University Institute of Pharmaceutical Sciences
PANJAB UNIVERSITY

CHITKARA UNIVERSITY

National Symposium-cum-Workshop
on

Contemporary Trends, Tools and Techniques in Pharma Quality by Design (QbD): From Conceptualization to Implementation

20-21 April 2023

Abstract Book

Organizers

University Institute of Pharmaceutical Sciences
PANJAB UNIVERSITY

CHITKARA UNIVERSITY

Sponsors

tynor

CALRAX HEALTHCARE PVT. LTD.

SB LIFESCIENCES PVT. LTD.
(A WHO-GMP & ISO 9001 : 2015 Pharmaceutical Manufacturing Company)

NITIKA

jmp STATISTICAL DISCOVERY

National Symposium-cum-Workshop

on

Contemporary Trends, Tools and Techniques in Pharma Quality by Design (QbD): From Conceptualization to Implementation

20-21 April 2023

Organizers

University Institute of Pharmaceutical Sciences (UIPS)

Chitkara College of Pharmacy (CCP)

Abstract Book designed and formatted at Glostem Private Limited

SYMPOSIUM PROGRAM
Venue: Golden Jubilee Seminar Hall, Panjab University Campus

Day 1: Thursday, 20th April 2023

Time	**Activity / Expert Talk**
08:00 to 08:45 a.m.	**REGISTRATION**
09:00 to 10:00 a.m.	**Inauguration** Lighting of Lamp PU anthem Welcome address: Professor Indu Pal Kaur About the Symposium-cum-Workshop: Professor Bhupinder Singh Bhoop Presidential remarks: Professor Renu Vig Release of the Sympoium Abstract Booklet Words of Gratitude: Professor Thakur Gurjeet Singh
10:00 to 11:00 a.m.	**Keynote Address on** ***Pharmaceutical Product Development and Manufacturing under QbD Framework*** Dr Gautam Samanta Vice President & Head, QbD & Tech Transfer, Cipla Ltd., Mumbai
11:00 a.m.	***Inaugural Tea***
SESSION	**Vital Fundamentals of Pharma QbD**
11:40 a.m. to 12:20 p.m.	Professor Harish Dureja Head, Department of Pharmaceutical Sciences; Director, Centre for IPR Studies & Professional Consultancy Cell; Maharshi Dayanand Univ., Rohtak, Haryana ***Design of Experiments (DoE): Concepts and Implementation***
12:20 to 12:45 p.m.	Professor Daisy Arora Khurana Professor & Academic Head, Department of Pharmacy, Panipat Institute of Engineering & Technology, Panipat, Haryana ***QbD-Enabled Development of Novel Drug Delivery system: Case Studies***
12:45 to 01:05 p.m.	Dr Poornima Tiwari Deputy Manager, R&D (QA), Nectar Lifesciences Ltd., Punjab ***Quality Risk Management (QRM): A Quintessential Element of Pharma Quality by Design (QbD)***
01:05 to 01:35 p.m.	***Consolidation and Q & A Session*** Professor Bhupinder Singh Bhoop, Session Chair Emeritus Professor, Chitkara University, Punjab
01:35 p.m.	***Lunch***
02:15 to 05:00 p.m.	Dr Muralidhara Anandamurthy JMP, Bengaluru, Karnataka ***QbD/ DoE Workshop using JMP Software***
05:00 to 06:00 p.m.	***Poster Sessions & Evaluations***

SYMPOSIUM PROGRAM
Venue: Golden Jubilee Seminar Hall, Panjab University Campus

Day 2: Friday, 21st April 2023

Time	**Activity / Expert Talk**
SESSION	**Diverse Applications over Pharma Product Life Cycle**
09:00 – 09:40 a.m.	Dr Asha Patel Associate Professor, Pharmaceutics Department, Parul Institute of Pharmacy, Parul University, Vadodara, Gujarat ***Application of Multivariate Tools and Chemometric Techniques for QbD-Enabled Pharmaceutical Product Development: Case Studies***
09:40 – 10:10 a.m.	Dr Gautam Samanta Vice-President, Cipla Ltd., Mumbai, Maharashtra ***Optimization and Scale-up of Active Pharmaceutical Ingredients using QbD, Modeling and Simulation***
10:10 – 10:35 a.m.	Professor Sachin Kumar Singh School of Pharmaceutical Sciences, Lovely Professional University, Phagwara, Punjab ***Role of QbD in Solidification of Liquid Formulations***
10:35 – 11:05 a.m.	***Tea***
11:05– 11:30 a.m.	Dr Teenu Sharma Assistant Professor, Chitkara College of Pharmacy, Rajpura, Punjab ***Analytical QbD: Application of QbD in Analytical Method Development***
11:30 – 12:20 p.m.	Professor Bhupinder Singh Bhoop Emeritus Professor, Chitkara University, Punjab ***Pharma QbD during Product Life Cycle: Vital Considerations & FAQs***
12:20 – 1.20 p.m.	***Panel Discussion and Q & A Session*** Dr Gautam, Prof Bhoop, Prof Vandana, Prof Indu Pal Kaur & Dr Muralidhara
01:20 p.m.	***Lunch***
02:20 to 05:00 p.m.	**VALEDICTORY SESSION**
02:20 – 03:20 p.m.	Valedictory Keynote Talk on ***Nano Formulation-by-Design: Translational Case Studies*** Professor Vandana Patravale Professor of Pharmaceutics, Department of Pharmaceutical Sciences & Technology, Institute of Chemical Technology, Mumbai
03:20 to 05:00 p.m.	Valedictory Function & Group Photograph Opening Remarks: Professor Bhupinder Singh Bhoop ***Presidential Remarks: Professor Archana Mantri, VC, Chitkara University*** Paper Presentation Awards Words of Gratitude

Symposium Organizers'

Patrons

Prof Renu Vig, Vice Chancellor, Panjab University, Chandigarh

Prof Archana Mantri, Vice Chancellor, Chitkara University, Punjab

Symposium Chair

Bhupinder Singh Bhoop

CCP, Chitkara University, Punjab

Organizing Secretaries

Indu Pal Kaur, UIPS, PU

Thakur Gurjeet Singh, CCP, CU

Steering Committee

Bhupinder Singh Bhoop Indu Pal Kaur Thakur Gurjeet Singh Kanwaljit Chopra

International Advisory Committee

Adnan Sabir, USA
Ajaz S Hussain, USA
Barry Gujral, USA
Brian Carlin, USA
Christine Dufes, UK
Deepika Aggarwal, Australia
Dinesh Jaiswal, USA
Kamalinder K Singh, UK
Mandip S Sachdeva, USA
Maria Jose Alonso, Spain
Nese Buket Aksu, Turkey
Paul W S Heng, Singapore
Rabbur Reza, Dhaka
Rishi Kapil, New Zealand
Rodney J Y Ho, USA
Sandeep Tiwari, USA
Sanjay Garg, Australia
Umesh Banakar, USA
Vinod Labhasetwar, USA
Yvonne Perrie, UK

National Advisory Committee

Anil Pareek, IPCA, Mumbai
Arvind Bansal, NIPER, Mohali
Ashish Baldi, MRSTU, Bathinda
Farhan Ahmed, Hamdard, Delhi
Gautam Samanta, Cipla, Mumbai
Gurpreet Kaur, PbiU, Patiala
Harvinder Popli, DPSRU, Delhi
Kamla Pathak, UPUMS, Etawah
Milind Umekar, SKBCOP, Nagpur
Monica Gulati, LPU, Phagwara
Rakesh Bhasin, Biocon, Bengaluru
Rakesh Sharma, SGTU, New Delhi
Ravleen S Khurana, Nagpur
Romi Singh, Sun Pharma, Gurgaon
Roop K Khar, BSAIP, Faridabad
Sanjay K Jain, Dr HSG Univ, Sagar
Sukhjeet Singh, Sentiss, Gurgaon
Sumit Madan, Sun Pharma, Gurgaon
Vandana Patravale, ICT, Mumbai
Vijay Kshirsagar, TRAC, Mumbai

Local Organizing Committee

Alka Bali, UIPS
Amita Sarwal, UIPS
Amarjot Kaur, CCP
Anil Kumar, UIPS
Balraj Saini, CCP
Chander Prakash, CCP
Gurpal Singh, UIPS
Inderbir Singh, CCP
Maninder Karan, UIPS
Neelima Dhingra Passi, UIPS
Neeraj Mittal, CCP
Om P Katare, UIPS
Pooja Mittal, CCP
Poonam Piplani, UIPS
Rajan Swami, CCP
Ranjana Bhansari, UIPS
Ranju Bansal, UIPS
Sonia Diman, CCP
Sangeeta Pilkhwal Sah, UIPS
Teenu Sharma, CCP
Vandita Kakkar, UIPS
Vivek R Sinha, UIPS

Symposium Chair

Professor Bhupinder Singh Bhoop

Acclaimed globally for his scientific research work, Prof Bhoop has over four decades towards pharmaceutical education, research and industrial consultancy. He has to his credit over 425 original publications, including 16 books by prestigious international publishers and 81 book chapters, Google H-index of 58, citations of over 12500. Working in the domain of Pharma QbD since 1994, he is considered as a Pioneer in the field in India. A widely travelled scientist, he has delivered more than 360 plenaries, keynote and invited talks in India and overseas, and trained thousands of industrial scientists of India, Canada, China, Taiwan, Dubai, and Bangladesh, on Formulation & Analytical QbD, and Nanomedicine. He has guided over 110 researchers, including 34 Ph.D.'s and 9 Post-Doctoral Fellows, completed 6 industrial consultancy assignments, and has 8 patents, 3 tech. transfers of nanotech-based drug delivery products, research grants over 7.30 crores, and 15 computer software to his credit. Based on published work, Stanford Univ., USA recognized him among Top 2% scientists across the world in 2020, 2021 and 2022. His work has fetched Prof Bhoop with awards and accolades like, Leading Educators of World (UK) 2007, Pharma Buzz Personality Award 2008, Shiksha Rattan Puruskar 2008, Innovative Scientist Award 2012 (CIIPP), QbD & Product Performance Award 2012 & 2013 (AAPS, USA), QbD Excellence Award 2013 (CPhI Asia), Outstanding Scientist Award 2014 (SelectBio, UK), Pharma QbD Outstanding Performance Award 2014 (Stat-Ease, USA), Bharathi Vidyapeeth APTI Pharmacy Teacher Award 2014, Prof Baichwal Oration Award 2015 (ICT, India), Scientist Par Excellence Award 2015 (Minitab Inc, UK), Eudragit Award 2015 (Evonik, Germany), Prof J S Rai Oration Award 2015 (GNDU, Asr), HT Performer of 2015, Innovative Healthcare Researcher Award 2016 (WWA), Name in Science Award (EBA, Oxford, UK) 2016, Chitkara University Excellence Award 2016, Prof D V S Jain Best Scientist Award 2018, Global QbD Excellence Award 2019 (Shanghai, China), Elsevier Best Research Paper Awards 2020 & 2021, Pharma Lok Pharma Excellence Award 2021, and many more. He is on Expert Panel of UGC, NBA, NAAC, AICTE, PCI, DST-SERB, DBT, UPSC, PPSC, Commonwealth Secretariat, and scores of prestigious universities in India and abroad. Currently, he is serving as an Emeritus Professor of Chitkara University. At Panjab University, he has been Chairman - University Institute of Pharm. Sciences (UIPS), Dean - Faculty of Pharm. Sciences, and Dean Alumni Relations. He has also been the Coordinator of UGC Centre of Advanced Studies, and Founder-Coordinator of National UGC Centre for Excellence in Nano Biomedical Applications. On the basis of his exemplary accomplishments, Mr Hamid Ansari, then Vice President of India, has nominated him to University Senate & Syndicate as its Fellow; Prof Ved Prakash, Chairman-UGC, conferred Honorary Fellowship of Punjab Academy of Sciences; and Indian Pharmaceutical Association (IPA) honoured him as IPA Fellow.

Organizing Secretary

Professor Indu Pal Kaur

Presently, Chairperson of UIPS, she is an independent Director of Nectar Lifesciences Limited too. Former Director of Sophisticated Analytical Instrumentation Facility (SAIF), and former Dean of Faculty of Pharmaceutical Sciences, Panjab University, she has been ranking amongst the top 2% most cited scientists across the globe as per Stanford University, USA (2019, 2020; 2021). Her research forte is enhancing bio-performance of drugs, plant extracts/phytochemicals and biomolecules. She has supervised 31 PhDs and 58 postgraduates, and has received funding of around 10 crores INR from Government and Industry. She has been a US-Fulbright Fellow (2017-18) and was awarded Women Scientist Award 2018 by OPPI. She was graced with BRIC Technology Exposition Award consecutively for two years, 2019 and 2020, Researcher of the Year award, by Sunpure Research Incubation Centre, 2019 and 2022, and won the Grand Innovation Challenge conducted by Indian Pharmaceutical Alliance in Nov 2021. She has received funding for the project and Beamtime Application at the ISIS facility – Rutherford Appleton Laboratory, UK, 2017; 2023. She has licensed four of her technologies to industry and filed 31 patent applications, out of which 13 are granted (including one in US). Most recently, Prof. Kaur was awarded with the prestigious National Intellectual Property Award 2021 & 2022 for being the "Top Indian Individual for Patent Filing, Granting & Commercialization" and the "WIPO Medal for Inventors", conferred by World Intellectual Property Organization (WIPO).

