

Eurotrade World
 Commerce, S.L.
CERTIFICATE OF ANALYSIS

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| 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 | | | |