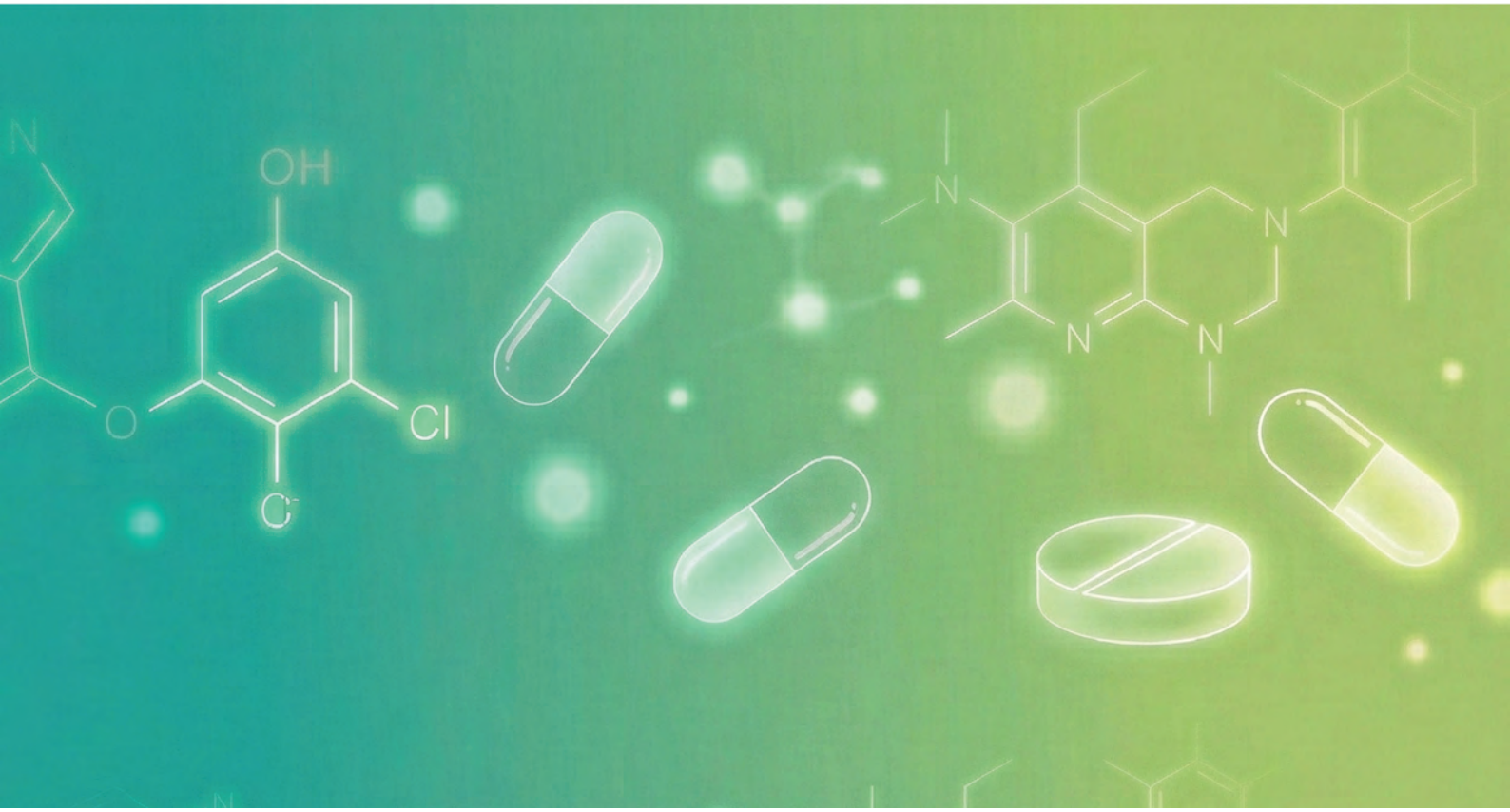
K. B. Institute of Pharmaceutical Education and Research
(A constituent college of Kadi Sarva Vishwavidyalaya, Gandhinagar)

KBICONN

Annual National Level Conference

Path to parity: Strategies in Generic Drug Development



SCIENTIFIC ABSTRACT BOOK

5th & 6th December, 2025

VISION

The institute intends to be the prominent public research and teaching institute in the field of pharmacy, linking the people of Gujarat to the nation and the world

MISSION

Through the scholarly pursuits of teaching, research and service, KBIPER is dedicated to preparing pharmacy professionals committed to lifelong learning, fostering excellence and innovations in research and developing and participating in professional practice and community outreach

ABOUT SVKM

Established in 1919 by philanthropist Pujya Chhaganbha, the Sarva Vidyalaya Kelavani Mandal is driven by the motto “Kar Bhala, Hoga Bhala” (Do Good, and Good Will Happen). From just 6 students, it has grown into a major educational trust in Kadi and Gandhinagar, now educating over 50,000 students and hosting more than 8,000 in its facilities.

The trust provides value-based, merit-based education to all, supported by its alumni and community. Its growth was heavily influenced by Shri Maneklal Patel, a visionary leader from a humble background who was recognized for his transformative work in education and community development. The trust continues this legacy of service through initiatives like adopting local Anganwadis and government schools.

ABOUT KSV

Kadi Sarva Vishwavidyalaya (KSV) is a University established vide Gujarat State Government Act 21, 2007 in May 2007. The university has been setup by Sarva Vishwavidyalaya Kelavani Mandal; a trust with more than 100 years of philanthropic existence. The trust provides need based education by developing courses of contemporary relevance. KSV is a university of excellence promoting research based activities which would foster higher economic growth.

ABOUT KBIPER

Established in 1995, KBIPER is first self-finance pharmacy institute of the state, a constituent college of KSV. The institute offers B. Pharm., M. Pharm., Pharm. D., Pharm. D. (PB), and PhD in Pharmaceutical Sciences. KBIPER is the first institute to start Pharm. D course in Gujarat in the year of 2010.

Institute has established the first Drug Information Centre in Gujarat. Since the inception, institute is notably progress in academic, research and social outreach. Concomitant accreditation by two accreditation agencies, NIRF ranking, GSIRF ranking, research lab and Instruments, animal house, ethics committees, medicinal garden, museum, strong alumni witnesses credible glorious journey of Institute year after year.

PATRONS

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President, Kadi Sarva Vishwavidyalaya

Dr. Gargi Rajpara
Director, Kadi Sarva Vishwavidyalaya

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ABOUT IPGA

The Indian Pharmacy Graduates' Association (IPGA), established in 1973, is a premier national professional body registered under the Societies Registration Act, 1860. It is dedicated to the upliftment and recognition of pharmacy professionals across India. With a robust network of 17 state branches and 11 local chapters, and affiliations with major organizations like the Indian Pharmaceutical Congress Association (IPCA), IPGA represents a powerful collective voice for the community.

The association's primary mission is to enhance the professional status of pharmacy graduates, ensuring they secure their rightful and pivotal place within the healthcare system. To achieve this, IPGA actively conducts a wide array of developmental activities, including workshops, annual conferences, and seminars focused on the latest advancements in pharmaceutical sciences. These initiatives are designed to continuously update the knowledge and practical skills of its over 10,000 life members. Beyond education, IPGA is committed to fostering strong professional relationships among its members and advocating for their contributions with key government and healthcare decision-makers. The quarterly newsletter, "IPGA Today," further strengthens this community by highlighting branch activities, member achievements, and critical updates from the field, ensuring a well-informed and connected membership.

ABOUT CONFERENCE

Generic drug development is a dynamic and fast-growing billion-dollar industry that is transforming global healthcare by making affordable and high-quality medicines accessible to all. Successful generic drug development demands a strategic blend of innovative formulation approaches, robust analytical method development, a thorough understanding of regulatory frameworks, and protection of intellectual property rights.

This National Conference on "Path to Parity: Strategies in Generic Drug Development" is designed to be a premier platform for scientists, academicians, industry leaders, and regulatory professionals to come together, share knowledge, and explore emerging trends and opportunities in this high-impact sector.

The conference will feature inspiring keynote address, expert-led sessions, and interactive poster presentations, creating avenues for participants to network, collaborate, and gain actionable insights into the evolving landscape of generic drug development.

Join us for this exciting event that bridges science, innovation, and regulation, and positions participants at the forefront of advancements shaping the future of generic pharmaceuticals.

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Chairman, Sarva Vidyalaya Kelavani Mandal (SVKM),
President, Kadi Sarva Vishwavidyalaya (KSV)

MESSAGE FROM THE CHAIRMAN (SVKM) AND PRESIDENT (KSV)

I am pleased to extend my warm congratulations to **K. B. Institute of Pharmaceutical Education and Research (KBIPER)**, **Gandhinagar** for organizing *KBICONN – National Conference on "Path to Parity: Strategies in Generic Drug Development."* This theme is timely and highly relevant as India continues to strengthen its position as a global leader in affordable and quality healthcare.

Focusing on *parity* in generic drug development reflects the institute's commitment to addressing real-world pharmaceutical challenges. By bringing together academicians, researchers, industry professionals, and regulatory experts, the conference will create a valuable platform for knowledge exchange and meaningful dialogue on advancing India's generic drug ecosystem.

KBIPER has consistently demonstrated excellence in education, research, and professional development. The efforts of the faculty and the enthusiasm of the students continue to elevate the institute's standing among the nation's leading pharmacy institutions. I am confident that this conference will further add to its achievements.
I encourage all participants to actively engage, collaborate, and draw inspiration from this academic gathering. May the discussions and interactions at KBICONN 2025 spark innovative ideas and contribute to a stronger, more equitable healthcare landscape for our country.

On behalf of Kadi Sarva Vishwavidyalaya, I extend my best wishes for the success of the conference and commend KBIPER for its dedication to academic and scientific advancement.

Mr. Vallabhbhai M Patel

MESSAGE FROM THE I/C DIRECTOR, (KSV)

Dr. Gargi Rajpara
I/C Director,
Kadi Sarva Vishwavidyalaya.

I am pleased to extend my appreciation to **K. B. Institute of Pharmaceutical Education and Research (KBIPER), Gandhinagar)** for organizing *KBICONN – National Conference on "Path to Parity: Strategies in Generic Drug Development."* The theme highlights an important area in India's healthcare ecosystem, where scientific rigor and regulatory alignment play a crucial role in ensuring accessible and high-quality medicines.

By creating a platform that brings together academicians, researchers, industry professionals, and students, KBIPER continues to demonstrate its commitment to academic enrichment and research-driven growth. The institute has consistently taken initiatives that foster collaboration and stimulate forward-thinking discussions, strengthening its contribution to Kadi Sarva Vishwavidyalaya and to the pharmaceutical community.

I encourage all participants to actively engage with the sessions, exchange ideas, and explore new perspectives that may guide future advancements in generic drug development. Such interactions are vital in shaping a knowledgeable and responsible scientific workforce for the nation.

I congratulate the organizing team for their efforts and wish KBICONN 2025 great success and meaningful outcomes.

Dr. Gargi Rajpara

MESSAGE FROM THE PRINCIPAL, KBIPER

Dr. Divyang Dave
Principal,
K.B. Institute of Pharmaceutical Education and Research (KBIPER)

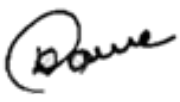
It gives me immense pride to welcome our distinguished guests, industry experts, and delegates to the **K. B. Institute of Pharmaceutical Education and Research (KBIPER)** for our National Conference, *KBICONN 2025*.

As we convene on the 5th and 6th December to explore the theme *"Path to Parity: Strategies in Generic Drug Development,"* we are doing more than just discussing pharmaceutical science; we are addressing the very cornerstone of equitable healthcare. The journey of a generic drug from the laboratory bench to the patient's bedside is paved with complex challenges in bioequivalence, regulatory compliance, and formulation strategy.

At KBIPER, our mission has always been to bridge the gap between theoretical knowledge and practical application. This conference is a manifestation of that vision. By hosting this dialogue, we aim to equip our students and researchers with the foresight needed to navigate the evolving demands of the global market. We are not just training pharmacists; we are molding the future architects of affordable medicine.

I am deeply grateful to the leadership of Kadi Sarva Vishwavidyalaya for their continued patronage and vision, which empowers us to host platforms of this magnitude.

I urge every participant to utilize this opportunity to challenge existing paradigms, forge new collaborations, and absorb the wealth of expertise present here. Let us ensure that the strategies discussed here translate into tangible solutions for the industry.
I wish everyone a thought-provoking and successful conference.



