



The NGSMIPS Herald

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Institute of Pharmaceutical Sciences, Mangalore



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BIOLOGICS AND BIOSIMILARS - REVOLUTIONIZING MEDICINE

VISION

To build a humane society through excellence in education and health care.

MISSION

To develop Nitte University as a centre of excellence, imparting quality education, generating competent, skilled manpower to face the scientific and social challenges with a high degree of credibility, integrity, ethical standards and social concern.

'For Private Circulation Only'



From the Editor's desk

In Science, writing is the most important means of communicating research findings. In a research based program such as the Pharmaceutical Sciences, scientific writing is integral in three key areas: recording data or outcome of experiments conducted, writing proposals for research funding and in publishing results in scientific journals. Keeping records of data from studies conducted and even research proposals may be relatively simple but making results of investigations publish-worthy in peer reviewed journals is altogether a different task, and often very difficult. Many research articles are rejected by reputed journals mostly for poor scientific writing. However, good scientific writing is not every researcher's cup of tea, and getting a paper published can be a very tedious and time-consuming process.

Good scientific writing is not only about good grammar and getting your spellings right, it is also about imparting information about your research work to other scientists and therefore must also be informative, clear, accurate and concise. The dissemination of research results and findings is an integral part of the research process and is considered to be as important as performing the actual research itself. Research articles are required to have a particular style or format that is acceptable to most journals and the scientific community. Writing in a scientific style may be hard in the beginning for novices, but clear communication and concise writing for a scientific audience can be trained and good writing sense is usually acquired through experience.

Around the world, research funding is often decided on the basis of the number and value of the publications in terms of impact factor, citation index and other tools. In order to prepare students to the research atmosphere in the graduate level, it is imperative that they are given some form of training in scientific writing in the under graduate level. This would definitely set them on the right path to a sound research career.

Marina Koland
Executive Editor

Text Book on Experimental Pharmacology by Dr. Himanshu Joshi released



Sri N. Vinay Hegde releases the book in the presence of the Authorities of the Nitte University

A new text book on Pharmacology entitled "An Alternative Approach to Experimental Pharmacology" written by Dr. Himanshu Joshi, Asst. Professor, was published. The book was released by Sri. N. Vinay Hegde, Chancellor of Nitte University on March 16, 2016 in the presence of Mr. Vishal Hegde, Pro-Chancellor (Administration) Nitte University, Dr. Shantharam Shetty, Pro-Chancellor (Hospital management and Medical P.G Studies) Nitte University, Dr. S. Ramananda Shetty, Vice Chancellor, Nitte University and other authorities of the University. The book promises to provide practical solutions to the problems being faced by students and teachers in conducting animal experiments in Pharmacology lab in view of the ban on experiments in animals.

CAMPUS BUZZ

One day symposium at NGSMIPS

A one day symposium on “Animals in Biomedical Research: The changing perspectives” was organized by the Department of Pharmacology, NGSM Institute of Pharmaceutical Sciences. This symposium was jointly sponsored by the I.C.M.R and Nitte University and was organized at the Nitte University Auditorium, Paneer campus on 22nd January 2016. The program was inaugurated by the Chief Guest Dr. U. S. Krishna Nayak (Dean, A. B. Shetty Memorial Institute of Dental Sciences). Also present was the Guest of Honour, Dr. Indrani Karunasagar (Director R&D, Nitte University), who in her address, quoted Mahatma Gandhi by saying that the greatness of a nation and its moral progress could be judged by the way its animals are treated. The resource persons at the symposium were, Dr. Ashok Shenoy K. (Professor, Dept. of Pharmacology, KMC, and Mangalore), Dr. N. A Madhyastha (Retired Prof. and Environmentalist Mangalore), Dr. Sheedhar Pai (Prof. & Head, Dept. of Pharmacology, Manipal), Dr. Vasanth Kumar Shetty (Veterinarian & Regional Research Officer, Mangalore), and Prof. Krishna Bhat (Biostatistician, KSHEMA, Mangalore). The symposium was attended by over 180 delegates from Goa, Kerala and Karnataka.

NGSMIPS ranked 18th in the country by the NIRF

The NGSM Institute of Pharmaceutical Sciences, one of the constituent colleges of Nitte University was placed in the 18th position among Pharmacy colleges under Category ‘A’ declared by the National Institutional Ranking Framework (NIRF) under the Ministry of Human Resource Development (MHRD), Government of India for Pharmacy (Research and Teaching).