Symposium Chair

Dr. Thakur Gurjeet Singh

A Ph.D. (Pharmaceutical Sciences), M. Pharm in Pharmacology from Punjabi University, a PDCR (Clinical Research) & PCPV (Pharmacovigilance), Dr Gurjeet carries an experience of 16 years in industry, Research and teaching. He is currently working as a Professor & Dean at Chitkara College of Pharmacy, Chitkara University, Punjab. He is engaged with projects on interception of drug dependence, ischemia, diabetic neuropathy & nephropathy, drug toxicology, epilepsy, Alzheimer's disease and stem cell research studies. He has more than 198 research publications in peer-reviewed journals (International & National), 25 book chapters, 11 books and 82 patents filed under his name. Till date, he has more than 190 Scopus-indexed publications with nearly 3000 citations, H-index of 27 and i10-index of 67 and cumulative impact factor of 1540.5 and RG Score of 37. He has attended more than 60 national and international conferences, UGC networking courses and various preclinical & clinical research training programs. He has guided thesis work for 65 M. Pharm students and 10 Ph. D candidates. He is a reviewer for several highly reputed international journals too. Chairperson of Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), he is also In-charge of Animal house facility at Chitkara College of Pharmacy, Chitkara University, Punjab. He is also Member Secretary for institutional human ethical committee registered with Department of Health Research and CDSCO New Delhi.

Resource Faculty

S. No.	Name	Designation
1.	Dr. Gautam Samanta	Vice President, Cipla Ltd., Mumbai, Maharashtra
2.	Professor Bhupinder Singh Bhoop	Emeritus Professor, Chitkara University, Punjab
3.	Dr. (Mrs.) Vandana B. Patravale	Professor of Pharmaceutics, Department of Pharmaceutical Sciences and Technology, Institute of Chemical Technology, Mumbai, Maharashtra
4.	Professor Harish Dureja	Head, Department of Pharmaceutical Sciences; Director, Centre for IPR Studies; Director, Professional Consultancy Cell; Maharshi Dayanand University, Rohtak, Haryana
5.	Dr. Muralidhara Anandamurthy	JMP
6.	Professor Sachin Kumar Singh	School of Pharmaceutical Sciences, Lovely Professional University, Phagwara, Punjab
7.	Professor Daisy Arora Khurana	Professor & Academic Head, Department of Pharmacy, Panipat Institute of Engineering and Technology, Panipat, Haryana
8.	Dr Asha S Patel	Associate Professor, Pharmaceutics Department, Parul Institute of Pharmacy, Parul University, Vadodara, Gujarat
9.	Dr Poornima Tiwari	R&D (DQA), Nectar Lifesciences Ltd.
10.	Dr Teenu Sharma	Assistant Professor, Chitkara College of Pharmacy, Rajpura, Punjab

Dr. Gautam Samanta

Currently, he is the Vice President and Head of Quality by Design and Technology Transfer (esp. APIs) at Cipla Ltd. His focused areas are the development of robust products and processes using QbD and PAT and the seamless transition of processes from R&D to manufacturing using modeling and simulation. Previously, he worked at Dr. Reddy's Laboratories in API development. He was awarded a Ph.D. degree from Jadavpur University, Calcutta. Following his Ph.D. degree, he pursued research as a postdoctoral research fellow at the National Institute of Health Sciences, Japan, and then at Texas Tech University, USA. After his postdoctoral research, he joined the faculty as a research assistant professor at the University of Houston, Texas, USA. He has published more than 55 papers in peer-reviewed international journals, including in the very prestigious journal, Nature. His work has been cited by more than 6000 researchers till date. Besides, he has also authored five book chapters. He is the inventor of five process patents. He is delivered numerous talks at global and national levels, mostly on QbD and PAT perspectives, and is a reviewer for many scientific journals, such as Analytical Chemistry, Journal of Chromatography A, etc.

Professor Vandana Bhalla Patravale

Currently, a Professor of Pharmaceutics at the Institute of Chemical Technology, Mumbai, she has earned more than 30 years of teaching and research experience. Till date, she has earned over 200 refereed publications with over 10000 citations (H index 52, i10 index of 131), 30 granted patents, 20 patents in pipeline and 2 trademark registries. She has published 2 books and 35 book chapters with international publishers. Besides being highly active in teaching, research and service throughout her career, she is an independent director of a device manufacturing company and is listed among top 2% of World scientists in pharmacy. Her areas of research include development of nanocarriers with major emphasis on infectious diseases, cancer and neurodegenerative disorders; medical device development, nanodiagnostics, nanovaccines, adopting QbD principles, wherever applicable and possible. She was awarded Most Iconic Healthcare (Global) Leader Award 2023, Topmost Healthcare Leader Global Award (Education) 2022, Abdul Kalam Technology Innovation National Fellowship 2021, Fellowship of Indian Chemical Society 2020, Kukreja Oration Award 2020, APTI's Dr. Manjushree Pal Best Pharmaceutical Scientist Award 2019, Shri Amrut Mody Distinguished Researcher Award 2018, OPPI Women Scientist Award 2015, Bill Melinda Gates Grant Award 2015, Best Pharmaceutical Scientist Award 2014, VASVIK Award 2013, Veneto Nanotech Award 2013, APTI Best Teacher Award 2012, Fellowship of Maharashtra Academy of Sciences, 2011, and K.H. Garda Distinguished Researcher Award 2009. She is Convener, APTI Women forum, Vice president-CRS Indian chapter (IC), editor of CRS-IC and APTI women forum newsletters, and is on editorial board of several peer-reviewed journals. She is actively collaborating with researchers as well as industries within country and abroad, and has completed In-

Professor Harish Dureja

Currently, he holds the position of Professor in Pharmaceutics and Head, Department of Pharmaceutical Sciences, Director, Centre for IPR Studies along with Director, Professional Consultancy Cell, all Maharshi Dayanand University (MDU), Rohtak. He earned his Master in Pharmacy in Pharmaceutics from Punjabi University, Patiala and Ph. D. in Pharmaceutical Sciences from MDU, and was awarded with 1st Gold-Medal for Best Ph.D. Thesis in the year 2008 on the basis of highest impact factor of publications. Dr. Dureja has been involved in teaching, research, mentoring, advising, and administration for over past 23 years. He has been awarded research projects of worth 1.5 Crore from AICTE, UGC, DST and Haryana-DST. He has been bestowed with several honours, like, MDU Research Award -2021; MDU Best Researcher Award-2020, Dr. R.L. Nicore award for Best article published in 2018 in IJPER, Young Pharmacy Teacher of the Year Award- 2014 by Association of Pharmaceutical Teachers of India, *Prof. M.L. Khorana Memorial Prize Award – 2005* for the publication in IJPS. He is actively involved in the fields of oral bioavailability improvement of BCS classes II drugs, nanoparticulate systems, *in silico* ADME modelling and pharmaceutical regulatory affairs He has guided over 60 postgraduate and 11 PhD theses, with ten more PhD theses being guided under his supervision. He has published over 250 publications in various International and National Journals of repute with an H-index of 32, and more than 4000 citations. Besides, he has authored five books and several invited book chapters on drug delivery in edited books of reputed Indian and international publishers. He has delivered more than 180 invited Lectures in various conferences, seminars and symposia. A reviewer with various reputed international journals, he is on the editorial board of renowned journals too, including Current Drug Delivery and Current Nanomaterials. He has worked as Chairman, Scien-

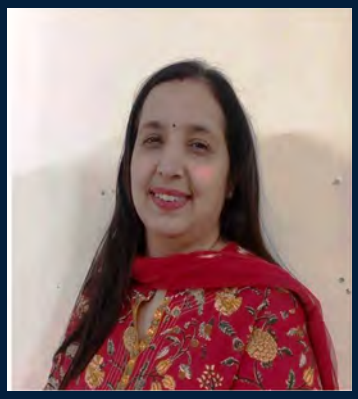
Dr Muralidhara Anandmurthy

Dr Muralidhara holds a B Tech, MBA and Ph.D. degrees to his credit. Currently, he is part of the globally renowned, JMP Global Academic Team. He has served for more than 20 years in Analytics and Data Science Industry and has earlier worked for Genpact, Target and Danske, holding various leadership positions. He is also a trainer in the area of Design of Experiments (DoE), Statistical Data Analysis and Data Science and machine learning. He has successfully conducted several workshops, including for IISc (Bangalore), IIMs, IITs, NITs, NIPERs, BITS-Pilani and many other academic institutions. He has also recently co-authored a book on Machine Learning for Business Analytics, released in April 2023 from Wiley International Publications. He specializes in conducting DoE/QbD workshops using JMP software.

Professor Sachin Kumar Singh

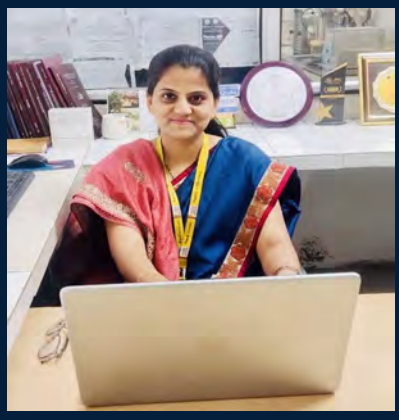
Presently, he is working as a Professor and Head, Pharmaceutical Chemistry and Pharmaceutical Analysis, at School of Pharmaceutical Sciences, Lovely Professional University, Punjab, India and a visiting Professor at Australian Research Centre in Complementary and Integrative Medicine (ARCCIM), School of Public Health, Faculty of Health, University of Technology, Sydney, Australia. With over 14 years of teaching and research experience, he has published more than 300 research papers, authored one book and 15 plus book chapters. He has filed 43 Indian patents, out of which six have been granted. He is expert in developing synbiotics-based oral formulations using QbD approach. He has successfully supervised 12 PhD scholars and 35 M Pharmacy students, and is currently guiding 3 more masters and 6 PhD students. He has many research projects in hand, and has completed one DST-SERB funded project too. He is also featured under top 2% scientists of world as per the list of 2021, published by Stanford University, USA. Currently his H-index is 36 with 5500 plus citations. He has been a recipient of Dr B.C. Deb memorial award for popularization of science by Indian Science Congress Association at 107th Indian Science Congress held at Bengaluru.

Professor Daisy Arora Khurana



Currently, a Professor and Academic Head Department of Pharmacy at Panipat Institute of Engineering and Technology, Panipat, Haryana, she is elected as Vice President of Society of Pharmaceutical Education and Research (SPER) Women's Forum too. She passed her M. Pharmacy with specialization in Pharmaceutics, topping the order of merit and receiving her gold medal from Punjab Technical University, Jalandhar (Punjab) in 2009. She completed her Doctoral research work in the field of "QbD and DoE-based development of cosmeceuticals" at Nanomedicine Research Center, ISF College of Pharmacy, Moga and Maharshi Dayanand University, Rohtak. With 14 years of research and academic experience, she has a vivid incline towards computer-aided optimization and the development of drug delivery systems. Her primary research areas are topical drug delivery, vesicular systems, DoE and QbD, and nano cosmeceuticals. She has also delivered a number of talks and guest lectures in various conferences and FDPs, and has attended many international conferences in India and abroad too, bagging Best Poster Awards at global level, Budding Nanotechnologist Award at NIPER, Mohali, and several Travel grant awards for international conferences. She has published a number of reviews and research articles in peer-reviewed journals of national and international repute. She has successfully organized a number of FDPs, International conferences and workshops as coordinating head and has also worked a peer team member of the NAAC, NIRF, NBA committee of the institute and coordinator of IQAC cell.

Dr. Asha S. Patel



An Associate Professor in the discipline of Pharmaceutics at Parul Institute of Pharmacy, Parul University, Vadodara, Gujarat, she has around 15 years of professional experience in industry, teaching and research. Completing her Ph.D. under (Late) Prof. Mukesh C. Gohel, Dr Asha received Best Ph.D. Thesis award from Gujarat Science Academy during Gujarat Science Congress, Gandhinagar. She has guided 25 postgraduate and 3 Ph.D. scholars, and is currently 5 more PhD scholars under her supervision. Besides 27 research papers in high IF peer-reviewed journals and one book chapter in Elsevier book, she has filed nine innovations for patenting, with one being granted and two being published. As a Principal Investigator, she has completed two major research projects from AICTE and Biotechnology Mission, Gandhinagar, and a minor research project grant from Gujarat Department of Science and Technology, and has also a couple of start-up and innovation projects sponsored from i-HuB, Govt. of Gujarat, under its Start-up and Innovation policy. She has received. She is having Best Faculty mentor award under Start up and innovation policy from Govt. of Gujarat in Sept 2020. She has delivered more than 30 Invited talks in various conferences, QIPs, STTP, Symposia, both at national and international levels. She is also awarded by Parul University as Best Faculty for Performance in Academic and Research, consecutively for four years in 2018, 2019, 2021 and 2022 and as Best Researcher Award in 2021 and 2022. Asha has area of expertise in development of targeted drug delivery system for therapeutic application in cancer, biomedical devices, biodegradable ophthalmic and complex injectables. She has organized more than seven GUJCOST-, AICTE- and ICMR-sponsored conferences and FDP/STTP as Coordinator and worked as scientific committee member in various national and international conferences held at the parent institute.

Dr Poornima Tiwari

A Ph.D. in synthetic organic chemistry, she has gained over 16 years of experience in diverse disciplines of quality management systems (QMS) related to drug substance and drug products. Presently working with ***Nectar Lifesciences Ltd.*** in R&D department as Deputy Manager, QA operations, she deals with quality systems. She is also expert auditor in the ISO and audited various organization for the implementation of quality system. She has served in various pharmaceutical manufacturing organization and has good exposure of QMS implementation in drug substance and drug product manufacturing organizations. She has rich experience in training human resources on various elements of quality systems, like change management system, corrective and preventive system and quality risk management (QRM). She is also related to various organizations involved in the drug-related quality systems and training. She has impressive track record of auditing the organizations for improvement of their quality systems and train people also to deliver the expertise as per QMS.