Dr. Divyang Dave

INDEX

SR No.	DETAIL	Page No.
01	Program Schedule	1
02	Keynote address by Prof. (Dr.) Atul Nasa	3
03	Plenary Lecture – 1 Mr. Varun Doshi	4
04	Plenary Lecture – 2 Dr. Hardik Joshi	5
05	Plenary Lecture – 3 Dr. Stavam Nagori	6
06	Plenary Lecture – 4 Dr. Dhaval Patel	7
07	Plenary Lecture – 5 Mr. Bhavik Joshi	8
08	Abstracts – Research Track (RS01-RS23)	9-31
09	Abstracts – Review Track (RV01-RV19)	32-50

PROGRAM SCHEDULE

December 5th, 2025

09:00 AM – 10:00 AM **Registration & Breakfast**

10:00 AM – 10:30 AM **Inauguration**

10:30 AM – 11:30 AM **Keynote Adress**

Prof. (Dr.) Atul Nasa,

Drug Control Officer, Drugs Control Department, Delhi, India

11:30 AM – 12:30 PM **Plenary Lecture - 1**

Mr. Varun B Doshi,

Managing Director, Stivaph Healthcare Pvt. Ltd. Ahemdabad, Gujarat, India

Topic: Path to Parity: Strategies in Generic Drug Development

12:30 PM – 01:30 PM **Lunch Break**

01:30 PM – 04:00 PM **Poster Session**

December 6th, 2025

09:00 AM – 10:30 AM **Plenary Lecture 2**

Dr. Hardik Joshi,
General Manager, F&D, Amneal Pharmaceutical, Ahmedabad, Gujarat, India
Topic: Strategic Framework for developing Generic Sterile Formulations.

10:30 AM – 12:00 PM **Plenary Lecture 3**

Dr. Stavan Nagori,

Formulation Development Head (DGM),Zydus Life Sciences Limited, Ahmedabad, Gujarat, India

Topic: Real-Time Holistic Developmental Approach for Pharmaceutical Generic Drug Development.

12:00 PM – 01:30 PM **Lunch Break**

01:30 PM – 02:30 PM **Plenary Lecture 4**

Dr. Dhaval Patel,

Associate Director, IPD Analytics, Vadodara, Gujarat, India

Topic: Patent Power Play: How brands protect and how generic competes.

02:30 PM – 03:30 PM **Plenary Lecture 5**

Mr. Bhavik Joshi,

COO & CEO, Neotranslations & Neocubes Pharma, Ahmedabad, Gujarat, India

Topic: Market entry for generic product from regulatory perspective – Europe to GCC

03:30 PM – 04:00 PM **Valedictory**

Prof. (Dr.) Atul Nasa
Drug Control Officer
Drugs Control Department, Delhi, India

About Speaker:

Prof. (Dr.) Atul Kumar Nasa, Pro Vice-Chancellor at SGT University, Gurugram, is a distinguished pharmacy professional with over 40 years of experience spanning industry, academics, administration, and regulatory affairs. A Ph.D. in Pharmaceutical Sciences, he has previously served as Head of Office/Controlling & Licensing Authority, Drugs Control Department, Government of NCT of Delhi, contributing significantly to the enforcement of Drugs & Cosmetics Act and multiple national regulatory frameworks.

Dr. Nasa has been a vital member of various national committees, including the Drugs Technical Advisory Board (DTAB), and actively contributes to policy formulation. He has served on governing bodies and academic councils of several universities and has been associated with the Pharmacy Council of India through various expert roles. As a resource person, he has delivered numerous lectures across academic institutes, industry forums, NGOs, and government platforms.

With strong academic and research credentials, he has published several papers and served as examiner and selection board member for multiple universities. A committed contributor to global pharmacy platforms, he has participated and delivered talks at international conferences including FIP meetings in Dublin, Glasgow, and Abu Dhabi.

Dr. Nasa has received numerous national recognitions such as the Best Drugs Control Officer Award (AIDCOC, 2017), IPA Fellowship, KC Chatterjee Memorial Award, IPGA Professional Excellence Award, Regulatory Person of the Year Award, Outstanding Young Professional Achievement Award, and Best Alumni Award from DIPSAR. His leadership roles include former President of IPCA, current President of IPGA, Managing Trustee of IPGA Welfare Trust, Vice President of AIDCOC, and Director at ICHA.

Known for his disciplined work ethic, leadership qualities, and commitment to the profession, Dr. Nasa continues to contribute extensively to pharmacy education, regulation, and professional development. His work remains a source of inspiration for the pharmacy fraternity.

Path to Parity: Strategies in Generic Drug Development

Mr. Varun B Doshi
Managing Director
Stivaph Healthcare Pvt. Ltd. Ahmedabad, Gujarat, India

Summary of Presentation:

Global human population is more than 8 Billion people & spread across 6 continents- 195 countries. Healthcare and medicines are a need for one & all, but huge disparity exists between the people in terms of their income levels and affordability of medicines.

A Pharmaceutical firm invests resources in R&D – *People, Money & Time.* The cost of these medicines is arrived at considering these investments. Such products are patented by the innovator company & so they can sell these medicines in a "competition free" market for a period of maximum 20 years.

Patents are for a predefined period & during this time such medicines are usually beyond the affordability of the masses- especially in Lower & Middle Income Countries (LMICs).

The aim of generics is to make medicine affordable to every section of society. So, firms who wish to launch generic versions start work on "Generic Drug Development" well before expiry of a patent.

Generic drug development is a multi- step process involving:

- Identification of products going off patent in near future
- Developing formulations that do not infringe the patents but are same as the patented product in terms of API, Dosage, Formulation, etc
- Developing analytical methods that would assess the efficacy & safety of such generics
- Bioequivalence studies – A critical step that proves the generics effectiveness in humans (at par with the originator)
- Regulatory approvals
- Upscaling from R &D to manufacturing & commercialization

Overall objective of various regulatory bodies, Government authorities, Patent Offices is to ensure a fine balance where:

- A innovator firm gets adequate opportunity to recover the investment, earn profits & thus are interested in investing in future research as well.
- Generic medicines availability that confirms the benefits of a medicine reach to every section of society- with quality & safety at par with the originator.

Strategic Framework for Developing Generic Sterile Formulations

Dr. Hardik Joshi
General Manager, F&D
Amneal Pharmaceutical, Ahmedabad, Gujarat, India

Summary of Presentation:

This talk provides a comprehensive and well-structured framework for the development of generic sterile formulations, with a strong emphasis on scientific rigor, proactive risk management, and alignment with regulatory standards. The discussion begins with the application of a **Quality by Design (QbD)** approach, which establishes a systematic foundation for development. Within this framework, the **Target Product Profile (QTPP)** is defined to outline the desired quality, safety, and performance characteristics of the final product. This is followed by identifying **Critical Quality Attributes (CQAs)** that directly impact product integrity, and evaluating **Critical Material Attributes (CMAs)** to understand how raw material properties influence formulation decisions and manufacturing outcomes. Together, these elements guide the overall formulation strategy and process design.

Key scientific considerations highlighted include careful **API selection**, evaluation of **excipient functionality and compatibility**, appropriate **filter selection**, and thorough **container–closure system** assessment. Special attention is given to **NMDA impurity evaluation**, reflecting current regulatory expectations for nitrosamine control in sterile drug products. The talk also elaborates on sterility assurance principles, comparing **aseptic processing** and **terminal sterilization**, and emphasizing the importance of contamination control strategies supported by robust microbiological quality programs.

Further topics include **analytical method development**, extractables and leachables studies, and comprehensive stability study design to ensure product quality throughout its shelf life. Strategic elements such as early **intellectual property (IP) landscaping**, **Paragraph IV opportunities**, and utilization of the **505(b)(2) regulatory pathway** are discussed as means to reduce development risk and enhance product differentiation. The talk concludes with an overview of regulatory expectations, lifecycle management considerations, and emerging trends influencing the future of sterile generic development.

Real time Holistic Developmental approach for Pharmaceutical Generic Drug Development

Dr. Stavan Nagori
Deputy General Manager
Zydus Cadilla Health Care, Ahmedabad, Gujarat, India

Summary of Presentation:

Generic drug development in the pharmaceutical industry follows a systematic, streamlined, and highly regulated pathway designed to ensure that the final product demonstrates therapeutic equivalence to the innovator medicine while remaining cost-effective and operationally feasible. The industrial development flow typically begins with a comprehensive and exhaustive **literature review**, during which scientific publications, regulatory guidelines, innovator product information, and prior art are thoroughly analyzed. This foundational step enables the team to understand the product landscape, identify potential challenges, and outline a feasible development strategy.

Following this, approval of the **cost of development** is secured, ensuring alignment with organizational budgets and commercial goals. The next stage involves defining the **Quality Target Product Profile (QTPP)**, which outlines the intended characteristics of the final product in terms of quality, safety, and efficacy. Based on the QTPP, **Critical Quality Attributes (CQAs)** are identified to determine the attributes that require stringent control during formulation and process development.

A detailed **reference product characterization** is then performed to analyze the innovator's physicochemical properties, formulation components, and performance characteristics. Using these insights, teams proceed to **prototype formulation development**, through which different formulation trials are designed to achieve the desired product profile. This is followed by establishing the **design space**, where key material and process parameters influencing product quality are evaluated and optimized.

Once a robust formulation is selected, the process moves to **pilot bioequivalence (BE) studies**, if required, followed by **scale-up batch manufacturing** to ensure manufacturing feasibility at larger levels. Subsequently, **exhibit batches** are manufactured under GMP conditions to demonstrate process reproducibility and support regulatory submissions. **Pivotal BE studies** are conducted to confirm therapeutic equivalence with the innovator product.

Finally, a comprehensive **regulatory dossier** is prepared and submitted within targeted milestone timelines. The aim of the present training was to offer participants a real-time, holistic understanding of this developmental workflow, helping them become industry-ready as they begin their careers in the pharmaceutical generic sector.

Patent Power Play: How Brands Protect and How Generics Compete

Dr. Dhaval Patel
Associate Director, IPD Analytics, Vadodara, Gujarat, India

Summary of Presentation:

The pharmaceutical industry thrives on continuous innovation, and at the core of this innovation-driven landscape lies the patent system. Patents function as powerful intellectual property tools that grant inventors exclusive rights over their discoveries, thereby shaping the competitive dynamics of the market. For brand-name or innovator companies, patents are far more than legal documents—they are strategic assets and protective shields. These companies rely on patents to safeguard years of research, significant financial investment, and the scientific breakthroughs that lead to new therapeutic solutions. By securing strong patent protection, innovators ensure market exclusivity, which allows them to recover development costs and generate revenue needed to support future innovation. They also employ sophisticated lifecycle management strategies, such as secondary patents on formulations, manufacturing processes, delivery systems, or new therapeutic uses, to extend their commercial advantage.

On the other side of this competitive landscape are generic pharmaceutical companies. For them, innovator patents represent both formidable barriers and valuable guides. While patents can delay or restrict market entry, they also offer detailed technical disclosures that help generic developers understand the reference product's composition, manufacturing approach, and intellectual property landscape. A successful generic development strategy therefore requires rigorous and systematic patent analysis. This involves evaluating patent validity, identifying weaknesses, monitoring expiry timelines, and determining where “design-around” opportunities or legal challenges—such as Paragraph IV certifications—may exist. The goal is to achieve timely market entry while ensuring freedom to operate without infringing existing patents.

This presentation explores the dynamic “power play” between innovator and generic companies, illustrating how patents are drafted, defended, challenged, and strategically navigated. By understanding these interactions, participants gain insight into how intellectual property shapes competition, influences development pathways, and ultimately impacts patient access to affordable medicines

Market entry for generic product from regulatory perspective – Europe to GCC

Mr. Bhavik Joshi
COO & CEO
Neotranslations & Neocubes Pharma, Ahmedabad, Gujarat, India

Summary of Presentation:

Expanding generic pharmaceuticals from Europe to the Gulf Cooperation Council (GCC) region offers major business potential, thanks to growing healthcare needs, cost-saving efforts, and government programs to improve access to affordable medicines. To succeed, companies must carefully manage different regulatory processes and compliance rules in both regions. This paper analyzes the steps needed to move a generic drug from EU approval to marketing authorization in GCC countries such as Saudi Arabia, United Arab Emirates, Qatar, Kuwait, Bahrain, and Oman.

The European regulatory system is built on unified scientific standards, proven bioequivalence rules, and clear approval routes such as centralized, decentralized, mutual recognition, and national procedures. This system is the main reference for preparing regulatory documents. In comparison, the GCC uses both a central registration pathway (GCC-DR) for regional approval and separate national submissions with specific requirements, especially in large markets like Saudi Arabia. Key technical factors include adjusting the Common Technical Document (CTD) to local formats, generating stability data for Zone IVb climates, choosing and justifying the reference medicine, meeting GMP and CPP standards, providing Arabic and bilingual labels, fulfilling local pharmacovigilance QPPV duties, and following unique pricing and tender rules in the region.

