CERTIFICATE OF ANALYSIS

Manufactured for	**Mackisen**				
Name of product:	**Vitamin B12**			**NPN**	**80085882**
Packaging Lot # :	**M2500829/1**	**Master Packaging Record #**		**Expiry Date :**	**11/2028**
		MPR	**MA-N882-90-V0**		
Manufacturing Lot # :	**M2500829**	**Master Manufacturing Record #:**		**MFG Date:**	**12/2025**
		MMR	**MA-N882-V0**		
Storage Conditions:	Store at room temperature (R.T), in closed dry containers and Keep away from high temperature & moisture.				
Physical Description:	Light to very light pinkish Color Powder In Empty Clear Veg Capsules Size"2"	90 count in Bottle-200 cc-38/400 white HDPE Round ,Cap-38-400 White HIS P/P, ribbed, plain liner.			

Physical Tests:

TESTES	Results	Specifications Low	Target	High	Strength	Method
Average Wt. of Capsules	297 mg	274	304	334	mg	USP <2091>
Wt. variation of Capsules	Conforms	Conforms as per USP weight variation +/- 10 %				USP <2091>
Disintegration	4 mins	NMT 30			min	USP <2040>
IDENTITY	Conforms	Conforms to standard				FTIR

Quantity / Potency :	**Results**		**Low**	**Target**	**High**	**Strength**	**Method**
Methylocobalamin (Vitamin B12)	500.79	mcg	450.000	500.000	750.000	mcg	USP Monograph (HPLC)
NON-MEDICINAL INGREDIENTS	Microcystalline Cellulose 101, Empty Clear vegetable capsule size "2"						

PURITY:

MICRO:	**Results**	**Limits**	**Method**
Total Plate Count	80 CFU/g	< 3000 c.f.u / g	USP<2021>/AOAC
Total Yeast	<10 CFU/g	< 300 c.f.u / g	USP<2021>/AOAC
Total Mold	10 CFU/g	< 300 c.f.u / g	USP<2021>/AOAC
E.Coli	Not Detected	Not Detected	USP<2022>/AOAC
Salmonella Spp	Not detected	Not Detected	USP<2022>/AOAC
Staphylococcus Aureus	Not Detected	Not Detected	USP<2022>/AOAC
HEAVY METALS:	**Results**	**Limits - 1 capsule / day**	**Method**
Arsenic	<0.0001 mcg / kg b.w./day	< 0.14 mcg / kg b.w./day	ICP-MS
Cadmium	<0.0001 mcg / kg b.w./day	< 0.09 mcg / kg b.w./day	ICP-MS
Lead	0.0002 mcg / kg b.w./day	< 0.14 mcg / kg b.w./day	ICP-MS
Total Mercury	<0.0001 mcg / kg b.w./day	< 0.29 mcg / kg b.w./day	ICP-MS

Prepared by: Jan 19 2026 **Approved by:** Jan 19 2026

Quality Assurance

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CERTIFICATE OF ANALYSIS

PRODUCT NAME: Biogenique B12

Batch/Lot No: 012513

Man Date: Jan.2025 **Expiry Date**: Dec.2026

Each unit dose contains: Vitamin B12 (Methylcobalamin): 500.00mcg.

Non-Medicinal Ingredient: Micro Crystalline Cellulose, Hypromellose.

Test	Method	Specifications	Result
Description	In-House	Clear-Clear size "0" vegetable Capsule filled with Light pink to white color fine Powder.	Complies
Weight variation	USP <2091>	505.00 mg± 7.5% (467.13mg to 542.88mg)	507.41 mg
Lock Length	In house	21.30 mm –21.90mm	Complies
Disintegration time	USP	NMT 30 minutes	06 minutes
Microbial Test			
Total Plate count	USP<2021>	NMT 100,000 CFU/g	<10CFU/g
Yeast & Mold	USP<2021>	NMT 1000 CFU/g	<10CFU/g
E.coli	USP<2022>	Negative	Negative
Salmonella	USP<2022>	Negative	Negative
S.aureus	USP<2022>	Negative	Negative
Pseudomonas aeruginosa	USP<62>	Negative	Negative

Heavy Metal			
Arsenic	ICP-MS at Finished Product Stage	<0.14 µg/kg b.w./ day	<0.001 µg/kg b.w./day
Cadmium		<0.09 µg/kg b.w./ day	<0.001 µg/kg b.w./day
Lead		<0.14 µg/kg b.w./ day	<0.001 µg/kg b.w./day
Mercury		<0.29 µg/kg b.w./ day	<0.001 µg/kg b.w./day
Quality Approved: Foram Patel		**Date:** Feb.05, 2025	
This is to certify that Biowell Laboratories products are manufactured under strict GMP conditions.			