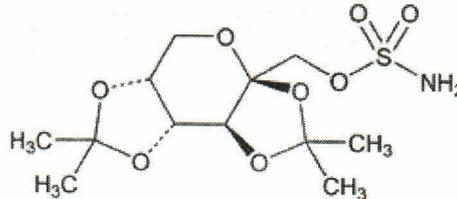


Topiramate USP43

Batch no 250808
 Mf date Aug 10 2025
 Exp date Aug 09 2028
 Batch size 526.5 kg

Molecular Structure



Molecular Formula $C_{12}H_{21}NO_8S$
 Molecular Weight 339.36
 CAS Registry Number 97240-79-4

Oct 28 2025

<u>Tests</u>	<u>Specifications</u>	<u>Results</u>
Appearance	White or almost white powder	Almost white powder
Solubility	Freely soluble in dichloromethane	Conforms
Identification	IR, HPLC	Positive
Specific rotation	$-28.6 \sim -35.0^\circ$, measured at $20^\circ C$	-32.1°
Related substances (HPLC)	Impurity A $\leq 0.3\%$ Fructose $\leq 0.3\%$ Single unidentified impurity $\leq 0.1\%$ Total impurities $\leq 0.5\%$	0.04% ND 0.01% 0.18%
Sulfated ash	$\leq 0.2\%$	0.06%
Sulphamates & sulphates	Sulphamates $\leq 0.1\%$ Sulphates $\leq 0.1\%$	Undetected Undetected
Water K. F.	$\leq 0.5\%$	0.07%
Residual organic solvents (GC)	Acetone $\leq 0.5\%$ Ethanol $\leq 0.5\%$ 2-Propanol $\leq 0.5\%$ Hexane $\leq 0.029\%$ Tetrahydrofuran $\leq 0.072\%$ Toluene $\leq 0.089\%$ Pyridine $\leq 0.02\%$	ND 0.0812% 0.02% Undetected Undetected Undetected Undetected
Assay (HPLC) oab	98.0 ~ 102.0% of $C_{12}H_{21}NO_8$	99.1%
Packaging and storage	Preserve in tight, light-resistant containers. Long time storage at $2 \sim 8^\circ C$	
Conclusion	Material complies with USP43	