Dr Teenu Sharma

With a teaching and research experience of more than 9 years, Dr Teenu is currently a faculty member at Chitkara College of Pharmacy, Rajpura, Punjab. She has earned to her credit a total of 44 publications till date, including 32 peer-reviewed research and review publications in peer-reviewed journals (cumulative impact factor of 105.7), and 12 book chapters. Almost one-half of her publications relate to the application of QbD principles in drug delivery formulation and/or analytical development of various drugs and bioactives. Being a Gold Medalist during her B. Pharm. and M. Pharm. (Pharmaceutics) at GNDU, Amritsar, she was awarded with DST Inspire SRF Research Fellowship for pursuing her Ph.D. at Panjab University, Chandigarh. She has been bestowed with "Best Research Paper Recognition Award 2020" by Drug Delivery and Translational Research (DDTR, CRS, USA) for her QbD-based formulation research work, Dr P D Sethi Award 2019 for QbD-based Pharmaceutical Analysis work (Kongposh Publications), Dr P D Sethi Award 2020 for Best Publication in HPTLC studies (Anchrom India), and several Best Paper Awards in scientific conferences too.

Contents

Formulation by Design (FbD)

National Symposium-cum-Workshop
on
Contemporary Trends, Tools and Techniques in Pharma Quality by Design (QbD):
From Conceptualization to Implementation
20-21 April 2023

TARGETED DELIVERY OF NEUROPEPTIDE: AN ADVANCED PARADIGM TO ADDRESS NEUROLOGICAL DISORDER(S)

***Samarth Kumar*[1,2]**, *Neeraj K Garg*[1], *Ashay Jain*[1], *Ajay Khopade*[1] *and Krutika K Sawan*[2]
[1]*FR&D Non-Orals, Sun Pharmaceuticals, Ind. Ltd., Vadodara, Gujarat, India*
[2]*Faculty of Pharmacy, Maharaja Sayajirao University of Baroda, Vadodara, Gujarat, India*

Email: Samarth.kumar@sunpharma.com

Oxytocin is a promising molecule for the management of various neurological disorders. However, limitation to cross Blood Brain Barriers (BBB) and frequent dose regime due to fast metabolism lead to limited brain exposure to this neuropeptide in psychiatric ailments. Therefore, efforts have been made to enhance the transportation of oxytocin crossway to BBB using lipid-polymer based hybrid complex. DoE enabled single step method was employed to prepare hybrid carriers which consists polycaprolacton as polymeric core enclosed within phospholipids boundaries. The effect of CMAs such as lipid, polymer-lipid ratio and concentration of surfactant on CQA viz. drug entrapment efficiency and particle size were systematically evaluated to optimized hybrid carriers. The optimized oxytocin loaded carriers were found to be spherical, size controlled with higher drug loading and entrapment efficiency. Oxytocin loaded formulation showed better cell uptake efficiency on BEND3 cells with higher ex vivo cellular toxicity vis-à-vis control formulation suggesting the enhanced potential of prepared dosage form to cross BBB. Greater compatibility, improved BBB surpassing potential to understand and address schizophrenia are corroborated with in vitro evidence, and formulated delivery vehicle shows its value in developing new tools for treating brain disorder.

FORMULATION AND EVALUATION OF PACLITAXEL LOADED NANOSTRUCTURED LIPID

Pooja Mittal[1] *and Brahmeshwar Mishra*[2]
[1]*Chitkara College of Pharmacy, Chitkara University, Rajpura, Punjab, India*
[2]*Department of Pharmaceutical Engineering and Technology, Indian Institute of Technology (IIT) BHU, Varanasi, Uttar Pradesh, India*

Email: poojamittal2009@gmail.com

Paclitaxel (PTX), a first line drug for the treatment of all forms of ovarian cancer. In the present study, PTX entrapped NLCs were developed and screening of the formulation components was performed by using principles of QbD. Higher entrapment with the impressive stability of the formulation was achieved by employing quality by design based strategies. Optimized levels by employing numerical optimization technique for each factor viz. surfactant concentration (X1), Lipid concentration (X2) & amount of organic solvent (X3) were 0.3 %, 0.76 % & 8.3 ml respectively. The resultant formulation exhibited a particle size of 121.44 nm, and entrapment efficiency of 94.27 %, & zeta potential of -20.21 mV with unimodal size distribution. In a nutshell, PTXNLC seems to be a superior alternative carrier system for the formulation industry to obtain the higher entrapment with excellent stability of the formulation.

FORMULATION AND IN-VITRO EVALUATION OF INJECTABLE PREPARATION OF APREMILAST IN-SITU GEL BY EXPERIMENTAL DESIGN

Vaibhav Singh, *Risha Aggrawal and Rohitas Deshmukh*
Institute of Pharmaceutical Research, GLA University, Mathura, Uttar Pradesh, India

Email: Vaibhav.singhmph.ceu21@gla .ac.in

Rheumatoid arthritis is characterized by inflammation and soreness of joint, swelling of degradation of articular structure. (RA) Rheumatoid arthritis is the chronic autonomic disorder followed by destruction of articular structure. The aim of own study is to developed Apremilast loaded insitu gel for the treatment of Rheumatoid Arthritis (RA). the purpose of this research to enhance the solubility and permibility of Apremilast using nanotechnological. A 3^2 full factorial design was used to develop Apremilast loaded nano insitu gel. Apremilast-loaded nanoparticles were developed by a solvent evaporation method and incorporate in-situ gel. A total 9 formulations were designed and made with different ratios of Eudragit RSPO and Poly Vinyl Alcohol. The NPs had particle size ranging from 150–290 nm and zeta potential of +19–28 mV, Entrapment efficiency 80.8 %, Drug loading 27.54 %,. The optimized nanoparticles were incorporated in the in-situ gel. The Apremilast nanoparticles loaded in situ gel had gelation temperature of 37.5 ± 1.7 °C, 55 ± 1.0 second gelation time and 866 ± 13 cps viscosity, with in vitro drug release profile 75.54 % for 24 h.

FORMULATION AND EVALUATION OF ORAL MUCOADHESIVE MICROSPHERES USING EXPERIMENTAL DESIGN

***Mahendra Prajapati**, Rohitas Deshmukh and Ranjit K Harwansh*
Institute of Pharmaceutical Research, GLA University, Mathura, Uttar Pradesh, India

Email: Mahendraprajapati530@gmail.com

A peptic ulcer is a disease that affects the stomach lining and is caused by Helicobacter pylori. The aim of this research is to design and evaluate the mucoadhesive microsphere of ofloxacin for the effective and safe treatment of peptic ulcers. Mucoadhesive microspheres for oral delivery of ofloxacin were successfully developed by using the emulsification cross-linking method. A 2^3 full factorial design using Design Expert 13 software was employed to study the effects of various independent variables (guar gum, sodium alginate, and chitosan) on the dependent variables (particle size and encapsulation efficacy). Fabricated mucoadhesive microspheres were characterized through Fourier transform-infrared, differential scanning calorimetry, scanning electron microscopy, particle size analysis, and also evaluated for % mucoadhesion test, swelling index, encapsulation efficiency, drug content, and drug release studies. Mucoadhesive microspheres were obtained in the size range of 26.27 ± 4.14µm to 41.48 ± 9.04µm. The optimized formulation had a particle size of 36.05 ± 1.32µm and an entrapment effectiveness of 89.06 %, respectively. The FT-IR result demonstrates that there was no chemical interaction, and the SEM photograph indicates that mucoadhesive microspheres are spherical and have pores. According to the findings of the multiple regression analysis, every factor had a statistically significant impact on every dependent variable. The mucoadhesive microspheres were prepared successfully, and the results clearly stated that prepared ofloxacin microspheres may be safe, effective, and drug release in a sustained manner.

QbD-DRIVEN DEVELOPMENT OF PHOSPHOLIPID-EMBEDDED LIPIDIC NANOCARRIERS OF RALOXIFENE: EXTENSIVE IN VITRO AND IN VIVO EVALUATION STUDIES

***Anjali Pant*[1]**, *Gajanand Sharma*[1], *Gurjeet Kaur*[2], *Gurpal Singh*[2], *Bhupinder Singh*[1,3]
[1]*University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh, India*
[2]*Department of Renal Transplant Surgery, Post Graduate Institute of Medical Education and Research, Chandigarh, India*
[3]*Chitkara College of Pharmacy, Chitkara University, Rajpura, Punjab, India*

Email: anjali4354@rediffmail.com

Biosimilars are biologic products, demonstrating no clinically meaningful differences in terms of quality, efficacy, safety, and immunogenicity compared with an existing licensed, originator biologic. Thus, biosimilars need a stringent regulatory mechanism for controlling their access to the market. The EMA has taken the lead in the regulatory approval framework for biosimilar products, and the WHO has published guidelines to facilitate global harmonization. The US FDA has been authorized to approve biosimilars by the BPCI Act, 2010. Biosimilars have been manufactured quite early since 2000s, in India, however, there were no regulations specific to biosimilars until 2012. In 2012, the first guideline, “Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India” was introduced by the joint efforts of the Central Drugs Standard Control Organisation (CDSCO) and the Department of Biotechnology (DBT). The basic concepts and main principles of approving biosimilars are similar among various nations, notwithstanding some differences in regard to the scope, the choice of reference product, and the data requirement. It has been observed that small changes in manufacturing processes can have significant undesirable clinical impacts in biosimilar manufacturing. As a result, regulatory authorities all over the world have adopted strict guidelines for the approval of biosimilars.

DESIGN, DEVELOPMENT AND OPTIMIZATION OF DONEPEZIL-LOADED NANOPARTICLES FOR BRAIN DELIVERY

Yogesh Garg *and Amit Bhatia*
Department of Pharmaceutical Sciences and Technology, Maharaja Ranjit Singh Punjab Technical University, Bathinda, India

Email: drbhatiaamit@gmail.com

Donepezil hydrochloride, a neuroprotective agent has poor blood-to-brain permeation due to the presence of the blood-brain barrier. The available formulation of Donepezil hydrochloride does only treat symptoms associated with Alzheimer's disease but the quality of treatment is poor. Thus, it is required to develop a novel drug delivery system that would provide the release of Donepezil hydrochloride directly into the brain avoiding the blood-brain barrier (nose-to-brain delivery). So, the work was based on the objective 'to develop and optimize a self-mucoadhesive nanoparticulate drug delivery system for the effective delivery of Donepezil hydrochloride to the brain through the intranasal route'. Donepezil hydrochloride-loaded chitosan nanoparticles were developed by using the ionotropic gelation method and optimized by the Design of Experiment approach. The optimized formulation has shown mean particle size (177.8 nm), drug payload (22.2 mg of Donepezil hydrochloride/100 mg of Chitosan), process yield (91.96 %), zeta potential (+ 16.6 mV) and mucoadhesive strength (9.26 g). The in-vitro drug release (> 90 % in 24 hours) and ex-vivo diffusion (> 70 % in 24 hours) were promising. The delivery of Donepezil hydrochloride to the brain was determined by employing Wistar rats. Approximately, three times more drug was quantified in the brain with high-performance liquid chromatography via nanoparticles (intranasal administration) vis-à-vis Donepezil hydrochloride in solution (oral/nasal administration). Finally, confocal laser scanning microscopy confirmed the localization of Rhodamine B (fluorescent dye) loaded nanoparticles in different regions of the brain. The above results concluded that the nose-to-brain delivery of Donepezil hydrochloride loaded mucoadhesive nanoparticles has better potential than other brain drug delivery routes.

QBD-ENABLED NOVEL LIPID-BASED NANO-VESICULAR CARRIERS OF LULICONAZOLE: FORMULATION DEVELOPMENT, CHARACTERIZATION AND EVALUATION

***Akanksha Mahajan*[1], *Gajanand Sharma*[1], *Bhupinder Singh*[1,2] *and O.P. Katare*[1]**
[1]*University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh, India*
[2]*Chitkara College of Pharmacy, Chitkara University, Punjab, India*

Email: akankshamahajan17@gmail.com

Luliconazole (LCZ) is a novel, broad-spectrum, imidazole anti-fungal drug for the treatment of fungal skin infections. The present study aimed to investigate lipid-based nano-vesicular formulation as an effective carrier system for LCZ delivery at fungal site employing Quality by Design (QbD) paradigms. Factor screening and quality risk management (QRM) studies identified phospholipid, solid lipid, solvent, and cosolvent as the (CMAs) (critical material attributes). Nano-vesicular system was systematically prepared employing QbD-oriented approach using *I*-optimal mixture, evaluating critical quality attributes (CQAs) like particle size, entrapment efficiency, and *in vitro* release profile. Besides, the developed systems were also evaluated for microscopic investigations *(*optical microscopy and FE-SEM), FT-IR and rheological studies, skin depth studies using CLSM, skin toxicity studies, *in vitro* antifungal susceptibility testing (MIC), and different cell culture studies. The optimized nano-vesicular system exhibited a particle size of 196 nm with enhanced permeation (29.9%) and retention (436.5 g/cm^2) across the stratum corneum (SC) as compared to the conventional system(s). The dermatokinetic profile of the developed formulation exhibited markedly better therapeutic efficacy than the conventional system(s). The cell culture studies showed 91.5% cell viability with no toxicity and the cellular uptake studies proved its direct access deep into the tough layers of skin, especially SC. Thus, the current studies demonstrate the developed system as a promising approach with superior therapeutic efficacy against fungal skin infections.

