

Topiramate USP43

Batch no

230502

Mf date Exp date May 04 2023 May 03 2026

Batch size

455.8 kg

Molecular Structure

Molecular Formula

 $C_{12}H_{21}NO_8S$

Molecular Weight

339.36

CAS Registry Number

97240-79-4

May 31 2023

<u>Tests</u>	<u>Specifications</u>		Results	
Appearance Solubility Identification	White or almost white powder Freely soluble in dichloromethane IR, HPLC			Almost white powder Conforms Positive
Specific rotation	-28.6 ~ -35.0 °	, measured at		−30. 4°
Related substances	Impurity A		\leq 0.3%	0. 13%
(HPLC)	Fructose		\leq 0.3%	0. 01%
	Single unidentified impurity ≤ 0.1%			0. 06%
	Total impuritie	S	\leq 0.5%	0. 25%
Sulfated ash	≤ 0.2%			0. 04%
Sulphamates & sulphates	Sulphamates	≤ 0.1%		Undetected
	Sulphates	≤ 0.1%		0. 002%
Water K.F.	≤ 0.5%			0. 12%
Residual organic	Acetone	≤ 0.5%		0. 005%
solvents (GC)	Ethanol	≤ 0.5%		0. 083%
	2-Propanol	≤ 0.5%		0. 02%
	Hexane	≤ 0.029%		Undetected
	Tetrahydrofuran ≤ 0.072%		Undetected	
	Toluene	≤ 0.089%		Undetected
	Pyridine	≤ 0.02%		Undetected
Assay (HPLC) oab	98.0 $^{\sim}$ 102.0% of $C_{12}H_{21}NO_8$			99.4%
Packaging and storage	Preserve in tight, light-resistant containers. Long time storage at 2 ~ 8°C			ntainers.
Conclusion	Material complies with USP43			