



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Vitamin B12 (Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	A8454		Prepared by	Sr. Tech Lead
CAS NO.	68-19-9		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A8454/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies Ph. Eur.</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	Colorless or white crystals. The pH of its solutions is about 5.5. On exposure to light in the presence of organic matter, it becomes gray or grayish black.	Dark red, crystalline powder or dark red crystals. It is hygroscopic	Dark red, crystals or powder. It is hygroscopic
2	Solubility	Not mentioned	Very soluble in water and even more so in boiling water; freely soluble in boiling alcohol; sparingly soluble in alcohol; slightly soluble in ether.	Sparingly soluble in water and in ethanol (96 per cent), practically insoluble in acetone.	It is sparingly soluble in water, and slightly soluble in ethanol (99.5)
3	Identification 1	UV absorption spectrum of sample shows maxima at 278	UV absorption spectrum of sample shows maxima at 278+/-1 nm, 361+/-1 nm and between 550 +/- 1 nm. The ratio of absorbance at 361 nm to 550 nm should be between 3.15 and 3.45, at 361 nm to 278 nm should be 1.7 and 1.9	UV absorption spectrum of sample shows maxima at 278 nm, 361 nm and between 547 and 559 nm. The ratio of absorbance at 361 nm to 547 and 559 nm should be between 3.15 and 3.45, at 361 nm to 278 nm should be 1.7 and 1.9	Infraed absorption spectrum obtained with sample should be concordant with spectrum obtained with Cyanocobalamine reference/working standard
4	Identification 2	Passes The Test	In RS test, the retention time of the major peak of the Sample solution corresponds to that of the Standard solution.	In RS test, 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).	Red color should not disappear
5	Identification 3	Passes The Test	A red or orange-red color should appear immediately after the addition of nitroso salt. The red color persists after boiling with the addition of HCl.	Not mentioned	A blue to green blue color should develop
6	pH	Not mentioned	Not mentioned	Not mentioned	Between 4.2 and 7.0
7	Related substances	Passes The Test	7β,8β-Lactocyanocobalamin: NMT 1.0% 50-Carboxycyanocobalamin: NMT 0.5% 34-Methylcyanocobalamin: NMT 2.0% 32-Carboxycyanocobalamin: NMT 1.0% 8-epi-Cyanocobalamin: NMT 1.0% Maximum unknown impurity: NMT 0.5% Total impurities: 3.0%	Impurity C: NMT 1.5% Impurity A: NMT 0.7% Impurity B,D,E,F (Each): NMT 0.5% Maximum unknown impurity: NMT 0.2% Total impurities: 3.0%	Total impurities: NMT 3.0%
8	Loss on drying	NMT 12.0%	NMT 12.0%	NMT 12.0%	NMT 12.0%
9	Assay (dried basis)	Between 96.0% and 102.0%	Between 96.0% and 102.0%	Between 96.0% and 102.0%	Between 96.0% and 102.0%
	Storage	Storage at 2-8°C, protected from light	Preserve in tight, light-resistant containers, and store at controlled room temperature.	In an airtight container, protected from light.	Containers—Tight containers.Light-resistant

Note - If you need any additional testing, you may use our Additional Testing Feature on the product page or contact your Clyzo representative.

Disclaimer - The information above is solely for your consideration. We do not recommend or affirm the suitability for any specific end use. We suggest the users should research & verify the specifications in accordance with their intended usage.