

Tamman Titoe Pharma Pvt Ltd 56-57, Sidco Pharmaceutical Complex, Alathur-603 110, Tamilnadu.

QUALITY CONTROL DEPARTMENT

Certificate of Analysis of Finished Product

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

Report No: TT/FG/224A/24-25 Report Date: 10-08-2024

Name of the product

:HOLYBION Injection 2ml

Generic Name

:Injection of Vitamin B-Complex with Vitamin B12

Batch No.

: VM408

Batch Size

: 100000

Mfg. Date.

: July-2024

Exp. Date.

: June-2026

Quantity of Sample

:100 Nos

Date of Sampling

Date of Commencement of analysis

:26-07-2024

:26-07-2024

Date of Completion of analysis

:09-08-2024

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	(NLT9.0mg)	12.22mg(122.20%)
Pyridoxine Hydrochloride I.P 4mg	(NLT 3.60 mg)	4.24mg(106%)
Riboflavin Sodium Phosphate I.P 4mg	(NLT 3.60 mg)	4.33mg(108.25%)
Nicotinamide I.P 40mg	(NLT 36.0 mg)	42.29mg(105.72%)
D-Panthenol I.P 6mg	(NLT 5.40mg)	6.37mg(106.16%)
Cyanocobalamin I.P 8mcg	(NLT 7.2mcg)	8.57mcg(107.12%)

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 CARRIEDOUT.

Analysed By: V B

Person In Date:

Alathur