Despite scientific alignment with ICH and reliance on foreign regulatory assessments in some cases, challenges persist, including inconsistencies in dossier expectations, variability in agency review timelines, evolving bioequivalence and biowaiver criteria, and mandatory local testing policies in selective jurisdictions. Furthermore, post-approval life cycle activities—such as variations, PSUR/PBRER submissions, manufacturing site changes, and safety reporting—require tailored regulatory strategies due to nonuniform regional implementation frameworks.

The findings demonstrate that an optimized regulatory entry strategy must integrate early GCC regulatory intelligence, sequential dossier planning from EU approval milestones, and proactive stakeholder engagement with local agents and health authorities. Leveraging EU approval history, establishing robust pharmacovigilance infrastructure, and ensuring pricing negotiations are aligned with tender cycles significantly reduce approval delays and accelerate commercial launch. This study concludes that a harmonized Europe-to-GCC regulatory transition model, supported by scientific evidence and strong procedural foresight, is essential for enhancing the speed and success of generic product availability across the Middle Eastern healthcare ecosystem.

Generic medicines availability that confirms the benefits of a medicine reach to every section of society- with quality & safety at par with the originator.

SCIENTIFIC ABSTRACTS

RS01

Phenylboronic Acid-Functionalized Pluronic F68 Micelles: Advanced pH-Responsive Systems for Targeted Chemotherapy of Paclitaxel

Vithlani Ashishkumar[*1], Dharmik Mehta[1]

[1] School of Pharmacy, RK University, Rajkot, Gujarat, India.

* Corresponding author: ashishvithlani@gmail.com, School of Pharmacy, RK University, Rajkot, Gujarat, India. Mo: 94290 97987

ABSTRACT:

The development of pH-responsive nanocarriers remains a critical focus for advancing targeted cancer chemotherapy. In this work, Pluronic F68 micelles were strategically engineered with 3-aminophenylboronic acid to facilitate controlled paclitaxel delivery. The synthesis involved initial succinylation of Pluronic F68 using microwave irradiation, thereby introducing carboxyl groups for subsequent functionalization. Carbodiimide-mediated conjugation with 3-aminophenylboronic acid yielded boronate-decorated copolymers, after which paclitaxel encapsulation was achieved through a solvent evaporation approach. The resultant micelles were comprehensively characterized with respect to physical structure and drug payload. Dynamic light scattering and transmission electron microscopy revealed uniform, spherical nanostructures with an average diameter of 102 ± 6 nm and a narrow size distribution. Drug loading efficiency reached $7.8 \pm 0.4\%$, with an encapsulation efficiency of $74 \pm 3\%$. Drug release studies confirmed the nanocarrier's pronounced pH-responsivity: significantly greater paclitaxel liberation occurred under mildly acidic conditions (pH 6.5), consistent with a tumor-selective profile, compared to physiological pH 7.4. These results validate both the physical integrity and functional adaptability of the boronic acid-functionalized micelles. This core investigation provides a foundation for future work on micellization mechanisms, in-depth cellular uptake, and extended biological assessment, which will be explored in separate, dedicated studies.

Key words: Boronic acid functionalization, Polymeric micelles, Nanocarriers, Cellular uptake, Targeted chemotherapy

RS02

DESIGND-COUMARIN–BENZIMIDAZOLE HYBRIDS AS A-GLUCOSIDASE BLOCKERS FOR COST-REALISTIC GENERICS DRUGS

Aditya Nayak[*1] **Dr.Ravi Pratap Pulla**[1]
[1]Department of Pharmaceutical Chemistry, Parul Institute of Pharmacy and Research, Limda, Vadodara, Gujarat 391760, India
*Corresponding author:- adityanayak3064@gmail.com , Parul Institute of Pharmacy and Research, Limda, Vadodara, Gujarat 391760, India
MO:-7008563582

ABSTRACT

Keeping with the conference theme *Path to Parity*, our aim was practical chemistry—molecules that a lab can build, scale, and control without exotic steps. We paired two dependable motifs: a coumarin ring, which is rigid and lets us tweak electronics and solubility at C-6/C-7 (OMe, OH, halogen), and a benzimidazole, whose N^1 is well placed for hydrogen bonding in glycosidase pockets. We then connected these pieces with short, no-nonsense linkers (–CH_2–, –O–CH_2–, –CO–NH–) to keep polarity in check while holding planarity. Up front, we set simple, oral-drug-friendly guardrails—MW -330–420, cLogP 2.0–3.6, HBD ≤2, HBA 4–6, TPSA 60–90 $Å^2$, and ≤6 rotatable bonds—so promising ideas wouldn't fail later for trivial reasons. Docking against α-glucosidase consistently placed the coumarin in π–π contact with aromatic residues, while the benzimidazole nitrogens reached acidic residues through hydrogen bonds; amide linkers added helpful carbonyl contacts that steadied the pose. As expected, C-7 electron donors on coumarin lifted stacking strength, and a para-halogen on the benzimidazole ring tightened the hydrophobic fit without pushing lipophilicity too far. The make-route is intentionally short: build benzimidazoles from *o*-phenylenediamine and aryl/heteroaryl aldehydes (oxidative cyclization), assemble coumarins under Pechmann or Knoevenagel conditions from inexpensive phenols, and finish with SN2, reductive amination, or amide coupling to install the linker. This flow supports the usual QbD checks—tracking lactone open/close and residual aldehydes, screening polymorphs, and using biorelevant dissolution for immediate-release tablets. Overall, these coumarin–benzimidazole hybrids show convincing α-glucosidase engagement and clean early ADME signals, giving a realistic, chemistry-first path from design to bench—and, ultimately, toward an affordable, bioequivalence-ready generic.

Keywords: Path to parity; α-glucosidase inhibitors; Coumarin; Benzimidazole; Hybrid scaffold; Linker optimization; Molecular docking; ADME; Quality-by-Design (QbD); Generic drug development; Bioequivalence.

RS03

Antibacterial evaluation and characterization of *Parthenium hysterophorus* L. as a potential lead for generic veterinary phytopharmaceutical development

Twinkleba V. Vaghela[1]*, Dr. Mehul Mehta[2], Dr. Jigisha Pancholi[3], Dr. Bhupesh R. Patel[4]

[1,4] *Department of Dravyaguna, ITRA, Jamnagar, India*

[2] *Department of Quality Control, ITRA- Pharmacy, Jamnagar, India*

3 Department of Microbiology, ITRA- Pharmacy, Jamnagar, India

*Corresponding Author: twinklebamanharba2203@gmail.com , Institute of Teaching and Research in Ayurveda (ITRA), Institute of National Importance, under Ministry of AYUSH, Govt. of India, Gurudwara Road, Jamnagar -361008. Mo: +91-8141247824

ABSTRACT

Parthenium hysterophorus L., an invasive weed belonging to the family Asteraceae, has attracted significant interest for its contrasting attributes—as an aggressive environmental contaminant and as a potential reservoir of pharmacologically active metabolites. The plant's bioactive potential, particularly in veterinary medicine, remains underexplored despite its folklore claims and abundant availability. This study aims to evaluate the antibacterial potential of *P. hysterophorus* extracts and to characterize its phytochemical constituents to support its development as a prototype for generic phytopharmaceuticals for veterinary applications. Fluorescence analysis under visible, short & long UV light was performed for preliminary screening of the drug using various solvents. Complementary chromatographic and spectroscopic techniques—including UV–Vis spectroscopy, FTIR analysis, and thin-layer chromatography (TLC)—were employed for chemical characterization. Quantitative assays for total phenolic content (TPC) and total flavonoid content (TFC) were conducted. The antimicrobial potential was assessed against *Staphylococcus aureus* and *Staphylococcus epidermidis* using the standard well diffusion method. The extracts exhibited significant antibacterial activity, correlating with the presence of phenolic and flavonoid compounds as identified through spectral and chromatographic profiles. The findings highlight *P. hysterophorus* as an eminent and abundantly available source of antimicrobial phytoconstituents and provide a scientific rationale for its potential development into a generic phytopharmaceutical for veterinary use.

Keywords: *Parthenium hysterophorus*, antibacterial, fluorescence, FTIR, UV-VIS, phenols, flavonoid, veterinary.

RS04

"Integration of PAT and In Silico Modelling for the Development of Bioequivalent Verapamil Extended-Release Capsules"

Mr. Rahul Sharma*[1], Dr. Rushiraj Jani[1]

[1] Institute of Pharmacy, Ganpat University, Ganpat Vidyanagar Mehsana-Gozaria, Highway, Kherva, Gujarat, India.

ABSTRACT:

The present study demonstrates the successful development of a generic Verapamil Extended-Release (ER) 240 mg capsule that is bioequivalent to the reference listed drug, Verelan®. A structured Quality by Design (QbD) approach was applied to optimize formulation and process parameters critical to extended-release performance. Advanced Process Analytical Technology (PAT) tools, including in-line Near-Infrared (NIR) spectroscopy and real-time particle imaging, were employed during pellet coating to monitor polymer deposition, control coating thickness, and ensure uniformity across batches. These tools enabled real-time decision-making and supported the establishment of a robust design space.

Predictive simulations using GastroPlus® physiologically based pharmacokinetic (PBPK) modelling were conducted to anticipate plasma concentration–time profiles and assess the influence of formulation variables on drug release and absorption. This modelling-guided strategy reduced the number of iterative trials required and helped identify an optimal coating level capable of mimicking the reference product's release behavior.

Overall, the formulation exhibited comparable in vivo performance to Verelan®. The integration of PAT tools and PBPK modelling highlights an efficient, data-driven pathway for developing robust generic ER formulations.

RS05

QbD-Centric Non-Infringing Formulation Strategies for Para IV Filing: A Case Study on Brexpiprazole Tablets

Dr. Rushiraj Jani*[1], Mr. Rahul Sharma[1]

1. Department of Pharmaceutics, Institute of Pharmacy, Ganpat University, Mahesana, Gujarat, India.

* Corresponding author: Dr. Rushiraj Jani, Associate Professor, Department of Pharmaceutics, Institute of Pharmacy, Ganpat University, Mahesana, Gujarat, India. Email: rushpharma@yahoo.co.in

ABSTRACT:

The development of generic formulations via Para IV filing requires a dual focus on regulatory compliance and intellectual property navigation. This work presents a Quality by Design (QbD)-centric approach for the formulation of brexpiprazole tablets, using Rexulti® 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg as the reference listed drug (RLD). A comparative analysis of RLD versus test composition highlights deliberate non-infringing strategies: (i) removal of low-substituted hydroxypropyl cellulose as disintegrant, (ii) substitution of magnesium stearate with unclaimed lubricant, and (iii) modification of coating composition by inclusion of plasticizer, absent in the innovator. Design of Experiments (DOE) was applied using a 3^2 full factorial design to evaluate critical formulation factors: disintegrant level as one factor and lubricant concentration as the second factor. The primary response was dissolution at 45 minutes. Process optimization studies assessed the impact of lubrication time and tablet hardness on dissolution, establishing robust operating ranges. Results demonstrated that dissolution performance could be tuned effectively by controlling excipient ratios and process parameters, ensuring bioequivalence while maintaining patent-safe differentiation. This study exemplifies how QbD principles can be integrated with strategic excipient selection and polymorph control to achieve a generic formulation pathway that is scientifically sound, regulatory compliant, and non-infringing. The approach provides a framework for rational Para IV development in complex CNS molecules such as Brexpiprazole.

Keywords:

QbD-centric development, 505(j), Para IV filing, Non-infringing development strategy

RS06

Innovative Bilayer Tablets of HMG-CoA Reductase Inhibitor and Nanosized Fenofibric Acid Derivative: A 505(b)(2) Regulatory Strategy

Dr. Rushiraj Jani[1],Mr. Hardipsinh Bhati[1]*

2. Department of Pharmaceutics, Institute of Pharmacy, Ganpat University, Mahesana, Gujarat, India.

* Corresponding author: Mr. Hardipsinh Bhati, Institute of Pharmacy, Ganpat University, Mahesana, Gujarat, India. Email: hkbhati301501@gmail.com

ABSTRACT:

Mixed dyslipidemia, characterized by elevated LDL-cholesterol and triglycerides, often requires combination therapy to achieve comprehensive lipid control. Rosuvastatin, an HMG-CoA reductase inhibitor, effectively reduces LDL-C by blocking cholesterol biosynthesis and enhancing LDL receptor activity, while fenofibrate, a fenofibric acid derivative acting through PPAR-α activation, lowers triglycerides and raises HDL-C by promoting lipoprotein lipase activity. Their complementary mechanisms make the combination clinically rational, addressing multiple facets of dyslipidemia in a single regimen. To improve patient compliance and therapeutic consistency, we developed a bilayer tablet comprising an immediate-release bilayer tablet comprising Rosuvastatin IR layer and a nanosized Fenofibrate layer (145 mg). The nanosizing process was optimized to enhance solubility and dissolution, overcoming the inherent bioavailability challenges of fenofibrate. Formulation development focused on bilayer stability, minimizing drug–drug interference, and achieving dissolution profile matching with reference products to ensure predictable pharmacokinetics. This innovative dosage form simplifies therapy by combining two widely prescribed agents into a single tablet, reducing pill burden and variability associated with separate dosing. From a regulatory perspective, the product is well-suited for a 505(b)(2) application, which allows reliance on established safety and efficacy data of the individual APIs while requiring bridging studies to confirm equivalence of the novel formulation. Importantly, successful approval under 505(b)(2) provides up to three years of market exclusivity for the new bilayer design, offering both therapeutic and commercial advantages. Thus, bilayer tablets of Rosuvastatin and nanosized Fenofibrate represent a promising innovation that integrates clinical rationale, formulation optimization, and regulatory opportunity to advance dyslipidemia management.