The ranking has been awarded from the overall recommendations arrived at by a Core Committee set up by MHRD, to identify the broad parameters for ranking various universities and institutions. The parameters broadly cover “Teaching, Learning and Resources”, “Research and Professional Practices”, “Graduation Outcomes”, “Outreach and Inclusive” and “Perception”.

Seminar on “Study and Work Opportunities Abroad”

The Institute – Industry Collaboration and Placement cell of NGSMIPS organized a seminar for students on “Study and Work Opportunities Abroad”, on 27th February 2016. The seminar dealt with procedures for applying to foreign universities for higher studies as explained by the resource person, Mrs. Priya, Manager of The Chopras, Mangalore. The students were also informed about the steps and procedures to be followed in visa procurement to

countries like UK, Australia, New Zealand, USA, Canada, Ireland, Singapore, Switzerland, and Malaysia. Mrs. Priya also explained application procedures and conduct of examinations such as GRE, GMAT, TOEFL, IELTS which was mandatory for the applicants to clear before seeking admission in Universities in the above countries.

‘Joint Alumni Meet 2016 - NGSMIPS & NMAMIT at Dubai’

The Nitte Education Trust and the Nitte University organized a Joint Meet for the alumni of NGSM Institute of Pharmaceutical Sciences and the Nitte Engineering College-NMAMIT on 19th February, 2016 at the Abraj Grand Hotel, Dubai. The function was attended by



Dr. S.Ramanand Shetty speaks at the Joint Alumni Meet in Dubai

200 alumni and their families. The Chief Guest, Dr. S.Ramanand Shetty, Vice Chancellor of Nitte University, in his address remarked that such reunions provide opportunities for keeping the alumni up to date with and assist the academic and research oriented developmental initiatives of their alma mater and should take pride in contributing by way of intellectual assistance. Dr. C. S. Shastry, Principal, NGSMIPS informed the alumni of the progress made by the college in the recent years and presented the future plans. He invited the attention of the alumni and requested their participation in realizing the objective of the college to establish the Nano-Science, CADD and psychopharmacological labs to facilitate advanced research. Dr. Ronald Fernandes, Professor, NGSMIPS expressed that events like these were important for both the institution and the alumni and helped to maintain good relationships that could benefit them. The alumni conveyed their willingness to contribute and partake in the progress and growth of their alma mater.

Guest lectures

The Department of Pharmacy Practice organized a guest lecture on March 10, 2016. Ms. Neerja Kumar,

Community Pharmacy, Pharmacy Educator & Consultant, Alberta, Canada was the speaker and in her discourse, she described the practice of Community Pharmacy in Canada. The lecture was attended by Pharm D, M.Pharm students and teaching faculty.

A guest lecture on 'Thomson Reuters Citation and Plagiarism' was organized by the Department of Pharmaceutical Chemistry on March 9, 2016. The resource person, Dr. Tanuj Kanchan, Associate Professor, KMC, Manipal explained at length the importance of the right ways of citing from various sources when preparing articles for publishing in journals. He also informed the audience on the various ways by which plagiarism was possible and the risks of predator journals.

Dr. Marina Koland, Professor, Dept. of Pharmaceutics, was invited as resource person at the ICMR sponsored national seminar on, "Advanced Pharmaceutical Technologies and Dosage Forms: Where does India stand in the current global context?", March 19, 2016, organized by the Department of Pharmaceutics, MCOPS, Manipal. She had delivered a lecture on, "Solid lipid nanoparticles: Nose to brain delivery in CNS disorders".

Students of NGSMIPS win prizes at Cultural and Sports competitions

Students of NGSMIPS have been a source of pride to the institution by bagging prizes in several cultural and sports competitions held outside as well as on campus recently.

The NGSMIPS team of boys and girls from B.Pharm and Pharm.D won the 1st Place in March Fast at the Third Inter Collegiate Athletic Meet, 2015-16, held on 13th February 2016 at Mangalore University Grounds, Konaje. The girls also bagged the women overall team championship as well as overall team championship. Some of the faculty of NGSMIPS also took part in various events and bagged many prizes.

NGSMIPS organized the 4th Nitte Kreedothesava 2016,

held on 23rd February 2016. The inaugural function was held at KSHEMA Auditorium and the Chief Guest for the function was Sri. Vishal Hegde, Pro-Chancellor (Administration), Nitte University and was presided over by Dr. M. S. Moodithaya, Registrar, Nitte University and the events were conducted at KSHEMA Ground, Deralakatte.

