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TRACK 10

REGULATORY BIOANALYSIS – PROSPECTUS AND CHALLENGES

03 November 2010 (Wednesday)

SESSION CHAIR : **DR. ALKA BEOTRA**
National Dope Testing Laboratory, Ministry of Youth Affairs and Sports, New Delhi, India

SESSION CO-CHAIR: DR. D. VIJAYA BHARATHI
Head, Bioanalytical-R & D-IPDO, Dr.Reddy's labs, Hyderabad India

SESSION INTRODUCTION

TITLE: ANALYTICAL STRATEGIES EMPLOYED FOR DOPING ANALYSIS IN XIX COMMONWEALTH GAMES-2010, IN INDIA

DR. ALKA BEOTRA, National Dope Testing Laboratory, Ministry of Youth Affairs and Sports, New Delhi, India

TITLE: FOCUS ON CHALLENGES IN REGULATED BIOANALYSIS; CASE STUDIES

DR. D. VIJAYA BHARATHI, Head, Bioanalytical-R & D-IPDO, Dr.Reddy's labs, Hyderabad India

TITLE: PREFORMULATION CHALLENGES AND ADVICES TO OBTAIN THE BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES OF PHARMACEUTICALS

DR. JOSÉLIA LARGER MANFIO, Biocinese – Biopharmaceutical Studies Center, Toledo, Brazil

COFFEE BREAK & POSTER SESSION

TITLE: GLOBAL HARMONIZATION TASK

DR. S. B. PURANIK, Srinivas College of Pharmacy, Mangalore, India

TITLE: METHOD VALIDATION, UNCERTAINTY ANALYSIS AND SAFETY EVALUATION OF MEPTYLDINOCAP IN GRAPES USING LIQUID CHROMATOGRAPHY- MASS SPECTROMETRY

DR. SUDEB MANDAL, Department of Chemistry, Kalyani University, WB, India

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Analytical Strategies Employed for Doping Analysis in XIX Commonwealth Games-2010, in India

Alka Beotra

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The control of drug abuse in athletes has become a highly specialized complex task which requires use of sophisticated testing procedures. Doping control analysis using instrumental analytical tools have been performed since the 1960s when various measures were initiated to control the misuse of performance-enhancing drugs in sports. Each major game viz. Olympics, Asian games and Commonwealth Games sees enormous advances in doping control. The analytical strategies employed for the XIX Commonwealth games testing in India is in compliance with the WADA 'prohibited list' which includes hundreds of substances, ranging from volatile stimulants to modified polysaccharides and glycoproteins. Apart from prohibited substances, there are few methods which are also prohibited viz. blood transfusion and other forms of blood doping. The determination of low molecular weight (700-800 Da) substances (stimulants, narcotics, anabolic agents, glucocorticosteroids, beta-2-agonists, beta blockers, diuretics, antiestrogens, cannabinoids) was performed mainly by chromatographic- mass spectrometric technique which is considered as the gold standard for antidoping analysis. The protein chemistry and molecular biology components (EPO, CERA, Blood transfusion, Human Growth Hormone) are analyzed by dedicated analytical techniques for the identification of high molecular masses viz. electrophoresis, luminometry etc. The presentation will focus on the various analytical strategies employed in the testing of the mega event so as to set a milestone of excellence in the field of doping control.

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Focus on Challenges in Regulated Bioanalysis; Case Studies

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Guidance from various regulatory authorities has helped significantly in the standardization of how to approach about regulated quantitative bioanalysis of small molecules. However there are some interpretation differences which are leading to dissimilar practices among bioanalytical scientists. Good scientific rationality must exist and assessment performed should be case specific.

There are many hot topics viz, Ion Suppression, Matrix Effect, Contamination Criteria, multi analytes, failed run investigation, Regression Type, Stability, Repeats and ISR.

Impact of above said areas on outcome of the bioequivalence study was incorporated in the current presentation in the form of case studies.