Keywords: 505(b)(2) pathway, Antihyperlipidemic drug, Nano-formulation, Bilayer tablet

RS07

To development & characterization of formulation containing Entada rheedii extract

Hardikkumar Patel[1] , Dr. Jignesh Modi[2] , Dr. Ankit Parulkar[3]

Department of Pharmaceutics, Swaminarayan university, Kalol, Gujarat

ABSTRACT

The present study was aimed to develop and evaluate the topical formulation of Entada rheedii extract. The seeds Entada rheedii were collected and size reduced. The seed powder was extracted by methanol and chloroform. The extract was evaluated for various physical parameters. The effective extract was further selected to prepare formulations. Various topical formulations (gel, plastibased cream and cream) were developed. The solubility of extract was affected by temperature and was found maximum in 1:1 of PEG 200 and DMSO at higher temperature. The incorporated extract in the system was found separated when extract was incorporated in original form. The incorporated solubilized form of extract in PEG 200 and DMSO in aqueous phase of stearic acid and TEA based cream was found optimum and stable. The developed formulation was characterized for pH, viscosity, spreadability, extrudability. Presence of anti-oxidant (BHT) in the formulation was found mandatory to prevent oxidation of formulation. The results of short term stability study revealed stable characteristics of optimized formulation. Further study required for effectiveness of extract.

RS08

Navigating Regulatory Diversity: A Comparative Study of Drug Product Registration Frameworks in Malaysia, Ghana, and India

Khushi Gor [*,1], Maitreyi Zaveri[1], Shirish Patel[2], Niranjan Kanaki[1]
[1]Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382024, Gujarat, India
[2]Otsuka Pharmaceutical India Private Limited
* Corresponding author: gorkhushi5@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar

ABSTRACT

This study, "Navigating Regulatory Diversity: A Comparative Study of Drug Product Registration Frameworks in Malaysia, Ghana, and India," explores how each country manages the process of approving pharmaceutical products. The work compares the regulatory systems of Malaysia's NPRA, Ghana's FDA, and India's CDSCO. The study reviews key elements such as required documents, submission platforms, review pathways, GMP certification, timelines, and registration fees. Although each country follows its own procedures and digital systems, all three place strong emphasis on quality, safety, and compliance with good manufacturing practices. The findings show that differences in review methods and documentation requirements can affect approval timelines. At the same time, there are clear opportunities for streamlining processes and making requirements more consistent. This information will help pharmaceutical companies and regulatory professionals plan more efficiently and improve access to safe and effective medicines.

Key words: Navigating Regulatory Diversity, Malaysia, Ghana, India

RS09

Lifecycle Continuity through Regulatory Compliance: Evaluating Post–Approval Change Strategies for APIs and Drug Products under Saudi Arabia & USA Frameworks

Sharlee Shah[*,1], Maitreyi Zaveri[1], Akshita Parekh[2], Niranjan Kanaki[1]

[1]Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382023, Gujarat, India

[2] Intas Pharmaceutics Ltd, Ahmedabad

* Corresponding author: sharleeshah0303@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar

ABSTRACT

This study evaluates post-approval change strategies for Active Pharmaceutical Ingredients (APIs) and drug products under the regulatory frameworks of Saudi Arabia & USA Ensuring lifecycle continuity through robust regulatory compliance is critical for maintaining product quality, safety, and efficacy throughout the pharmaceutical product lifecycle. The research highlights different regulatory classification systems, risk-based change management approaches, and submission pathways mandated by health authorities, alongside international harmonization efforts such as ICH Q12. Key factors include change control systems, technical assessments, and regulatory communication that enable efficient implementation of changes without disrupting supply. This comprehensive evaluation supports industry stakeholders in optimizing regulatory strategies to achieve lifecycle continuity and compliance in diverse global markets.

Keywords: Post-approval changes, lifecycle continuity, marketing authorization, lifecycle management.

RS10

Bridging Regulatory Speed: A US–EU Perspective on Rapid Drug Approvals

Nidhi Bhadauria*,[1], Maitreyi Zaveri[1], Shirish Patel[2], Zuki Patel[1]
[1]Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382024, Gujarat, India
[2]Otsuka Pharmaceutical India Private Limited
* Corresponding author: nidhibhadauria83@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar

ABSTRACT

The growing demand for timely access to critical medicines has led regulators to develop flexible pathways balancing urgency and evidence. This poster compares the United States Food and Drug Administration's Emergency Use Authorization (EUA) and Accelerated Approval (AA) with the European Medicines Agency's Conditional Marketing Authorization (CMA) and Accelerated Assessment (AAss). EUA allows temporary use of promising products during emergencies with limited data, while AA grants earlier approval based on surrogate markers predicting clinical benefit. In Europe, CMA provides conditional market access where complete evidence is pending, and Accelerated Assessment shortens review timelines for medicines addressing significant public health needs. The comparison reveals varying approaches in regulatory agility, data thresholds, and post-approval commitments, reflecting distinct philosophies toward risk tolerance and patient access. Understanding these nuances aids in aligning global development strategies and accelerating therapeutic availability during urgent situations.

Key words: Rapid Drug Approvals, Emergency Use Authorization, Accelerated Approval, Conditional Marketing Authorization, Accelerated Assessment.

RS11

Regulatory Requirements for Participation in UNICEF Tenders for Parenteral Products

Aditi Muskan Jha[*, 1], Maitreyi Zaveri[1], Shirish Patel[2], Zuki Patel[1]

[1]Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382023, Gujarat, India

[2]Otsuka Pharmaceutical India Private Limited

* Corresponding author: dearaditi2002@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar

ABSTRACT

This study examines the regulatory requirements for participation in UNICEF procurement programs for parenteral (injectable) pharmaceutical products. The objective of the research is to identify the essential quality, safety, and compliance standards necessary for manufacturers to qualify for UNICEF global supply tenders. A prospective research approach was used, supported by a structured literature review and an in-depth analysis of UNICEF procurement documentation, WHO Prequalification (PQP) guidelines, and Good Manufacturing Practice (GMP) standards. Case studies of both successful and unsuccessful submissions were analyzed to understand common procedural challenges. Key regulatory components identified include WHO prequalification procedures, GMP certification, documentary completeness of product dossiers, sterility and stability data, and adequate clinical or bioequivalence evidence when required. The study is expected to highlight common challenges such as gaps in dossier preparation and maintaining continuous compliance throughout the product lifecycle. The findings will contribute to developing a strategic quality and regulatory compliance framework aimed at assisting manufacturers in improving submission quality and increasing their success rate in UNICEF procurement initiatives.

Keywords: UNICEF procurement, parenteral products, WHO PQ, GMP compliance, regulatory dossier, global health supply

RS12

Comparison Study of CTD Module 3, 4 and 5: Generics versus Complex Generic (Liposomal Injectables) in the USA, EU, and Japan

Manasvi Kotadia*[,1], Maitreyi Zaveri[1], Shailesh Khacharia[2], Zuki Patel[1]
[1]Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382023, Gujarat, India
[2] Intas Pharmaceutics Ltd, Ahmedabad
* Corresponding author: manasvikotadia13@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar

ABSTRACT:

The study aimed to compare the data requirements in CTD Modules 3, 4 and 5 for standard generic formulations versus complex liposomal injectables across the USA, EU, and Japan. Specific objectives included evaluating additional data expectations for complex generics, assessing regional regulatory variations, and developing a structured comparison framework to support global submission strategies. A comprehensive regulatory comparison was performed using publicly available guidelines, agency reflections, and case studies from EMA, FDA, and PMDA. The analysis focused on data depth and technical requirements under each module, with emphasis on QbD principles for complex formulations. Key evaluation areas included: **Module 3 (Quality):** QTPP establishment; identification of CQAs, CMAs, and CPPs; detailed physicochemical characterization such as particle size, zeta potential, entrapment efficiency, lipid composition, and membrane integrity. **Module 4 (Non-clinical):** Comparative biodistribution, animal PK, toxicokinetic, and local tolerance studies. **Module 5 (Clinical):** Comparative pharmacokinetic, safety, and immunogenicity evaluations. Complex liposomal generics required significantly more detailed characterization and bridging data than conventional generics. While harmonized CTD structure is maintained, regional differences were observed in study design expectations and justification of equivalence. The study highlights that a systematic, QbD-driven approach is essential for successful global submissions of liposomal injectables. Understanding region-specific CTD requirements ensures robust comparability and efficient regulatory approval across major markets.

Key words: Liposomal Injectables, USA, EU, Japan

RS13

Drug Safety of Anti-hypertensive Drugs Utilizing Pharmacovigilance Data: Signal Management Following Traditional Method vs Process Automation

Yash Patel[*,1], Zuki Patel[1], Mrugank Parmar[2], Maitreyi Zaveri[1]
[1]Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382023, Gujarat, India
[2] Step-up Pharmatech, Ahmedabad
* Corresponding author: yashpatel101001@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar

ABSTRACT

The study aimed to identify and prioritize new safety signals associated with anti-hypertensive drugs, apply traditional and automation-driven signal detection methods, and perform a comparative evaluation of both approaches for improved pharmacovigilance efficiency. Safety data were extracted from the EudraVigilance database containing Individual Case Safety Reports (ICSRs). The process involved several steps as outlined as: Signal Detection using disproportionality analysis (PRR, ROR) and qualitative review to identify potential associations. Signal Validation to confirm the credibility of detected signals by assessing case quality, temporal relationship, and biological plausibility. Signal Confirmation and prioritization through PRAC or Lead Member State review within 30 days of validation. Implementation of automation-based tools to streamline validation and confirmation processes. Comparative analysis of manual vs automated systems for accuracy, time efficiency, and transparency. Automation-driven processes significantly reduced detection and validation time compared to traditional manual review. The automated approach demonstrated improved consistency in identifying recurrent patterns across ICSRs, while traditional methods allowed for deeper clinical interpretation. Integration of both approaches enhanced overall signal detection accuracy and transparency in documentation within EudraVigilance and EPITT systems. Process automation in pharmacovigilance offers a promising advancement in signal management, reducing manual workload and enabling faster regulatory decision-making without compromising scientific integrity. Combining automated and traditional methods ensures a balanced, efficient, and reliable system for monitoring the safety of anti-hypertensive drugs.

Key words: Signal Management, Individual Case Safety Reports, Traditional Method, Process Automation

RS14

Regulations for Strengthening Pharmaceutical Supply Chain: A Global Perspective

Isha Makadia[*,1], Maitreyi Zaveri[1], Rahul Nayak[2], Niranjan Kanaki[1]
[1]Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382023, Gujarat, India
[2] Makcur Laboratories Ltd., Ahmedabad
* Corresponding author: ishamakadia942@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar

ABSTRACT

The present study aims to evaluate and compare global regulatory frameworks that strengthen the pharmaceutical supply chain, with emphasis on the European Union's Falsified Medicines Directive (FMD) and the United States Drug Supply Chain Security Act (DSCSA). It focuses on understanding their role in improving supply chain integrity, medicine authenticity, and patient safety. The study also reviews Track and Trace (T&T) systems, assesses stakeholder responsibilities, identifies key challenges such as cost and interoperability, and proposes strategies for global harmonization to ensure transparency and prevent the entry of falsified medicines. A comprehensive literature review was conducted using official regulatory documents from the European Commission, U.S. FDA, and World Health Organization (WHO). FMD and DSCSA have significantly enhanced pharmaceutical supply chain transparency and reduced counterfeit medicine incidents in their respective regions. The EU-FMD uses a centralized verification system (EMVS) connecting 27 EU member states. The US-DSCSA follows a distributed electronic system enabling real-time data exchange between authorized trading partners. Both frameworks serve as global reference models for developing countries such as India, Brazil, and ASEAN nations that are now adopting similar Track and Trace regulations. Regulatory systems like the EU-FMD and US-DSCSA demonstrate how serialization, verification, and digital traceability can safeguard public health and ensure medicine authenticity. Comparative analysis highlights that both models, despite structural differences, achieve the common goal of supply chain integrity and patient safety. The study underscores the importance of global harmonization through WHO and GS1 standards to achieve interoperability across markets.

