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Chiral HPLC resolution of a potentially serious global health crisis

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A few years ago there was a potentially serious health issue in Pakistan and Paraguay which spurred investigation and responsive action by both the United States Pharmacopeial Convention (USP) and The Food and Drug Administration (FDA). This crisis resulted in the deaths of adults and children who had ingested Dextromethorphan Cough Syrup. It was later determined and confirmed that toxic levels of the controlled substance, levomethorphan, an enantiomer of dextromethorphan, was found in the drug formulation and was responsible for the resulting deaths. USP has thus charged with developing a quantitative procedure for monitoring levomethorphan and simultaneously incorporating this method as a revision to the documentary standard within its compendium. At the time of the public health issue, the existing USP Dextromethorphan monograph did not include a quantitative procedure for the determination of its enantiomer, levomethorphan. Hence a chiral HPLC method was developed to bring the monograph up-to-date and simultaneously address obvious safety concerns associated with the enantiomer. The proposed HPLC method separates levomethorphan and dextromethorphanone (another impurity, dextromethorphan Related Compound C) from dextromethorphan; and allowed quantitation to satisfy acceptance criteria requirements for these impurities (0.10%). Hence, manufactured lots which test higher than the specified limit of levomethorphan can be rejected thus helping to prevent potential safety issues in the future. A complete overview of the issues encountered in the development of this chiral HPLC method along with the challenges associated with the implementation of a global procedure which utilizes a schedule 11 controlled substance as a public standard will be presented.

Biography

Clydewyn M Anthony is a Senior Scientific Liaison in the Chemical Medicines Division at The United States Pharmacopeial Convention (USP) and is currently responsible for the modernization of documentary standards for Over-The-Counter drug formulations. He completed his PhD in Analytical Chemistry at The Pennsylvania State University and BS in Chemistry in Hunter College at the City University of New York. Prior to joining USP in May 1999, he worked as a Research Chemist with Texaco Inc. where he was responsible for performing and overseeing the compositional analyses of motor oils, gasolines and all aftermarket petroleum related products on both the domestic and international markets. He also held the position of Criminalist with the New York Police Forensic Investigation Department, worked on thousands of narcotics and arson related cases, and testified as an Expert Witness on behalf of the New York City Police Department.

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