Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section

Analytical Profile of Mecobalamin Dispersible Tablets

Analytical Profile No.: Mecoba 081/82/AP 174

Mecobalamin Dispersible Tablets contain not less than 90.0% and not more than 125.0% of the stated amount of Mecobalamin.

Usual Strength: 1500 mcg

1. Identification:

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

2. Assay: *Determine by liquid chromatography*
(**Note:** Use low-actinic glassware, and keep the following solutions from exposure to light.)

2.1 Test solution: Finely powder NLT 30 tablets. Transfer a portion of the powder, nominally equivalent to 5 mg of Mecobalamin, 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 minutes and immediately pass through a nylon membrane filter of 0.2micron pore size.

2.2 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.

2.3 Reference solution: Weigh accurately about 25.0 mg of Mecobalamin RS and dissolve in mobile phase to make exactly 50 ml and mix with the aid of ultrasound until completely dispersed. Dilute 5.0 ml of this solution to 25 ml with mobile phase.

2.4 Chromatographic system:

Column: C18 (4.6mm X 250mm, 5µm)
Flow rate: 0.6 ml/min
Wavelength: 266 nm
Injection volume: 50 µl
Column Temperature: 40ºC

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.

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.

2.5 System suitability requirement: Inject system suitability solution & standard solution.

(Note: The relative retention time for Cyanocobalamin & Hydroxocobalamin are 0.8 & 1.0 respectively.)

Resolution: NLT 3 between Cyanocobalamin & Hydroxocobalamin peaks in system suitability solution.

Column efficiency: NLT 6000 theoretical plates in standard solution.

RSD: NMT 2.0% in standard solution.

2.6 Procedure: Inject the reference solution five times and test the solutions. Measure the peak responses.

Calculate the content of Mecobalamin.

3. Other tests: As per Pharmacopoeial requirements.