Key words: Supply Chain, Track and Trace, centralized verification system**,** Global Perspective

RS15

A Comparative Study of the Regulatory Landscape for Prefilled Syringes (PFS) in the Philippines and Uganda

Bhumi Solanki[*,1], Maitreyi Zaveri[1], Rahul Nayak[2], Niranjan Kanaki[1]
[1]Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382023, Gujarat, India
[2] Makcur Laboratories Ltd., Ahmedabad
* Corresponding author: solankibhumid@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar

ABSTRACT

The objective of this study is to compare the regulatory frameworks governing the registration, evaluation, and approval of Prefilled Syringes (PFS) in the Philippines and Uganda. The study aims to identify similarities, differences, and key regulatory challenges influencing the approval timelines and compliance requirements for PFS, particularly focusing on combination products such as Enoxaparin Sodium Injection (0.6 mL). A comparative descriptive approach was used by reviewing official regulatory guidelines, submission formats, and approval processes from the Philippine Food and Drug Administration (FDA) and Uganda National Drug Authority (NDA). Data were collected from official websites, published regulatory documents, and secondary literature. Key focus areas included dossier format (ACTD vs. CTD), module 1 country-specific requirements, evaluation timelines, and post-approval obligations. The study found that the Philippines follows the ASEAN Common Technical Dossier (ACTD) format, whereas Uganda adopts the Common Technical Document (CTD) aligned with ICH guidelines. The Philippines requires additional labeling and local manufacturer documentation, while Uganda emphasizes GMP compliance and WHO-prequalified testing data. Approval timelines are generally longer in Uganda due to limited regulatory resources. While both countries aim to ensure product safety and efficacy, regulatory harmonization remains limited. Streamlining documentation requirements and adopting a unified review mechanism could enhance efficiency and reduce duplication of efforts, promoting faster access to high-quality PFS products in both regions.

Key words: Prefilled Syringes, ACTD, CTD, Philippines, Uganda.

RS16

Regulatory Lifecycle management of solid oral dosage form in Nigeria and Kenya.

Kumar Shreya[*,1], Maitreyi Zaveri, Shruti kharidia[2], Vinit Movaliya[1]
[1]Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382023, Gujarat, India
[2]Regtech India solution, Ahmedabad
* Corresponding author: shreyakumar14112002new@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar

Abstract:

Solid oral dosage forms (SODFs) regulatory lifecycle management (RLM) guarantees constant product quality, safety, and effectiveness during the stages of development, approval, and post-marketing. The Pharmacy and Poisons Board (PPB) and NAFDAC-regulated RLM systems in Kenya and Nigeria are compared in this study. Both adhere to global guidelines established by AMRH, ICH, and WHO, Pharmacovigilance, GMP compliance, variation management, CTD-based dossier submission, and renewal are important procedures. The EAC-MRH program fosters harmonization and speedier product access across the region. By guaranteeing high-quality medications through coordinated monitoring and regional collaboration, effective RLM improves transparency, regulatory effectiveness, and public health.

Key words:

Regulatory lifecycle management (RLM), Post marketing surveillance, NAFDAC, Pharmacy and Poisons Board (PPB), Regulatory Harmonization

RS17

Application of Failure Modes and Effects Analysis (FMEA) for Conducting Multiple Risk Assessments in a New Pharmaceutical Facility

Harsh Patel[*,1], Maitreyi Zaveri[1], Rajnish Verma[2], Zuki Patel[1]
[1]Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382023, Gujarat, India
[2] Pharmazone, Ahmedabad
* Corresponding author: harshpateloo686@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar

ABSTRACT:

A new pharmaceutical manufacturing facility's five key areas will undergo multiple, systematic risk assessments as part of the study's implementation of the Failure Modes and Effects Analysis (FMEA) methodology. To evaluate possible risks within the various functional systems of the new facility, five distinct FMEA applications were conducted. A cross-functional team with members from production, engineering, and quality assurance participated in each assessment. In order to determine Risk Priority Numbers (RPNs), potential failure modes were identified and their severity, occurrence, and detectability were rated. Appropriate corrective and preventive measures were suggested, put into place, and then reassessed to ensure they were successful in reducing the risks that were identified. This was done based on the prioritization. The overall approach followed the principles of ICH Q9 and WHO guidelines for pharmaceutical risk management. The application of FMEA across multiple systems led to the identification of several high-risk failure modes requiring control measures. Implementation of targeted mitigations—such as procedural improvements, maintenance optimization, monitoring enhancement, and personnel training—resulted in a significant reduction in RPN values across all applications. The results demonstrated the effectiveness of the FMEA approach in proactively managing potential risks before facility startup. The study demonstrates that applying FMEA across multiple operational domains provides a robust framework for proactive risk identification and control in a new pharmaceutical facility. From facility design through operational readiness, the methodical application of FMEA improves process reliability, safety, and product quality in addition to fortifying GMP compliance.

Keywords: Failure Modes and Effects Analysis (FMEA), Risk Priority Numbers (RPNs), Multiple Risk Assessments, New Pharmaceutical Facility

RS18

Global harmonization Through MDSAP: One Audit for Multiple Markets

Amisha Patel[*,1], Maitreyi Zaveri[1], Preeti Vani[2], Vinit Movaliya[1]
[1]Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382023, Gujarat, India
[2] SLTL (medical division), Gandhinagar
* Corresponding author: amisha8838@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar

ABSTRACT:

The globalization of the medical device industry has led to increasing regulatory complexity, with manufacturers required to meet diverse quality and compliance standards across multiple jurisdictions. The Medical Device Single Audit Program (MDSAP), developed by the International Medical Device Regulators Forum (IMDRF), was introduced to streamline this process by allowing a single, comprehensive audit of a manufacturer's Quality Management System (QMS) to satisfy the regulatory requirements of multiple authorities. This poster explores how MDSAP promotes global harmonization by integrating the requirements of ISO 13485:2016 with country-specific regulations from participating authorities, including the U.S. FDA, Health Canada, TGA (Australia), ANVISA (Brazil), and MHLW/PMDA (Japan). The structure of the MDSAP audit, benefits such as reduced audit duplication, improved regulatory transparency, and enhanced market access, as well as current challenges faced by small and medium manufacturers, are discussed. Recent developments, including the adoption of hybrid audits, digital documentation practices, and the growing interest from other regulatory bodies like the UK MHRA and Singapore HSA, highlight MDSAP's expanding global influence. Overall, MDSAP represents a significant step toward a unified global regulatory framework, improving both efficiency and consistency in medical device quality oversight and ultimately contributing to better patient safety worldwide.

Keywords: MDSAP, ISO 13485, regulatory harmonization, quality management system, medical device compliance, IMDRF

RS19

Trends and Regulatory Challenges in Pharmaceutical Submission: A Critical Analysis of Health Authority Requirements on Nitrosamine impurity, Elemental Impurity, Forced Degradation, and Genotoxicity

Darshan Patel*[,1], Niranjan Kanaki, Shruti Kharidia[2], Maitreyi Zaveri [1]
[1]Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382024, Gujarat, India
[2] Regtech India Ltd, Ahmedabad
* Corresponding author: darshan20051910@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar

ABSTRACT

The evolving landscape of global pharmaceutical regulations has placed increased emphasis on the identification, assessment, and control of potential impurities and degradation products that may compromise drug safety and quality. This poster critically examines current regulatory expectations and emerging trends related to nitrosamine impurities, elemental impurities, forced degradation studies, and genotoxicity assessments in pharmaceutical submissions. Recent high-profile recalls due to nitrosamine contamination have prompted stringent guidelines from regulatory agencies such as the US FDA, EMA, and WHO, emphasizing risk-based approaches and robust analytical methodologies. Similarly, the implementation of ICH Q3D has standardized the control of elemental impurities, driving the adoption of advanced instrumentation and comprehensive risk assessments. Forced degradation studies, guided by ICH Q1A(R2), continue to play a vital role in establishing product stability and impurity profiles, while genotoxicity testing frameworks ensure the early identification of mutagenic risks in active substances and excipients. Despite harmonization efforts, significant challenges persist, including varying regional interpretations, data package inconsistencies, and analytical method validation complexities. This critical analysis underscores the need for proactive regulatory intelligence, cross-functional collaboration, and adoption of innovative analytical technologies to ensure compliance and safeguard patient safety in a rapidly changing regulatory environment.

Keywords:

Pharmaceutical regulations, Nitrosamine impurities, Elemental impurities, Forced degradation, Genotoxicity, ICH guidelines

RS20

Design of Experiments-Based RP-HPLC Bioanalytical Method Development and Validation for Ticagrelor Quantification in Rat Plasma: A Cost-Effective Approach for Generic Drug Development

Mariyambibi Mandarawala*[1], Ashok Mahajan[2], Shailesh Koradia[3], Moinuddin Soniwala[4]

[1], [3] Krishna School of Pharmacy & Research, Drs. Kiran & Pallavi Patel Global University (KPGU), Krishna Edu Campus, Vadodara, Gujarat, India

[2] Indukaka Ipcowala College of Pharmacy, The Charutar Vidya Mandal University (CVMU), New VV Nagar, Anand, Gujarat, India

[4] B K Mody Government Pharmacy College, Rajkot, Gujarat, India

[5]Food and Drug Laboratory, Near Polytechnic Campus, Nizampura, Vadodara, Gujarat, India

*Corresponding author: mariyambibimandarawala.ksp@kpgu.ac.in, Krishna School of Pharmacy & Research, Drs. Kiran & Pallavi Patel Global University (KPGU), Krishna Edu Campus, Vadodara, Gujarat, Mo: 99988 62855

ABSTRACT

A cost-effective and robust RP-HPLC bioanalytical method was developed and validated for the quantification of Ticagrelor (TGR), a P2Y12 receptor inhibitor used in acute coronary syndromes, to support generic drug development. A 3^2 full factorial design was employed to optimize chromatographic conditions on a C18 column using an isocratic mobile phase of trifluoroacetic acid buffer, acetonitrile, and methanol (46:48:6, v/v/v) at a flow rate of 1.0 mL/min, with UV detection at 278 nm and verapamil as the internal standard. The method was validated as per ICH M10 guidelines and successfully applied to a rat pharmacokinetic study. Ticagrelor eluted at 14.2 min with symmetrical peak shape and linearity over 100–4000 ng/mL (R^2 = 0.9938 ± 0.0006). The method showed LOD and LOQ of 15.6 and 47.3 ng/mL, respectively, with intra- and inter-day precision below 6.16%, accuracy between +0.47% and +2.81%, recovery of 88.91 ± 2.92%, and negligible matrix effects (<2.17%). Stability was confirmed under all test conditions. Pharmacokinetic parameters obtained in rats included C_{max} 428.56 ± 42.86 ng/mL, t_{max} 1.75 ± 0.27 h, and $AUC_{0–t}$ 2040.79 ± 204.08 ng·h/mL. The developed factorial design–based RP-HPLC method provides a sensitive, precise, and economical alternative to LC–MS/MS for bioanalytical quantification and pharmacokinetic studies supporting generic drug development.

Keywords

Ticagrelor · RP-HPLC · Factorial design · Bioanalytical validation · Pharmacokinetics

RS21

"Development and Validation of a Green HPTLC Method for Quantification of Axitinib in Rat Plasma

Ms. Dishita G. Parmar[1, *] and Dr. Ashok N. Mahajan[2]

Krishna School of Pharmacy and Research, KPGU [1]

Indukaka Ipcowala College of Pharmacy, The CVM University [2]

[*] Ms. Dishita G. Parmar: dishita.parmar@cvmu.edu.in Mob no. 9265479239

Dr. Ashok N. Mahajan: ashok.mahajan@cvmu.edu.in

ABSTRACT

Axitinib, a potent and selective second-generation vascular endothelial growth factor receptor (VEGFR-1, VEGFR-2, and VEGFR-3) tyrosine kinase inhibitor, is an effective therapeutic agent for the treatment of advanced renal cell carcinoma. Due to its poor aqueous solubility and low plasma concentration, developing a sensitive and reliable analytical method is crucial for accurate bioanalysis. In the present study, a simple, precise, and eco-friendly high-performance thin-layer chromatographic (HPTLC) method was developed and validated for the quantification of axitinib in rat plasma in accordance with the ICH M10 guideline on Bioanalytical Method Validation. Chromatographic separation was achieved using toluene: isobutanol (8:2 v/v) as the mobile phase, and densitometric detection was performed at 320 nm. The method demonstrated excellent linearity ($r^2 > 0.99$), accuracy, precision, and recovery within acceptable bioanalytical limits, with satisfactory LOD and LOQ values indicating adequate sensitivity for pharmacokinetic applications. The environmental impact of the developed HPTLC method was assessed using GAPI, AGREE, and the RGB algorithm, and results were compared with a reported HPLC method in rat plasma. The proposed HPTLC method exhibited a superior greenness profile with minimal solvent consumption, reduced waste generation, and higher AGREE and whiteness scores. Overall, the developed method provides a reliable, cost-effective, and environmentally sustainable approach for the bioanalytical estimation of axitinib in rat plasma.

