned} \text{Amount (mg) of } dl\text{-norepinephrine (} C_8H_{11}NO_3\text{)} \\ = \text{amount (mg) of Norepinephrine Bitartrate} \\ \text{Reference Standard} \\ \times \frac{A_T}{A_S} \times 0.5016 \end{aligned}$$

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

Storage—Light-resistant.

Norethisterone

ノルエチステロン



$C_{20}H_{26}O_2$: 298.42

17-Hydroxy-19-nor-17 α -pregn-4-en-20-yn-3-one [68-22-4]

Norethisterone, when dried, contains not less than 97.0% and not more than 103.0% of $C_{20}H_{26}O_2$.

Description Norethisterone occurs as a white to pale yellowish white, crystalline powder. It is odorless.

It is soluble in chloroform, sparingly soluble in ethanol (95) and in tetrahydrofuran, slightly soluble in diethyl ether, and very slightly soluble in water.

It is affected by light.

Identification (1) To 2 mg of Norethisterone add 2 mL of sulfuric acid: the solution shows a red-brown color and a yellow-green fluorescence. Add 10 mL of water to this solution cautiously: a yellow color develops and a yellow-brown precipitate is formed.

(2) To 0.025 g of Norethisterone add 3.5 mL of a solution of 0.05 g of hydroxylammonium chloride and 0.05 g of anhydrous sodium acetate trihydrate in 25 mL of methanol. Heat under a reflux condenser on a water bath for 5 hours, cool, and add 15 mL of water. Collect the precipitate formed, wash with 1 to 2 mL of water, recrystallize from