

SHANDONG OCTAGON CHEMICALS LIMITED

CERTIFICATE OF ANALYSIS

Product name	Topiramate (Cas 97240-79-4)		
Batch No.	20200301	Mfg. date	2020.03.15
Rep. Date	2020.03.19	Exp. date	2022.03.14
Packaging	25kg/Drum	Batch Size	580.6kg
Test Items	Standards: USP40		Results
Appearance	White to off-white powder		White powder
Identification	Should conform		Conforms
Specific rotation	-28.6°~ -35.0°, at 20°C		-29.6°
Solubility	Freely soluble in Dichloromethane		Conforms
Water	NNT0.5%		0.14%
Residue on Ignition	NMT0.2%		0.11%
Heavy metals	Not more than 10ppm		<10ppm
Related compounds HPLC (Test 1)	Fructose:NMT 0.3%		0.11%
	Compound A: NMT 0.3%		0.06%
	Other individual impurity: 0.1%		0.095 %
	Total impurities not more than 0.5%		0.265%
Limit of sulfamate and sulfate	Sulfamate:NMT 0.10%;		ND
	Sulfate :NMT 0.10%.		ND
Residual Solvents	1,2-dichloroethane: NMT5ppm		<LOD
	Pyridine: NMT200ppm		<LOD
	Acetone: NMT5000ppm		0.0002%
	Ethanol: NMT5000ppm		0.018%
	MIBK: NMT5000ppm		<LOD
Assay	98.0%~102.0%		99.1%
Conclusion	It meets the requirements of USP40 Standards		
Storage	Store in a well-closed container at ambient temperature		
Prepared by: LI	Reviewed by: WEI	Released by:Zhang	