RS22

Barrier to implementation of generic medicine in prescription Among the healthcare professional.

Mitul Prajapati*[1] , Patel Keshveeben[1], Dr. Akashkumar P. Mathuria[2]

[1] K.B. Institute of Pharmaceutical Education and Research , Kadi Sarva Vishwavidyalaya , Gandhinagar , Gujarat , India.

[2] Assistant Professor ,Department of Pharmacology and Pharmacy Practice , K.B. Institute of Pharmaceutical Education and Research , Kadi Sarva Vishwavidyalaya , Gandhinagar , Gujarat , India.

*Corresponding author: mp1209486@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector-23 , Gandhinagar, Mo: 9913158277

ABSTRACT:

Background: Perceptions about prescribing generic medicines vary widely among healthcare professionals, especially between government and private physicians. Private practitioners often have greater flexibility in brand selection, which can influence their attitudes toward generics. Although generic medicines are clinically interchangeable with branded products and meet the same standards of quality, safety, and efficacy, their use remains lower than expected. Despite offering equivalent therapeutic outcomes at a reduced cost, concerns about effectiveness, manufacturing quality, patient acceptance, and regulatory clarity continue to limit their acceptance. Assessing the knowledge, attitude, and perception of healthcare providers is essential to identify barriers to effective generic prescribing.

Objective: The objective of this study is to examine the key barriers affecting the implementation of generic medicine prescribing and dispensing practices. It aims to evaluate how these barriers influence efforts to reduce prescription costs. Additionally, this review seeks to synthesize findings from published research that explore the perspectives of physicians, pharmacists, and patients regarding the use and acceptance of generic medicines.

Methodology: This study was designed as a cross-sectional survey to understand how healthcare professionals view the use of generic medicines in their daily practice. A total of 100 participants—including doctors, pharmacists, and nurses from both government and private sectors—were approached using a convenient sampling method. Data were gathered at one point in time through a structured questionnaire that explored their knowledge, attitudes, and perceptions, along with the barriers they face while prescribing or dispensing generics. The responses were compiled and summarized using simple descriptive statistics to compare trends and differences between government and private practitioners.

RS23

EVALUATION OF ANTI-ASTHMATIC ACTIVITY EXERTED BY METHANOLIC EXTRACT OF ANNONA SQUAMOSA LEAVES

Arpit Kaneriya[1], Udit Trivedi[1] , Tamoghna Sarkar[2]

[1]Department of Pharmacology, School of Pharmacy, RK University, Rajkot, Gujarat, India

Corresponding author : arpitkaneriya8@gmail.com Department of Pharmacology, School of Pharmacy, RK University, Rajkot, Gujarat, India mo:9328200236

ABSTRACT:

Asthma continues to be a major global respiratory disorder characterized by chronic inflammation and airway hyperresponsiveness. Current therapeutic regimens often pose challenges such as side effects and limited accessibility in low-resource regions. The present study explores the anti-asthmatic activity of the methanolic extract of *Annona squamosa* leaves as a promising phytopharmacological alternative. Methanolic extraction was performed using maceration, followed by phytochemical analysis confirming the presence of alkaloids, flavonoids, terpenoids, and saponins. Pharmacological evaluation was conducted using in vitro models—isolated chicken ileum (for spasmolytic activity) and tracheal chain (for bronchodilator activity)—along with a heat-induced hemolytic assay to assess anti-inflammatory potential. The extract demonstrated significant relaxation of acetylcholine- and histamine-induced contractions, indicating potent bronchodilatory and antihistaminic effects. In the hemolytic assay, notable membrane stabilization was observed, comparable to the standard diclofenac, suggesting anti-inflammatory efficacy. These results validate the pharmacological basis of *Annona squamosa* in asthma management and support its potential inclusion in the development of affordable plant-based therapeutics.

RV01

Advances in Generic Drug Formulation & Product Development

Andrea Grace[1], Kundalini Jayswal[1], Dhruvi Patel[1], Dr. Chintan Patel[2]
[1]Student, PharmD 5th Year,
[2]Assistant Professor, Department of Pharmacology and Pharmacy Practice,
K. B. Institute of Pharmaceutical Education and Research, Gandhinagar-382023, Gujarat, India.
*Presenting author:
Andrea Grace- Contact no: +91-8154096270
Email id: andreajoseph550@gmail.com

ABSTRACT

Poor aqueous solubility remains a major challenge in the development of bioequivalent generic formulations for Biopharmaceutics Classification System (BCS) Class II and IV drugs. Lipid-Based Drug Delivery Systems (LBDDS) have emerged as a promising approach to overcome solubility and absorption barriers, improving the in vivo performance of generic formulations. This study focuses on the formulation and evaluation of a lipid-based system for a poorly soluble model drug to achieve bioavailability comparable to the innovator product. Various lipid excipients and surfactants were optimized using a Quality by Design (QbD) approach to ensure reproducibility and scalability. In vitro dissolution and in vivo pharmacokinetic data demonstrated enhanced solubility, consistent drug release and improved absorption. The results highlight LBDDS as a cost effective and feasible strategy in developing high-quality generics that meet bioequivalence standards. This approach supports the “Path to Parity” by bridging formulation innovation with affordability in global healthcare.

Keywords: Lipid-based systems, Generic drugs, Bioequivalence, QbD, Solubility Enhancement

RV02

QbD-Based Process Understanding of Lyophilization with Continuous Monitoring Using PAT Tools

Mr. Jay G. Baldaniya*[1], Dr. Rushiraj Jani[1],
[1]Department of Pharmaceutics, Institute of Pharmacy, Ganpat University, Mahesana, Gujarat, India.
* Corresponding author: Mr. Jay G. Baldaniya, Institute of Pharmacy, Ganpat University, Mahesana, Gujarat, India. Email: jaybaldaniya525@gmail.com

ABSTRACT:

Lyophilization is a critical unit operation in pharmaceutical manufacturing, employed to stabilize thermo-labile drug substances. A Quality by Design (QbD) framework provides systematic process understanding by linking Critical Process Parameters (CPPs) to Critical Quality Attributes (CQAs), thereby ensuring robust cycle design and product performance. The freeze-drying cycle comprises three major stages—freezing, primary drying, and secondary drying—each governed by distinct CPPs. Freezing rate, degree of supercooling, and annealing conditions determine ice crystal morphology and pore architecture, which in turn influence mass transfer. Primary drying efficiency is dictated by product temperature relative to collapse/eutectic thresholds, chamber pressure, shelf temperature, and sublimation kinetics. Secondary drying requires precise control of desorption conditions to achieve target residual moisture levels critical for stability. Continuous process monitoring through Process Analytical Technology (PAT) tools strengthens QbD implementation by providing real-time, non-invasive insights into these CPPs. Raman and near-infrared spectroscopy enable in-line mapping of phase transitions and drying endpoints. Wireless thermal sensors such as TEMPRIS provide accurate product temperature profiling within blister or vial configurations. Pressure-based tools including Pirani gauges and capacitance manometers, complemented by advanced techniques such as tunable diode laser absorption spectroscopy (TDLAS), mass spectrometry, and manometric temperature measurement (MTM), allow precise tracking of sublimation kinetics and endpoint determination. The integration of QbD principles with PAT-enabled monitoring establishes a holistic control strategy for lyophilization, reducing cycle time, improving scalability, and ensuring consistent CQAs. This technical framework advances lyophilization as a reproducible, efficient, and regulatory-compliant manufacturing process for solid oral and parenteral dosage forms.

Keywords:

Lyophilization, QbD-centric development, Critical Process Parameters, Process analytical technology

RV03

Cutting-Edge Strategies in Gastroretentive Drug Delivery: A Review

Ritesh Shah*[1] , Het Solanki[1], Anita Lalwani[2]

[1]K. B. Institute Of Pharmaceutical Education and Research, Kadi Sarva Vishwavidayalaya, Gandhinagar, Gujarat, India

[2]Department Of Pharmaceutics, Professor & Head, K. B. Institute Of Pharmaceutical Education and Research, Kadi Sarva Vishwavidayalaya, Gandhinagar, Gujarat, India

*Corresponding author: riteshshah7001@gmail.com , K.B. Institute Of Pharmaceutical Education and Research, Sector 23, Gandhinagar, Mo: 9824039272

ABSTARCT

Gastro-retentive drug delivery systems (GRDDS) are advanced oral controlled release formulations designed to prolong gastric residence time and enable site-specific drug delivery in the stomach and upper gastrointestinal tract. They are particularly beneficial for drugs with a narrow absorption window, instability at higher intestinal pH, or those requiring localized gastric action. GRDDS enhance bioavailability, reduce dosing frequency, and improve therapeutic efficacy compared to conventional dosage forms. The major approaches include floating, high-density, mucoadhesive, swelling or expandable, raft-forming, and magnetic systems. Recent innovations integrate multiple retention mechanisms such as floating–mucoadhesive or expandable–mucoadhesive combinations, and employ novel polymers including pH-responsive, enzyme-sensitive, and superporous hydrogels to achieve reliable gastric retention and controlled release. Formulation development demands careful optimization of physicochemical properties, polymer selection, on one end and consideration of gastric motility, and fed–fasted conditions on the other. Several marketed formulations exemplify the success of GRDDS, including Valrelease® (Diazepam, floating capsule), Madopar® HBS (Levodopa/Benserazide, floating system), Liquid Gaviscon® (alginate raft-forming system), Cifran OD® (Ciprofloxacin, effervescent tablet), Baclofen GRS® (expandable tablet), and Glumetza® (Metformin HCl, AcuForm® technology). These products validate GRDDS as a clinically and commercially viable strategy for enhancing drug absorption and patient compliance. Current research focuses on hybrid retention systems, predictive modeling, and 3D-printed personalized dosage forms, reinforcing GRDDS as a transformative platform in oral controlled drug delivery.

RV04

Impact of Regulatory Science on Complex Generics: Overview of Regulatory Guidelines and Approval Pathways

Mukti Kapdi[*,1], Maitreyi Zaveri[1], Pragnesh Donga[2], Vinit Movaliya[1]
[1]Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382023, Gujarat, India
[2] ARKRI Therapeutics, Ahmedabad
* Corresponding author: kapdimukti26@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar

ABSTRACT:

Complex generics, such as inhalation therapies, long-acting injectables, transdermal systems, and drug-device combinations, present unique scientific and regulatory challenges compared to traditional generics. The complexities in their formulation, delivery, and analysis make it harder to demonstrate therapeutic equivalence to reference products. Because of this, regulatory bodies like the U.S. FDA, EMA, and WHO have created specialized and changing guidelines to support their development and approval. This paper provides an overview of the main regulatory frameworks that govern complex generics, focusing on recent changes related to the Generic Drug User Fee Amendments (GDUFA III, FY 2023-2027). It also highlights global efforts to improve efficiency, transparency, and predictability in the regulatory process. We conducted a comparative analysis of the main regulatory frameworks. This included examining FDA Product-Specific Guidance (PSGs), EMA's hybrid application pathways, and WHO and ICH initiatives. We paid special attention to the FDA's pre-ANDA program and the assessment meetings started under GDUFA III.

GDUFA III improves early scientific collaboration and open communication through pre-ANDA meetings, sets PSG timelines, and enhances regulatory science initiatives. These changes aim to reduce multiple review cycles while encouraging innovation, all while maintaining high standards for safety, efficacy, and quality. The changing regulations around complex generics underline the need for collaboration, clarity, and harmonization. Early engagement with regulatory agencies and consistent international standards is crucial for speeding up approvals and ensuring patient access to affordable, high-quality alternatives.

Keywords: Complex generics, Regulatory frameworks, GDUFA III, Bioequivalence, Product-specific guidance, Global harmonization, pre-ANDA program

RV05

Comparative Evaluation of Regulatory Registration & Approval Pathways for Semaglutide 14 mg Tablets in Emerging South American Markets: Chile, Peru & Bolivia

Vishesh Modi*[,1], Vinit Movaliya, Nirav Patel[2], Maitreyi Zaveri[1]
[1]Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382023, Gujarat, India
[2] Step-up Pharma tech, Ahmedabad
* Corresponding author: visheshmodi003@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar

ABSTRACT:

The regulatory registration and approval processes for Semaglutide 14 mg tablets in three developing South American markets—Bolivia, Peru, and Chile—are compared in this paper. The goal is to examine how this antidiabetic drug's regulatory frameworks, application types, dossier formats, evaluation schedules, and approval requirements differ and are similar. The Institute of Public Health (ISP) in Chile, the General Directorate of Medicines, Supplies and Drugs (DIGEMID) in Peru, and the State Agency for Medicines and Health Technologies (AGEMED) in Bolivia are examples of national authorities that oversee different regulatory processes in each country. The evaluation reveals that although all three nations adhere to important international standards including WHO and ICH guidelines, there are differences in dossier submission methods, documentation language, reliance procedures, and regional needs for clinical data. Peru uses the VUCE system for electronic submissions under DIGEMID, while Chile uses a structured evaluation through ISP with possibilities for simpler registration. Bolivia's procedure is still more labour-intensive and manual, and it depends less on outside regulatory rulings. In comparison to Bolivia and Peru, Chile has a more coordinated and effective strategy overall. The study comes to the conclusion that implementation of reliance pathways and regional regulatory harmonization might greatly improve access to cutting-edge treatments like semaglutide in these countries, guaranteeing prompt patient availability while upholding safety, quality, and efficacy criteria.