The NGSMIPS women team for both Throw ball & Volley ball bagged the runners up trophy at the Sixth Nitte Accolades 2015-16 held on 8th – 11th March 2016 at KSHEMA Ground, Deralakatte,.

Ms. Swathi K. of III B.Pharm won the first prize in Rangoli competition at the Anandotsava'16 held at NMAMIT, Nitte between 25th – 27th February 2016.

Mr. Pravas Lakhey Shrestha of Final Year B.Pharm secured the Mr. NET Title at the Inter N.E.T Best Physique 2016. This event was organized by NMAMIT at Nitte, Karkala on 10th March 2016.

The Cultural Day extravaganza named, 'Festin o Beats' 2016' was held on 15th March 2016 at KSHEMA Auditorium. Class wise competitions in various cultural programmes like Singing (Solo/Duet/Group), Dancing (Solo/Duet/Group), Fashion Show and Spot dance were conducted and later prizes were distributed to the winners in both sports and cultural events by the Principal, Dr. C.S. Shastry and Vice Principal, Dr. R. Narayana Charyulu.

Industrial Trip for Final Year B.Pharm

The students of final year B.Pharm visited pharmaceutical industries in Hyderabad from 17th to 22nd March 2016. The Industries included Yeluri Formulation Pvt. Ltd., and Mylan Laboratories Ltd. The educational tour proved to be very informative to the students who witnessed various processes that they are required to know as per their curriculum. They were accompanied by teaching faculty, Mr. Shanon Ben Mascarenhas and Mr. Srinivas Hebbar.



Sri Vishal Hegde lights the Inaugural Lamp



DEPARTMENT ACTIVITIES

DEPARTMENT OF PHARMACEUTICAL CHEMISTRY

RESEARCH PUBLICATIONS

Dr. B.C. Revanasiddappa, Asst. Professor

Novel Benzimidazole – Oxadiazole Hybrid Molecules as Promising Antimicrobial Agents. *Royal Society of Chemistry* 2016; Vol. 6: 8303-8316

Dr. Pankaj Kumar, Asst. Professor

Synthesis, Biological and Pharmacological Studies of some substituted pyrazolines derived from Aryloxy Acetyl Hydrazines. *Indian Journal of Heterocyclic Chemistry* Oct-Dec. 2015; Vol. 25: 137-140

Dr. Abhishek Kumar, Asst. Professor

Synthesis, antimicrobial and Cytotoxic activity of Novel 1,5 Benzodiazepine Derivatives. *Indian Journal of Heterocyclic Chemistry* Oct-Dec. 2015; Vol. 25: 161-164

Mr. Vijay Kumar M, Asst. Professor

1. Synthesis and antidiabetic evaluation of novel pyrazolone derivatives. *Indian Journal of Heterocyclic Chemistry* Oct-Dec. 2015; Vol. 25: 169-172
2. Correlation of Antioxidant Principles with Cardioprotective Activity of Madhuca longifolia (Koenig) Leaves on Isoproterenol Induced Myocardial Infarction, *Research Journal of Pharmaceutical, Biological and Chemical Sciences* Jan – Feb 2016; 7(1) : 971-977

PAPERS PRESENTED AT CONFERENCES

Dr. Jainey P. James, Asst. Professor, presented a poster on her research paper entitled, “Microwave assisted synthesis of pyrazolines bearing isonicotinyl hydrazides as antitubercular, anticancer and antioxidant agents” at the 5th International Convention of Association of Pharmacy Professionals from 22nd to 23rd January 2016 organized by Anna University, Tiruchirappalli, T N.

DEPARTMENT OF PHARMACEUTICS

RESEARCH PUBLICATIONS

Mr. Jobin Jose, Asst. Professor

Prolonged drug delivery system of an antifungal drug by association with polyamidoamine dendrimers, *International Journal of Pharmaceutical Investigation* 2016; 6(2): 123-127

PAPERS PRESENTED AT CONFERENCES

Mrs. Sneh Priya, Asst. Professor, presented a poster entitled, “A study of Quetiapine Fumarate nanoemulsion for delivery in to the brain through intranasal route” at the 5th International Convention of Association of Pharmacy Professionals from 22nd to 23rd January 2016 organized by Anna University, Tiruchirappalli, T N.

