

23rd International Conference and Exhibition on
PHARMACEUTICAL FORMULATIONS
&

13th International Conference and Exhibition on
PHARMACOVIGILANCE & DRUG SAFETY

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SCIENTIFIC TRACKS & ABSTRACTS

Formulations 2020 & Pharmacovigilance 2020

Solubility Enhancement of Poorly Soluble Drugs: A Design of Experiment Approach to Develop Nanosuspensions

Alptug Karakucuk

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The poor aqueous solubility issues of drug molecules limit drug absorption through oral or dermal route and eventually, lower bioavailability due to hydrophobicity. Moreover, it is a big challenge to formulate poorly soluble drugs to increase solubility to obtain sufficient activity. Several new drug candidates, which are coming in regard to target-receptor geometry by high throughput screening, have high molecular mass and high Log P value that contributes to insolubility. According to Biopharmaceutical Classification System, the Class II and IV drugs consider as poorly soluble. Physical modifications (micronization, polymorph formation, solid dispersions, cyclodextrin complexes, use of organic solvent), chemical modifications (prodrug preparation, salt forms) or nanotechnological approaches (micelles, liposomes, nanoemulsions, etc.) are considered to overcome low water solubility problems. Physical and chemical modifications have several disadvantages such as not applicable to each drug active substance, not providing sufficient increased saturation solubility or causing loss of activity. In the last years, it is considered that drug nanosuspensions are one the most successful approaches to formulate poorly soluble compounds. Nanosuspensions are dispersed systems which have nanometer range, typically 200-600 nm, pure drug particles. They contain minimum amount of stabilizing agents such as surfactants and/or polymers. Nanosuspensions can be produced by precipitation, wet milling, high pressure homogenization, or combination of these methods. With unique properties of nanosuspensions by providing increased surface area of drug articles, they can improve saturation solubility and dissolution rate of poorly soluble drugs and hence oral or dermal bioavailability. The specific function of Quality by Design is known as Design of Experiment (DoE). The DoE approach statistically examines the interactions between variables within the design area and enables the development of formulations by taking into account the optimum product characteristics. DoE approach helps to develop nanosuspension formulation by reducing the number of experiments which brings cost and time saving.

Biography

Alptug Karakucuk was born in Turkey in 1988. He was graduated at Gazi University Faculty of Pharmacy in year 2012. He also took his Ph.D at Gazi University, Department of Pharmaceutical Technology in 2017 as a research and teaching assistant. He is still Ph.D., instructor at the same department. He is also co-founder and general manager of Fiber Pharma Drug, Cosmetics and Consulting Co. He published or presented several scientific studies in international areas, patented and commercialized some products, participated in scientific projects as researcher or coordinator.

Encapsulation of API: A promising platform for improving dispersity and bioavailability

Andrew Ebenazer

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The majority of the active pharmaceutical ingredients (API) are poorly soluble in water, thus require the formulation process for improving bioavailability. Conventionally, the addition of excipients was in common practice, however, higher bioavailability could be affected due to lack of dose proportionality. As to overcome this, encapsulation techniques have provided answers to entrap the API inside the hydrodispersive capsule as a safe carrier. The capsule chosen should serve the purpose of biocompatibility, dispersion stability, and targeted bioavailability. i) Emulsions: Encapsulate is a micelle system of surfactants. A simple emulsification technique along with essential oils, an easier and effectual formulation. Emulsification is carried out by a high energy process aided by the mechanical devices or low energy process aided by the internal physical property of the system. The emulsion system poses the advantage of blending multiple components into a single system for combinational drug delivery. (ii) Polymeric encapsulation: The utilization of polymers for encapsulation has gained upper hand over the emulsion system as most of them are hard colloidal particles, unlike emulsions. Mostly preferred ones are natural polymers such as gelatin, chitosan, agarose, alginate for entrapment of API. These polymeric capsules can be additionally coated with other polymers or adjuvants or other functional groups for the benefit of sustained and controlled release applications. (iii) Lipid encapsulation: The encapsulate is typically a lipid such as triglycerides, fatty acids, steroids. The formulation is typically carried out by hot or cold homogenization or spray drying. The lipid encapsulation provides good stability for lipophilic drugs with an added advantage in topical applications. Overall encapsulation of the API provides the possibility of formulating customized delivery vehicles for the targeted applications. Also, all these formulations can be converted into nanometric form by altering the surfactant concentration or system components or by altering the energy intensity, which further aids the dispersity and bioavailability.