Keywords: Semaglutide 14 mg tablet, Chile, Peru, Bolivia, Regional Harmonization & Market Authorization

RV06

Regulatory Approval for Registration of Ferric Carboxy Maltose Injection 50mg/ml : A Comparison Across South Africa, Singapore and Saudi Arabia

Nikunj Sureliya[*,1], Zuki Patel[1], Nirav Patel[2], Maitreyi Zaveri [1]
[1]Department of Pharma Regulatory Affairs, K.B. Institute of Pharmaceutical Education and Research (KBIPER), a constituent college of Kadi Sarva Vishwavidyalaya (KSV), Sector-23, Gandhinagar-382023, Gujarat, India
[2] Step-up Pharmatech, Ahmedabad
* Corresponding author: nikunj.sureliya01@gmail.com, K.B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar

ABSTRACT:

Pharmaceutical product regulatory approval processes differ greatly between international markets, which affects product registration schedules and tactics. The regulatory processes for the licensing of Ferric Carboxymaltose Injection 50 mg/ml in South Africa, Singapore, and Saudi Arabia are compared in this review. These nations each have unique regulatory systems that are impacted by regional and global norms. The South African Health Products Regulatory Authority (SAHPRA), which oversees approvals in the country, places a strong emphasis on local testing, submitting dossiers in CTD format, and relying on foreign evaluations to increase efficiency. The Health Sciences Authority (HSA) in Singapore employs a simplified, risk-based methodology, using verification routes for Pharmaceutical Product Authorized by reference agencies and reliance pathways like the ASEAN Common Technical Dossier (ACTD). In the meanwhile, the Saudi Food and Drug Authority (SFDA) of Saudi Arabia comply with ICH-aligned CTD regulations with particular regional modifications, such as Arabic labelling and required local testing. The comparison provides insights into trends in regulatory convergence by highlighting variations in submission format, evaluation schedules, reliance mechanisms, and post-approval procedures. Patients' access to vital medications like ferric carboxymaltose is being accelerated and duplication of effort is gradually being reduced through harmonization through international collaboration and dependency pathways.

Keywords: Ferric Carboxymaltose Injection, SAHPRA, HSA, SFDA, Reliance Pathways,

RV07

Comparative study: USAFDA vs CDSCO regulatory pathways for generics

Vanshika Modi [1], Calina kpadia[1], Dr. Akash Mathuria[2], Zuki Patel[2]
[1] Student, PharmD 5th Year,
[2]Assistant Professor, Department of Pharmacology and Pharmacy Practice,
K. B. Institute of Pharmaceutical Education and Research, Gandhinagar-382023, Gujarat, India
*Presenting author:
Vanshika Modi- Contact no: +91-9737340449
Email id: modivanshika04@gmail.com

ABSTRACT

The regulation of generic drugs is crucial for ensuring access to safe, effective, and affordable medicines worldwide. This study compares the approval processes used by the US Food and Drug Administration (FDA) and India's Central Drugs Standard Control Organization (CDSCO). While both agencies aim to maintain high standards of quality, safety, and efficacy, their frameworks differ. The US FDA follows the Hatch-Waxman Act, focusing on Abbreviated New Drug Applications (ANDA) and stringent bioequivalence testing. In contrast, the CDSCO operates under the Drugs and Cosmetics Act, with ongoing efforts to align more closely with international standards. Understanding these differences helps pharmaceutical companies navigate regulatory requirements and supports global public health improvements.

Keywords: Generic drugs, US FDA, CDSCO, ANDA, regulatory pathway, bioequivalence.

RV08

Real-World Pharmacovigilance Analysis of NSAID-Associated Adverse Events in Rheumatoid Arthritis Patient

Amruta S Wagh*, Snigdha Das Mandal

[1]Department of Pharmacology, Parul Institute of Pharmacy and Research, Parul University, Limda, Vadodara-391760, Gujarat, India.

*Corresponding author: amrutaswagh.11@gmail.com, Parul Institute of Pharmacy and Research, Parul University, Limda, Vadodara-391760, Gujarat, India.

ABSTRACT:

Non-steroidal anti-inflammatory medicines (NSAIDs) are extensively used to relieve pain and inflammation in cases with rheumatoid arthritis (RA). Still, their long- term use frequently leads to adverse medicine responses (ADRs), affecting patient safety and treatment issues. This retrospective study examined real- world data from post-marketing surveillance reports, sanitarium ADR records, and published literature to understand the pattern, frequence, and inflexibility of NSAID- related ADRs in RA cases. Information was grouped by types of NSAID, cure, patient demographics, nature of ADR, and clinical issues, with reason assessed using WHO- UMC and Naranjo scales. Gastrointestinal problems similar as indigestion, gastritis, and upper GI bleeding were the most common ADRs, especially with diclofenac and ibuprofen. COX- 2 impediments showed smaller stomach- related issues but had a advanced rate of cardiovascular side effects. Liver complications were more frequent in aged cases and in those taking corticosteroids or DMARDs along with NSAIDs. Severe responses were substantially linked to long- term use, high boluses, multiple specifics, age over 55 times, and health conditions. Utmost cases recovered after stopping the medicine, though many required sanitarium care. These findings punctuate that NSAID- related ADRs continue to pose a major challenge in RA remedy, emphasizing the need for conservative prescribing, regular monitoring, and patient mindfulness to ameliorate treatment safety.

Keywords: Rheumatoid arthritis, NSAIDs, adverse goods, pharmacovigilance, gastrointestinal toxin, cardiovascular threat, medicine safety

RV09

Pharmacovigilance Analysis of Generic Drug Substitution and Polypharmacy in Parkinson's Disease: Real-World Challenges

Saurav Nagda*, Sayan Chatterjee

[1]Department of Pharmacology, Parul Institute of Pharmacy and Research, Parul University, Limda, Vadodara-391760, Gujarat, India.

*Corresponding author: sauravnagda1701@gmail.com , Parul Institute of Pharmacy and Research, Parul University, Limda, Vadodara-391760, Gujarat, India.

ABSTRACT:

Parkinson's disease (PD) management frequently needs long-term pharmacotherapy and generic substitution is an extensively accepted approach to enhance access and reduce costs of therapy. Despite generics being made to be therapeutically identical to a brand drug, subtle differences in formulation, excipient or bioavailability can at times impact clinical response. This setting gets even more complicated in PD patients taking several drugs at the same time (multitherapy or polytherapy), increasing the risks related to drug-drug interactions and adverse drug reactions (ADR). With this review we intend to evaluate the impact of both generic substitution and polypharmacy on drug therapeutic safety and effectiveness in PD, as well as seeking the contribution to one such case with pharmacovigilance challenges accomplishment. A systematic qualitative review comprising literature of 2018-2025 as well as data from global pharmacovigilance databases like WHO-VigiBase and Indian PvPI was performed. Reports implicating the generic form of Levodopa-Carbidopa-Rasagiline-Prampexole for ADR trends, therapeutic failures and interaction based complications were reviewed. The results indicate, that the majority of substutitions with generic drugs did not result in a clinically relevant change in efficacy, but they found individual cases with changed motor control, dyskinesia and orthostatic hypotension after substitution. Several co-medications also developed a complex attribution of ADR and they were frequently under-reported. The joint impact of generic substitution and polypharmacy arises as critically important challenges for phamacoepidemiological surveillance in general. Enhancements in active ADR reporting systems, raising clinician awareness and the use of digital monitoring tools will be vital to promote patient well-being and treatment reliability across real-world PD care.

Keywords:

Parkinson's disease; Generic drug substitution; Polypharmacy; Pharmacovigilance; Post-marketing surveillance; Adverse drug reactions; Therapeutic equivalence; Drug–drug interactions; WHO-VigiBase; Real-world evidence.

RV10

Descriptive Study: Role of Adverse Drug Reaction (ADR) Reporting in Ensuring the Safety of Generic Medicines

Dhruvi Patel[1], Simi Patel[1], Dr. Jinal Chaudhary[2]
[1] Student of Pharm D 5th Year
[2]Assistant professor, Department of Pharmacology and Pharmacy Practice.
K. B. Institute of Pharmaceutical Education and Research, Gandhinagar-382023, Gujarat, India

ABSTRACT

Background: Generic medicines are widely used because they are more affordable than branded drugs. Although they have the same active ingredient, small differences in color, preservatives, or manufacturing process can sometimes cause side effects in certain patients. Monitoring and reporting these side effects—known as Adverse Drug Reactions (ADRs)—helps make generic medicines safer for everyone. Objective: To understand how ADR reporting helps in identifying and preventing side effects related to generic medicines and to promote awareness about its importance in maintaining drug safety. Methods: Information was collected from published articles, WHO guidelines, and data from the Pharmacovigilance Programme of India (PvPI) to study how ADR reporting supports the safety monitoring of generic drugs. Results: ADR reporting has helped detect safety issues in some generic products and allowed timely actions like quality checks, label updates, or withdrawal of unsafe batches. However, many ADRs still go unreported because of lack of awareness among healthcare professionals. Conclusion: Reporting ADRs plays a vital role in ensuring the safety of generic medicines. By regularly reporting any suspected side effects, healthcare professionals, pharmacists, and patients can together improve the quality and trust in generic drugs.

Keywords: ADR reporting, generic medicines, pharmacovigilance, drug safety, PvPI

RV11

Generics: Misuse & Misconception

Meet S Gupta*[1], Vishwa Patel[1], Sandipkumar Bhatt[2]

Student: [1]K. B. Institute of Pharmaceutical Education and Research, Kadi Sarva Vishwavidyalaya, Gandhinagar, Gujarat, India, 382016

Professor: [2]Department of Pharmacology and Clinical Pharmacy, K. B. Institute of Pharmaceutical Education and Research, Kadi Sarva Vishwavidyalaya, Gandhinagar, Gujarat, India, 382016

*Corresponding author: meet.gupta604@gmail.com, Mo: 9909725620

ABSTRACT:

To review the prevailing misconceptions surrounding generic medicines and explore the factors contributing to their misuse, despite established regulatory assurance of quality, safety, and efficacy. A narrative review approach was adopted by examining 7 published literature, regulatory guidelines, and policy documents related to generic drug development, bioequivalence standards, prescriber attitudes, and patient perceptions. Sources included peer-reviewed journals, WHO reports, and national regulatory frameworks. Key themes were synthesized to identify recurring patterns of misuse and misconception. Findings indicate that misconceptions stem largely from a lack of awareness about bioequivalence requirements, distrust in manufacturing quality, and the belief that lower cost equates to inferior therapeutic outcomes. Misuse was commonly linked to inappropriate substitution practices, poor counselling by healthcare providers, and inconsistent branding leading to patient confusion. Evidence also shows that limited regulatory literacy among patients and even healthcare professionals contributes significantly to hesitation in adopting generics, despite studies confirming their clinical equivalence to branded formulations. Misconceptions and misuse of generic medicines continue mainly due to poor awareness and communication, along with biases favouring branded drugs. Better education, clearer regulatory messaging, and standardized substitution practices are key to improving their proper use.

RV12

Real-World Pharmacovigilance Challenges and Adverse Drug Reaction (ADR) Reporting Patterns in Generic Drugs.

Aarchi Soni, Namrashi Pandya , Heta Patel, Dr. Rohit Patel
K. B. Institute of Pharmaceutical Education and Research, Gandhinagar-382023, Gujrat, India
Presenting author : Aarchi Soni – Contact no : +91- 8320211151
Email id : aarchisoni159@gmail.com

ABSTRACT

Generic Medicines account for a significant proportion of global drug consumption, yet real-world safety monitoring for these products remains limited. This study explores the key pharmacovigilance challenges associated with generic drugs and examines existing patterns of adverse drug reaction (ADR) reporting. Major barriers identified include limited patient awareness, under-reporting by healthcare professionals, Variability in formulation quality and difficulties in attributing ADRs specifically to generic products. Additionally, inconsistencies in reporting systems, lack of standardized post-marketing surveillance and misconception regarding the Safety equivalence of generics further impede effective pharmacovigilance. Reviewed real-world evidence indicates that ADR reporting for generic drugs is significantly lower compared to branded counterparts, despite widespread use. Enhancing pharmacovigilance requires improved regulatory oversight, strengthened Spontaneous reporting systems, periodic Safety update programs, training of healthcare professionals and Patient education initiatives. This poster highlights the need for more robust real-world safety monitoring to ensure early detection od ADRs and reinforce the safe use of generic medicines in Clinical Practice.