QBD-BASED OPTIMIZATION OF SPRAY DRIED NELFINAVIR MESYLATE POWDER FORMULATION FOR HIV TREATMENT: IN-VITRO AND IN-VIVO EVALUATION

Sonu Kumar, *Sunil Kamboj, Sheshank Sethi and Vikas Rana*
Pharmaceutics Division, Department of Pharmaceutical Sciences and Drug Research, Punjabi University, Patiala, India

Email: sonukumarnokhwal1998@gmail.com

The current strategy was aimed to produce spray-dried nelfinavir mesylate (NFM) powder to achieve improved oral bioavailability using Quality by design approach. A feed mixture containing solubilized NFM, solid substrate, and the solvent system was prepared for this purpose. NFM was dissolved in a mixture of Maisine 35-1 (200 mg), Tween80 (500 mg), and Transcutol HP (300 mg). The Neusilin® UFL2, (magnesium aluminometasilicate), Aerosil 200® (colloidal silica), and Syloid 244 FP® (porous silicon dioxide) were used as a solid substrate with a high specific surface area. To select the appropriate solid substrate and develop optimized SDNP, the central composite design-response surface methodology (CCD-RSM) with three-factor (two numeric and one categorical) at three levels was used. The solid characterization by scanning electron microscopy, differential scanning calorimetry, and powder X-ray diffraction studies shows absence of crystalline NFM in the formulations. The solid substrate significantly improved drug dissolution. The bioavailability study resulted in increased Cmax and AUC for SDNF. The brain and lymph node distributions were significantly higher in the tissue distribution studies compared to the putative form.

OPTIMIZATION OF LULICONAZOLE NANO SPONGE – FORMULATIONS EMPLOYING BOX- BEHNKEN DESIGN

Addanki Anusha [1,2] *and Annammadevi GS* [1]
[1]*GITAM School of Pharmacy, GITAM (Deemed to be University), Visakhapatnam, Andhra Pradesh, India*

Email: mannam@gitam.edu

Luliconozole, is a BCS Class-II, an anti-fungal drug. The objective of this work was to design, develop, optimize, and evaluate nano sponges' formulations for effective delivery of Luliconazole through transdermal route in onychomycosis treatment. In this work, 3-factor, 3-level Box- Behnken design was used to optimize the process parameters like EC concentration (A), PVA (B) and Stirring speed (C). Three dependent variable's Vesicle size, entrapment efficiency, PDI and Zeta potential were measured as responses. Mathematical equations and response surface plots were used to relate the dependent and independent variables. Nanocarrier LCZ-NS was optimized based on the particle characterizations and drug encapsulation. It was further evaluated for physicochemical characterizations; FTIR, DSC, XRD and SEM. Selected LCZ-NS composed of LCZ (1%), EC (5%) and 8% of PVA showed, PS (287.92±6.52 nm), PDI (0.243±0.11), ZP (-30.59±2.08 mV), %EE 82.69±0.51%) and %DL (15.83 ± 0.51%), respectively. Fabricated NS also revealed; polymer-drug compatibility, drug-encapsulation, non-crystalline state of the drug in the spherical NS as per the physicochemical evaluations.

FORMULATION AND EVALUATION OF NANOSTRUCTURED LIPID CARRIERS (NLCS) OF BRINZOLAMIDE BY BOX-BEHNKEN DESIGN

Chandrashekhar Mahadeo Chakole *and Meenakshi Kanwar Chauhan*
NDDS Lab, Delhi Institute of Pharmaceutical Sciences and Research, DPSR-University
Pushp Vihar Sec-3, New Delhi, India

Email: meenakshikanwar@yahoo.com

Brinzolamide (BZ) was chosen as the model drug for this study because it causes less discomfort to the eyes than other antiglaucoma drugs. Brinzolamide (1% w/v) eye drops have been prescribed in glaucoma management. However, treatment with this drop becomes expensive due to its high cost and more frequent administration, which leads to poor patient compliance. The objective of this work is to prepare NLCs of brinzolamide with a reduced drug concentration for comparative evaluation with commercial BZ eye drops (1% w/v). The NLCs were prepared using a combined approach of melt emulsification and ultrasonication technique. The optimization of NLCs was performed using a three-factor, three-level (3^3) Box–Behnken design. The optimized NLC formulation has an average size of 121.6±4.011, polydispersity index of 0.433±0.009, and % entrapment efficiency (%EE) of 85.37±0.22%. *In vitro* release shows extended release, while an *ex vivo* study exhibited a 3-fold increase in corneal permeability compared to commercial eyedrop preparations. Pharmacodynamic evaluation was performed using New Zealand albino rabbits, BZ-NLC formulations have shown more IOP-lowering potential than commercial eye drops despite their lower concentration. The BZ-NLCs formulation was successfully optimized using Design Expert 13; it showed better ocular hypotensive effects in rabbit's eyes and might have cost-effective therapy in glaucoma.

QbD-STEERED DEVELOPMENT OF SOLID SELF-NANOEMULSIFYING DRUG DELIVERY SYSTEMS OF BROMOCRIPTINE: EXTENSIVE *IN VITRO* AND *IN VIVO* EVALUATION

***Sumant Saini*[1,2]**, *Atul Jain*[3], *Thakur Gurjeet Singh*[4], *Monica Gulati*[1], *Bhupinder Singh*[1,4]
[1]*School of Pharmaceutical Sciences, Lovely Professional University, Phagwara, Punjab, India*
[2]*University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh, India*
[3]*Department of Pharmaceutics, Delhi Institute of Pharm Sciences & Research, New Delhi, India*
[4]*Chitkara College of Pharmacy, Chitkara University, Punjab, India*

Email: sumantarya15@gmail.com

The current studies entail development and evaluation of solid self-nanoemulsifying drug delivery systems (S-SNEDDS) employing porous carriers for enhancing pharmacodynamic activity of bromocriptine mesylate (BM) against Parkinson's Disease (PD). Equilibrium solubility studies and pseudo-ternary phase diagrams facilitated selection lipid, surfactant and cosolvent. Postulation of cause-effect Ishikawa fishbone diagram, followed by risk assessment and factor screening studies, delineated amount of oil as the CMA and homogenisation speed as the CPP. The L-SNEDDS were systematically optimized using Central Composite Design, and evaluated for emulsification time, globule size and *in vitro* drug release as CQAs. S-SNEDDS formulations were prepared by adsorbing L-SNEDDS onto the porous carriers, *viz.* Aerosil 200, Aeroperl 300, Neusilin US2 and Fujicalin SG, and evaluated for oil adsorption tendency, micromeric behaviour, flow properties and compaction characteristics using Kawakita, Heckel and Leuenberger plots for choosing Neusilin UFL2 as the most suitable solid carrier for formulating S-SNEDDS. Nearly 2.6-fold improvement in the *in vitro* drug release rate was observed from the optimized S-SNEDDS ($p < 0.005$) *vis-a-vis* pure BM. Evaluation of the *in vivo* pharmacodynamic efficacy, analysed using a battery of behavioural and biochemical tests, unequivocally construed markedly superior therapeutic potential of nano-engineered drug delivery system over pure BM.

FORMULATION AND OPTIMIZATION OF NANOVESICLES LOADED IN SITU GELLING SYSTEM BY DESIGN OF EXPERT (DOE) APPLICATION

Pratibha Sharma, *Monika Yadav, Ikksheta Sharma and Indu Pal Kaur*
University Institute of Pharmaceutical Sciences, Panjab University Chandigarh, India

Email: pratibhapulastya@gmail.com

Vesicles are concentric bilayer colloidal particles made-up of amphiphilic molecules surrounding an aqueous compartment. They have gained a great acceptance in drug delivery. We have developed and patented a novel (341360; granted on 13/07/2020) nanovesicular (NV) system. The developed system is thin and free flowing and not suitable for topical application. Hence, NV dispersion was designed into an in-situ gelling system to improve its flow property, viscosity, adhesivity and other mechanical characteristics favoring topical application and stay on the skin following gelation. The present study is designed to select and optimize the best combination of in situ gelling polymers through statistical optimization using randomized central composite design employing Design-Expert® 13.0.5.0 (Stat-Ease, Inc.). In the preliminary screening various combinations of viscosity enhancing polymers were tried in combination with poloxamer 407 (P407). All the tried combinations were characterized for flowability, physical stability, syringeability and gelling temperature. The concentration of P407 and carbopol 934P were selected as factors and gelling temperature and gelling time were selected as responses for the final optimization of the in-situ gel. The optimized gel showed pseudoplastic behavior and good sol-gel transition.

DEVELOPMENT AND OPTIMIZATION OF CAPSAICIN LOADED NANOVESICULAR SYSTEM FOR TOPICAL DELIVERY

***Ikksheta Sharma**, Srishty Jaiswal and Indu Pal Kaur*
UIPS, Panjab University, Chandigarh, India

Email: pratibhapulastya@gmail.com

The present study is designed to develop an optimized nanovesicular system (NV). Capsaicin (Cap) was used as a model drug. Modified ethanol injection was used to form capsaicin-loaded nanovesicles (Cap-ves). Volume of solvent employed, the amount of film-forming surfactant, and the amount of polymeric-supporting surfactant, were selected as key variables using the Taguchi L8 array. For depicting the final quality of the product, a quality target product profile (QTPP) and key quality attributes (CQA) or response variables were established. Central composite design was used for optimization. Optimized nanovesicles showed particle size of 232 nm, entrapment efficiency-73.87%, total drug concentration-96.29%. The optimized NV were characterized with DSC, TEM, and in vitro release, in vivo skin permeation, stability and safety studies. Ex vivo investigations on skin penetration showed that intact vesicles were transported favorably up to the dermis (at 2 hours) and subcutaneous tissue (at 6h). In contrast to free capsaicin, which demonstrated considerable skin irritation, capsaicin nanovesicles at a dose (1.5% w/v) were non-irritant on topical application (rats and rabbits). The developed novel nanovesicular composition prepared employing much less expensive alternatives has a potential far beyond Cap-ves and can be successfully commercialized as products of varied application including topical, ocular and nasal.

DESIGN AND OPTIMIZATION OF ALGINATE BEADS BY QUALITY BY DESIGN (QBD) APPLICATIONS FOR THEIR SUITABILITY TO DELIVERY OF GINGER EXTRACT AND *LACTOBACILLUS ACIDOPHILUS*

***Parneet Kaur Deol*[1]**, *Sima Kujur[2] and Indu Pal Kaur[2]*
UIPS, Panjab University, Chandigarh, India

Email: simakujur96@gmail.com

The present study applies the concept of quality by design (QbD) for developing orally administrable calcium alginate beads loaded with cobiotic-ginger extract (GE) and Lactobacillus Acidophilus bacteria (LAB) for regulating oxidative stress, inflammation and dysbiosis mediated gut ailments. Encapsulation efficiencies of GE and LAB were chosen as response variables and polymer concentration, gelling agent concentration, PEG concentration, polymer solution, temperature, hardening time, stirring speed, and hardening temperature were found some of the most suitable materials and process factors. However, seven factor orthogonal Taguchi design was used for screening the critical variable affecting the development of GE-LAB beads and were systematically optimized using D-optimal experimental design for maximum entrapment (92 ± 2.3% for GE, and 30 ± 1.2% for LAB) and sustained release. The beads were coated with eudragit-S100 for colonic-targetability, as established by in vitro release. Conclusively, the batches manufactured in adherence to good manufacturing practice reveal consistent quality with minimal batch to batch variability.

IMPLEMENTATION OF QUALITY BY DESIGN (QBD) APPROACH FOR DEVELOPMENT OF CURCUMIN-LOADED SOLID LIPID NANOPARTICLES AND THEIR WOUND HEALING

Simarjot Kaur Sandhu, *Srishti Naryal and Indu Pal Kaur*
UIPS, Panjab University, Chandigarh, India

Email: srishtinaryal97@gmail.com

Hot high-pressure homogenization was employed for the preparation of C-SLNs. Formulation was op-timised for material attributes and process parameters using the Taguchi design for the screening of significant factors affecting the critical quality attributes (CQAs) followed by central composite design (CCD) for optimization using Design expert software. Critical material attributes (CMAs) viz. concentration of surfactant and cosolvent were selected based on their significant effects on critical quality attributes: particle size, and entrapment efficiency (EE) of the formulation. The optimised C-SLN formulation was established to be safe, autoclavable, and stable with a controlled release (zero-order; 5 days). It exhibited a particle size of 170 nm, PDI of 0.143, EE (75%), drug assay (0.6% w/w), and improved solubility (6×105 times). C-SLNs led to downregulation of the inflammatory response and oxidative stress, expedited re-epithelialization, angiogenesis, and improved granulation tissue formation. This led to accelerated wound closure within a period of 11 days. Optimised C-SLNs demonstrated significant antibacterial activity against Staphylococcus aureus 9144, while free curcumin dispersion exhibited no effect. C-SLNs thus, represent a promising novel wound healing therapy, especially for infected wounds, due to their impact on mature biofilm disruption.

