World Journal of Pharmaceutical and Life Sciences
WJPLS
www.wjpls.org
SJIF Impact Factor: 6.129

EVOLUTION AND CHALLENGES OF PHARMACEUTICAL PRODUCTION IN CONTEMPORARY GLOBAL INDUSTRY

Dr. Osman Ahmed*[1] Khadeeja[1] and Dr. Anas Rasheed[2]

[1]Department of Pharmaceutical Analysis, Deccan School of Pharmacy, Hyderabad.
[2]CSO, Gaelib Medications Private Limited, Hyderabad.

***Corresponding Author: Dr. Osman Ahmed**
Department of Pharmaceutical Analysis, Deccan School of Pharmacy, Hyderabad.

Article Received on 15/11/2023 **Article Revised on 05/12/2023** **Article Accepted on 25/12/2023**

ABSTRACT

The pharmaceutical production industry is a complex and dynamic sector that relies on advanced technology, rigorous regulation, and the demand for innovative drugs. Key trends include the adoption of advanced manufacturing technologies, continuous manufacturing, Quality by Design (QbD), and green chemistry practices. Challenges include increasing demand and supply chain complexity, biopharmaceutical complexity, and regulatory hurdles. However, advancements in Industry 4.0 and smart manufacturing, such as IoT, artificial intelligence, and machine learning, are transforming pharmaceutical production. Personalized medicine integration is reshaping pharmaceutical production, requiring flexible manufacturing processes. Green chemistry innovations are being developed, including sustainable manufacturing processes and environmentally friendly solvents. These trends have significant implications for the global pharmaceutical market, affecting drug availability, affordability, and healthcare system efficiency. Addressing challenges, embracing innovation, and ensuring regulatory alignment are crucial for a robust pharmaceutical production industry.

KEYWORDS: Manufacturing, Quality by Design (QbD), and green chemistry practices.

Brief Overview of the Current State

The pharmaceutical production industry stands at the intersection of cutting-edge technology, rigorous regulation, and an ever-increasing demand for innovative and life-saving drugs. In today's world, pharmaceutical manufacturing is a highly complex and dynamic sector that plays a pivotal role in ensuring the availability and quality of medications worldwide.

Key Trends in Pharmaceutical Manufacturing

- **Advanced Manufacturing Technologies:** The industry is experiencing a transformative shift with the adoption of advanced manufacturing technologies. Automated systems, robotics, and data analytics are enhancing efficiency, reducing production costs, and ensuring precision in pharmaceutical processes.
- **Continuous Manufacturing:** Traditional batch manufacturing is giving way to continuous manufacturing, offering benefits such as reduced time-to-market, enhanced quality control, and increased flexibility in adapting to changing demands.
- **Quality by Design (QbD):** The Quality by Design approach is gaining prominence, emphasizing the proactive design of manufacturing processes to ensure product quality. This systematic methodology enhances the understanding of production processes, leading to improved product consistency and regulatory compliance.
- **Green Chemistry Practices:** Sustainability is a growing concern, leading to the adoption of green chemistry principles in pharmaceutical manufacturing. Companies are increasingly incorporating eco-friendly practices to minimize environmental impact and promote sustainability throughout the production lifecycle.

- **Challenges in Pharmaceutical Production**
- **Increasing Demand and Supply Chain Complexity:** The rising global demand for pharmaceuticals, exacerbated by the ongoing COVID-19 pandemic, poses significant challenges in meeting production requirements. Ensuring a resilient and efficient supply chain becomes paramount to prevent shortages and maintain uninterrupted drug access.

- **Biopharmaceutical Complexity:** The production of biopharmaceuticals, including monoclonal antibodies and gene therapies, introduces a new level of complexity. Manufacturing processes for these advanced therapies require specialized expertise, stringent quality control, and dedicated facilities.
- **Regulatory Hurdles:** Stringent regulatory requirements, while essential for ensuring product safety, can impede innovation and introduce delays in the approval of new manufacturing technologies. Harmonizing global regulations remains a challenge for the industry.

