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Technical Datasheet

Cyanocobalamin

Meets USP-NF, EP, BP, JP and IP testing specifications

Product Code: TC183M

Product Description :

Molecular weight: 1355.37
Molecular formula: $C_{63}H_{88}CoN_{14}O_{14}P$
CAS No.: 68-19-9
Synonym : Vitamin B_{12}

Quality Control:

Appearance (USP)
Dark red crystals or amorphous or crystalline red powder, very hygroscopic
Appearance (EP, BP)
Dark red crystalline powder or dark red crystals, very hygroscopic
Appearance (IP)
Dark red crystalline powder, very hygroscopic
Appearance (JP)
Dark red crystals or powder, hygroscopic
Solubility (USP)
Soluble in alcohol; sparingly soluble in water; insoluble in acetone, in chloroform, and in ether
Solubility (EP, BP)
Sparingly soluble in water and in ethanol (96%), practically insoluble in acetone.
Solubility (JP)
It is sparingly soluble in water, and slightly soluble in ethanol (99.5%)
Solubility (IP)
Sparingly soluble in water and in ethanol (95%); practically insoluble in chloroform, in acetone and in ether
Identification A : Absorption ratio 1 : UV (USP, EP, BP, IP)
1.70 - 1.90 (Ratio of A361/A278)
Identification A : Absorption ratio 2 : UV (USP)
3.15 - 3.40 (Ratio of A361/A550)
Identification A, Absorption ratio 2 : UV (EP, BP, IP)
3.15 - 3.45 (Ratio of A361/A547-559)
Identification 1 : UV (JP)
Both spectra exhibit similar intensities of absorption at the same wavelengths
Identification B (USP)
A red or orange-red colour appears immediately after addition of nitroso R salt. The red colour persist after boiling with the addition of hydrochloride acid
Identification B, HPLC (EP, BP)
The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (c)
Identification B, TLC (IP)
The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution
Identification 2 (JP)
The red colour does not disappear
Identification C (IP)
A blue colour is formed and is taken into the benzyl alcohol layer
Identification C, HPLC (USP)
The retention time of the major peak of the sample solution corresponds to that of the standard solution
Identification 3 (JP)
A blue to blue-green colour develops

Clarity and colour of solution (JP)
20mg in 10 mL of water is clear and red in colour
pH (0.5% in water) (JP)
4.2 - 7.0
Related compounds : System suitability : Resolution : HPLC (USP)
>= 2.5 between cyanocobalmin and 7b, 8b-lactocyanocobalmin, system suitability solution
Related compounds : 7b, 8b-Lactocyanocobalmin : HPLC (USP)
<= 1.0%
Related compounds : 50-Carboxycyanocobalamin : HPLC (USP)
<= 0.5%
Related compounds : 32-Carboxycyanocobalamin : HPLC (USP)
<= 2.0%
Related compounds : 34-Methylcyanocobalmin : HPLC (USP)
<= 1.0%
Related compounds : 8-epi-Cyanocobalamin : HPLC (USP)
<= 1.0%
Related compounds : any other unidentified impurity : HPLC (USP)
<= 0.5%
Related compounds : Total impurity : HPLC (USP)
<= 3.0%
Related substances: impurity C : HPLC (EP, BP)
<= 1.5%
Related substances: impurity A : HPLC (EP, BP)
<= 0.7%
Related substances: impurity B, D, E, F: for each impurity: HPLC (EP, BP)
<= 0.5%
Related substances: unspecified impurities: for each impurity: HPLC (EP, BP)
<= 0.2%
Related substances: Total impurity : HPLC (EP, BP)
<= 3.0%
Related substances: HPLC (JP)
The total area of the peak other than cyanocobalamin obtained from the sample solution is not larger than the peak area of cyanocobalamin from the standard solution
Related substances: HPLC (IP)
The sum of the areas of all the secondary peaks is not more than the area of the principal peak in the chromatogram obtained with reference solution (a). Ignore any peak with an area less than that of the principal peak in the chromatogram obtained with reference solution (b).
Loss on drying (at 105°C, 2 hr) (USP)
<= 12.0% (at pressure <= 5 mm of mercury)
Loss on drying (at 105°C, 2 hr) (EP, BP)
<= 12.0% (0.4g by drying in vacuo)
Loss on drying (at 105°C, 2 hr) (IP)
<= 12.0% (at pressure of 1.5 - 2.5 kpa)
Loss on drying (at 100°C, 4 hr) (JP)
<= 12% (at pressure not exceeding 0.67 kPa, phosphrous (V) oxide)
Assay (UV, on dried basis) (USP, EP, BP, JP, IP)
96.0 - 102.0%

Storage and Shelf Life:

Store at 2 - 8°C away from bright light.
Shelf life is 36 months.
Use before expiry date given on the product label.

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