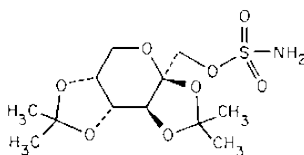




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CERTIFICATE OF ANALYSIS

TOPIRAMATE USP



Molecular Formula: C₁₂H₂₁NO₈S
Molecular Weight: 339.36 g/mol

Lot No. 17031001170412
CAS # 97240-79-4
Storage Condition Room Temperature

Manufacture Date 02/2017
Expiration Date 01/2020
Country of Origin India

TEST	SPECIFICATION	RESULT
Description	A White to off-White powder.	Complies
Solubility	Freely soluble Methylene Chloride.	Complies
Identification (IR)	Complies with USP specification	Complies
Identification (HPLC)	Complies with USP specification	Complies
Optical Rotation	(-28.6°) – (-35.0°)	-29.7°
Water	≤ 0.5%	0.05%
Residue on Ignition	≤ 0.2%	0.13%
Heavy Metals	≤ 0.001%	Complies
Fructose	≤ 0.3%	BDL
Topiramate Related Compound A	≤ 0.3%	0.09%
Individual Impurity	≤ 0.1%	0.06%
Total Impurities	≤ 0.5%	0.3%
Limit of Sulfate	≤ 0.1%	0.02%
Limit of Sulfamate	≤ 0.1%	BDL
Assay (anhydrous)	98% - 102%	100.1%
Methanol	≤ 2000 ppm	BDL
Acetone	≤ 2000 ppm	1266 ppm
Cyclohexane	≤ 2000 ppm	973 ppm
Particle Size	90%, < 75 μm	43 μm

Quality Signature
Compendium
Date
Conclusion

USP 39
04/12/2017
APPROVED