DEPARTMENT OF PHARMACOGNOSY

RESEARCH PUBLICATIONS

Dr. Divya Jyothi, Asst. Professor

Formulation and Evaluation of an Herbal Anti-inflammatory Gel containing Trigonella Foenum Greacum Seed Extract. *International Journal of Pharmacy and Pharmaceutical Sciences* 2016; 8(1): 41-44

PAPERS PRESENTED AT CONFERENCES

Dr. Divya Jyothi, presented a poster entitled “Antidiabetic potential of herbal capsules containing trigonella foenum-graecum seed extract” at the 5th International Convention of Association of Pharmacy Professionals from 22nd to 23rd January 2016 organized by Anna University, Tiruchirappalli, T N.

DEPARTMENT OF PHARMACY PRACTICE

RESEARCH PUBLICATIONS

Mr. Rajesh K.S., Asst. Professor

Preliminary Photochemical Investigation and Anti-venom Activity of coix lacrymajobi root extract against daboia russelli venom-induced myonecrosis. *Asian Journal of Pharmaceutical and Clinical Research* 2016; Vol 9(1)

MEDICINE MISUSE AND ITS CONSEQUENCES!

Dr. Murali Badanthadka

Deputy Director, NUCARE

The use of medicine has become an integral part of life in the current generation. Needless to mention, presently medicine use starts before conceiving a baby for various reasons. Once pregnancy is confirmed, a series of medicines are used for improving the health of the mother or the new born. Many a time unnecessary multivitamins, calcium and iron supplements are given to the pregnant mother, which otherwise is available in fruits and in a healthy diet. After the delivery, again medicine is given in one form or the other like - vaccinations, booster doses, maintenance doses, preventive doses so on and so forth. In other words, journey towards the use of medicine starts before conception by the parents and then the baton is transferred to the baby after the delivery. Thereafter, medicines are used in one form or the other till once last breath by making frequent visits to hospitals. In sharp contrast, our own grand parents lived healthy or disease-free-lives without using a single pill till the end! Plethora of examples are available in the society to strengthen this statement. Our curious mind makes us to think that, since we carry the same genes of our grandparents; why should there still be so many complications? Where is the missing link? What was that our parents or grandparents had which we don't have? Are we missing something compared to our grandparents? And that could be the reason for frequent use of medicine. This questions our daily habits particularly food for the belly and the brain. Are we taking the right food at the right time in the right way? Our Grandparents did not use milk packets, fast food items, cold storage foods etc. Similarly, they are not exposed to electronic gadgets, internet, WhatsApp, Facebook either. Misuse of these facilities provokes an individual to self-medicate and take medicine without having knowledge about its actual effect on the body. Undoubtedly our life has transformed to a greater extent at the cost of a healthy life.

The billion dollar question is, how to maintain the precious healthy life which we received as a gift? What do we have to do to maintain a healthy life?

In the present scenario, many drugs are used in different systems of medicine like – Allopathic, Homeopathic, Ayurvedic, Siddha and Unani. Essentially all these systems of medicine help to correct altered physiology (pathophysiology) and bringing physiology back to normal. Use of one system of medicine within the dose range is most acceptable. However, taking a polypharmacy approach to treat any condition or disease is a disaster because of possible drug interactions, which we don't know about. On the contrary, overuse of medicines particularly antibiotics and multivitamins is a big question of concern in public health. This happens because of two main reasons: a) Access to internet information and doing self-medication without knowing about the drug or its action b) Having a poor opinion of the doctor if he is not prescribing costly antibiotics. Almost daily we could see or read about the development of drug resistance that results in difficulty

in treating patients. Because of this, treating infectious diseases has become a big challenge and question of concern in the clinical scenario. Now microorganisms also know how to deal with drugs which they come across. They develop systems either not to absorb these agents or metabolise absorbed agents so quickly that they are not harmed. Needless to say, microorganisms are becoming smarter with time because they are already exposed to a higher concentration of the drug or its metabolites from the environment. This happens because, all the drugs or chemicals consumed by humans or animals goes to the environment in one form or the other. For example, in a situation where parents are giving an unnecessary antibiotic course to their loved ones when they catch a cold or fever. In reality, these kids get pyrexia probably due to dehydration, lack of rest or are over stressed due to school activity.

