OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Conference on
Pharmaceutical Regulatory Affairs

October 21-23, 2013 DoubleTree by Hilton Hotel San Francisco Airport, USA

Chirality in pharmaceutical product development: A regulatory perceptive

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Abstract

There is a trend in pharmaceutical industry towards the development of chiral drugs. Several factors have influenced this trend in the pharmaceutical industry towards the development of the chiral drugs to provide more potent selective and specific drugs. Over 1/3 rd of the marketed drugs worldwide are chiral and the regulators now only will approve new chiral drugs in the single enantiomer form and even then insists on full profiling of the role of the individual enantiomers *invivo*. The importance of chirality lies not only in the product development but in the area of analytical and bioanalytical method development. Development of chiral analytical method /bioanalytical methods as per regulatory requirements requires a series of selection process to get the adequate resolution and quantification. Selection of compatible mobile phases and stationary phase that suits the particular need is very important. This presentation gives a brief description of chiral products, excipients followed by functions and effects of its chiral forms. This presentation also describes the case studies of the chiral quantification in bioanalytical and analytical methods and their applications.

Biography

Kishore Kumar Hotha has more than 10 years expertise in analytical/Bioanalytical Research. His focus is on method development using Liquid Chromatography (HPLC)/Liquid Chromatography with Mass Spectrometry (LC/MS/MS) for the Quantification of biological matrices and their applications to pharmacokinetic studies. He is having broad experience in the area of small and large molecules method development. He completed his PhD from Jawaharlal Technological University. He has published more than 30 papers in reputed journals. He is working as a senior scientist in Novel Laboratories Inc which is a is a full-service pharmaceutical company that develops, manufactures, markets and distributes difficult to develop, technology-driven specialty generics for the US and European markets.