Keywords: ADR reporting; real-world evidence; Drug Safety; Under-reporting; Healthcare professionals; patient awareness; Regulatory challenges.

RV13

Role of Pharmacovigilance in Ensuring Safety of Generic Medicines

Anshul Gondaliya*[1], Hema Rathod[2], Sandipkumar P. Bhatt
K.B. INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH KADI SARVA VISHWAVIDYALAYA GANDHINAGAR, GUJARAT
Department of pharmacy practice K.B.institute of pharmaceutical education and research Gandhinagar, Gujarat
*corresponding author: anshulgondaliya@gmail.com K.B.institute of pharmaceutical education and research Gandhinagar, Gujarat

ABSTRACT

Pharmacovigilance is the crucial discipline dedicated to continuously assessing the risk benefits ratio of medicines, thereby ensuring their safe use in the real-world population. The increasing use of generic medicines necessitates robust pharmacovigilance (PV) to ensure their continued safety and effectiveness. While generics are approved based on bioequivalence to the reference product, differences in inactive ingredients (excipients) or manufacturing processes can potentially affect the safety profile in a real-world, heterogenous population. PV activities, including the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs), are crucial for generics throughout their lifecycle, particularly in the post-marketing phase. A key role of PV is to distinguish and attribute ADRs specifically to the generic product, as reporting systems often struggle to differentiate between brand and generic versions of the same active ingredient. Continuous post-marketing surveillance enables the early identification of rare or long-term safety signals that may not have been apparent during abbreviated clinical trials. Strengthening global harmonization and surveillance methodology for generics is vital to maintain public confidence and ensure the overall benefit-risk balance remains favorable for all pharmaceutical products.

RV14

Artificial Intelligence and Digitalization in Drug Product development

Saloni Gosai*

Krishna School of Pharmacy and Research

Drs. Kiran and Pallavi Global University

ABSTRACT

Artificial intelligence offers crafts which drift research optimize formulations and decline resource-intensive work required to demonstrate equivalence to the reference listed drug (RLD). Core challenge for generic manufacturers is achieving bioequivalence—ensuring the generic drug is absorbed into the bloodstream at the same rate and extent as the brand-name product. Various crucial model like: Predictive Formulation Modeling, Predicting Bioequivalence (BE): AI models, including Physiologically Based Pharmacokinetic (PBPK) modeling, Complex Generics, Automated Regulatory Submissions, Bottom line, Digitalization and Artificial Intelligence (AI) are transforming generic drug development by making the process faster, cheaper, and more predictable.

RV15

Artificial Intelligence & Digitalization in Generic Product Development

Kartavya Patel[1]*, Yashvi Patel[2], Sandipkumar P. Bhatt[2]
K. B. Institute of Pharmaceutical Education and Research, Kadi Sarva Vishwavidyalaya, Gandhinagar, Gujarat, India.
Corresponding author: kartavyapatel2604@gmail.com, K. B. Institute of Pharmaceutical Education and Research, Sector 23, Gandhinagar, Gujarat, 380023, India.

ABSTRACT:

Artificial Intelligence (AI) and digitalization are transforming generic pharmaceutical product development by shifting traditional trial-and-error methods toward prediction-based, data-driven approaches. AI supports pre-formulation by predicting drug–excipient compatibility, solubility enhancement strategies, and stability risks, thereby reducing unnecessary laboratory experimentation. Machine learning algorithms further optimize formulation parameters such as excipient ratios, binder concentration, granulation conditions, and dissolution behavior, enabling faster and more accurate matching with the innovator profile. Digital twin technology enables virtual simulation of dissolution performance, scale-up conditions, and stability behavior, reducing physical experimentation and improving process predictability. AI-based physiologically based pharmacokinetic (PBPK) modeling predicts Cmax, Tmax, and AUC before conducting human bioequivalence (BE) studies, significantly lowering BE failure risk and overall development cost. In-silico tools such as AutoDock Vina and SwissADME provide molecular-level insights for interaction prediction, impurity profiling, and ADME assessment. Furthermore, AI accelerates analytical method development by predicting mobile phase composition, gradient conditions, and impurity resolution for HPLC, thereby reducing method development timelines from weeks to days. This review is based on structured literature analysis, regulatory guidance documents, PBPK modeling evidence, and evaluation of AI-driven in-silico tools relevant to generic drug development. Overall, AI-driven predictive systems enhance formulation accuracy, analytical efficiency, and regulatory readiness—contributing to faster, more reliable, and cost-effective development of high-quality generic medicines.

Keywords:

Artificial Intelligence; Digitalization; Generic Drugs; PBPK Modeling; In-silico Tools; Formulation Optimization.

RV16

Pharmacological and Therapeutic Equivalence Perspectives in the Management of Ulcerative Colitis: Bridging Mechanisms and Clinical Outcomes

Rahul Kuwar*, Jagdish Kakadiya
[1]Department of Pharmacology, Parul Institute of Pharmacy and Research, Parul University, Limda, Vadodara-391760, Gujarat, India.

*Corresponding author: kuwarrahul78@gmail.com, Parul Institute of Pharmacy and Research, Parul University, Limda, Vadodara-391760, Gujarat, India.

ABSTRACT:

Ulcerative colitis (UC) is an idiopathic, chronic and recurrent IBD characterized by abnormal mucosal inflammation, immune dysregulation and oxidant damage in the colon. Although a number of treatments are available, long-term disease-free remission with an acceptable quality of life can be difficult to achieve. The current study aims to explore the pharmacological basis and therapeutic equivalence considerations in UC by integrating the molecular pathways and clinical endpoints for new opportunities of safer and more efficacious treatments. An online search was conducted to find scientific papers discussing the main inflammatory mediators and oxidative biomarkers including TNF-α, IL-6, MPO, and MDA that are involved in disease pathogenesis as well as treatment response. Particular focus was given to the NF-κB, COX-2 and JAK/STAT signaling cascades that lead to inflammation and mucosal damage. Manipulating these pathways therapeutically has led to substantial advances in the promotion of mucosal healing, cytokine inhibition and relapse prevention. Although there is a difference in the clinical efficacy and safety profiles among formulations, it is essential to assess therapeutic equivalence based on mechanism of action. Combining biomarker-guided testing with pharmacological insight has the potential to improve predictability and reliability of treatment responses. This model connects preclinical knowledge to the clinic, advocating for rational drug design and personalized management of UC. Conclusion This study underscores the value of mechanism-guided pharmacotherapy, efficacy–safety–bioequivalence optimization for better management of ulcerative colitis.

Keywords: Ulcerative colitis, pharmacological mechanisms, therapeutic equivalence, NF-κB, JAK/STAT, oxidative stress, inflammation, mucosal healing, biomarkers, drug efficacy.

RV17

From Tradition to Modernity: Pharmacological Validation of Herbal Generics in Rheumatoid Arthritis

Richa Jain*, Zalak Shah

1Department of Pharmacology, Parul Institute of Pharmacy & Research, Parul University, Limda, Vadodara-391760, Gujarat, India

*Corresponding author: richajain70090@gmail.com , Parul Institute of Pharmacy & Research, Parul University, Limda, Vadodara-391760, Gujarat, India

ABSTRACT

Rheumatoid arthritis (RA) is a chronic autoimmune disease that leads to sustained synovial inflammation, cartilage destruction, and erosive joint changes. While conventional disease-modifying antirheumatic drugs (DMARDs) are still the mainstay of management, they are frequently associated with long-term side effects, availability and cost issues. Herbal generics scientifically validated and standardized herbal formulations drawn from traditional systems of medicine, as potential alternatives for long-term sustainable management of RA are in focus among the scientific community recently. In this review the information from published literature regarding pharmacological validation of herbal generics in RA is systematically organized. Cited studies retrieved from PubMed, Scopus and ScienceWide reveal the anti-arthritic effect of some herbal products and its mechanism which has the ability to modulate various inflammatory mediators (tumor necrosis factor-alpha [TNF-α]; interleukin6, IL-6; nuclear factor-kappa B, NFκB) and endogenous antioxidant defenses (superoxide dismutase, SOD; catalase, CAT;). These multimodal actions also lead to decreased oxidative stress, inhibition of cytokine signaling, and enhanced joint function. When compared with conventional DMARDs, validated herbal generics can be effective and may possess better safety and tolerability. Analytic standardisation, regulation and pharmacovigilance need to be also incorporated for standardization, efficacy and worldwide recognition. Therefore, integrating ancient herbal knowledge and modern pharmacological advances is a promising roadmap for novel, affordable and ecological remedies against rheumatoid arthritis.

Keywords: Rheumatoid arthritis, Herbal generics, Pharmacological validation, Anti-inflammatory, Oxidative stress

RV18

Comparative Pharmacology of Branded and Generic formulations of Allopathy and Herbal Formulations: Implications for Therapeutic Consistency in Female Reproductive Health

Anthony Cordeiro*, Jagdish Kakadiya

[1]Department of Pharmacology, Parul Institute of Pharmacy and Research, Parul University, Limda, Vadodara-391760, Gujarat, India.

*Corresponding author: cordeiroanthony36@gmail.com , Parul Institute of Pharmacy and Research, Parul University, Limda, Vadodara-391760, Gujarat, India.

ABSTRACT

In this review, we discuss comparative pharmacology of allopathic and herbal drugs in branded and generic forms, available in allopath markets for female reproductive health disorders such as polycystic ovarian syndrome (PCOS), infertility, hormonal imbalance etc. To evaluate differences in effectiveness, safety, and pharmacological equivalence which could affect treatment response. Literature from 2010 to 2024 was comprehensively summarized in major scientific databases with respect to formulation composition, bioavailability, pharmacokinetics and clinical efficacy. Allopathic Herbal brands advocate better uniformity for being made under standard manufacturing conditions with strict adherence to regulatory authorities. Generic preparations are cost-effective; however, active ingredient concentration, dissolution rate and excipient content may vary with these products, and such variability could impact on bioequivalence as well as clinical response. Herbal generics in particular are non-standardized and quality assured with relation to its phytochemical standardization, which results into the ambiguity of pharmacodynamics. In summary, the comparative analysis underscores that therapeutic equivalence of branded and generic products is contingent on the accuracy in manufacturing, regulation and bioequivalence testing. It is, necessary to improve on standardization/quality control processes for both the allopathic and herbal preparations to maintain safe, efficacious, efficacious pharmacotherapy in female reproductive health management.

Keywords: Branded formulations; Generic drugs; Herbal pharmacology; Therapeutic consistency; Female reproductive health

RV19

Therapeutic Bioequivalence of Branded and Generic Formulation of Allopathic and Herbal in the Management of Oligospermia: A Pharmacological Perspective

Harshita Patel*, Jagdish Kakadiya[1]
[1]Department of Pharmacology, Parul Institute of Pharmacy & Research, Parul University, Limda, Vadodara-391760, Gujarat, India
*Corresponding author: harshitapatel772@gmail.com, Parul Institute of Pharmacy and Research, Parul University, Limda, Vadodara-391760, Gujarat, India

ABSTRACT

Oligospermia is one of the leading cause of male infertility condition, is still a complicated problem that is treated with a variety of pharmaceutical treatments, including allopathic and herbal treatment. Many branded and generic medications make claims about their therapeutic efficacy in increasing sperm parameters, but their therapeutic reliability and comparative pharmacological equivalency have not been yet sufficiently proved. The purpose of this research is to critically assess the available data related to the therapeutic bioequivalence of generic and branded formulation of allopathic and herbal drugs used to manage and treat oligospermia condition. Comparative research on pharmacokinetic and pharmacodynamic characteristics, manufacturing quality, phytochemical consistency, and clinical results documented in human and animal models are included in this analysis. Gonadotropins, antioxidants, clomiphene citrate-based treatments, and herbal remedies including Mucuna pruriens, Withania somnifera, and polyherbal combinations are all given special attention.The investigated literature findings indicate that branded and generic allopathic formulations typically maintain sufficient bioequivalence, but there is still a great variability in herbal medicines is seen because of variations in raw material standardization, formulation procedures, and regulatory control. In order to guarantee real therapeutic equivalency, the review emphasizes the critical necessity for standardized evaluation procedures, verified preclinical models, and quality control procedures. In the pharmacological treatment of oligospermia, establishing bioequivalence standards for herbal generics may improve clinical predictability, safety, and reproducibility.

Keywords: Oligospermia, Bioequivalence, Branded vs Generic, Herbal Formulations, Pharmacological Standardization

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