Advancements in Pharmaceutical Manufacturing

- **Industry 4.0 and Smart Manufacturing:** The convergence of digital technologies under Industry 4.0 is transforming pharmaceutical production. Smart manufacturing technologies, including the Internet of Things (IoT), artificial intelligence, and machine learning, enable real-time monitoring, predictive maintenance, and improved process optimization.
- **Personalized Medicine Integration:** The move towards personalized medicine is reshaping pharmaceutical production. Customized drug formulations and patient-specific treatments require flexible manufacturing processes that can accommodate variations in drug composition and dosage.
- **Green Chemistry Innovations:** Companies are investing in research and development to implement green chemistry innovations. This includes the development of sustainable manufacturing processes, reduced waste generation, and the use of environmentally friendly solvents.

Implications for the Global Pharmaceutical Market

The trends and advancements in pharmaceutical production have far-reaching implications for the global market. The industry's ability to adopt and integrate new technologies influences drug availability, affordability, and the overall efficiency of healthcare systems worldwide. Addressing challenges, embracing innovation, and ensuring regulatory alignment are critical to sustaining a robust pharmaceutical production industry that meets the healthcare needs of a growing and dynamic global population.

INTRODUCTION

Importance of Pharmaceutical Production

The significance of pharmaceutical production in providing essential medicines to the global population cannot be overstated. It serves as the backbone of healthcare systems worldwide, translating scientific innovations into tangible solutions that improve and save lives. The accessibility and affordability of medicines, driven by efficient production processes, are fundamental to addressing public health challenges and promoting well-being.

Pharmaceutical production ensures a reliable supply of a diverse range of medications, from common over-the-counter drugs to complex life-saving treatments. It plays a pivotal role in disease prevention, management, and treatment, contributing directly to the achievement of global health goals. The industry's ability to meet the increasing demand for innovative and generic drugs is crucial for maintaining public health and addressing emerging health threats.

Historical Evolution of Pharmaceutical Manufacturing Practices

The journey of pharmaceutical manufacturing practices is a fascinating exploration of scientific progress, regulatory advancements, and technological breakthroughs. Historically, pharmaceutical production was characterized by manual and empirical processes. The discovery of penicillin in the early 20th century marked a transformative period, leading to the mass production of antibiotics and the establishment of modern pharmaceutical manufacturing.

The mid-20th century witnessed the development of Good Manufacturing Practices (GMP), setting the foundation for standardized production and quality control. Advances in organic chemistry and molecular biology in subsequent decades fueled the growth of biopharmaceuticals, introducing new complexities and challenges to manufacturing processes.

The late 20th century and the beginning of the 21st century saw the advent of sophisticated technologies, automation, and stringent regulatory oversight. Continuous manufacturing, Quality by Design (QbD), and green chemistry principles emerged as key paradigms, reflecting a shift towards precision, sustainability, and efficiency in pharmaceutical production.

Overview of the Current Landscape

In the contemporary pharmaceutical production industry, the landscape is dynamic and multifaceted, shaped by a combination of scientific, technological, and regulatory factors. Advanced manufacturing technologies, such as automation, robotics, and data analytics, are revolutionizing production lines, enhancing efficiency, and ensuring the reproducibility of processes.

The embrace of continuous manufacturing methodologies reflects a departure from traditional batch processes, offering advantages in terms of cost-effectiveness, reduced time-to-market, and improved quality control. Quality by Design (QbD) principles guide the proactive design of manufacturing processes, emphasizing the importance of understanding and controlling variables to ensure product quality.

Sustainability has become a focal point, with the integration of green chemistry practices aimed at minimizing environmental impact and promoting eco-friendly production. The industry is also witnessing the convergence of digital technologies under the umbrella of Industry 4.0, ushering in an era of smart manufacturing characterized by real-time monitoring, predictive maintenance, and data-driven decision-making.

In conclusion, the current state of pharmaceutical production reflects a culmination of historical milestones, scientific advancements, and a commitment to meeting the healthcare needs of a global population. As the industry continues to evolve, it holds the promise of driving innovation, enhancing accessibility, and shaping the future of medicine on a global scale.