SYSTEMATIC DEVELOPMENT, CHARACTERISATION AND EVALUATION OF AMPHOTERICIN B LOADED SOLID LIPID NANOPARTICLES FOR PARENTERAL DELIVERY

Mohammad Ramzan, *Vishal Bhatia and Indu Pal Kaur*
UIPS, Panjab University, Chandigarh, India
Email: sauravhans4@gmail.com

In the present study, we developed and optimized Amphotericin B (AmB) loaded solid lipid nanoparticles (SLNs) for increasing systemic bioavailability and decreasing nephrotoxicity. Taguchi design comprising 8 runs for 7 factors operating at 2 levels each, was applied for pre-optimizing the critical material and process attributes influencing AmB-SLN physical characteristics. Particle size, entrapment efficiency, and total drug content (drug assay) of AmB were taken as response variables. The concentration of lipid, concentration of surfactant, and rate of stirring were identified as the most significant factors as per Pareto charts. Box Behnken design (BBD) was applied for the final optimization of the formulation. Model suitability was validated by applying ANOVA between the 17 experimental runs suggested by BBD. Optimized formulation exhibited drug assay of 95.6%, entrapment efficiency of 88.5%, particle size 275 nm, PDI of 0.29, and Zeta potential of -23.86mV with significant systemic bioavailability. Cytotoxicity study on HEK 293 cell lines indicated significant reduction in nephrotoxicity for the developed optimized formulation.

DESIGN AND OPTIMIZATION OF NANOLIPIDIC CARRIERS FOR EFFECTIVE MANAGEMENT OF DIABETIC FOOT ULCER USING BOX-BEHNKEN DESIGN

***Praveen Kumari**, Parina Kumari and Vandita Kakkar*
UIPS, Panjab University, Chandigarh, India

Email: kumariparveen82@gmail.com

Diabetic foot ulcer is a serious complication of diabetes, associated with poor glycemic control, neuropathy, chronic inflammation and extremely slow wound closure resulting in amputation or losses of limbs, high health care cost and poor quality of patient\'s life. The usage of bioactives, in this regard, is documented to exhibit diverse pharmacological activities. However, their low bioavailability primarily pose serious impediment against their potential therapeutic usage. Therefore, the present research work was carried out to explore the untapped potential of nanolipidic carriers (NLCs) for co-delivery of nutraceutical and vitamin. NLCs will aid in improving the low bioavailability and poor stability issues associated with nutraceutical and vitamin, respectively. The nanocarriers were prepared by hot emulsification method employing the principles of Quality by Design. Factor screening studies were performed using 7-variables-8-runs Taguchi design to select “vital few” critical method/process parameters, influencing critical material attribute (CMAs). Subsequently, response surface optimisation studies were conducted on the identified critical method/process parameters, viz.,solid lipid concentration (X1), liquid lipid concentration (X2), and sonication time (X3), with chosen CMAs, viz.,particle size, polydispersity index, zeta potential and entrapment efficacy, employing a 3-factors-17-runs, Box-Behnken design. In a nutshell, the application of QbD has aided in developing a robust, reproducible and nanosize formulation for the co-delivery of nutraceutical and vitamin.

QBD: AN EFFECTIVE APPROACH FOR THE DEVELOPMENT OF NOVEL PHARMACEUTICALS

Gaurav Krishna *and Kamal Shah*
Institute of Pharmaceutical Research, GLA University Mathura, Uttar Pradesh, India

Email: gk1297@gmail.com

Quality of a product is the prime concern for acceptance by customer. Quality by design (QbD) is a systematic and modern factual approach for the development of novel pharmaceuticals. It follows various ICH guidelines such as Q8 (pharmaceutical development), Q9 (quality risk management), Q10(pharmaceutical quality systems), Q11 (development and manufacture of drug substances), Q12 (pharmaceutical product lifecycle management), Q13 (continuous manufacturing) and Q14 (analytical procedure development). Various essential parameters of QbD like as QTPP,CQA,CPP,CMA are used for the evaluation of manufacturing process as well as tested the quality of many pharmaceutical. These parameters are the key aspects which improve the quality of the novel pharmaceuticals. The quality of desired product can be achieved with the help of tools like risk assessement, Design of Experiment (DoE), Minitab and PAT that can help in optimization of whole process of product development, simultaneously minimizing the errors and assessing risk management factors. Various applications of PAT are in spectroscopy techniques like Raman spectroscopy, UV-Visible and NMR-spectroscopy. Apart from these several other application are in Near Infrared spectroscopy (NIR), focused beam reflectance measurements (FBRM), nanometric temperature measurement (MTM), tunable diode laser absorption spectroscopy (TDLAS). The QbD is an futuristic approach in the design and development of pharmaceuticals.

COMPREHENDING PARADIGM SHIFT IN THE VACCINE DEVELOPMENT BY ENABLING THE QBD AND PAT TOOLS

Naman Kapil *and Rajan Swami*
Chitkara College of Pharmacy, Chitkara University, Rajpura, Punjab, India

Email: kapil.naman208@gmail.com

Lately world has witnessed the havoc of COVID-19, hence it become very decisive to recognize the quality of vaccines. The development of vaccine was the only recourse in this particular scenario. Therefore, hence it is essential to maintain the quality of the vaccines by carefully optimization and continues estimation. Quality by Design (QbD) is an international regulatory eteraty contrivance with the goal of incorporating quality in the drug development process. Consiquently, the pharmaceutical industries have witnessed an organic shift from traditional optimization method to incorporate QbD and PAT novel tools into the vaccine development. However, the heterogeneity related to vaccines impair the utilization of these tools. Even though improved operation control, reducing operational cost and compliance resulting from continuous real time quality assurance significantly benefit the pharmaceutical vaccine developers. Hence, amalgamation of three major technique can be carried out that can assist in governing the prudent process more precisely accurately and in a more regulatory affable way. Through this current work, a brief overview of mentioned techniques in relation with continuous vaccine development is presented.

Applications of QbD in Other Pharma Disciplines

IMPLEMENTING QBD PRINCIPLES IN THE DEVELOPMENT OF STABILITY INDICATING ASSAY METHOD OF ROSMARINIC ACID

Palak Karia
Vivekanand Education Society's College of Pharmacy, Chembur, Mumbai, Maharashtra, India

Email: palak.karia@ves.ac.in

Rosmarinic acid is a water-soluble phenolic molecule that is an ester of caffeic acid and 3, 4-dihydroxyphenyl lactic acid. It is primarily responsible for its anti-inflammatory and antioxidant properties. In this study, an AQbD-based stability-indicating assay method for Rosmarinic acid was established. AQbD is the use of QbD to analysis in order to obtain robust analytical results. Analytical quality by design (AQbD) is becoming more popular in the pharmaceutical industry as a part of risk management, drug development, and the pharmaceutical quality system. In AQbD-based method development, an Analytical Target Profile (ATP), Critical Analytical Attributes (CAA's), and Critical Method Parameters (CMP's) are all explicitly established. CAA's were found through risk assessment. Risk assessment was carried out using Failure mode and Effects Analysis (FMEA) approach. Experimental design approach was used to optimize forced degradation conditions utilized in the stability-indicating assay method. The optimized method contained Acetonitrile and 20 mM Phosphate buffer (pH 3) in the ratio 25:75 with a flow rate of 0.8 ml/min. The developed RP-HPLC Stability indicating assay was linear, specific, and accurate, separating degraded products from Rosmarinic acid.

A PARADIGM SHIFT IN ANALYTICAL PROCEDURE DEVELOPMENT: ICH Q14

Rakshita, *Teenu Sharma and Sonia Dhiman*
Chitkara College of Pharmacy, Chitkara University, Punjab, India

Email: rakshitasalalli@gmail.com

Very recently, on 22nd March 2022, a new guidance, i.e., ICH Q14 has been endorsed by the Members of the ICH Assembly. This guideline describes the application of quality by design (QbD) principles to analytical method development. It is integration of science and risk-based approaches for developing and maintaining analytical procedures suitable for the assessment of the quality of drug substances and drug products. This concept of QbD in analytical method development is also known as AQbD (analytical quality by design). It allows the analytical method for movement within method operable design region (MODR). Unlike current methods, analytical method developed using AQbD approach would reduce the number of out-of-trend (OOT) results and out-of-specification (OOS) results due to the robustness of the method within the region. QbD approach to method development would potentially lead to a more robust/rugged method due to emphasis on risk assessment and management than traditional or conventional approach. An important component of the AQbD would facilitate the understanding of dependent variables or factors, and their interaction effects by a desired set of experiments on the responses to be analyzed. Thus, application of ICH Q14 to develop and optimize new or revised analytical procedures for studying release and stability of the commercial drug substances and products can provide better assurance of the performance of the procedure, and can provide an opportunity for more efficient regulatory approaches to related post approval changes.

ANALYTICAL QbD ENABLED LIQUID CHROMATOGRAPHIC (LC) METHOD DEVELOPMENT FOR RALOXIFENE: APPLICATION IN STRESS-INDUCED DEGRADATION AND BIOANALYSIS

***Gajanand Sharma*[1]**, *Anjali Pant*[1], *Sumant Saini*[2], *Atul Jain*[3], *Ravi Pratap Barnwal*[4] *and Bhupinder Singh*[1,5]

[1]*University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh, India*
[2]*School of Pharmaceutical Sciences, Lovely Professional University, Phagwara, Punjab, India*
[3]*Delhi Institute of Pharmaceutical Sciences and Research, Delhi Pharmaceutical Sciences and Research University, New Delhi, India*
[4]*Department of Biophysics, Panjab University, Chandigarh, India*
[5]*Chitkara College of Pharmacy, Chitkara University, Rajpura, Punjab, India*

Email: gajanand.uips@gmail.com

A sensitive, rapid, reproducible, and economical high-performance LC (HPLC) method is systematically developed using QbD principles and validated for the quantification of raloxifene hydrochloride (RLX-HCl). Failure mode and effect analysis (FMEA) and factor screening studies were carried out using Taguchi design, indicating buffer volume and flow rate as the critical method parameters (CMPs), resulting in a significant effect on chosen critical analytical attributes, i.e., tailing factor and theoretical plate number. Optimization of method conditions was performed employing face-centred cubic design. Method operable design region (MODR) was earmarked and optimized using 0.05 M citrate buffer, acetonitrile, and methanol (57:40:3 v/v/v) as mobile phase at 0.9 mL.min-1 flow rate, λmax of 280 nm and column temperature of 40°C. Validation of developed analytical method was accomplished as per ICH guidelines Q14 confirming high levels of linearity, precision, accuracy, robustness, and sensitivity. Application of Monte Carlosimulations and magnitude of variance inflation factor for multicollinearity assessment among CMPs enabled the attainment of best plausible chromatographic resolution and corroboration of the MODR. Stress-induced degradation and bioanalytical method using rat plasma samples was carried out finally corroborating the aptness of developed HPLC methods for RLX- HCl quantification in the biological fluids and marketed dosage form.

THE POWER OF QBD AND AI IN PERSONALIZED CHEMOTHERAPY: CURRENT TRENDS AND FUTURE PROSPECTS

Rohit Grover *and Anjali Sharma*
Guru Gobind Singh College of Pharmacy, Yamunanagar, Haryana, India

Email: 705rgrover@gmail.com

Personalized medicine is an emerging field that aims to provide tailored treatments based on an individual's unique genetic makeup, lifestyle, and environment. Chemotherapy, a widely used treatment for cancer, can have varying degrees of efficacy and toxicity in different patients. Therefore, the use of Quality by Design (QbD) and Artificial Intelligence (AI) can help optimize personalized chemotherapy dosing and improve patient outcomes.

QbD is a systematic approach that involves designing quality into a product or process from the outset. QbD helps to identify critical process parameters (CPPs) and critical quality attributes (CQAs) that affect the quality of the final product. AI is another powerful tool that can be used to optimize personalized chemotherapy. AI algorithms can analyse large amounts of patient data, such as genetic information, clinical history, and treatment response, to identify patterns and predict outcomes.

The use of QbD and AI in personalized chemotherapy has several potential benefits. It can help reduce treatment variability and improve patient outcomes, minimize adverse events and drug-related toxicity, and ultimately lead to more efficient use of healthcare resources. Additionally, the integration of these technologies into the drug development process can help reduce time-to-market and lower costs. The aim of the study is to compile recent data of optimization using both techniques which will be beneficial for the pharmaceutical scientist working in this field.

DESIGNING AND OPTIMIZATION OF THE EXTRACTION PROCESS FOR ECLIPTA ALBA LINN. USING RESPONSE SURFACE METHODOLOGY

***Dubey Priya**, Malik Jai and Karan Maninder*
Department of Pharmacognosy, University Institute of Pharmaceutical Sciences – Centre of Advanced Study, Panjab University, Chandigarh, India

Email: priyadubey1160@gmail.com

The Asteraceae family includes the commercially significant plant Eclipta alba Linn. (Often known as bhringraj). The present study was designed to optimize its extraction procedure (based on residue weight and wedelolactone content determined by TLC densitometry). The dry powder material was extracted by using four different extraction techniques namely Soxhlet, reflux, maceration, and ultrasonication. For each technique, four solvents acetone, ethanol, 50% ethanol & 80% ethanol were used to extract the drug. The whole study was divided into two sets of the experiment. In the first set of experiments, particle size, and the drug-to-feed ratio was kept constant and the drug was extracted with each solvent using all four extraction technique for different time duration. The efficiency of the extraction technique and solvent was assessed on basis of residue weight and wedelolactone content. Particle size and the drug-to-feed ratio were changed in the second set of experiments, which involved extracting the drug using an extraction technique, solvent, and time duration chosen based on the outcomes of the first set of extraction. The response surface methodology with the central composite design was applied with the assistance of a design expert to predict the experimental conditions for the best wedelolactone yields using three parameters, extraction time, particle size, and solute-solvent ratio, and two responses, residue weight and wedelolactone (%).