Biography

Andrew Ebenazer has his expertise in Nanoencapsulation/ Nanoformulation of active compounds, toxicity studies on target and non-target organisms and biosafety studies. Further have a hands on expertise in developing the rapid qualitative, and quantitative analytical methods. Proficiency in handling, troubleshooting LCMS, Preparative HPLC, Analytical HPLC, UPLC, UHPLC, flash chromatography systems. A consultant in providing ecosafety solutions and industry oriented training workshops.

Chromatographic Analysis of Chloranilines in Aqueous Environments

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Environmental problems come first in the system of global problems after the problems of peace and war, and recently, as one of the most important global problems in the world, environmental problems are, above all, in the interests of all mankind. Aniline and its chlorinated derivatives, which are of great industrial importance, are used in the manufacture of textiles, cosmetics, medicines, food, paper and plastics. Aniline, which belongs to the class of dyes, changes its colour by mixing with clean water in the waste water, first of all, by contaminating the water. In addition to visual pollution, it prevents sunlight from entering the depths of the water by adsorbing or reflecting sunlight. This prevents the growth of various microorganisms and the photosynthesis of aquatic plants. As a result, the composition of natural waters changes and the amount of oxygen is significantly reduced. Research shows that the discharge of wastewater without treatment of aniline and its derivatives leads to the destruction of living organisms. Also, the fact that aniline is well soluble in water significantly increases this risk. With the help of highly efficient capillary columns and methods of modern concentrations of selective detectors (ECD, NPD), chloranilines can usually be determined directly from the required sensitivity level (0.05 µg / dm³ and 0.5-5 µg / dm³). The reason for this unsatisfactory sensitivity is that the presence of an amine group in chloranilines interferes with the sample and causes erosion and asymmetry of individual chromatographic peaks. The NH₂ group, on the other hand, is highly reactive to modify anilines. Using this, the removal of the amine group will have an equally positive effect on both the extraction concentration of anilines and their chromatographic determination. A solution with a concentration of 10 ppm (mass of solute in ppm-1 l of solution) is capable of destroying 50% of the organisms that are in the water and use it for 96 hours. The toxic effects of these compounds have been studied in several water sources in Azerbaijan.

Recent Publications

1. Daignault S.A., Noot D. K., Williams D. T. A review of the use of XAD resins to concentrate organic compounds in water // Water Res. - 1988. - V. 22 No 7. - P. 803-813.
2. Jink G. A., Richarg J. J. Interferences in solid phase extraction using C-18 bonded porous silica cartridges // Anal. Chem. - 1988. - V. 60. -No 13. - P. 1347-1350.
3. Pawliszyn J. Solid Phase Microextraction. Theory and Practice. - New York: Wiley, 1997. - 275 p.
4. Ouyang G., Rawliszyn J. SPME in environmental analysis // Anal Bioanal Chem. - 2006. - V. 386. - P. 1059-1073.

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5. Little J.L. Artifacts in trimethylsilyl derivatization reactions and ways to avoid them // J. Chromatogr. A - 1999. - V. 844. - P. 1-22.

Biography

Nabat Abdullayeva is a graduate from Sumgayit State University, Azerbaijan. The title of the dissertation is "Chromatographic Analysis of Chloranilines in Aqueous Environments". I am doing research on sampling wastewater from paints and pharmaceutical plants operating in Azerbaijan.

Drug-induced hypersensitivity reactions and their associated predictors using spontaneous reported ADRs from the Tanzania Medicines and Medical Devices Authority (TMDA) vigflow database 2017-2018

