



PHARMA MONARCH

DEPARTMENT OF PHARMACEUTICS - NEWS LETTER

An Official Publication of

DEVAKI AMMA MEMORIAL COLLEGE OF PHARMACY

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FROM THE EDITOR'S DESK

A warm welcome to all the members and Readers!

We the editorial committee have a great privilege on releasing the Third issue of "Pharma Monarch", in this year.

Dear friends, our newsletter has a sole purpose of making you equipped and informed about the current happenings in our Pharmaceutics Department, and highlights the progress and activities.

I am sure this Newsletter will give an ample opportunity to the students and faculty to bring their talents and contribute significantly to the profession. And glad to inform you that in this edition, we have very informative article on the importance of the Design of experiments which is relevant to improve the formulation development in Pharma sector.

As an Editorial Head, I take this opportunity to congratulate the editorial board members and students for their efforts made and the contributions given to bring out this newsletter, a compendium of all the blooming ideas which constantly surface within the department and wish them all the best for their future.

And I extend my sincere thanks to our beloved Management and Principal for generous support and grant permission to release this issue which will serve as a platform for today's Pharmacist to share the knowledge and recent advances pertaining to the profession.

In the ever-changing scenario, we do believe this Newsletter would be a good source of reliable information and use.

I hope you have enjoyed reading previous issues and I am sure that you will appreciate reading this edition as well.

We shall be pleased to receive feed-back from the readers for improving the contents as well as usefulness.

Awaiting your observations and comments.

Have A Great and Happy Reading!

Best Regards,
Prof. Dr. R. Nethaji,
Editor-in- Chief

IN THIS ISSUE

- ☞ Department Activities
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- ☞ Upcoming Pharma Events

"No one should go without their medication. If you are a Medicare beneficiary, do not leave the Pharmacy counter without your prescriptions"~ Mike Leavitt



In the remembrance of
Shri. K.V. Sankaranarayanan
(01.01.1948 - 12.07.2013)
Founder, Devaki Amma Memorial Institutions

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DEPARTMENT ACTIVITIES

RESEARCH ACTIVITIES

Completed Research Projects

The Department has successfully completed the following research projects of PG and UG students recently and they are listed as follows:

Project Title	Students Name	Guided by
Formulation and Evaluation of Mucoadhesive Tablets of Pantoprazole Sodium	Ms. Neema K Ramesh	Dr. R. Nethaji
Preparation and Characterization of Nanoparticles containing Cefuroxime Axetil	Mrs. Vandana G	Dr. R. Nethaji
Formulation and <i>In-vitro</i> Characterization of Ranitidine Hydrochloride Loaded Floating Microsphere for the Treatment of Gastric Ulcer	Mrs. Aswathi U P	Mr. P. Manikandan
Formulation and Evaluation of Emulgel containing <i>Chromolaena Odorata (L) King and Robins Leaves Extract</i>	Ms. Swetha S	Mr. P. Manikandan
A Review on Antimicrobial and Antioxidant Properties of <i>Terminalia Bellerica</i>	Anjala Shirin PK, Athira EN, Renila MK & Vyshnav K	Mrs. Vidya S
Novel Drug Delivery Systems - A Review	Farsana Nasri, Nasreena Ettuveetil, Nijitha K Rajan & Rinjuna Reenas	Mrs. Anjali Narayanan
Minimization of Toxic Effect of Tobacco Smoking by Aqueous Absorption Method by Designing and Fabricating A Novel Equipment	Haritha E, Shahid Ali & Jumana Thasneem KT	Mrs. Binjusha E

Ongoing Research Projects

The department is inspired by identifying future needs of resources to be felt by fast developing academics and scientific research in the area of Pharmaceutics. The following research title in the pipeline:

Project Title	Students Name	Guide by
Development and Evaluation of Mucoadhesive Tablet of Esomeprazole	Mr. Shakir Ali KP	Dr. R. Nethaji
Preparation and Characterization of Repaglinide Transdermal Patch	Mrs. Farseena	Dr. R. Nethaji
Formulation and Characterizations of <i>Averrhoa Carambola</i> Fruit Extract Loaded Gel	Mr. Rashid Mon	Dr. R. Nethaji

RESEARCH PUBLICATIONS

The faculty members are encouraged to involve in research activities. They too involved in research and carried out various activities, which are evidenced by their paper publications and communication in reputed international journals.