PROACTIVE QUALITY RISK MANAGEMENT: ESSENTIAL FOR SUCCESSFUL QBD IMPLEMENTATION

Anjali Sharma[1], *Devkant Sharma*[2] *and Geeta Deswal*[1]
[1]*Guru Gobind Singh College of Pharmacy, Yamunanagar, Haryana, India*
[2]*CH. Devi Lal College of Pharmacy, Jagadhari, Haryana, India*

Email: sharma.sharmaa.anjali@gmail.com

Quality Risk Management is a systematic process for identifying, evaluating, and controlling potential risks to product quality. The use of QRM in QbD helps to identify potential quality risks and ensures that appropriate measures are taken to mitigate them. The QbD approach to drug development focuses on designing and developing products with a thorough understanding of how process parameters affect product quality. The use of QRM in QbD helps to identify potential quality risks early in the development process, allowing for timely and effective risk management strategies. This approach ultimately leads to the development of high-quality products that meet regulatory requirements and are safe for patient use. Effective QRM is an ongoing process that requires continuous monitoring and evaluation of product and process risks. It involves a proactive approach to risk management, with a focus on identifying potential risks before they occur. This approach helps to minimize the likelihood of quality issues arising and ensures that appropriate measures are in place to address any issues that do arise. In conclusion, the use of QRM in QbD is essential for the successful development and commercialization of high-quality pharmaceutical products. Present study aims to focus on the importance of risk management for the development of high-quality products by implementing quality by design approach.

Novel Drug Delivery Systems (NDDS)

DEVELOPMENT AND FORMULATION OF NANOPARTICULATE CARRIERS WITH ENHANCED ANTIFUNGAL ACTIVITY

Pallavi Bassi
Chitkara College of Pharmacy, Chitkara University, Punjab, India

Email: pallavibassi1@gmail.com

Fluconazole is the most commonly used antifungal agent for treating fungal skin infections. However, due to the development of resistance against Candida species, its utility is limited. As a result, there is a need to optimize and improve Fluconazole's antifungal efficacy. In the present study, attempt was made to develop an effective antifungal formulation containing fluconazole and neem extract loaded silver nanoparticles. Antimicrobial properties of metal nanoparticles have been reported. Fluconazole -loaded silver nanoparticles were prepared by green synthesis and incorporated into carbopol 934P gel for topical application. Nanoparticles were characterized in terms of zeta potential, morphology, particle size. Fourier transform infrared spectroscopy (FTIR) analysis was used to confirm the drug's compatibility with the excipients. The silver nanoparticles had an average size of about 60nm. The developed formulation showed sustained drug release and good antifungal activity in comparison to control group.

DEVELOPMENT & CHARACTERIZATION OF CALCITRIOL LOADED *IN-SITU* GEL FOR ENHANCING ORTHODONTIC TOOTH MOVEMENT

Nitasha Chauhan *and Amit Bhatia*
Department of Pharmaceutical Sciences and Technology, Maharaja Ranjit Singh Punjab Technical University, Bathinda, Punjab, India

Email: drbhatiaamit@gmail.com

Introduction: Orthodontics is a branch of dentistry which deals with the irregularities of teeth e.g. straightening of crooked tooth, reduction of gap between teeth etc. This treatment involves an application of force (braces) on the teeth to align them properly. But the treatment takes around two years or even more to get complete. Some side effects related to longer orthodontic therapy are demineralization, gingivitis, root resorption etc. So, there is an urgent need to develop a novel formulation to enhance orthodontic tooth movement and decreasing treatment time.

Objective: The purpose of the study was to formulate and characterize calcitriol loaded *in-situ* gel for enhancing orthodontic tooth movement.

Materials & Method: Calcitriol, Kolliphor P407 were used for the preparation of *in-situ* gel by using cold process method.

Results: The prepared formulation showed the phase change within 4 second at body temperature, whereas the *in-vitro* drug release and an *ex-vivo* permeation study showed 99% and 71% of drug release respectively within 2 minutes.

Conclusion: The prepared formulation was non-invasive in nature and planned to deliver at the local site (gums) in the form of droplets which converted into gel within seconds and show better drug release as well as better therapeutic action.

DESIGN AND DEVELOPMENT OF MYCOPHENOLATE MOFETIL LOADED MICROEMULSION FOR THE TREATMENT OF PSORIASIS

***Mohit Kumar**, Palakdeep Kaur and Amit Bhatia*
Department of Pharmaceutical Sciences and Technology, Maharaja Ranjit Singh Punjab Technical University, Bathinda, Punjab, India

Email: maddysharma3303@gmail.com

The aim of this study was to design and develop a microemulsion formulation of Mycophenolate mofetil (MMF) for the treatment of psoriasis. Different oils, surfactants, and co-surfactants were screened for drug solubility. Various formulations of MMF were prepared by using the water titration method and pseudo-ternary phase diagrams were constructed. The optimized formulation was characterized for optical transparency, pH, globule size, PDI, surface charge, transmittance, drug content, *in vitro* drug diffusion study, *ex vivo* skin permeation and deposition, and stability studies. The optimized MMF microemulsion had shown a globule size of 79.24 nm, PDI of 0.217, zeta potential of -0.971 mV, pH 5.6, and % transmittance 99.97%. By the developed The HPLC method was developed in order to determine drug content in microemulsion formulation which was found to be 98.65± 0.78%. The *In vitro* diffusion study performed by using dialysis membrane showed 49.273 ± 0.823 % of drug release within four hours and at the end of seven-hour period, almost whole the drug (99.26 ± 1.28%) diffused from the prepared microemulsion. The drug permeated through rat skin and was found to be 0.911µg/cm^2/hr. Stability studies showed that the MMF microemulsion was stable at room temperature, in deep-freeze conditions, and when subjected to forced centrifugation studies. The developed formulation might a good alternative for the treatment of psoriasis.

SITE SPECIFIC LOCALIZATION OF GEMCITABINE TO BREAST CANCER TISSUE USING CHITOSAN NANOPARTICLE-BASED GEL

Komal Sall *and Rajan Swami*
Chitkara College of Pharmacy, Chitkara University, Punjab, India

Email: komalsallmail@gmail.com

Breast cancer is the most leading cause of cancer related death around the world in women. In 2021, there were 2,088,987 new breast cancer cases and 672,323 deaths from the disease. Based on the type and cancer extent, there are many current treatments of breast cancer are available i.e., radiation, surgery, and systemic therapies (chemotherapy, target and hormonal). However, the therapies are associated with serious side effect due to the exposure of drugs/radiations to the non-cancerous tissue. Hence efforts should be done to localize the drug delivery to the affected area or tumor only. Gemcitabine (GEM) is a nucleoside analog chemotherapeutic agent that has a wide spectrum of anticancer activities. Moreover, when it is given through the oral route, it is rapidly metabolized by an extensive deamination enzyme that decreases its oral bioavailability. Localized administration GEM loaded chitosan Nanoparticle (GEM-CH NPs) using skin route have numerous advantages, such as target drug delivery, sustained release of drug as well as reduced systemic exposure of drug, which further may reduce hematological toxicity. Hence, our strategy is to deliver GEM-CH NPs with considerably high skin permeability to improve their bioavailability in localized adjoining breast cancer tissue only with alleviating the indigenous side effects of the naïve drug.

NOVEL TOPICAL DRUG DELIVERY SYSTEM OF TAMOXIFEN FOR THE TREATMENT OF PSORIASIS

***Gursharanpreet Kaur*[1]**, *Gajanand Sharma*[1], *Bhupinder Singh*[1,2] *and OP Katare*[1]
[1]*University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh, India*
[2]*Chitkara College of Pharmacy, Chitkara University, Punjab, India*

Email: gursharanpreetkaurchahal@gmail.com

The current research intends to investigate lipid-based nano liposomal system of Tamoxifen (TAM) with enhanced stability and delivery potential in psoriasis. In the present study, the synergistic potential of lipid-phospholipid is explored as a promising strategy towards combating psoriatic skin. The values of particle size, Polydispersity index (PDI) and zeta potential of the developed carrier system were found to be 458.1 nm, 0.1 and -10.62 mV respectively. The system was further incorporated in a lotion which was found to be a shear-thinning system with the yield value of 15.87 Pa. The skin permeation studies exhibited the superiority of the prepared nano-liposomal lotion over conventional formulation. Further, the dermatokinetic studies and pharmacodynamic studies viz. rat tail psoriasis model, imiquimod induced psoriatic model confirmed better permeation and enhanced skin bioavailability of Tamoxifen to the epidermis as well as dermis *vis-à-vis* the conventional product. Further combination of tamoxifen with other molecules is being studied to enhance the therapeutic efficacy of formulation.

FLEXIBLE MEMBRANE VESICLES: A NOVEL DRUG DELIVERY SYSTEM FOR TOPICAL DELIVERY OF ETODOLAC

***Mohd Askari*[1], *O.P Katare*[2] *and Kaisar Raza*[1]**

[1]*Department of Pharmacy, School of Chemical Sciences and Pharmacy Central, University of Rajasthan, Ajmer, Rajasthan, India*

Email: askarimehdi768@gmail.com

Etodolac, a BCS class □ non-steroidal anti-inflammatory drug, has shown promising results in the management of musculoskeletal pain and conditions like osteoarthritis. Orally, it is a potent drug, though there are a few challenges like low solubility, peptic ulcers, gastro-intestinal bleeding, and gastric disturbances. In this context, the recent development of novel drug delivery system has been quite encouraging to address these issues, wherein phospholipid plays a crucial role. Flexible membrane vesicles (FMVs) are new generation liposomes in which cholesterol has been replaced by edge activator so that the FMVs can deform and pass through the narrow constriction (even more than 10 times lesser than their own size). This high deformability gives better penetration of intact vesicles into or across the skin. The FMVs were prepared, and the characterization and evaluated in apt animal models. The vesicle size, PDI, zeta -potential, drug entrapment and drug loading of FMVs were found to be 476.23 nm, 0.256, -14.33mV, 61.02% and 28.78%, respectively. The clinical efficacy of ETO-FMVs was evaluated in an open-label clinical trial and it was observed that the topical delivery of ETO by the FVM-gel was 3.2 folds enhanced in comparison to conventional formulation. The average improvement in pain, stiffness and physical function scores was found to be 52.78%,54.64% and 42.42%, respectively. The present studies provide evidence for the safe and effective delivery of etodolac that can be transformed in the form of a viable topical product.

ENHANCED ACECLOFENAC DELIVERY USING LIPOSPHERES WITH IMPROVED DERMATOKINETIC ATTRIBUTES IN RHEUMATOID ARTHRITIS PAIN THERAPY

***Anil Thakur*[1]**, *Gajanand Sharma*[1], *Gurpal Singh*[1], *Ravi Pratap Barnwal*[2], *Bhupinder Singh*[1,3] *and OP Katare*[1]

[1]*University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh, India*
[2]*Department of Biophysics, Panjab University, Chandigarh, India*
[3]*Chitkara College of Pharmacy, Chitkara University, Punjab, India*

Email: thakuranil841@gmail.com

The present work focuses on the development of lipid-based lipospheres of aceclofenac (ACE) with enhanced stability and delivery potential to the inflammatory sites in rheumatoid arthritis. In the current study, the combined potential of lipid-phospholipid liposphere with aceclofenac was explored as a promising strategy towards combating pain-related infection sites. The values of particle size, Polydispersity index (PDI) and zeta potential of the developed carrier system were found to be 308.8 nm, 0.299 and -31.9 mV respectively. The system was further incorporated in a hydrogel which was found to be a shear-thinning system with the yield value of 2.089 Pa. The skin permeation studies exhibited the superiority of the prepared liposphere-loaded gel formulation over the MKT gel. Further, the dermatokinetic studies and pharmacodynamic studies viz. radiant heat tail-flick model, formalin-induced paw-licking model, paw edema model, xylene-induced ear edema model, air pouch inflammation model in mice confirmed better permeation and enhanced skin bioavailability of ACE to the epidermis as well as dermis *vis-à-vis* the MKT product. In conclusion, the current findings can provide a suitable alternative for the development of an effective topical formulation of ACE in the liposphere system.

FORMULATION DEVELOPMENT, CHARACTERIZATION AND EVALUATION OF PHOSPHOLIPID BASED NANOSTRUCTURED CARRIER OF ASCORBIC ACID

***Luke Ruatdika Khiangte*[1]**, *Akanksha Mahajan*[1], *Bhupinder Singh*[1,2] *and OP Katare*[1]
[1]*University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh, India*
[2]*Chitkara College of Pharmacy, Chitkara University, Punjab, India*

Email: khiangteluke@gmail.com

The present work focuses on the development, design and evaluation of a topical drug delivery system of ascorbic acid to create a stable form to tackle drug and dosage form-related difficulties. The novelty of the formulation emphasizes on the entrapment of the drug in a suitable nanostructured carrier system composed of phospholipids in combination with other excipients which aims to contribute to unique type of vesicles to achieve better safety, efficacy, and stability. The developed nanostructured carrier system not only improved the skin permeation potential of the drug, but also presented an increase in its efficacy. The Vesicle size, PDI, zeta potential, and drug release were found to be 254 nm, 0.199, 0.267 mV, and 51.43% respectively. The skin permeation studies exhibited the superiority of the prepared nanocarrier system over the marketed formulation. Further, the dermatokinetic studies and skin safety studies confirmed better permeation and less irritancy potential of ascorbic acid into the epidermis as well as dermis *vis-à-vis* the marketed product. In conclusion, the current findings can provide a suitable alternative for the development of an effective topical formulation of Ascorbic Acid in a nano-structured carrier system.