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Preformulation Challenges and Advices to Obtain the Bioavailability and Bioequivalence Studies of Pharmaceuticals

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Actually the approval at a Bioavailability/Bioequivalence Studies is a great challenge after a development of Pharmaceuticals. In many instances, the reproach in these studies were correlated successfully to dissimilar drug blood levels caused mainly by impaired absorption. A biopharmaceutical assessment of drug substance is crucial in generic drug product development. An extensive formulation screening has gained increasing attention during the last years after it became evident that decrease the failure bioequivalence risk. Bonding, binding, isomerism and polymorphism (dissolution behavior) are important processes that influence that activity and elimination of many drugs. The identification, characterization and quantification of crystal forms are becoming increasingly important within the pharmaceutical industry. A combination of different physical analytical techniques (as differencial scanning calorimetry, for instance) is usually necessary for this task. Herein a drug categorization according to the biopharmaceutical classification system (BCS) is helpful. The drug solubility in indifferent systems and the permeability assays are very important determinations at characterization of drug substance. In light of the FDA's recent guidances, there is an increased awareness of the potential relevance of dissolution tests but also realizes the need for individualizing the method on a case by case. The evaluation of dissolution profiles changing the media to obtain a pH gradient or simulate fed and fasted conditions may be a tool for predicting bioavailability, and in some cases, replace clinical studies to determine bioequivalence. The permeability assay is considered to be the development gold standard for in vitro prediction of in vivo human intestinal permeability and bioavailability of orally administered drugs (as Caco-2 cells). Although the cost and the ethics aspects bioavailability testing in animals can be an alternative to predict the bioequivalence. The association of well-made characterization of drug, the relevant dissolution profile test and permeability assay gains the maximal information from which factors could have an impact on the oral bioavailability.

Global Harmonization Task

S. B. Puranik

Srinivas College of Pharmacy, Mangalore, India

The Global Harmonization Task Force (GHTF) was founded in 1993 by the governments and industry representatives of Australia, Canada, Japan, the European Union, and the United States of America to reduce regulatory burdens and costs for local government and industry. The other emerging issues of international significance can also be put to the GHTF for a common solution and promotes technological innovation and facilitates international trade. The GHTF encourages the technological innovation and facilitates international trade by converging harmonized guidance documents in standards and regulatory practices related to the safety, performance and quality of medical devices. The GHTF develops four different Study Groups, Study Group 1: is charged with comparing operational medical device regulatory systems around the world. Study Group 2: examines the requirements for the reporting of adverse events involving medical devices, post-market surveillance. Study Group 3: is responsible for examining existing quality system requirements in countries that already have well-developed device regulatory systems. Study Group 4: is charged with the task of examining quality system auditing practices. GHTF provides an opportunity for countries to participate and observe regulatory developments that they could adopt. The current trend towards a regional harmonization will be useful for countries and also supported by parallel regional structure.

Biography

Dr. S. B. Puranik has completed his Ph.D in Quality Assurance from RGUHS Bangalore. He is the Prof & HOD Quality Assurance of Srinivas College of Pharmacy, Mangalore, India. He has published more than 25 papers in reputed journals and serving as a Prof & HOD Quality Assurance Srinivas College of Pharmacy, Mangalore, India.

Method Validation, Uncertainty Analysis and Safety Evaluation of Meptyldinocap in Grapes Using Liquid Chromatography- Mass Spectrometry

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Meptyldinocap (one isomer of dinocap) is a novel powdery mildew fungicide, is going to introduce in India by Dow AgroSciences to replace dinocap. An analytical method for the quantitative determination of meptyldinocap (2,4-DNOPC) as 2,4 dinitro-octylphenyl (2,4-DNOP) in grapes was developed as well as validated using liquid chromatography tandem mass spectrometry (LC-MS/MS). The method comprised of an extraction with an acetone: methanol: 4N HCl (100:10:5, v/v/v) mixture followed by hydrolytic conversion of parent 2,4-DNOPC to the corresponding phenol metabolite (2,4-DNOP) and clean up was done by liquid: liquid partition using ethyl acetate. Final quantization was performed by LC-MS/MS of 2,4-DNOP with negative electrospray ionization using the gradient elution. The method was validated at concentrations ranging from 0.025-2 µg/g and the limit of quantification (LOQ) of meptyldinocap in grape samples was 0.025µg/g. The recovery of meptyldinocap grapes was found to be 92-94 % spiked at different levels with analyte and the relative standard deviation for repeatability (RSD_r) and reproducibility (RSD_R) were acceptable (less than 10%). The method was rugged as evident from a low global uncertainty of measurement at 0.05µg/g. Moreover, the developed and validated method was used to study its dissipation and residue (at harvest) of meptyldinocap in grape field ecosystem under Indian tropical climate with a view to ensure human and environmental safety.

Biography

Dr. Sudeb Mandal has completed his Ph.D from University of Kalyani and Bidhan Chandra Krishi Viswavidyalaya. He is a trainee Scientist in India's leading contract research and testing organization. He has published more than 4 papers in reputed international journals.