Elias M. Bukundi

Muhimbili university of Health and allied sciences, Tanzania

Hypersensitivity reactions are public health problem which contribute to 10% to 20% of hospitalization. The objective of this analysis was to determine the prevalence, signal and risk factors for drug-induced hypersensitivity from spontaneous reported at TMDA Vigflow database from January 2017 to December 2018. A secondary data analysis of 321 spontaneous reported ADRs cases were analysed. Predictors of drug induced hypersensitivity was identified using multivariate logistics analysis. Drug induced hypersensitivity statistical association (Signals) was determined using reporting odds ratio (ROR). Mapping of the geographical distribution of the reported ADRs was done using QGIS. The prevalence of drug-induced hypersensitivity was 39.56%, the independent predictors for drug-induced hypersensitivity were reports from southern highland zones (OR=7.29), oral route of administration (OR=37.50), reports from other health professional (R=6.508), age group between 15-28 years (OR=0.180), having a non-serious adverse reaction (R=3.97) and being recovered from ADRs at the time of reporting (R=4.076). A signal associated with drug-hypersensitivity was detected in Isoniazid tabs, cotrimoxazole tabs, Artemether lumefantrine tabs, RHZE and antiprotozoal ATC group of drugs. Mara region, Kagera region, Njombe region, Katavi region, Simiyu region, Songwe region and Mtwara region did not report any ADRs in 2017 to 2018. More attention should be given to patients aged 15-28, those who use drug by oral route, non-serious adverse reaction, living the Southern highland zone, those using anti TB drugs, ALU, Antibiotics and antiprotozoal drug.

Biography

Elias M. Bukundi is registered Pharmacist who is who undertaking his Masters degree in Applied Epidemiology at Muhimbili university of Health and allied sciences in Tanzania. He is a region Pharmacist in Kagera Region in Tanzania. Currently he is attending his field placement at the TMDA for six months where he conducted data set analysis on reported reported ADRs at the TMDA.

Medication Safety during COVID 19

Fatima Yousef Ghethan

King Abdullah Medical City

The COVID-19 pandemic and the response of the healthcare system has affected the ability of healthcare to ensure medication safety in several ways. These include challenges associated with medication shortages, changes to the pharmacy workflow, an ever-changing evidence base associated with the pharmaceutical treatment of COVID-19 complications, and limited availability of personal protective equipment (PPE). Pharmacists are the best-positioned professionals to ensure safety through the preparation, delivery, and ongoing management of medications. However, like the majority of healthcare providers, the usual pharmacy workflow and operations have been greatly impacted by the response to COVID-19 have modified the physical settings of care for pharmacists, necessitating changes to their workflows. Additionally, pharmacist workflows may be interrupted or require modification due to increased informatics and technology changes associated with monitoring medication supplies or when systems are operating with a decreased workforce (colleagues are forced to work from home, are sick, or may be furloughed). Lastly, redeployment of healthcare personnel to new areas and specialty of care may introduce safety risks due to unfamiliarity with workflows and processes. For example, the Institute for Safe Medication Practices recently shared a case study in which there was a failure to engage barcode medication administration, a best practice in medication safety, when healthcare staff was assigned to a new patient care area. Also the recommendation of using automation during COVID-19.

The Role of Innovative Clinical Trials in Novel Drug Development

Ibrahim Aminu Shehu

Sharda University, Greater Noida, Uttar Pradesh, India

Traditionally, a randomized clinical trial (RCT) is known to be the mainstream for novel drug development and a pipeline for therapeutic and safety evaluation of any drug candidate before entering into the market. Unfortunately, it takes tedious and complex protocols that consume huge amounts of resources, and time. Therefore, this poses the limitation in the trial, including the short study period, recruiting a small number of participants, and lack of funding by the sponsors, which in turn expedites the safety and efficacy failure, as well as the chances of several adverse drug events following the market feedback. Thanks to the recent innovation in clinical trial space that allows the flexible modifications of RCT, which consist of the evaluation of human pharmacokinetic bioequivalence, the inclusion of phase 0 stage, and adoption of “master protocol” in clinical trial design among others. The aforesaid strategies bring about the study flexibility and upper potential solutions to the inherent limitations of RCTs. This research survey in-depth literature on the specific research keywords in the recognized global scientific databases like PubMed, Elsevier, Science Direct, Google Scholar, et al. More so, we focus on highlighting the recent strategies adopt in designing the innovative clinical trials along with their associated benefit and perspectives.

Biography

Ibrahim Aminu Shehu is a young scientist of 28 years old, an indigenous citizen of Kano State, Nigeria, who currently pursuing a Masters Degree in Pharmaceutical Sciences specialized in Drug Design and Development at Sharda University, Greater Noida, India. He is a licensed Pharmacist (Reg. No. 025144), and a member of the Pharmaceutical Society of Nigeria (PSN). He has 3 years of working experience in hospital and community pharmacy. He is a founder of HabibaMed Pharmaceuticals. Ibrahim has 3 publications in reputable journals with 2 accepted abstracts while 5 manuscripts were under some journal consideration. Moreover, he is currently executing two projects aiming to be concluded before the year ending.