SYSTEMATIC DEVELOPMENT, CHARACTERISATION AND EVALUATION OF KETOCONAZOLE LOADED SOLID LIPID NANOPARTICLES FOR TOPICAL DELIVERY

Mohammad Ramzan, *Saurav Hans and Indu Pal Kaur*
University institute of pharmaceutical sciences, Panjab University, Chandigarh, India

Email: ramzan.pharma@gmail.com

The study focused to evaluate and investigate optimized (using QbD by Central Composite Design) and novel ketoconazole (KTZ)-loaded solid lipid nanoparticles (KTZ-SLNs; 2% w/v KTZ) for enhanced permeation across skin. We addressed solid lipid nanoparticle with optimum level of Compritol® 888 ATO and tween 80 to achieve desired size, %EE, and %TDC. KTZ-SLNs were evaluated for size, size distribution, zeta potential (ZP), percent entrapment efficiency (%EE), drug release, morphology (HRTEM and FESEM), thermal behaviour (DSC), spectroscopic (FTIR), and solid-state/diffraction characterization (X-ray diffraction, XRD). The spherical, optimized KTZ-SLN formulation showed particle size of 293 nm and high EE of 88.5%. In vitro release was slow and sustained; and ex vivo permeation parameters were significantly high in KTZ-SLNs treated group as compared to free drug suspension and marketed product (Nizral®; 2% KTZ w/v) treated groups. Confocal Raman spectroscopy experiment showed that KTZ-SLNs could penetrate beyond the human stratum corneum into viable epidermis. Fluorescent microscopy also indicated improved penetration of KTZ-SLNs. KTZ-SLNs were photostable and showed long-term stability over 12 months under set conditions.

RECENT ADVANCES IN BRAIN SPECIFIC DRUG DELIVERY USING COMPUTATIONAL

Sarwal Amita, *Bharti Sunil and T.V.S. Padmajyoti*
University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh, India

Email: sarwalamita@gmail.com

The Blood-Brain Barrier (BBB) is a highly selective barrier between the brain and the rest of the body. For the treatment of Neurological disorders, the therapeutic agents should cross the BBB. Various strategies and techniques have been developed for the brain targeted drug delivery. In order to avoid psychotropic side effects, drugs targeted to other parts of the body should not cross the BBB ideally. Therefore it is important to predict the BBB permeability of the drugs by measuring two important parameters, log BB (the concentration of drug in brain divided by the concentration in blood) and log PS (permeability surface area product). Computational approaches for the prediction of these two parameters such as QSAR models, Machine Learning (ML) models, etc., are quick and reliable.

Management of the distribution of drug to CNS across BBB is more challenging than the development of drugs to treat CNS complications. Avoiding the knowledge of distribution coefficients, the brain penetration potential of new drug candidates can also estimated by using Molecular size, shape and H - Bonding descriptors with the help of softwares like Daylight CIS, HYBOT, MOLOC, etc. Adaptation of tools like QbD, DoE helps in screening and optimization of formulations, making them promising vectors for brain targeting. The formulation of BBB targeting technologies is very active field for research and development.

DEVELOPMENT, OPTIMIZATION AND CHARACTERIZATION OF ATORVASTATIN LOADED SOLID LIPID NANOPARTICLES FOR TOPICAL DELIVERY IN AGE RELATED MACULAR

***Monika Yadav**, Maneesha Rana and Indu Pal Kaur*
UIPS, Panjab University, Chandigarh, India

Email: maneesharana96@gmail.com

Statins are gaining attention for the management of age-related macular degeneration (AMD) due to their pleiotropic nature. However, their oral formulation may show insignificant ocular concentration attributed to their poor bioavailability and existence of blood-aqueous barrier in eye. In the current study, we aimed to develop, self-administrable eye drops composed of atorvastatin (ATS) loaded solid lipid nanoparticles (SLNs) by applying quality by design. In the preoptimization studies, the concentrations of all components, including the lipid and surfactants or co-surfactants were taken as critical material attributes. Particle size and entrapment efficiency were taken as critical quality attributes. A central composite design was applied to get the optimized ATS-SLNs using the Design Expert. The optimized ATS-SLNs were found to be 8 and 12 times more bioavailable in the aqueous and vitreous humor, respectively than free ATS. Three tier (in vitro, ex vivo, and in vivo) ocular safety, higher corneal flux (2.5-fold), and improved stability (13.62 times) including photo stability of ATS on incorporation in ATS-SLNs were established. Overall, the developed SLNs delivered a system with good solubility, stability and promised the delivery up to posterior eye.

SIMULTANEOUS CANCER TREATMENT WITH PHOTOTHERMAL THERAPY AND CHEMOTHERAPY USING GOLD NANORODS COATED WITH METHOTREXATE- CONJUGATED HYALURONIC ACID

Nutan Shukla *and Ratnesh Das*
Dr. Harisingh Gour Central University, Sagar, Madhya Pradesh, India

Email: nutanshukla14@gmail.com

Upon near-infrared (NIR) irradiation, combined treatment comprising of photothermal therapy (PTT) and chemotherapy (CHT) offers synergistic effects by inducing localized heat to intended tumor sites and simultaneously allowed delivering drugs thus to minimize undesired side-effects but enhance cytotoxic therapies. In this study we developed a novel platform that enables simultaneously to respond light stimuli with localized heat and released drugs using drug contained gold nanorods (GNRs). Methotrexate (MTX), a model anticancer drug is attached through hydrolytic ester bonding to targeting molecular hyaluronic acid (HA) that is coated onto GNRs. Based on the rationale, HA provides a good scaffold for high biocompatibility to shield risky GNRs, targeting for a CD44 receptor, and easy chemical binding of drugs. Upon a single light irradiation, MTX-HA functionalized GNRs (MTX-HA @GNRs) provide localized heat to cancer areas for PTT and the elevated temperature accelerates hydrolytic cleavage of the ester bond onto GNRs in physiological condition for CHT, ultimately releasing MTX to cells. In contrast to previous combination therapies that do not concurrently offer heat and drugs upon light stimuli, our NIR triggered CHT with PTT provides clinically effective options with combinatorial treatment that possesses high efficacy resulted in in vitro tests.

PROMISES OF A NOVEL SORAFENIB-LOADED MICROEMULSION IN THE MANAGEMENT OF BREAST CANCER

Nishtha Chaurawal *and Kaisar Raza*
Central University of Rajasthan, Dept. of Pharmacy School of Chemical Sciences and Pharmacy, Ajmer, Rajasthan, India

Email: nishthachaurawal1@gmail.com

Breast cancer is the most prevalent cancer of the world in recent times. Sorafenib tosylate (SFB) is a drug that inhibits the tumor growth and proliferation for the management of cancer. Besides its effectiveness, the drug also exhibits several challenges. The current study focuses on the development and evaluation of microemulsion (ME) for the delivery of SFB in order to manage breast cancer. The optimized SFB-loaded ME was characterized for *in-vitro* and *in-vivo* studies. The particle size of the optimized formulation was found to be 58.8 ± 0.02 nm with a zeta potential of 0.05 ± 0.03 mV. The optimized formulation offered entrapment efficiency of 72.64 ± 0.84%. The IC_{50} value of SFB-loaded ME was substantially improved as compared to the free SFB at the concentration of 0.75 µM. The data obtained from cellular uptake study inferred the higher cellular internalization of SFB from the optimized formulation compared to the free SFB and the marketed product. furthermore, the *in-vivo* pharmacokinetic studies inferred that the bioavailability of SFB had been increased by 1.5 folds after encapsulating in the ME system. The above results provided a future scope for oral SFB in its nano-form for safe and effective management of breast cancer.

Drug Regulatory Affairs and Other Pharma Trends

AI IN THE HEALTHCARE: REGULATORY PERSPECTIVES

Himanshu Sharma *and Teenu Sharma*
Chitkara College of Pharmacy, Chitkara University, Punjab, India

Email: honeyhimanshu.sharma@gmail.com

The use of artificial intelligence (AI) in healthcare has potentially revolutionized the healthcare sector, but it also raises concerns around privacy, security, and ethics. In this context, several regulatory frameworks have been established to harmonize the use of AI in healthcare. The Health Insurance Portability and Accountability Act (HIPAA) sets standards for the protection of medical records and personal health information, while the US Food and Dru Administration (FDA) regulates medical devices that use AI algorithms. Likewise, General Data Protection Regulation (GDPR) governs the collection, use, and protection of personal data in Europe, and ethical guidelines have been developed by organizations like American Medical Association and the World Health Organization. While regulations are still evolving, the responsible and ethical use of AI in healthcare is a top priority for policymakers and healthcare providers. Regulations and guidelines around the use of AI in healthcare may differ by country and region, but they generally emphasize the importance of transparency, accountability, and fairness in the development and use of AI algorithms. As AI continues to play a vital role in healthcare, it is likely that additional regulations and guidelines will be needed to ensure the safe and ethical use of this technology.

QUALITY BY DESIGN (QBD) AS A TOOL FOR GLOBAL REGULATORY COMPLIANCE

Diwakar Shukla *and Pooja Mittal*
Chitkara University, Rajpura, Punjab, India

Email: diwakarshukla663@gmail.com

The international council for technical requirement for pharmaceuticals for human use (ICH) has recognized QbD as a key tool for pharmaceutical process and for filling the regulatory compliance. According to ICH Q8 (R1) guidelines, a systematic approach to the development that beings with predefined objectives which emphasizes product and process control, quality risk management. The ICH Q9 (R1) is intended to provide guidelines on the tools for quality risk management that can be applied in various aspects of pharmaceutical quality. The development of consistency by pharmaceutical companies can lower the danger of product recalls, increase public safety, and meet quality standards. When determining the regulatory requirements and rules that apply to your product, the QbD is employed as a first step. To detect the possible risk, it is also helpful to identify the critical quality attributes (CQAs), critical process parameters (CPPs) of the product, CPPs parameters that affect CQAs, and user risk assessment tools like failure mode and effect analysis (FMEA) which includes a preventive tool that lower potential risks. It is a current inclination among pharmaceutical industry to implement Advanced QbD (AQbD) in method development processes as a part of risk management, pharmaceutical development and pharmaceutical quality systems (ICHQ10).

BIOSIMILARS: ASSESSMENT OF CURRENT REGULATORY GUIDELINES

Urmi Bhadouria *and Teenu Sharma*
Chitkara College of Pharmacy, Chitkara University, Punjab, India

Email: urmibhadouia12@gmail.com

Biosimilars are biologic products, demonstrating no clinically meaningful differences in terms of quality, efficacy, safety, and immunogenicity compared with an existing licensed, originator biologic. Thus, biosimilars need a stringent regulatory mechanism for controlling their access to the market. The EMA has taken the lead in the regulatory approval framework for biosimilar products, and the WHO has published guidelines to facilitate global harmonization. The US FDA has been authorized to approve biosimilars by the BPCI Act, 2010. Biosimilars have been manufactured quite early since 2000s, in India, however, there were no regulations specific to biosimilars until 2012. In 2012, the first guideline, "Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India" was introduced by the joint efforts of the Central Drugs Standard Control Organisation (CDSCO) and the Department of Biotechnology (DBT). The basic concepts and main principles of approving biosimilars are similar among various nations, notwithstanding some differences in regard to the scope, the choice of reference product, and the data requirement. It has been observed that small changes in manufacturing processes can have significant undesirable clinical impacts in biosimilar manufacturing. As a result, regulatory authorities all over the world have adopted strict guidelines for the approval of biosimilars.

CHALLENGES FOR CLINICAL STUDIES IN INDIA: A REGULATORY PERSPECTIVE

Tanya Sood *and Teenu Sharma*
Chitkara College of Pharmacy, Chitkara University, Punjab, India

Email: tanyakuthiala@gmail.com

Clinical trials are crucial to the drug development process, as this guarantees the efficacy and safety of any new treatment and serve as the foundation for releasing more advanced and effective therapeutics onto the market. All pharmaceutical-related research and regulatory concerns in India fall under the purview of the Drug Controller General of India (DCGI) and Central Drugs Standard Control Organisation. Numerous regulatory challenges, both regulatory and operational, however complicate clinical research in India. Lack of GCP trainings and empowerment of ethical committees, making consent more informed are a few aspects to be taken care of. CDSCO should adopt a more focused approach towards passing orders for regulating compensation for injury or death related to a trial. Rules mandating submission of those SAEs reports where the sponsor agrees to pay fair compensation should be suitably amended to truncate further analysis of an SAE by the expert committee. Thus, there is ardent to need to address these regulatory challenges as these had grave ramifications, from a counterfactual perspective, for public health due to delays in introduction of new and relevant therapeutics worsening of the problem of drug lag in the country.

NAVIGATING THE REGULATORY LANDSCAPE: APPROVING VACCINES IN TIMES OF GLOBAL HEALTH EMERGENCIES

Sahil Bains *and Neeraj Mittal*
Chitkara College of Pharmacy, Chitkara University, Punjab, India

Email: Sahil.bains.9216@gmail.com

A vaccine is a biological preparation that induces active, acquired immunity against a specific infectious disease. It has been thoroughly investigated and confirmed that vaccines are safe and effective. But the issue of vaccine development and licensing has been thrust into the spotlight by the early 2020 COVID-19 pandemic. Concerns have been raised about the regulatory mechanisms that regulate vaccine licensing, especially during times of global health emergencies as countries scramble to protect their populations from the spread of infectious disease. In order to ensure the safety and effectiveness of vaccines, the approval process is intended to be quick and flexible during times of emergency. Vaccine approval and surveillance are both handled by regulatory bodies, which can be found in many different nations, to derive the ethical and legal implications of emergency vaccine approval.

