

Eurotrade World
 Commerce, S.L.
CERTIFICATE OF ANALYSIS

NAME OF PRODUCT	Topiramate		
BATCH NO.	101017	SAMPLING DATE	17/10/2010
MANUFACTURING DATE	17/10/2010	PACKING	25kg/ Package
EXPIRE DATE	16/10/2013	QUANTITY	400kg
TESTING SPECIFICATION	USP 32		
ITEM TESTED	STANDARD		RESULTS
Identification	Infrared Absorption		Complies
	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation , as obtained in the Assay		Complies
Appearance	White to off-White Powder		Complies
Specific rotation	Between -28.6° and -35.0°, measured at 20°		-31.60°
Solubility	Freely soluble in Dichloromethane		Complies
Water	Not more than 0.5%		0.1%
Residue on Ignition	Not more than 0.2%		0.08%
Heavy metals	Not more than 10ppm		Complies
Related compounds by TLC			
Related compounds by HPLC (Test 1)	Fructose not more than 0.3% Compound A not more than 0.3% Other individual impurity not more than 0.1% Total impurities not more than 0.5%		Fructose 0.2% Compound A 0.05% individual impurity 0 % Total impurities 0.25%
Limit of sulfamate and sulfate	Sulfamate ion not more than 0.10%; Sulfate ion not more than 0.10%.		Complies
Assay	Topiramate contains not less than 98.0% and not more than the equivalent of 102.0% of C ₁₂ H ₂₁ NO ₈ S, calculated with reference to the Anhydrous Basis.		99.2%
The material complies with respect to USP 32			