

Pu 2659

Vitamin B12 Methylcobalamin Pure Powder 98% HPLC				
Product Code :			1704240	
Certificate of Analysis				
Version SDS	Date	Conclusion	Written by	Sign
001	2020-10-20	Conform	A.CONVERT Quality assistant	
			Validated by	Sign
			A.GILLET Quality assurance	
Manufacturing				
Product name	Methylcobalamin			
Chemical name	Mecobalamin			
Cas Number	13422-55-4			
E-number	-			
Additives / Carrier	None			
Compliance	JPXV			
Batch number	O-1704240-200902	Manufacture Date	2020-09	
		Best Before Date	2023-09	
Properties	Specifications		Results **	
Organoleptic				
Appearance	Dark red crystals or crystalline powder		Complies	
Physical and Chemical				
Identification	UV: conforms to standard		Complies	
	Chemistry: positive		Complies	
Solubility	Clear and red color		Complies	
Related substance	≤ 2.0% by HPLC		1.8%	
Individual impurity	≤ 0.5% by HPLC		Complies	
Water	≤ 12% by K.F		7.3%	
Assay				
Assay (on dry basis)	≥ 98.0% by HPLC		99.5%	
Microbiological				
Total plate count	≤ 10 000 CFU/g		< 10 cfu/g	
Yeast & mould	≤ 100 CFU/g		< 10 cfu/g	
Others	Endotoxin		< 200 EU/mg	
	Total enterobacteriaceae		< 10 cfu/g	
Contaminants*				
Heavy metals	≤ 10 ppm		Complies	
Arsenic	≤ 2 ppm		< 1 ppm	
Lead	≤ 3 ppm		Complies	
Cadmium	≤ 1 ppm		Complies	
Mercury	≤ 0.10 ppm		Complies	
Others	Residual solvent		Acetone = 0.02% Ethanol = 0.02%	
Shelf Life	3 years			
Allergens	Absence			
Ionization	Certified in compliance with Regulation 1999/2/CE & 1999/3/EC.			
TSE/BSE	Certified in compliance with Regulation 999/2001/EC			
Nanomaterials	Certified in compliance with Decree 2012/232 & Decree dated August 6th, 2012			
GMO	Certified in compliance with Regulation 1829/2003/EC & 1830/2003/EC			

*According to a control plan

Remarks: To be stored in original tightly closed package away from moisture and sunlight

Abbreviations: * ND: not determined / NA: not applicable