Considering the evolution theory, our genes are evolved to a greater extent with time. In parallel, India has become the hub for diabetes and cardiovascular related complications. Needless to mention that, compared to the genes of a western individual, an Indian's gene requires heavy eating and hard working. If one looks at the current change in life-style and copy of western practices, our genes fail to cope-up with the changed scenario. This could be the major reason for development of diabetes and diabetes mediated cardiovascular complications. Unnecessary overuse of cholesterol lowering agents is the best example in the current scenario. Majority of the doctors prescribe statins for controlling elevated cholesterol or triglyceride levels. They don't even think of suggesting a change in life-style practices or in food habits. Many a time correcting food habits with regular exercise controls these levels. After all, elevated cholesterol level alone is not considered dangerous. It is dangerous only in association with other risk factors like – smoking, increased alcohol intake, irregular diet, stress etc. Instead of correcting ourselves from doing these mistakes, we are over doing the same mistake by taking all necessary precautionary medicines including multivitamins, antacids etc. This results in increase of prescription length and cost burden to the patient or health care system. Instead of self-medication, it is reasonable to believe that, some of these measures will either help to prevent or mitigate various complications such as:

- a) Correcting the life style by improving the food habits intended for the belly and the brain.
- b) Doing optimum exercise and giving adequate rest to the body and mind.
- c) Making judicious use of medicine only after consultation with health care individuals

After all, after stressful work both body and mind demand maintenance like a vehicle. Unfortunately we ignore these facts and put only vehicles for service without fail, which we know we can purchase again!

BIOLOGICS, BIOSIMILAR & INTERCHANGEABLE BIOLOGICALS: REVOLUTIONIZING THE PRACTICE OF MEDICINE

Mr. Prashant Nayak

Assistant Professor

Department of Pharmaceutics



Biologics or biopharmaceuticals are a highly-effective class of medicines that are based on naturally occurring proteins and produced using living cells. They are much larger than the chemically-synthesized small molecule medicines that still represent the majority of medicines.

While biologics have transformed the practice of medicine, they are contributing to a growing crisis that is threatening both the sustainability of healthcare systems and patient access. Biologic medicines are often the only available treatments for life-threatening conditions such as cancer and rheumatoid arthritis and as a result, the global market is growing at least twice as fast as that for small-molecule medicines. By 2017, it is estimated that seven of the top 10 pharmaceuticals worldwide will be biologics and 30 percent of the pharmaceutical industry pipeline is comprised of biologics¹.

The Patient Protection and Affordable Care Act (Affordable Care Act), signed into law by President Obama on March 23, 2010, amends the Public Health Service Act (PHS Act) to create an abbreviated licensure pathway for biological products that are demonstrated to be “biosimilar” to or “interchangeable” with an FDA-licensed biological product. This pathway is provided in the part of the law known as the Biologics Price Competition and Innovation Act (BPCI Act). Under the BPCI Act, a biological product may be demonstrated to be “biosimilar” if data show that, among other things, the product is “highly similar” to an already-approved biological product².

A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.

Alternative or non-comparable”, versions of existing

products that have not been approved using the comparability method used in highly regulated markets, are – by definition -- not biosimilars.

Biosimilars are approved biologics with comparable quality, safety and efficacy to a reference product. They are approved via stringent regulatory pathways (in highly regulated markets such as the EU, US, Japan, Canada and Australia) following loss of exclusivity of their originator reference products.

Biosimilar medicines offer more choices at affordable prices thereby increasing patient access without increasing overall spending. Furthermore, utilization of biosimilars can free up resources that can then be used to fund new medical breakthroughs. In addition, competition motivates producers of patent-protected medicines to come up with genuinely innovative products – driving the ‘virtuous circle’ of innovation. With over USD 70 billion worth of biologics coming off patent by 20183.

An interchangeable biological product is biosimilar to an FDA-approved reference product and meets additional standards for interchangeability. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.

FDA requires licensed biosimilar and interchangeable biological products to meet the Agency’s rigorous standards of safety and efficacy.

Biologics have an inherent variability because they are produced in living organisms. In addition, biologic medicines undergo changes when their manufacturing process is changed, in fact no two batches of the same biologic can be considered identical. ICH Comparability Guidelines in 1996 Forms the basis for regulatory guidelines used in the evaluation of biosimilars⁴.

A biosimilar is approved if and only if, it is so similar to the originator biologic product that statistically you can’t tell the two apart in terms of ability to treat the disease, safety profile and overall quality: the three things that matter the most to doctors and patients.

References:

1. Biosimilars in rheumatology: the wind of change Christian Schneider, Ann Rheum Dis 2013 72: 315-318
2. U.S. Food and Drug Administration.
3. Evaluate Pharma, February 2013, Internal Sandoz Analysis
4. ICH Comparability Guidelines

ONE DAY SYMPOSIUM ON “ANIMALS IN BIOMEDICAL RESEARCH : THE CHANGING PERSPECTIVES”



CULTURAL DAY CELEBRATIONS

