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Cyanocobalamin Tablets

DEFINITION
Cyanocobalamin Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of cyanocobalamin ($C_{63}H_{88}CoN_{14}O_{14}P$).

IDENTIFICATION
• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay,Procedure 1* or *Procedure 2*.

ASSAY
[NOTE—Where more than one assay procedure is given in the monograph, the requirements may be met by following any one of the specified procedures. The procedure used is stated in the labeling only if *Procedure 1* is not used.]

• **PROCEDURE 1**
[NOTE—Use low-actinic glassware throughout this procedure.]

Mobile phase: Methanol and water (7:13)

Standard solution: 5 µg/mL of cyanocobalamin from USP Cyanocobalamin (Crystalline) RS in water

Sample solution: Finely powder NLT 30 Tablets. Transfer a portion of the powder, equivalent to 500 µg of cyanocobalamin, to a 100-mL volumetric flask, add 60 mL of water, and sonicate for 5 min. Dilute with water to volume, and filter.

Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: 361 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 0.5 mL/min

Injection volume: 100 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cyanocobalamin ($C_{63}H_{88}CoN_{14}O_{14}P$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of cyanocobalamin from USP Cyanocobalamin (Crystalline) RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of cyanocobalamin in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

• **PROCEDURE 2**
[NOTE—Use low-actinic glassware throughout this procedure. Inject samples within 30 min.]

Buffer: Dissolve 470.5 mg of low UV hexanesulfonic acid sodium salt in water, add 1 mL of phosphoric acid, dilute with water to 1000 mL, and mix. Adjust with 50% potassium hydroxide to a pH of 3.5.

Mobile phase: Acetonitrile and *Buffer*. See *Table 1* for gradient.

Table 1

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Time (min)	Acetonitrile (%)	Buffer (%)
0	1.0	99.0
0.5	1.0	99.0
1.2	2.3	97.7
1.4	5.0	95.0
2.5	7.0	93.0
5.0	18.0	82.0
5.5	25.0	75.0
6.5	25.0	75.0
7.0	1.0	99.0
8.0	1.0	99.0

Standard solution: 1 µg/mL of cyanocobalamin from USP Cyanocobalamin (Crystalline) RS in water

Sample solution: Finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 25 µg of cyanocobalamin, to a suitable Erlenmeyer flask with a stopper, pipet 25 mL of water, sonicate for 5 min, and shake vigorously for 2 min. Pass through a membrane filter of 0.45-µm pore size.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: UPLC

Detector: UV 361 nm

Column: 2.1-mm × 10-cm; 1.7-µm packing L1

Column temperature: 35°

Flow rate: 0.5 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cyanocobalamin ($C_{63}H_{88}CoN_{14}O_{14}P$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of cyanocobalamin from USP Cyanocobalamin (Crystalline) RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of cyanocobalamin in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- **Disintegration ⟨701⟩**

Medium: Water

Time: 30 min. If the label recommends to disintegrate the Tablets in the mouth before swallowing: NMT 3 min

Acceptance criteria: Meet the requirements

- **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers.

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• **Labeling:** Tablets that are intended to be disintegrated in the mouth before swallowing are so labeled. The labeling states with which assay procedure the product complies only if *Procedure 1* is not used.

• **USP Reference Standards** ⟨11⟩
USP Cyanocobalamin (Crystalline) RS

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

Topic/Question	Contact	Expert Committee
CYANOCOBALAMIN TABLETS	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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