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Hydroxocobalamin Injection

» Hydroxocobalamin Injection is a sterile solution of Hydroxocobalamin in Water for Injection. It contains not less than 95.0 percent and not more than 115.0 percent of the labeled amount of hydroxocobalamin ($C_{62}H_{89}CoN_{13}O_{15}P$).

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass, protected from light.

USP Reference standards ⟨11⟩—
USP Cyanocobalamin (Crystalline) RS

Identification—Dilute 3.0 mL of Injection with pH 4.0 buffer (prepared by dissolving 2.61 g of sodium acetate and 20.5 g of sodium chloride in 5.25 mL of glacial acetic acid and sufficient water to make 1500 mL of solution) to 100 mL: the UV-visible absorption spectrum of this solution exhibits maxima at 352 ± 2 nm and 525 ± 2 nm. The ratio A_{352}/A_{525} is between 2.7 and 3.3.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.4 USP Endotoxin Unit per µg of hydroxocobalamin.

pH ⟨791⟩: between 3.5 and 5.0.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

Assay—

pH 9.3 Buffer—Dissolve 23.8 g of sodium borate and 402 mg of boric acid in sufficient water to make 1500 mL of solution, and mix.

Standard preparation—Dissolve a suitable quantity of USP Cyanocobalamin (Crystalline) RS, accurately weighed, in *pH 9.3 Buffer* and dilute quantitatively, and stepwise if necessary, to obtain a solution having a known concentration of about 30 µg per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 5 mg of hydroxocobalamin, to a 50-mL volumetric flask containing about 25 mL of *pH 9.3 Buffer*. Add 5.0 mL of potassium cyanide solution (1 in 10,000), allow to stand at room temperature for 30 minutes, dilute with *pH 9.3 Buffer* to volume, and mix. Transfer 15.0 mL of this solution to a second 50-mL volumetric flask, dilute with *pH 9.3 Buffer* to volume, and mix.

Procedure—Concomitantly determine the absorbances of the solutions in 1-cm cells at the wavelength of maximum absorbance at about 361 nm, with a suitable spectrophotometer, using *pH 9.3 Buffer* as the blank. Calculate the quantity, in mg, of hydroxocobalamin ($C_{62}H_{89}CoN_{13}O_{15}P$) in each mL of the Injection taken by the formula:

$$(1346.36/1355.37)(0.1667C/V)(A_U/A_S)$$

in which 1346.36 and 1355.37 are the molecular weights of hydroxocobalamin and cyanocobalamin, respectively; C is the concentration, in µg per mL, of USP Cyanocobalamin (Crystalline) RS in the *Standard preparation*; V is the volume, in mL, of Injection taken; and A_U and A_S are the absorbances of the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
HYDROXOCOBALAMIN INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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