Current Regulatory Framework

Role of Regulatory Bodies

Regulatory bodies play a paramount role in safeguarding public health by overseeing pharmaceutical production and ensuring the quality, safety, and efficacy of medicines. Key entities such as the Food and Drug Administration (FDA), European Medicines Agency (EMA), World Health Organization (WHO), and other national health agencies establish and enforce standards to regulate pharmaceutical manufacturing practices globally.

The FDA, as the primary regulatory authority in the United States, assesses and approves new drug applications, monitors post-market safety, and conducts inspections to ensure compliance with Good Manufacturing Practices (GMP). Similarly, the EMA governs the approval and monitoring of medicines in the European Union, collaborating with national agencies to maintain a unified approach to pharmaceutical regulation. The WHO extends its oversight to a global scale, guiding countries in establishing regulatory frameworks and ensuring access to quality medicines.

Compliance Requirements for Good Manufacturing Practices (GMP) and International Standards

Compliance with Good Manufacturing Practices (GMP) is a cornerstone of regulatory oversight, setting the benchmark for quality assurance in pharmaceutical production. GMP encompasses a comprehensive set of guidelines that govern every aspect of manufacturing, including facility design, equipment calibration, personnel training, documentation, and quality control. Adhering to GMP ensures that pharmaceutical products are consistently produced and controlled to meet the required quality standards.

International organizations, such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), contribute to the harmonization of regulatory standards globally. ICH guidelines provide a framework for the development, registration, and post-approval of pharmaceutical products, fostering collaboration among regulatory bodies from different regions.

Compliance requirements extend beyond GMP to encompass various international standards, including ISO (International Organization for Standardization) standards related to quality management systems. Certification to ISO 9001, for example, demonstrates an organization's commitment to quality and customer satisfaction, contributing to regulatory compliance and global market access.

Impact of Regulatory Changes on Pharmaceutical Production

Regulatory changes exert a profound influence on pharmaceutical production, shaping industry practices, and ensuring continuous improvement in quality and safety. Changes may result from advancements in scientific understanding, emerging technologies, or the need to address evolving public health challenges. The impact of regulatory changes includes:

- **Adoption of Advanced Technologies:** Regulatory bodies encourage the adoption of advanced manufacturing technologies to enhance efficiency, reduce costs, and improve the overall quality of pharmaceutical products. This may include the integration of automation, continuous manufacturing, and data-driven analytics.
- **Stricter Compliance Requirements:** As the understanding of pharmaceutical science evolves, regulatory bodies may revise and tighten compliance requirements. Manufacturers must stay abreast of these changes to ensure ongoing adherence to GMP and other relevant standards.
- **Global Harmonization:** Efforts towards global harmonization aim to streamline regulatory processes, reduce duplication, and facilitate the global distribution of pharmaceutical products. This trend has a significant impact on the internationalization of pharmaceutical production.
- **Increased Focus on Patient-Centric Approaches:** Regulatory changes often reflect a growing emphasis on patient-centric approaches, such as personalized medicine and patient engagement. These shifts influence manufacturing practices to accommodate the production of customized treatments and enhance patient outcomes.

In conclusion, the role of regulatory bodies is pivotal in upholding the integrity of pharmaceutical production. Compliance with GMP and international standards ensures that pharmaceutical companies meet the highest quality standards, and regulatory changes drive continuous improvement, innovation, and a commitment to patient safety across the industry.

Quality by Design (QbD) Approach

Explanation of the Quality by Design (QbD) Concept

Quality by Design (QbD) is a systematic and scientific approach to pharmaceutical development and manufacturing that emphasizes the proactive design of quality into the product and its manufacturing processes. Unlike traditional approaches that rely on quality testing at the end of the production cycle, QbD integrates quality considerations from the initial stages of product development.