Dr. R. Nethaji *et al.*

Development and Evaluation of Gastro-Retentive Cefadroxil Floating Microspheres, *World Journal of Pharmacy and Pharmaceutical Sciences*, Vol.8, Issue 7, 2019, 932-948.

Mr. P. Manikandan *et al.*

Preparation and *in-vitro* Evaluation of Diclofenac sodium Transdermal Patch, *Saudi Journal of Medical and Pharmaceutical Sciences* (Communicated).

Formulation and *In-vitro* Characterization of Ranitidine Hydrochloride Loaded Floating Microsphere for the Treatment of Gastric Ulcer, *Asian Journal of Pharmaceutical and Clinical Research* (Communicated).

Formulation and Evaluation of Emulgel containing *Chromolaena Odorata (L)* King and Robins Leaves Extract, *International Journal of Pharmaceutical Sciences and Research* (Communicated).

CONFERENCES PARTICIPATION & PRESENTATION

Our teaching faculties and M. Pharm students were sponsored to take part as delegates in various National and International conferences to update the current trends and developments in the field of their specialization. It is evidenced by their participation as given below.

Mrs. Anjali Narayanan, Asst. Professor, and our Post Graduate students **Ms. Aiswarya M, Ms. Anju T, Mrs. Harishma CM, Ms. Gayathri CP & Ms. Sruthi NK**, have participated as delegate in one day Symposium on "Glimpses of the Indian Pharmaceutical Industry: from Global Perspectives to Local Reality" organized & conducted by National College of Pharmacy, Kozhikode, held on 7th January 2019.

Our Post Graduate students **Mr. Shakir Ali KP & Mr. Rashid Mon**, have actively participated and presented their research poster in Two Days National Conferences on "Drug Discovery and Development: A Focus on Newer Technologies", organized by Department of Pharmaceutics, SRM College of Pharmacy, SRM Institute of Science and Technology, Kattankulathur, held on 7th & 8th February 2019.

Mrs. Binjusha E, Asst. Professor, has participated and presented her research papers "Formulation, Development, Evaluation and Optimization of Proniosomal Transdermal System of Antihypertensive Drug" during International Conference on "Clinical Pharmacy and Pharmaceutical Technology", Organized by Jamia Salafiya Pharmacy College, Malappuram, held on 16th February 2019.

Mrs. Anjali Narayanan, Asst. Professor & **Mrs. Neethu K**, Lecturer, have participated as delegate and presented a poster on "Formulation and Evaluation of Sodium Caseinate Coated Erlotinib Loaded Zein Nanoparticles for Cancer Therapy", in a National Seminar on "Contemporary Advances in Pharmaceutical Sciences" Organized by Prime College of Pharmacy, Palakkad, held on 23rd February 2019.

Mr. P. Manikandan, Asst. Professor, has participated as delegate in a workshop "Hands on training on Materials Science Suite Simulation Technology in Pharmaceutical Formulation Development, Schrodinger Material Science Suite Software" organized and conducted by Department of Pharmaceutics, PSG College of Pharmacy, Coimbatore, held on 1st & 2nd March 2019.

Our PG students **Mr. Shakir Ali KP & Mr. Rashid Mon**, have participated as delegate in an international seminar on "Current Trends in Herbal Drugs and Pharma Industry", organized by Kerala Pharmacy Graduates Association, held on 29th & 30th March 2019 at Govt Medical College, Trivanthapuram.

