

QUALITY CONTROL DEPARTMENT
Certificate of Analysis of Finished Product

(Under Drug And Cosmetic Act. 1940 & The Rules There Under)

Report No: TT/FG/197/25-26
Report Date: 12-08-2025

Name of the product	: HOLYBION Injection 2ml
Generic Name	: Vitamin B-Complex with Vitamin B12 Injection
Batch No.	: VM505
Batch Size	: 95000
Mfg. Date.	: JULY -2025
Exp. Date.	: JUNE-2027
Quantity of Sample	: 100 Nos
Date of Sampling	: 16-07-2025
Date of Commencement of analysis	: 16-07-2025
Date of Completion of analysis	: 31-07-2025

TEST NAME	SPECIFICATION	OBSERVATION
Description	A Yellow colour solution	A Yellow colour Solution
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.	Complies to IP specification
Extractable Volume	NLT- 2.0ml /Ampoule	2.1 ml
Particulate matter	No visible particles	Complies
Sterility Test	To comply as per IP	Complies
Assay Each ml contains :	(NLT 90 %)	
Thiamine Hydrochloride I.P 10 mg	(NLT 9.0mg)	11.53mg(115.30%)
Pyridoxine Hydrochloride I.P 4mg	(NLT 3.60 mg)	4.18mg(104.50%)
Riboflavin Sodium Phosphate I.P 4mg	(NLT 3.60 mg)	3.90mg(97.50%)
Nicotinamide I.P 40mg	(NLT 36.0 mg)	39.59mg(98.975%)
D-Panthenol I.P 6mg	(NLT 5.40mg)	6.1000mg(101.67%)
Cyanocobalamin I.P 8mcg	(NLT 7.2mcg)	8.7564Mcg(109.45%)

OBSERVATION: In the opinion of the undersigned the sample referred to above is of **Standard Quality** / ~~Not Standard Quality~~ as in the act and the rules made there under for the reason given below.

REMARKS : **COMPLIES AS PER LABEL CLAIM / IHS WITH RESPECT TO THE ABOVE TESTS ONLY CARRIED OUT.**

Analysed By: 
Date: 12/08/25

Checked By: 
Date: 12/08/2025

Person In-Charge of Testing
Date: 12/8/2025