



HANGZHOU DINGYAN CHEM CO., LTD  
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## CERTIFICATE OF ANALYSIS

NO: DYC051907052

Product name	Topiramate
CAS Number	97240-79-4
Molecule Formula	C <sub>12</sub> H <sub>21</sub> NO <sub>8</sub> S
Batch number	TB-20190203
Manuf. Date	2019-02-17
Testing Date	2019-03-15
Restest Date	2021-02-16

Items	Standard	Result
Appearance	White to off-white powder	White powder
Solubility	Freely soluble in dichloromethane	Conform
Identification	Infrared absorption The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay	Conform  Conform
Related compounds	Fructose $\leq 0.3\%$ Compound A $\leq 0.3\%$ Individual unknown $\leq 0.1\%$ Total impurities $\leq 0.5\%$	Not detected 0.13% 0.08% 0.27%
Residue on ignition	$\leq 0.2\%$	0.07%
Heavy metals	$\leq 10\text{ppm}$	Conform
Specific rotation	$-28.6^{\circ} \sim -35.0^{\circ}$ , measured at $20^{\circ}$	$-31.1^{\circ}$
Water	$\leq 0.5\%$	0.16%
Sulfamate and sulfate	Sulfamate $\leq 0.1\%$ Sulfate ion $\leq 0.1\%$	Not detected Not detected
Assay	98.0~102.0%,calculated on anhydrous basis	99.4%
Residual solvent	1,2-dichloroethane $\leq 5\text{ppm}$ Pyridine $\leq 100\text{ppm}$ Ethanol $\leq 1000\text{ppm}$ MIBK $\leq 1000\text{ppm}$ Acetone $\leq 1000\text{ppm}$	Not detected 12ppm 581ppm 13ppm 7ppm
Storage	Preserve in tight, light-resistant containers, and store at controlled room temperature	
Conclusion:Comply with USP38 specification.		



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QUALITY CONTROL: *Hangzhou Dingyan Chem Co., Ltd.*  
Quality Control *Luyi Tang*  
Signature(x)

CHECK:姚仙娟

INSPECTOR: 刘清风