QUALITY BY DESIGN (QBD) IN GENERIC DRUG DEVELOPMENT

Parag Bhayana *and Rajni Bala*
Chitkara College of Pharmacy, Chitkara University, Punjab, India

Email: Paragbhayana1@gmail.com

Quality by Design (QbD) precepts provide opportunities for enhancing efficiencies and reducing costs, especially for generic products. Over 80% of prescriptions dispensed in the United States utilised generic dosage forms. QbD promotes product quality by applying statistical, analytical, and risk management strategies in the design, development, and manufacturing phases. To apply QbD as a systemic approach, the company starts by understanding, step by step, the space design, the design of the dosage form, the manufacturing process, and the critical process parameters that are essential to the product quality. QbD speaks to real and significant changes in how industry and regulatory agencies approach the regulatory process. Relevant documents from the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), ICH Q8, Pharmaceutical Development, along with ICH Q9, Quality Risk Management, and ICH Q10, Pharmaceutical Quality Systems, indicate on an abstract level how quality by design acts to ensure drug product quality. Especially for the generic drug manufacturers or (ANDA sponsors), who were not actively involved in the ICH processes, there is a need for more concrete descriptions of quality by design.

DEVELOPMENT AND VALIDATION OF STABILITY-INDICATING ASSAY METHODS FOR VALBENAZINE

Aastha Bishnoi, *Tanvi Gupta and Alka Bali*
University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh, India

Email: aasthabishnoi97@gmail.com

The present research was designed for the development and validation of stability indicating assay methods for valbenazine and characterization of its stress degradation products. Valbenazine is a highly selective vesicular monoamine transporter 2 inhibitor indicated for hyperkinetic movement disorders, particularly tardive dyskinesia. Stress testing is intended to identify the likely degradation pathways, and to validate the stability indicating procedures. Drug molecules possess several reactive sites which are susceptible to degradation under various stress conditions of hydrolytic, oxidative, thermal and photolytic stress which can lead to formation of various degradation products or impurities which not only reduces the active drug content but can also contribute to the toxic effects of the drug thus limiting the therapeutic use. The drug was found to be degraded under conditions of acid and alkali hydrolysis and remained stable under oxidative, thermal and photolytic degradation conditions. Hyphenated mass spectrometric technique (LC-MS/TOF has been utilized for identification and characterization of various stress degradation products. The relative retention times of the degradation products formed in all types of stress condition revealed the LC-UV method was able to separate a total of four degradation products (I-IV) from the standard drug. Reverse phase-UPLC method was developed and enhanced for suitable resolution of the drug from their degradation products. LC-MS/TOF studies on VAL were conducted to elucidate its complete mass fragmentation pattern for assistance in the characterization of structures of various degradation products which were further authenticated by their mass fragmentation pattern and comparison with their theoretical masses.

DEVELOPMENT AND VALIDATION OF STABILITY INDICATING ANALYTICAL METHODS OF IDELALISIB

***Akshay Kumar**, Marella Mahesh and Alka Bali*
University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh, India

Email: akshaynegi96@gmail.com

Chemical stability of pharmaceutical molecules is a matter of great concern as it affects the safety and efficacy of the drug product. Stress testing is intended to identify the likely degradation products which further helps in determination of the intrinsic stability of the molecule and establishing degradation pathways, and to validate the stability indicating procedures. Idelalisib was subjected to forced degradation under conditions of hydrolysis (neutral, acidic and alkaline), oxidation, photolysis and thermal stress, as suggested in the ICH guideline Q1A(R2). The drug showed significant degradation under alkaline and acidic hydrolytic as well as photolytic conditions. In total, four degradation products (I-IV) were formed under varied conditions, which could be separated by chromatography of respective degraded solutions on Phenomenex C-18 (100 mm x 4.6 mm; 2.6 µ, Kinetex) column using isocratic elution method. Detection wavelength was selected as 270 nm, 280 nm and 290 nm. MS/TOF accurate mass studies were carried out to establish the complete fragmentation pathway of the drug and degradation products, which, in turn, was utilized in characterization of the products. The degradation pathway of the drug leading to generation of four products degradation products I-IV was postulated.

REGULATORY FRAMEWORK FOR DRUGS FOR RARE DISEASES AND ITS CHALLENGES

Sejal Kundra *and Teenu Sharma*
Chitkara College of Pharmacy, Chitkara University, Punjab, India

Email: kundrasejal0688@gmail.com

The growing number of people suffering from rare diseases, facilitates the development and authorisation of medicines for rare diseases, which are termed 'orphan medicines'. Orphan drugs have become a key area of focus in drug development for resolving unmet medical needs, but these drugs require a designation from the regulatory agency called orphan drug designation. Requests for an orphan drug designation can be submitted through the FDA Form 4035. Orphan drug designations may be requested by sponsors for a previously unapproved drug or for a new orphan indication for an already-marketed drug. Sponsors may not apply for orphan drug designation for products for which marketing applications have already been filed or that already have approval under a new drug application (NDA) or biologic licence application (BLA). However, the life-threatening and progressive nature of many rare diseases, combined with the small number of patients available to participate in clinical studies, often makes it impractical or impossible to conduct research using the same models used for more common conditions. Thus, primary goal for FDA should be to facilitate development of therapeutics for rare disorders by promoting predictability, consistency, and reasoned flexibility in the regulatory process within and across its review units.

COMPARITIVE PHYTOCHEMICAL EVALUATION OF VASAVALEHA: AN SEMISOLID AYURVEDIC

***Shivani Sharma**, Geetanshi Saini and Rohit Goyal*
School of Pharmaceutical Sciences, Shoolini University, Solan, Himachal Pradesh, India

Email: geetanshisaini555@gmail.com

Background: Vasavaleha is a herbal formulation recommended to be used for asthma, tuberculosis, fever and respiratory infections.

Objective: The present study aimed evaluating systemic bioavailibilty of piperine and vasicine after administration of Vasavaleha using HPLC/LC-MS.

Material and methods: Different fractions of formulation was made and evaluated under HPLC at 254nm which confirm the presence of vasicine and piperine. Piperine obtained from methanolic extract was used as standard. For bioavailbility studies animals were treated with extract, lab formulation, and pure piperine (20mg/kg, p.o) and vasicine (50mg/kg, p.o) and blood was collected at 1, 2, 4, 8, and 12-hrs, centrifuged and plasma separated.

Results: The results showed that piperine and vasicine was detected in both extract and formulations, with the highest yield obtained in the chloroform fraction i.e. 0.1579% and 0.1560% as compared to the formulations. The percent yield of piperine in plasma was highest after 2 hours i.e. 2.6520%, while the marketed formulation and prepared formulation showed the highest yield after 1 hour i.e. 0.35156% and 0.054665% respectively.

Conclusion: These findings have significant implications for the use of Vasavaleha in various therapeutic applications, and the study highlights the importance of careful fractionation and identification of active constituents for optimizing the biological activity of herbal formulations.

DEVELOPMENT AND VALIDATION OF AN ANALYTICAL METHOD FOR RALOXIFENE HYDROCHLORIDE LOADED NANOSTRUCTURED LIPID CARRIERS

Subhodip Singha, *Aayush Kaushal, Yogita Jore, Ajay Kumar, Vandita Kakkar and Poonam Piplani*

University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh, India

Email: Subhodip0404@gmail.com

The approval of Raloxifene hydrochloride, a nonsteroidal benzothiophene approved by the Food and Drug Administration (FDA) for the prevention and treatment of post-menopausal bone loss at a dose of 60 mg/day acted as a boon for the mankind. However, Raloxifene possess bioavailability limited to 2% by oral route because of extensive first-pass metabolism. NLCs are drug-delivery systems composed of both solid and liquid lipids as a core matrix and possess increased solubility, improved permeability and bioavailability. An accurate and precise analytical method development is an integral part of formulation development to assess the quantity of drug impurity present in formulation. Therefore, the present work was envisaged to develop a cost -effective, simple, analytical method using reversed phase HPLC for quantification of Raloxifene Hydrochloride in NLC's with high accuracy and precision. The developed analytical method of Raloxifene Hydrochloride showed the limit of detection (LOD) and limit of quantitation (LOQ) as 0.03ug/ml and 0.10ug/ml respectively and percentage recovery from the prepared NLCs was found to be 92.85 ± 1.20% when determined by RP-HPLC and 90.48 ± 1.84% by UV spectrophotometer respectively that substantiated the applicability of the developed analytical method.

SOLUBILITY THE MAIN CONCERN FOR POORLY WATER-SOLUBLE DRUGS: FROM METHODS TO SOLUTIONS

Komal Singh *and Neha Bajwa*
University institute of pharmaceutical sciences (UIPS), Chandigarh University, Punjab, India

Email: kmkomalsingh99@gmail.com

The most important variable that affects a drug's bioavailability is its aqueous solubility. One of the biggest issues facing the pharmaceutical business is improving water solubility, which is the key to improving therapeutic efficacy. During the first screening procedure, over 50% of recently created medications are discovered to be insoluble or weakly soluble. The solubility of the medicine can be increased using a variety of techniques. The method entails both chemical and physical drug modification. Any medicine that is absorbed, must be present at the absorption site in the form of a solution. Poorly soluble medications can be made more soluble using a variety of approaches, like physical and chemical alterations to the drug and other strategies. Using a surfactant, complexation, and so on are examples of solid dispersion. The choice of a solubility-improving technology is influenced by pharmacological properties, absorption sites, and the requirements for the dosage form. In order to serve as a quick reference, this study attempted to gather information on various solubility improvement methods and organize it systematically.

National Symposium-cum-Workshop
on
Contemporary Trends, Tools and Techniques in Pharma Quality by Design (QbD):
From Conceptualization to Implementation
20-21 April 2023

NOVEL PHARMACOLOGICAL INTERVENTIONS ON ROLE OF FATTY ACID SYNTHASE AND FREE FATTY ACID IN THE PATHOGENESIS OF DIABETIC AND NON DIABETIC LIVER INJURY

Onkar Bedi[1,2], Niharika Srivastava[3], Davinder Parsad[3] and Pawan Krishan[2]

[1]*Chitkara College of pharmacy, Chitkara University, Punjab, India*

[2]*Department of Pharmaceutical Sciences and Drug Research, Punjabi University, Patiala, Punjab, India*

[3]*Department of Dermatology, Venereology and leprosy, PGIMER, Chandigarh, India*

Email: onkar.bedi@chitkara.edu.in

Background: The onset and development of liver damage is considered to be influenced by drugs and bad dietary habits.

Objectives: Novel pharmacological interventions on role of fatty acid synthase and free fatty acid in the pathogenesis of diabetic and non-diabetic liver injury

Methods: The current study also aims to investigate the relation between paracetamol and high fructose + high fat produced diabetic and non-diabetic liver damage with references to multiple biochemical markers in the context of innovative pharmacological therapies with respect to their anti-adipogenic and hepatoprotective effect. Pterostilbene, Arbutin and Purpurin were used for the management of high fat high fructose diet (HFHF) and paracetamol (PCM) induced liver injury in rodent 28-week and 8-day model respectively. The various biochemicals, oxidative stress parameters were considered for the evaluation of selected interventions. For the sake of scientific credibility, the expression of fatty acid synthase (FASN), and is individualistically linked to diabetes-related fatty liver diseases, was assessed using qRT-PCR.

Results: High fat and fructose diet intake for 28 weeks markedly ($P<0.05$) upsurge the level of glucose as compared to control diet treated experimental rodents. The scenario was reversed in the case of paracetamol treated rodents there was no significant ($P<0.05$) increased in the level of glucose which depicted the difference of diabetic and non-diabetic liver injury models. The lipid, liver, inflammatory (IL-6) level and oxidative stress parameters was shown to possess significant improvement in PTS, ARB and PUR treated groups as compared to the disease treated rodent groups. The abnormal de novo lipogenesis associated with significant ($P<0.05$) upsurge in the level of serum FFA in disease treated groups in comparison to different drug treated groups.

University Institute of Pharmaceutical Sciences (UIPS)

University Institute of Pharmaceutical Sciences (UIPS) of Panjab University is one of the oldest, most prestigious and premier pharmaceutical institutes of India, established in 1944. Known for its excellence in pharmaceutical education and research, and committed to serve the society by adopting global quality standards and ethical values to generate innovative medicinal products, breakthrough research outcomes, and superior professional services using entrepreneurial approach, the UIPS has been ranked among the top public pharmacy institutes in the MHRD-NIRF rankings by Govt. of India. Owing to its accomplishments galore in research publications, patents, landmark discoveries, tech-transfers of nanotech-enabled drug delivery products, onsite industrial training programs, numerous awards and accolades earned by its globally renowned faculty, the Institute is seen with marked degree of esteem in the entire techno-scientific world. Over a dozen of its faculty and researchers adorn the Top 2% list of most widely-cited scientists promulgated by Stanford University, USA. The productivity of its trained and skilled human resources and placement of its alumni has been ranked par-excellence in India and beyond.

Chitkara College of Pharmacy (CCP)

Established in 2005, Chitkara College of Pharmacy (CCP), in Chitkara University, Rajpura, Punjab, is a front-runner institute across the country in pharmaceutical education and research. Well-groomed through innovative teaching technologies and hands-on training on contemporary practices and future challenges, the students of CCP in Bachelors, Masters or Doctoral research programs are considered as highly employable, locally as well as globally. With its courses customized to meet the ever-evolving requirements of the pharma profession, one can find its alumni in frontline positions among pharma industry, hospitals, communities, academia, drug control and research institutes, the world over. Supported by highly qualified and diversified faculty, well-equipped laboratories and a well-resourced library, while collaborating with industry partners and research centres, CCP has developed comprehensive research portfolios with over 185 patents and 1450 Scopus-indexed publications. Marked with 20th rank as per MHRD-NIRF and several other notable accomplishments, the institute is all set to be a torch-bearing Centre of Excellence for higher education in Pharmaceutical Sciences across the Nation.