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Methylcobalamin Tablets

DEFINITION

Methylcobalamin Tablets contain NLT 90.0% and NMT 125.0% of the labeled amount of methylcobalamin ($C_{63}H_{91}CoN_{13}O_{14}P$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in *Strength*.

STRENGTH

• PROCEDURE

Buffer solution: 3.1 g/L of sodium dihydrogen phosphate dihydrate in water. Adjust with phosphoric acid (1 in 100) to a pH of 3.5.

Mobile phase: Transfer 200 mL of acetonitrile to a 1-L volumetric flask and dilute with *Buffer solution* to volume. Then add 3.76 g of sodium 1-hexane sulfonate, and mix to dissolve.

[NOTE—Use low-actinic glassware, and keep the following solutions from exposure to light.]

System suitability solution: 0.05 mg/mL of cyanocobalamin from [USP Cyanocobalamin \(Crystalline\) RS](#) and 0.05 mg/mL of [USP Hydroxocobalamin Acetate RS](#) in *Mobile phase*

Standard solution: 100 µg/mL of [USP Methylcobalamin RS](#) in *Mobile phase*

Sample solution: Finely powder NLT 30 Tablets. Transfer a portion of the powder, nominally equivalent to 5 mg of methylcobalamin, to a 50-mL volumetric flask, add a suitable amount of *Mobile phase*, swirl gently, and dilute with *Mobile phase* to volume. Shake vigorously for 10 min and immediately pass through a nylon membrane filter of 0.2-µm pore size.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 266 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 0.6 mL/min

Injection volume: 50 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for cyanocobalamin and hydroxocobalamin are 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3 between the cyanocobalamin and hydroxocobalamin peaks, *System suitability solution*

Column efficiency: NLT 6000 theoretical plates, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of methylcobalamin ($C_{63}H_{91}CoN_{13}O_{14}P$) 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 [USP Methylcobalamin RS](#) in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–125.0%

PERFORMANCE TESTS

- [DISINTEGRATION AND DISSOLUTION \(2040\), Disintegration](#): Meet the requirements
- [WEIGHT VARIATION \(2091\)](#): Meet the requirements

CONTAMINANTS

- **MICROBIAL ENUMERATION TESTS (2021)**: The total aerobic microbial count does not exceed 3×10^3 cfu/g, and the total combined molds and yeasts count does not exceed 3×10^2 cfu/g.
- **ABSENCE OF SPECIFIED MICROORGANISMS (2022), Test Procedures, Test for Absence of Escherichia coli**: Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE**: Preserve in tight, light-resistant containers.
- **USP REFERENCE STANDARDS (11)**
 - [USP Cyanocobalamin \(Crystalline\) RS](#)
 - [USP Hydroxocobalamin Acetate RS](#)
 - [USP Methylcobalamin RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
METHYLCOBALAMIN TABLETS	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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