RESEARCH PAPER AWARD

Ms. Teena Thomas, Lecturer, has participated and presented a research paper entitled "Formulation of Coconut Endocarp Gel and Evaluation of its Antimicrobial Activity" and has bagged best poster presentation award in the "International Conference on Clinical Pharmacy and Pharmaceutical Technology", Organized by Jamia Salafiya Pharmacy College, Malappuram, held on 16th February 2019. She has presented this poster as a part of her research work. Her presentation was very well appreciated by participants and faculties, which is a memorable moment for our Department and College.

FACULTY ACHIEVEMENTS

Our department congratulate, **Mr. P. Manikandan**, Asst. Professor, who has been awarded Degree of Doctor of Philosophy in Pharmaceutics for his thesis entitled "Development and Characterization of Flutamide Loaded Matrix Tablets for the Treatment of Prostate Cancer", from Karpagam University, Coimbatore, Tamil Nadu, under the esteemed guidance of Prof. Dr. R. Sundara Ganapathy. He has over 12 years of teaching and research experience and published more than 12 research articles in various peer reviewed national and international journals. He has participated in various National conferences and presented more than 10 research articles.



NEW FACE

Mrs. Mishahal T. M., has joined in our department on 16th July 2018. She has completed her B. Pharm, at JDT Islam College of Pharmacy, Calicut and M. Pharm from College of Pharmaceutical Sciences, Govt. Medical College, Calicut. Her research interests are Targeted drug delivery systems, Nanofibrous scaffold for skin tissue regeneration in burns and Natural biological active compounds.



Mrs. Neethu K., has joined in our department on 23rd July 2018. She has earned her B. Pharm, from JDT Islam College of Pharmacy, Calicut and M. Pharm from College of Pharmaceutical sciences, Govt. Medical College, Thiruvananthapuram. Her research interests include anti-cancer formulations, Nanoparticles drug delivery systems, Natural bioactive compounds and Novel drug delivery systems.



PHARMA ARTICLES

HOW DESIGN OF EXPERIMENTS CAN IMPROVE FORMULATION DEVELOPMENT

Prof. Dr. R. Nethaji, Dept. of Pharmaceutics

Mixtures can be defined as a combination of ingredients where the response is a function of the proportion, rather than the amounts, of the ingredients. Formulation development often boils down to determining the optimum combination of ingredients in a mixture, which can make the difference between success and failure in many diverse fields of research, such as materials, pharmaceuticals, adhesives and coatings. The traditional approach to experimentation changes only one process factor at a time (OFAT) or one component in a formulation. However, with this approach, it's easy to overlook interactions of factors or components, a likely occurrence in developing formulations.

Statistically-based design of experiments (DOE) provides validated models, including any significant interactions, that make it possible to confidently predict response measures as a function of the inputs. The payoff is the identification of 'sweet spots' where you can achieve all product specifications and processing objectives. Industrial experimenters typically turn to two-level factorials as their first attempt at DOE. These designs consist of all combinations of each factor at its high and low levels. With large numbers of factors, only a fraction of the runs needs to be completed to produce estimates of main effects and simple interactions. However, when the response depends on proportions of ingredients, such as in chemical or food formulations, factorial designs don't work well because they focus on the absolute amounts of the ingredients while it's the proportions that count in mixtures.

To begin to explain how DOE can optimize a formulation, let's look at the example of how goldsmiths from ancient times have mixed gold with a small amount of copper to create a lower melting point solder that allowed them to connect intricately designed wire to the backbone of bracelets and necklaces. Even though copper melts at a higher temperature than gold, when mixed together, these two metals melt at a lower temperature than either one alone. One could never predict this beneficial combination of ingredients without actually mixing them together for experimental purposes.

