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### Liquid Chromatography for Enantiomeric Purity of Chiral Pharmaceuticals

evelopment of reliable analytical methods for determination of enantiomers has always been increasing in the fields of chromatography, pharmacology, medicine, asymmetric synthesis, mechanistic studies, extra-terrestrial chemistry, life sciences etc. And, still separation of enantiomers and determination of their purity is challenging and important. With the most infamous example of thalidomide as an enantiomeric drug having unwanted side effects in the background the regulatory agencies in the US, Japan and EC and certain other countries insist on registration of single enantiomer of a new drug and ask the pharmaceutical companies to present full information on the stereochemistry and stereoselectivity of both the enantiomers including the necessary stereoselective analytical methods because there exist potential differences between pharmacodynamics and pharmacokinetics of the enantiomers of racemic drugs. Yet, with "a few" exceptions, chiral synthetic racemic drugs are being approved for marketing and pharmaceutical applications, of course, with the appropriate demonstration and justification. This presentation covers some aspects of stereochemistry of the drugs that are marketed and administered as racemic mixtures with an emphasis on current status of analytical chemistry methods for enantioseparation and control of enantiomeric purity. There is also a brief discussion on related historical knowledge keeping in view that today we know that the number of pharmacologically active substances produced by nature is large, and the spectrum of biological activities of natural products is extraordinarily broad. There is a discussion on various methods developed primarily at our laboratory for chromatographic resolution of racemates of several pharmaceuticals (e.g., -blockers, NSAIDS, anta-acids, DL-amino acids, Bupropion, Baclofen, Etodolac, Carnitine, and Mexiletine). Included among them are, (i) a de novo approach/method of mixing the chiral selector with the silica gel while making the TLC plates, it is a less exploited area that has great potential; (ii) Separation under both achiral phases in TLC as well as HPLC but using either a simple enantiomerically pure L-amino acid or a chiral ligand exchange reagent in sample preparation; (iii) Indirect approach of enantioseparation. There were synthesized and characterized several new chiral derivatizing reagents (CDRs) capable of detecting different drug enantiomers at nano and pico molar level. To ensure the success of diastereomeric synthesis and the reliability of enantioseparation the configuration of diastereomers so separated was established in our recent studies particularly because most of the time diastereomer corresponding to pure enantiomer of the analyte is not available. As the first report in literature, we developed methods for establishing molecular dissymmetry and determining absolute configuration of diastereomers, so separated, (and thus the enantiomers) of (RS)-Baclofen, (RS)-Betaxolol, (RS)-propranolol, (RS)-metoprolol and (RS)-atenolol with supplementing application of TLC, HPLC, 1H NMR, LCMS, and the software based on density functional theory (using the Gaussian 09 Rev. A.02 program and hybrid density functional B3LYP with 6-31G\* basis set). The methods are of significant importance to pharmaceutical industry and analytical laboratories for determination and control of enantiomeric purity of a variety of drugs.

#### Biography

Ravi Bhushan has an expertise in "Enantiomeric resolution of compounds of pharmaceutical importance using liquid chromatography". So far, he has guided 28 doctoral and 50 masters' theses, published more than 230 research papers in international refereed journals and chapters in books and encyclopedia. He edited four Special Issues of Biomedical Chromatography on chiral resolutions as Guest Editor. He received Alexander von Humboldt fellowship of Germany in 1988, and European Economic Community Fellowship in 1992. He is an elected Fellow of the Royal Society of Chemistry, London, and Fellow of National Academy of Sciences India, (FNASc). He received 'Outstanding Teacher Award' of the year 2007 at IIT Roorkee, and Khosla Research Prize and Silver Medal of University of Roorkee. His current research interest includes enantioseparation with both achiral phases of chromatography in the absence of any external chiral species.

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