



SNJ
LIFECARE PRIVATE LIMITED
A WHO-GMP CERTIFIED COMPANY

U24110GJ2020PTC111897
www.snjlifecare.com
marketing@snjlifecare.com
+91 99790 33098

CERTIFICATE OF ANALYSIS

Product Name :	Topiramate USP	Mfg. Lic. No.:	G/25/2349
Synonyms :	NA		
Batch No. :	TPM/25006	A.R. No. :	TPM/25/020
Mfg. Date :	MAY-2025	Batch Size :	252.720 Kg
Retest/Exp. Date :	APR-2028	Dispatch Qty. :	200.000Gm(Market Sample)
Release Date :	22/08/2025	Date of Dispatch :	NA
Specification No. :	As per customer requirement	Page No. :	Page 1 of 2
Customer Name :	Mersi Pharma		

Sr. No.	Test	Observations/Results	Specification
1.0	Description	Complies	A white to off White Powder
2.0	Solubility	Complies	Freely soluble in dichloromethane
3.0	Identification By HPLC	Complies	Retention time of major peak of sample solution corresponds to that of the standard solution as obtain in the assay.
4.0	Identification By IR	Complies	IR spectrum of test is concordant with the IR spectrum of the standard obtain in the same manner
5.0	Specific Optical Rotation (4-10 mg/ml in methanol at 20 °C)	-30.87°	Between -28.6° to -35.0°
6.0	Organic impurity		
	Fructose	Not Detected	NMT 0.3 %
	Topiramate Related compound A	Not Detected	NMT 0.3 %
	Any individual unspecified impurity	0.06 %	NMT 0.1 %
	Total Impurity	0.06 %	NMT 0.5 %
7.0	Heavy metal	Complies	NMT 10 ppm
8.0	Residue on ignition	0.06 %	NMT 0.2 %
9.0	Water content	0.12 %	NMT 0.5 %
10.0	Assay	99.03 %	98.0 to 102.0 % (On anhydrous basis)
11.0	Residual Solvents		
	Acetone	1.55 ppm	NMT 5000 ppm

Name	Nancy Sajitani	Himanshi Parsana	Dr. Rakesh Kachhadia
Designation	officer	Jr. Executive	Head
Sign			
Date	22/08/2025	22/08/2025	22/08/2025
	PREPARED BY	CHECKED BY	APPROVED BY

Reg. Office : "Avadh House" 57-Jay Park, Rajnagar Chowk, Nana Mava Main Road, Rajkot-360001 (Gujarat) India
Factory Address : Survey No. 247/1, Rajkot-Morbi Highway, B/H Madhav Hotel, AT: Hadala, Tal. & Dist: Rajkot-363650 (Gujarat) India.

Ok, Free sample
28/8/25
ET



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Specification No.	: As per customer requirement	Page No.	: Page 2 of 2
Customer Name	: Mersi Pharma		

Sr. No.	Test	Observations/Results	Specification
	MDC	4.26 ppm	NMT 600 ppm
	Cyclohexane	Not detected	NMT 3880 ppm
	IPA	33.79 ppm	NMT 5000 ppm
	Pyridine	Not detected	NMT 200 ppm
	THF	1.16 ppm	NMT 720 ppm
	Methanol	407.25 ppm	NMT 3000 ppm
12.0	Limit of Sulfamate and Sulfate		
	Sulfate	Not Detected	NMT 0.1 %
	Sulfamate	Not Detected	NMT 0.1 %
13.0	Particle Size (D90)	12.359 µm	NMT 20 µm
14.0	Bulk Density	0.28 gm/ml	For Information
15.0	Tapped Density	0.49 gm/ml	For Information

Storage condition: Store in a well closed container at dry place.

Remarks: The product complies / ~~does not comply~~ with above mentioned prescribed standards.

Ok, Free Sample
Gutait

Name	Nancy Sgitar	himanshu pancha	Dr. Paritaj Kuchhadia
Designation	Officer	Jr. Executive	Head
Sign			
Date	22/08/2025	22/08/25	22/08/2025
	PREPARED BY	CHECKED BY	APPROVED BY