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# Optimization solutions for validation procedures in the quality control of enantiomers; Chirality tests for antidepressants Citalopram and Venlafaxine

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Chirality exists everywhere in the nature and plays a significant role in a number of aspects of our life. The consideration of the aspect of chirality is very important for the environment, as well as for some industries, more concretely for the pharmaceutical industry. More than half of the medicines used are chiral. On the other hand it's known that for most of them the pharmacological effects are due to one of the enantiomers only. The problem of the chiral purity of the used medicines leads to a more strict control and detailed consideration at the approval of newly-developed medicines. The chiral analysis also finds clinical applications, which include monitoring of metabolites with chiral properties.

There is a difference in the quantity and quality of enantiomers activity. This is the case with the antidepressant drugs citalopram and venlafaxine from SSRIs and SNRIs classes. They are in the first several most commonly prescribed antidepressants on the pharmaceutical market, with more then 15 million prescriptions. At last few years the present of lot of generic products containing Citalopram and Venlafaxine sets new challenges before quality control procedures and the developing of analytical programs for *in vivo* monitoring. In addition is increased the illegal usage of antidepressant agents in different preparations and combinations which convert it in to seriously problem for pharmaceutical and toxicological practices.

The aim of this study is the investigation of analytical and chromatographic parameters and conditions to develop HPLC chirality test for simultaneously determination of enantiomeric forms of Citalopram and Venlafaxine with wide range of application but especially for quality control of drugs and for studying of chemical stability in different media. Validation procedures in quality control of Citalopram and Venlafaxine are the main guaranty for the assurance and compliance of using analytical methods. The obtained data from analysis will compared on the base of European Pharmacopoeia criteria to serve in the analytical and toxicological practice and for regulatory institutions for quality control of novel generic drugs. Chiral HPLC method for analysis of pure enantiomers and racemic mixtures Citalopram give also possibilities for answering of very debatable in the area of the patent justice and intellectual property questions about the ingenious of chiral molecule and chances for manifestation of it properties.

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