Key components of the QbD concept include

- **Design Space:** QbD defines a design space, which is the multidimensional combination and interaction of input variables (e.g., raw materials, equipment parameters) and process parameters that have been demonstrated to provide assurance of quality.
- **Risk Assessment:** QbD employs risk-based methodologies to identify and understand potential sources of variability in the manufacturing process. This allows for the implementation of controls to mitigate risks and ensure consistent product quality.
- **Real-Time Monitoring:** Continuous monitoring of critical process parameters and product attributes in real-time is a core aspect of QbD. This enables immediate identification of deviations and allows for timely corrective actions.
- **Continuous Improvement:** QbD fosters a culture of continuous improvement by encouraging the use of scientific knowledge and technological advancements to enhance product quality and process efficiency.

Benefits of QbD in Ensuring Product Quality and Process Efficiency

The adoption of the QbD concept in pharmaceutical production yields numerous benefits

- **Enhanced Product Quality:** QbD focuses on understanding the relationship between formulation, process parameters, and product quality. This leads to the development of robust processes that consistently produce high-quality pharmaceuticals, reducing variability and ensuring product reliability.
- **Improved Process Understanding:** QbD encourages a thorough understanding of the manufacturing process and its variables. This increased understanding enables manufacturers to optimize processes, minimize risks, and enhance overall efficiency.
- **Reduced Batch Failures and Rework:** By identifying and controlling potential sources of variability, QbD minimizes the likelihood of batch failures. This results in fewer deviations, reduced need for rework, and a more streamlined production process.
- **Cost Savings:** QbD contributes to cost savings by reducing the need for extensive testing and reprocessing. The enhanced efficiency and reduced variability lead to a more economical use of resources.
- **Faster Time-to-Market:** The systematic approach of QbD facilitates a faster and more predictable product development process. Understanding critical parameters early in development allows for accelerated regulatory submissions and approvals.

Challenges and Considerations in Implementing QbD

Despite its advantages, implementing QbD poses certain challenges and considerations

- **Resource Intensity:** The initial implementation of QbD requires significant resources, including time, expertise, and financial investments. Training personnel and integrating new technologies can be resource-intensive.
- **Cultural Shift:** Adopting a QbD mindset necessitates a cultural shift within an organization. Employees need to embrace a proactive, science-based approach, and management must champion a culture of continuous improvement.
- **Regulatory Interaction:** While regulatory bodies support the principles of QbD, clear communication with regulatory authorities is crucial. Establishing the acceptability of QbD elements in regulatory submissions may require a dialogue to ensure alignment.
- **Data Management:** QbD relies on extensive data collection and analysis. Proper data management systems must be in place to handle the volume of information generated during the implementation of QbD.

In conclusion, Quality by Design (QbD) represents a transformative approach to pharmaceutical production, emphasizing a proactive and scientific methodology. While challenges exist in its implementation, the benefits of enhanced product quality, improved efficiency, and a culture of continuous improvement make QbD a valuable framework for ensuring excellence in pharmaceutical manufacturing.

CONCLUSION

The landscape of pharmaceutical production stands at a pivotal juncture, shaped by a historical evolution marked by scientific milestones, regulatory frameworks, and technological breakthroughs. This comprehensive review delves into the current state, key trends, challenges, and advancements, offering a panoramic view of an industry integral to global healthcare.

Evolution and Challenges: The pharmaceutical production industry has evolved from manual processes to embrace advanced manufacturing technologies, continuous manufacturing, Quality by Design (QbD), and green chemistry practices. Challenges, including the complexities of biopharmaceuticals, supply chain demands, and regulatory hurdles, have emerged alongside unprecedented global health events, exemplified by the ongoing COVID-19 pandemic. These challenges underscore the need for resilience, innovation, and a strategic response to ensure a robust pharmaceutical production ecosystem.

Advancements Shaping the Future: In response to challenges, the industry has witnessed transformative advancements driven by Industry 4.0 and smart manufacturing. The integration of IoT, artificial intelligence, and machine learning has ushered in an era of real-time monitoring, predictive maintenance, and unparalleled process optimization. Personalized medicine and green chemistry innovations have added new dimensions, necessitating flexible manufacturing processes and sustainable practices. These advancements hold the promise of revolutionizing drug development, production, and accessibility on a global scale.

