

## Topiramate USP43

Batch no 241213

Mf date Dec 15 2024

Exp date Dec 14 2027

Batch size 500 kg

Molecular Structure

Molecular Formula

 $C_{12}H_{21}NO_8S$ 339. 36

Molecular Weight

CAS Registry Number 97240-79-4

Feb 20 2025

<u>Tests</u>	<u>Specifications</u>	Results
Appearance	White or almost white powder	Almost white powder
Solubility	Freely soluble in dichloromethane	
Identification	IR, HPLC	Positive
Specific rotation	$-28.6~\sim -35.0^\circ$ , measured at $20^\circ C$	−32. 2°
Related substances	Impurity A $\leq 0$ .	3% 0.06%
(HPLC)	Fructose $\leq 0$ .	3% 0. 01%
	Single unidentified impurity $\leq 0$ .	1% 0. 14%
	Total impurities $\leq 0$ .	5% 0. 26%
Sulfated ash	≤ 0.2%	0. 04%
Sulphamates & sulphates	Sulphamates ≤ 0.1%	Undetected
	Sulphates ≤ 0.1%	0. 002%
Water K.F.	≤ 0.5%	0. 08%
Residual organic	Acetone ≤ 0.5%	ND
solvents (GC)	Ethanol ≤ 0.5%	0. 0836%
2 2	2-Propanol ≤ 0.5%	0. 02%
	Hexane ≤ 0.029%	Undetected
	Tetrahydrofuran ≤ 0.072%	Undetected
	To1uene ≤ 0.089%	Undetected
	Pyridine ≤ 0.02%	Undetected
Assay (HPLC) oab	98.0 $^{\sim}$ 102.0% of $C_{12}H_{21}NO_8$	99. 8%
Packaging and storage	Preserve in tight, light-resistant containers.  Long time storage at 2 ~ 8°C	
Conclusion	Material complies with USP43	x , , ,