The experiment described in the above table was performed to determine the temperature at which various mixtures of copper and gold begin to melt. The input values are expressed on a coded scale of zero to one, which statisticians prefer for modeling mixtures. The replication designated in the descriptor columns by ditto marks provides a measure of pure error that quantifies the inevitable variations in blending the materials and measuring the responses. The equation below was fitted from the experimental data by using least squares regression to plot the predicted response of any given composition of a gold-copper mixture. It models the melt point as a function of the two ingredients, gold and copper, symbolized by x_1 and x_2 respectively.

$$\text{Melt point} = 1044 x_1 + 107_1 x_2 - 543 x_1 x_2$$

This mixture model, developed by Henri Scheffé (1958), is derived from the second order polynomial for process response surface methods (RSM), also known as a quadratic equation. The mathematical details are spelled out in the accompanying reference. Two things distinguish Scheffé's polynomial from that used for RSM. First, there is no intercept. Normally this term represents the response when factors are set to zero - set by standard coding to their midpoints for process modeling. However, the constituents of the mixture are coded on a zero-to-one scale so it doesn't make sense to set all components to zero. Although this experiment requires the control of two inputs - gold versus copper, only one X axis is needed on the response surface graph because of the complete inverse correlation of one component with the other. Another difference from RSM is that the formulation equation lacks squared terms. This is because the $x_1 x_2$ term captures the non-linear blending behavior.



Here are some general guidelines for setting up a formulation experiment and analyzing the results, starting with the Scheffé equations for predicting the response from two components. The hat (^), properly known as a circumflex, over the letter y symbolizes that we want to predict this response value. The β (beta) symbols represent coefficients to be fitted via regression.

DOE software has the potential to eliminate the need for statistical expertise on the part of the users by walking the user through the complete process. For example, the software prompts the user to enter the factors and responses and select the type of experiment while providing information that will help the user pick the best type. The software will then generate a randomized list of experimental runs. As each run is completed in the order given, the results are entered into the software. The software then generates tabular and graphical data that helps define the region where quality product is produced.

As an example of how these methods are used in the real world, VerGo Pharma Research Laboratories Pvt. Ltd was recently hired by a generic pharmaceutical manufacturer to develop a bioequivalent with different polymorphic forms for an anti-depressant drug that had been patented in crystalline form only. Bioequivalence requires that a drug be pharmaceutically equivalent and that it be delivered at the same rate and same level of bioavailability so that its efficacy and safety can be expected to be the same as the original product. Using conventional one-factor-at-a-time testing methods, it would have taken several years to determine the right combination of inactive ingredients to achieve the required *in-vitro* dissolution and *in-vivo* plasma drug profile. VerGo compressed this development process to only four months by using Design-Expert software for DOE to reduce the number of tests required to determine the effects of inactive ingredients on bioavailability in both fed and fasting conditions. The software selected values for a total of 20 runs with the diluent ranging from 0 to 194 milligrams per tablets and the two disintegrating agents ranging from 0 to 80 mg per tablet. The experiment included 5 replicates which were used to measure the reproducibility of the results.

After running the experiments, Formulation Development for VerGo, entered the results into the DOE software along with the ideal values for the dissolution rate at each pH value/time point pair. These dissolution rate values were selected to match the values achieved by the original drug based on the assumption that if the proposed generic performs the same as the original drug in the lab it is likely to also perform the same in clinical testing. The software generated a prediction of the concentration of each variable required to meet all of the target dissolution values. VerGo's scientists then prepared a new batch of tablets with the recommended concentration values. These tablets matched the desired dissolution profile within +/- 5%, which is within the acceptable margin of error.

VerGo then prepared a larger batch of tablets with this formation for use in clinical testing with volunteer patients. The patients took the drugs in both fed and fasting conditions, and the concentration of the drug in their blood was measured at set intervals. The results showed that VerGo was the first company that was able to match the blood concentration levels of the active ingredient to the original pharmaceutical over the full time profile within an acceptable margin of error. The application provides a good example of how DOE can compress the development process for formulation development by identifying potential effects caused by interactions between ingredients.

