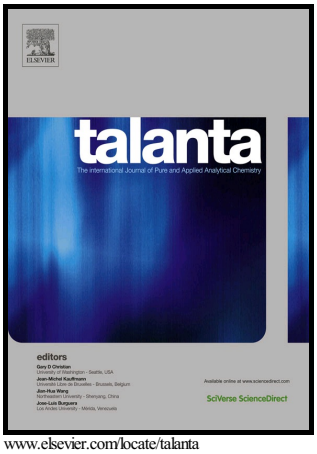

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Capillary zone electrophoresis method to assay tipranavir capsules and identification of oxidation product and organic impurity by quadrupole-time of flight mass spectrometry

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ABSTRACT

Tipranavir (TPV) is one of the most recently developed protease inhibitors (PI) and it is specially recommended for treatment-experienced patients who are resistant to other PI drugs. In this work, a simple and friendly environmental CZE stability-indicating method to assay TPV capsules was developed and two TPV organic impurities were identified by high resolution mass spectrometry (HRMS). The optimized analytical conditions were: background electrolyte composed of sodium borate 50 mM, pH 9.0 and 5% of methanol; voltage +28 kV; hydrodynamic injection of 5 s (100 mbar), detection wavelength 240 nm, at 25 ºC. The separation was achieved in a fused silica capillary with 50 µm x 40 cm (inner diameter x effective length), using furosemide as internal standard. All the validation parameters were met and the method was specific, even in the presence of degradation products and impurities. Oxidation was indicated as the main degradation pathway among those