Global Implications: The implications of these trends and advancements are profound, extending far beyond the confines of production facilities. The industry's ability to adopt new technologies directly influences drug availability, affordability, and healthcare system efficiency worldwide. As personalized medicine takes center stage, the paradigm of pharmaceutical production shifts towards tailored treatments, demanding adaptable manufacturing processes. Green chemistry practices align the industry with sustainability goals, addressing environmental concerns and contributing to a more responsible approach to drug manufacturing.

Regulatory Landscape: Regulatory bodies, including the FDA, EMA, and WHO, play a critical role in shaping pharmaceutical production standards. The emphasis on Good Manufacturing Practices (GMP) and international standards ensures the quality and safety of pharmaceuticals. However, the industry grapples with the challenge of harmonizing regulations globally, with evolving standards impacting manufacturing practices and necessitating ongoing adaptation.

Quality by Design (QbD): The Quality by Design (QbD) approach emerges as a cornerstone for ensuring excellence in pharmaceutical production. By integrating quality considerations from the outset, QbD fosters enhanced product quality, improved efficiency, and a culture of continuous improvement. Despite challenges in implementation, the benefits of QbD in reducing batch failures, optimizing processes, and accelerating time-to-market underscore its importance in shaping the future of pharmaceutical manufacturing.

In conclusion, the journey of pharmaceutical production is an unfolding narrative of innovation, challenges, and global impact. As the industry continues to evolve, the imperative lies in navigating uncertainties, embracing technological frontiers, and sustaining a commitment to excellence. The path forward demands collaboration, adaptability, and a shared vision of a pharmaceutical production landscape that not only meets the healthcare needs of today but also paves the way for a healthier and more resilient future.

REFERENCES

1. Y. C. Mayur*, Osman Ahmad, V. V.S. Rajendra Prasad, M. N. Purohit, N. Srinivasulu, S. M. Shanta Kumar, “Synthesis of 2-Methyl N10 -Substituted Acridones as Selective Inhibitors of Multidrug Resistance (MDR) Associated Protein in Cancer Cells". Medicinal Chemistry, Bentham Science Publishers, 2008; 4(5): 457-465(9).
2. Osman Ahmed*, Pankaj Sharma, Jaya Sharma, “Synthesis and Pharmacological Study of Azetidinone Derivatives” International Journal of Pharmaceutical Science & Education, 2013; 11-18.
3. Osman Ahmed*, Pankaj Sharma, Jaya Sharma, Dr. Indrajeet Singhvi, “Synthesis and Anticonvulsant Activity of Some Substituted Azetidinone Derivatives” Asian Journal of Pharmaceutical Research and Development, 2013; 5.
4. Osman Ahmed*, Dr. Md Salahuddin, Vinutha. K, Pankaj Sharma. “Design, Synthesis and Biological Evaluation of Some Novel Substituted Thiazolidinone Derivatives as Potent Antihyperglycemic Agents”. International Journal of Pharmaceutical Research Scholars, 2013; 2(3).
5. Osman Ahmed*, Md Salahuddin, Pankaj Sharma, Indrajeet Singhvi “Synthesis and biological investigations of some new thiazolidinone derivatives as anti-tubercular agents”, American Journal of Pharmtech Research, 2013; 3: 193-201.
6. Osman Ahmed*, Md. Salahuddin, Iffath Rizwana, M.A.Aleem, Pankaj Sharma, “Synthesis, Characterization and Biological Evaluation of Novel thiazolidinone derivatives as Anti-inflammatory Agents”, Indo American Journal of Pharmaceutical Research, 2013; 3(10): 8121-8126.
7. Osman Ahmed*, Pankaj Sharma, Indrajeet Singhvi. “Synthesis and Anti-Hyperglycemic activity of Some Novel Thiazolidinone Derivatives”. Indo American Journal of Pharmaceutical Research, 2014; 4(02): 1008-1014.
8. Osman Ahmed*, Pankaj Sharma, Indrajeet Singhvi. “Anticonvulsant Activity of Some Novel Substituted Thiazolidinone Derivatives against Maximal Electro Shock Induced Seizure”. International Journal of Pharmaceutical Research Scholars, 2014; 3(1): 289-294.
9. Osman Ahmed*, Mohd Haseeb Ur Rahman, Abdul Najeeb, Sk. Md. Noorullah, S.A.Azeez Basha, Design, “Synthesis and Anti- inflammatory activity of certain fused Novel Thienopyrimidines Derivatives”, International Journal of Pharmaceutical Research Scholars, 2013; 2(4): 82-87.
10. Syed Aamer Ali, SK Danda, Syed Abdul Azeez Basha, Rasheed Ahmed, Osman Ahmed, Mohd Muqtader Ahmed. “Comparision of uroprotective activity of reduced glutathione with Mesna in Ifosfamide induced hemorrhagic cystitis in rats”. Indian Journal of Pharmacology, 2014; 46: 105-108.
11. Osman Ahmed*, Syed Azeemuddin Razvi, T K Md Rayees, M A Nafay Shoeb, Md Salahuddin. “Synthesis Characterization and Anti-inflammatory activity of some substituted pyrimidine derivatives”. Indo American Journal of Pharmaceutical Research, 2014; 4(05): 2301-2306. DOI: 10.1044/1980-iajpr.14369.

