



QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

OCEAN
HEALTHCARE PVT. LTD.

Product Name	TRIBUTAN			Page :1 of 3
Generic Name	Vitamin B1, B6 and B12 Soft gelatin capsules			
Product Code	V00008	Specification No.	SPE/FPV00008/04	
Batch No.	21056	Batch Size	3,00,000 capsules	
AR.No.	2122/QCF/00053	Sampled Qty.	100 capsules	
Mfg. Date	04/2021	Sampled Date	20/05/21	
Exp. Date	03/2023	Date of Release	01/06/21	
Working standard number	For B1 = WS/T01/05; For B6 = WS/P03/05; For B12 = WS/C06/04			

S.No.	Tests	Specification	Observations
1	Description	Orange coloured, oval shaped opaque soft gelatin capsules containing pink coloured oily mass.	Orange coloured, oval shaped opaque soft gelatin capsules containing pink coloured oily mass.
2	Identification test	The principal peak in the chromatogram obtained with the test solution of Assay for Vitamin B1, B6 and B12 corresponds to the principal peak in the chromatogram obtained with the respective standard solution	Complies
3	Average Fill Weight (in mg)	700.0mg $\pm$ 7.5 % (647.5 mg to 752.5 mg)	671.2 mg
4	Uniformity of fill Weight (In %)	Not more than two capsules deviate from the average weight by more than $\pm$ 7.5% and none deviates by more than $\pm$ 15.0%.	-1.4% to 1.8%
5	Disintegration time (in minutes)	Not More Than 30 minutes	12 minutes



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6	Loss on drying of capsule shells (at 105°C for 2 hours)	8.0% to 20.0% w/w		9.6%
7	Uniformity of Dosage Units (Weight Variation) Vitamin B1, Vitamin B6 and Vitamin B12	Acceptance Value ≤ 15		Vitamin B1 = 2.4 Vitamin B6 = 2.1 Vitamin B12 = 3.1
8	Dissolution Vitamin B6 - By HPLC	Not less than 75% of the labelled amount should be dissolved.		Average = 103% Minimum = 96% Maximum = 108%
9	Assay: Each Soft Gelatin Capsule contains:	Label claim	Release Limit	121.1mg (121.1%) 211.3 mg (106.6 %) 310.3mcg (155.2%)
	Thiamine Mononitrate (Vitamin B1) BP	100 mg	90.0 mg to 140.0 mg (90.0% to 140.0%)	
	Pyridoxine Hydrochloride (Vitamin B6) BP	200 mg	180.0 mg to 240.0 mg (90.0% to 120.0%)	
	Cyanocobalamin (Vitamin B12) BP	200 mcg	180.0 mcg to 320.0 mcg (90.0% to 160.0%)	
10	Microbial Limit Test Total Aerobic microbial Count Total Yeast and Mold Count Escherichia coli	Not more than 1000 cfu / g Not more than 100 cfu / g Should be absent / g		35 cfu / g Less than 10 cfu / g Absent / g



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S.No.	Tests	Specification	Observations
	Salmonella	Should be absent / 10 g	Absent / 10g
	Pseudomonas aeruginosa	Should be absent / g	Absent / g
	Staphylococcus aureus	Should be absent / g	Absent / g

Remarks: The sample complies as per In House Specification.

Prepared by: K. Prabakaran	Checked by: M. Sivaraman	Approved by: N. Saravanan
Department: QC	Department: QC	Department: QA
Sign/Date: 20/06/21	Sign/Date: 20/06/21	Sign/Date: 01/06/21