References:

1. Mark Anderson and Pat Whitcomb, "A Primer on Mixture Design: What's In It for Formulators?," Stat-Ease, 2009.
2. John Cornell, "Experiments with Mixtures: Designs, Models, and the Analysis of Mixture Data," Wiley, 2002.

PHARMA COMPANIES WORLD TOP 10 PHARMACEUTICAL COMPANIES

Pharmaceutical industry is undergoing a tremendous deal of change. Many pharmaceutical companies, who are providing the better products. The Pharma industry is one of the most sought after, and flourished industries. As the pharmaceutical drug manufacturers are one of the reasons for the economic well-being of a nation. On the other hand, the Pharma industry is responsible for the economic development. That is the main reason for both research and development of newer and better products for various kinds of diseases. Here, listed the top 10 pharmaceutical companies in the world:

Johnson & Johnson: It's one of the top pharmaceutical manufacturers across the globe. It is a household name, known for providing the pharmaceutical and consumer goods across a range of industries to its consumer healthcare division. This company has over 182 marketed drugs, with market leaders in Hepatitis C, HIV/AIDS, Arthritis, and digestive conditions. Johnson & Johnson brings the superior medical products to advance the health and well-being of people around the world.



Novartis: It is a global healthcare company based in Switzerland. It provides solutions to address the evolving needs of patients across the globe. The pharmaceutical company strives for the growth areas of healthcare. It specializes in the development of biological therapies and also contains specialists divisions for prescription pharmaceuticals, eye care and generics and bio-similar. Its current top grossing pharmaceutical drugs include Gleevec for cancer and Gilenya for multiple sclerosis.

Roche: Roche is one of the top companies in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company that provides medicine in oncology, immunology, ophthalmology, neuroscience, and infectious diseases. It is also a leader in diabetes management and in vitro diagnostics and tissue-based cancer diagnostics. Its best selling drugs include cancer treatments MebThera, Avastin, Herceptin and Xeloda.

Pfizer: The popular pharmaceutical manufacturer across the globe develops and produces a wide range of vaccines for therapeutic areas including oncology, cardiology, and immunology. The products of this company are meant to treat an array of illness across a range of therapeutic areas. The sales of vaccine keep Pfizer among the world's biggest pharmaceutical companies. The company also acquired a leading sterile injectables company Hospira in a \$17 billion deal that enhances the portfolio of generics and bio-similar products.

Sanofi: It is the French pharmaceutical company that specializes in prescription and over the counter (OTC) medicines in seven major therapeutic areas such as cardiovascular, central nervous system, diabetes, internal medicine, oncology, thrombosis and vaccines. The product named the diabetes blockbuster Lantus remains the source of much of the company's turnover.

Merck: It's provides the best medicines and it has received FDA approval for insomnia treatment Belsomara and Zerbaxa. The research and development of Merck has led to the approval of more new drugs than any other company. Their specialist therapeutic areas include oncology, neurodegenerative diseases, fertility and endocrinology. This company provides leading innovations and solutions for the people to make them healthier.

Glaxo Smith Kline: GSK always takes on some of the world's biggest healthcare challenges. It delivers a sustainable business and health benefits to patients through its high quality products. GSK develops a broad range of products in pharmaceuticals, vaccines and consumer healthcare, and has leading products across various therapeutic areas including cardiovascular and respiratory disease, asthma, cancer, infections, mental health, diabetes and digestive conditions. It is one of the best companies to have a good growth in emerging markets. GSK applied for regulatory approval in 2014 for the first malaria vaccine and currently has one of the leading candidates for an Ebola vaccine undergoing clinical trials.

AstraZeneca: It's provides medicines for major diseases including cancer, gastrointestinal infection, cardiovascular disease, neurological disorders, respiratory disease and inflammation. Top selling products of AstraZeneca include cholesterol treatment Crestor, provides Pharma solutions for a strong pipeline of oncology therapies.