The Pharmacoepidemiological Aspect of Psychoactive Prescription Containing Drug of Abuse and Misuse in Sub Saharan Africa

Abubakar Mukhtar

Sharda University, Greater Noida Uttar Pradesh, India

Background: The use of psychoactive prescription drugs such as sedative/hypnotics, anxiolytics, antiepileptic's, and opioids analgesics has become widespread all over the world and continues to pose a threat to the overall healthcare system. Opioids analgesics are one of the most prescribed psychotropic drugs for varying reasons, partly due to their increasing accessibility and partly associated with the prescription patterns among health care professionals. Furthermore, the wide availability coupled with a public misunderstanding about the potential addiction and harmful effect of the substances, have contributed to the recent increase of the non-medical use of prescription opioids and an equivalent increase in emergency visits for opioids use-related problems.

According to the UNODC, it is estimated that around 155-250 million people with an age range from 15 - 65 had previously used illicit substances, with cannabis illicit use been the most widely (130-190 million people) followed by amphetamine-like stimulants, opiates, and cocaine. Nonetheless, Opiates are ranked first in terms of use related harms and destructions.

A broader understanding of the extent of illicit drug use and misuse necessitates the deployment of various parameters. For instance, it is estimated that there are between 700,000 to 3 million users of opioids in Africa, even though the vast majority of data is missing to ascertain the true figures. Mauritius, Kenya accounts for the highest prevalence use of opioids with 1.9% and, 0.7% respectively. According to the report, South Africa is the only country in Africa with an active drug use surveillance system based on demand.

Objectives: As a regulation, consumption, and availability differ according to the geographical location, this review aims to study the pharmacoepidemiological aspect of opioids analgesic prescription abuse and misuse and to investigate the trends and variations in Sub Saharan African countries.

Methodology: The review aims to summarise established literature contented in original articles, reviews, systemic reviews, meta-analysis, reports, pre-prints, and short communications that coincides with the specific objective of the research, by searching the specific keywords in the various indexing site like Scopus, Research Gate, Google Scholar, Science Direct, J-Gate, and PubMed.

Biography

My name is Abubakar Mukhtar, I am currently a master's student of Pharmacovigilance and Pharmacoepidemiology from Sharda University India, I did my Bachelor of Pharmacy at October 6 University Egypt with two-year working experience in Nigerian hospitals and community Pharmacies. I am Passionate about Pharmacovigilance and creating drug safety awareness. So far I have one publication and one accepted abstract.

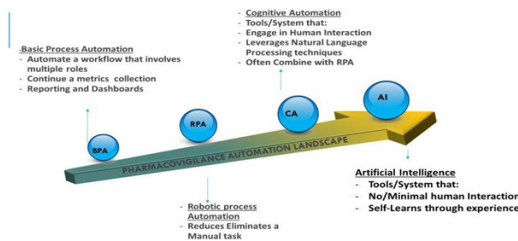
Automation in Pharmacovigilance

Sunil Nighot

Johnson & Johnson Pvt Ltd., India

In today's world of empowered patients and increased attention to drug safety, the role of Pharmacovigilance has never been more crucial. Healthcare organizations need to instill robust practices to detect, assess, report on and prevent adverse effects, both to ensure regulatory compliance and reduce risk for patients. Pharmacovigilance processes, however, are traditionally highly manual and resource-intensive. As such, adverse events are reported across the globe in multiple languages and formats and in structured, unstructured and handwritten documents from affiliates, partners and distributors. Typically, large Pharma companies receive anywhere from 300,000 to 500,000 adverse events a year. These documents are processed manually by large teams that identify and extract relevant information and enter it into the safety system. This is followed by quality and medical review before the data is reported to regulatory bodies. Automation of pharmaceutical safety case processing represents a significant opportunity to affect the strongest cost driver for a company's overall Pharmacovigilance budget.

Solution:



Benefits of Robotic Automation



Reduces **cost**, as we automate transaction processing
 Helps to provide higher **productivity** benefits
 Higher **efficiency** in process & reduction of **non value added** activities



Reduces **transactional errors**
 Drives higher **accuracy**
Mistake proof processes
 Enhances **compliance & controls**



Drives improvements in **business outcome through improvement in time, quality & cost of transaction**
 Accelerating **business outcomes** without increasing program complexity or headcount
 Increases **customer satisfaction**