

5th International Conference and Exhibition on Analytical & Bioanalytical Techniques

August 18-20, 2014 DoubleTree by Hilton Beijing, China

In vitro drug interaction assessment between leviteracetam and amitriptyline by HPLC, UV DSC and infrared spectroscopy

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In present study, it is described an *in vitro* drug interaction assessment of prophylactic agents used in treatment of migraine; leviteracetam and amitriptyline. Several drugs even though not marketed as single dosage form are co-administered leads to drug interactions. Leviteracetam is an antiepileptic drug and amitriptyline is a tricyclic antidepressant, are used as prophylactic drugs in treatment of migraine. As per literature survey, no analytical methods are available for their simultaneous analysis. In present study, a simple RP-HPLC and UV method for simultaneous determination of leviteracetam and amitriptyline has been developed. For HPLC method, a mixture of acetonitrile, methanol and phosphate buffer of pH 3 in the ratio 40:40:20 was used as mobile phase. Elution was carried out in C18 column and detected using PDA detector. The developed method was validated following ICH guidelines. *In vitro* dissolution study was performed by HPLC and UV methods in order to assess the influence of one drug on the dissolution behavior of other drug in simulated intestinal juice and gastric juice. Aliquots were withdrawn periodically with an interval of 15 min from 0 to 180 min and their concentrations were determined by RP-HPLC and UV spectroscopy and the results were compared. Remarkable decrease in absorption was observed when two drugs were simultaneously introduced for dissolution studies compared to their absorbance as individual drugs. HPLC results also show the antagonistic effect of one drug on the dissolution pattern of the other. It was also performed the IR, DSC interaction studies in order to check the changes in the significant peaks due to drug interactions. By both the techniques changes in the peaks were observed indicating the structural modification of the drugs which may be the factor for changes in the dissolution behavior of combination of drugs.

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