

the anhydrous basis, 5 mol/L hydrochloric acid TS, 20 mL, 100 mm).

pH Dissolve 0.20 g of Riboflavin Sodium Phosphate in 20 mL of water: the pH of the solution is between 5.0 and 6.5.

Purity (1) Clarity and color of solution—Dissolve 0.20 g of Riboflavin Sodium Phosphate in 10 mL of water: the solution is clear and yellow to orange-yellow in color.

(2) Lumiflavin—To 0.035 g of Riboflavin Sodium Phosphate add 10 mL of ethanol-free chloroform, and shake for 5 minutes, then filter: the filtrate has no more color than the control solution.

Control solution: To 3.0 mL of $\frac{1}{60}$ mol/L potassium dichromate VS add water to make 1000 mL.

(3) Free phosphoric acid—Weigh accurately about 0.4 g of Riboflavin Sodium Phosphate, dissolve in water to make exactly 100 mL, and use this solution as the sample solution. Measure exactly 5 mL each of the sample solution and Phosphoric Acid Standard Solution, transfer to separate 25-mL volumetric flasks, add 2.5 mL of hexaammonium heptamolybdate-sulfuric acid TS and 1 mL of 1-amino-2-naphthol-4-sulfonic acid TS to each of these flasks, mix, and add water to make 25 mL. Allow to stand for 30 minutes at $20 \pm 1^\circ\text{C}$, and perform the test with these solutions as directed under the Ultraviolet-visible Spectrophotometry, using a solution prepared with 5 mL of water in the same manner as a blank. Determine the absorbances, A_T and A_S , of the subsequent solutions of the sample solution and the standard phosphoric acid solution at 740 nm: the free phosphoric acid content is not more than 1.5%.

$$\begin{aligned} &\text{Content (\% of free phosphoric acid (H}_3\text{PO}_4)) \\ &= \frac{A_T}{A_S} \times \frac{1}{W} \times 257.8 \end{aligned}$$

W: Amount (mg) of Riboflavin Sodium Phosphate calculated on the anhydrous basis.

Water Place 25 mL of a mixture of methanol for Karl Fischer method and ethylene glycol for Karl Fischer method (1:1) in a dry flask for titration, and titrate with water determination TS to the end point. Weigh accurately about 0.1 g of Riboflavin Sodium Phosphate, place quickly into the flask, add a known excess volume of Karl Fischer TS, mix for 10 minutes, and perform the test: the water content is not more than 10.0%.

Assay Conduct this procedure without exposure to daylight, using light-resistant vessels. To about 0.1 g of Riboflavin Sodium Phosphate, accurately weighed, dissolve in diluted acetic acid (100) (1 in 500) to make exactly 1000 mL, then pipet 10 mL of this solution, and add diluted acetic acid (100) (1 in 500) to make exactly 50 mL. Use this solution as the sample solution. Separately, dry Riboflavin Reference Standard at 105°C for 2 hours, weigh accurately about 0.015 g, dissolve in 800 mL of diluted acetic acid (100) (1 in 400) by warming, cool, add water to make exactly 1000 mL, and use this solution as the standard solution. Perform the test with the sample solution and the standard solution as directed under the Ultraviolet-visible Spectrophotometry, using water as the blank, and determine the absorbances, A_T and A_S , at 445 nm. Add 0.02 g of sodium hydrosulfite to 5 mL of each solution, shake until decolorized, and immediately measure the absorbances, A_T' and A_S' , of the solutions.

$$\begin{aligned} &\text{Amount (mg) of C}_{17}\text{H}_{20}\text{N}_4\text{NaO}_9\text{P} \\ &= \text{amount (mg) of Riboflavin Reference Standard} \\ &\quad \times \frac{A_T - A_T'}{A_S - A_S'} \times 1.2709 \times 5 \end{aligned}$$

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

Riboflavin Sodium Phosphate Injection

Riboflavin Phosphate Injection Vitamin B₂ Phosphate Ester Injection

リン酸リボフラビンナトリウム注射液

Riboflavin Sodium Phosphate Injection is an aqueous solution for injection. It contains not less than 95% and not more than 120% of the labeled amount of riboflavin ($\text{C}_{17}\text{H}_{20}\text{N}_4\text{O}_6$; 376.36).

The concentration of Riboflavin Sodium Phosphate Injection should be stated as the amount of riboflavin ($\text{C}_{17}\text{H}_{20}\text{N}_4\text{O}_6$).

Method of preparation Prepare as directed under Injections, with Riboflavin Sodium Phosphate.

Description Riboflavin Sodium Phosphate Injection is a clear, yellow to orange-yellow liquid.

pH: 5.0 – 7.0

Identification (1) To a measured volume of Riboflavin Sodium Phosphate Injection, equivalent to 1 mg of Riboflavin according to the labeled amount, add water to make 100 mL, and proceed with this solution as directed in the Identification (1) and (2) under Riboflavin Sodium Phosphate.

(2) To a measured volume of Riboflavin Sodium Phosphate Injection, equivalent to 0.05 g of Riboflavin according to the labeled amount, and evaporate on a water bath to dryness. Proceed with this residue as directed in the Identification (4) under Riboflavin Sodium Phosphate.

Assay Conduct this procedure without exposure to daylight, using light-resistant vessels. To an accurately measured volume of Riboflavin Sodium Phosphate Injection, equivalent to about 0.015 g of riboflavin ($\text{C}_{17}\text{H}_{20}\text{N}_4\text{O}_6$), add diluted acetic acid (100) (1 in 500) to make exactly 1000 mL, and use this solution as the sample solution. Proceed as directed in the Assay under Riboflavin Sodium Phosphate.

$$\begin{aligned} &\text{Amount (mg) of Riboflavin (C}_{17}\text{H}_{20}\text{N}_4\text{O}_6) \\ &= \text{amount (mg) of Riboflavin Reference Standard} \\ &\quad \times \frac{A_T - A_T'}{A_S - A_S'} \end{aligned}$$

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