Bayer: This Company manufactures and produces the high quality medicines and thus, it contains the best portfolio of more than 5000 products. This company also operates in consumer healthcare and agricultural chemicals in addition to human and veterinary pharmaceuticals. The top five drugs include anticoagulant Xarelto, eye medicine Eylea, cancer drugs Stivarga and Xofigo, and pulmonary arterial hypertension drug Adempas.

Gilead Sciences: US Biopharmaceutical Company is known for producing antivirals, a solid commercial portfolio of life-saving drugs in cardiovascular and respiratory therapies. It has gained the place in the top ten lists above several big Pharma names. This company provides the medicines for HIV/AIDS, cancer, liver disease and cardiovascular disease.

(Source: <https://www.pharmaceutical-tech.com/articles/top-10-pharmaceutical-companies-in-the-world>)

UPCOMING PHARMA EVENTS.....

- ⇒ Indian Pharma Expo (IPE) 2019, to be held on 16th-18th July 2019, at Pragati Maidan, New Delhi.
- ⇒ IASTEM- 687th International Conference on Medical, Biological & Pharmaceutical Sciences (ICMBPS), 23rd - 24th September, 2019, Chennai.
- ⇒ 4th International Conference on Innovations in Pharmaceutical Sciences (ICIPS 2019), 9th-10th August 2019, at Guru Nanak Institutions Technical Campus, Hyderabad.
- ⇒ 71st Indian Pharmaceutical Congress (IPC), 20th - 22nd December 2019, at Sri Ramachandra Institute of Higher Education and Research, Porur, Chennai.



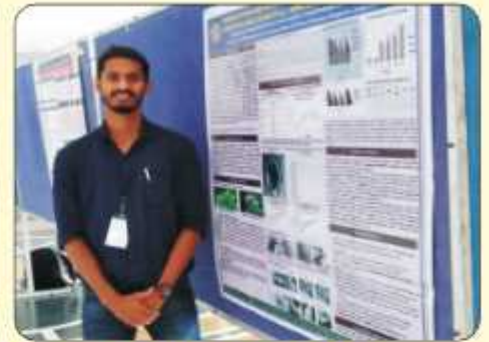
GLIMPSES OF DEPARTMENT ACTIVITIES



Symposium Participation
(Rendezvous - 2019)



M. Pharm Students Presenting Research Posters at SRM College of Pharmacy



At Glance of Research Presentation
(JSPC Pharmacon- 2019)



Poster Presentation
(Pharma Conclave -2019)



Workshop Participation & Training



Research Poster Presentation



Best Poster Award
(JSPC Pharmacon - 2019)

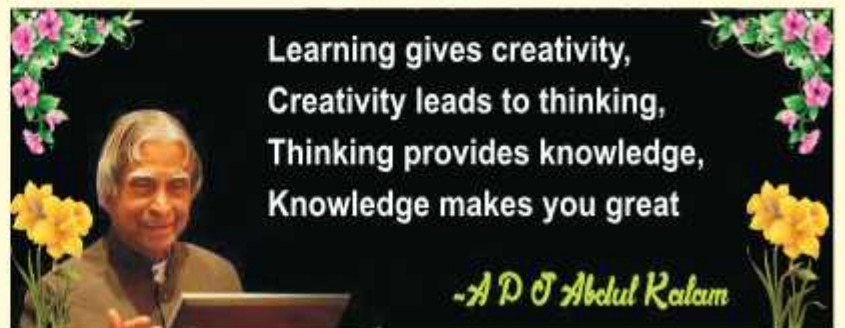


Doctoral Award

"Research is creating new knowledge" ~ Neil Armstrong

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Learning gives creativity,
Creativity leads to thinking,
Thinking provides knowledge,
Knowledge makes you great

-A D O Abdul Kalam

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