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Cyanocobalamin Injection

» Cyanocobalamin Injection is a sterile solution of Cyanocobalamin in Water for Injection, or in Water for Injection rendered isotonic by the addition of Sodium Chloride. It contains not less than 95.0 percent and not more than 115.0 percent of the labeled amount of anhydrous cyanocobalamin ($C_{63}H_{88}CoN_{14}O_{14}P$).

Packaging and storage—Preserve in light-resistant, single-dose or multiple-dose containers, preferably of Type I glass, and store at controlled room temperature.

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

Identification—The absorption spectrum, in the range of 300 nm to 550 nm, of the solution employed for measurement of absorbance in the *Assay* exhibits maxima at the same wavelengths as that of a similar solution of USP Cyanocobalamin (Crystalline) RS, concomitantly measured, and the ratio A_{361}/A_{550} is between 3.15 and 3.40.

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

pH ⟨791⟩**:** between 4.5 and 7.0.

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

Assay—Dilute, if necessary, an accurately measured volume of Injection, equivalent to not less than 300 µg of cyanocobalamin, quantitatively and stepwise with water to a concentration of about 30 µg per mL. Dissolve an accurately weighed quantity of USP Cyanocobalamin (Crystalline) RS in water, and dilute quantitatively and stepwise with water to obtain a Standard solution having a known concentration of about 30 µg per mL. Concomitantly determine the absorbances of both solutions in 1-cm cells at the wavelength of maximum absorbance at about 361 nm, with a suitable spectrophotometer, using water as the blank. Calculate the quantity, in µg, of $C_{63}H_{88}CoN_{14}O_{14}P$ in each mL of the Injection taken by the formula:

$$10(C/V)(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Cyanocobalamin (Crystalline) RS in the Standard solution; V is the volume, in mL, of Injection taken; and A_U and A_S are the absorbances of the solution from the Injection and the Standard solution, respectively.

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

Topic/Question	Contact	Expert Committee
CYANOCOBALAMIN INJECTION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

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