12. Osman Ahmed*, Farhana Begum, Nishat Fatima, Md. Salahuddin. "Synthesis and Biological Activity of Some Novel Pyrimidine Derivatives". International Journal of Pharmaceutical Research Scholars, 2014; 3(4): 103-108.
13. Ms. Farhana Begum, Osman Ahmed, Md. Salahuddin, Nishat Fatima. "Synthesis, Characterization and Anti-Hyperglycemic Activity of Novel Pyrimidine Derivatives". Indo American Journal of Pharm Research, 2014; 4(11): 5501-5506. DOI: 10.1044/19 80-iajpr.141042
14. Osman Ahmed*, Mehruq Fatima, Juveriya Parveen, Asma Farheen, Ayesha Binth Saleh, Dr. Syed Mahmood Ahmed. Changes in Pulmonary Function Test (PFT) Before and After Adding Tiotropium Bromide to the Ongoing Therapy of Severe Persistant Asthamatics. Indo American Journal of Pharm Research, 2015; 5(01). DOI: 10.1044/1980-iajpr.141266.
15. Mohd Khader, Mohd Mahboob Shareef, Syeda Huda Noorain, Osman Ahmed. Synthesis, Characterization and Biological Activity of Some Novel Pyrimidine Derivatives. Indo American Journal of Pharm Research, 2015; 5(03).
16. Fayeza Batool, Osman Ahmed, Anas Rasheed. An Assay Method for the Simultaneous Estimation of Acetaminophen and Tramadol using RP-HPLC Technology. Indo American Journal of Pharmaceutical Research, 5(7): 2605-2610.
17. Fayeza Batool, Osman Ahmed, Anas Rasheed. A Stability Indicating Method for the Simultaneous Estimation of Acetaminophen and Tramadol in Pharmaceutical Dosage Form. American Journal of PharmTech Research, 2015; 5(04): 674-683.
18. Humeera Rafeeq, Talath Fatima, Afiya Ansari, Osman Ahmed. Personalized Medicine - A Boon For Treating Rheumatoid Arthritis. Indo American Journal of Pharmaceutical Research, 5(8).
19. Humeera Rafeeq, Osman Ahmed, M.A Khaleq, Samee A, Amer M. Progress In The Treatment of Neuroblastoma. Indo American Journal of Pharmaceutical Research, 5(8).
20. Talath Fatima, Osman Ahmed, Amer Mahboob, Afiya Ansari, Amatullah Fathimah. Personalized Medicine - A Review – Progress In The Treatment of Non Small Cell Lung Cancer (NSCLC) In A New Era of Personalised Medicine. Indo American Journal of Pharmaceutical Research, 5(8).
21. Talath Fatima*, Osman Ahmed, Afiya Ansari, Amatullah Fathimah, Amer Mahboob. Novel Therapeutic Approaches to a Chronic Inflammatory Disorder – Asthma. International Journal of Pharmaceutical Research Scholars, 2015; 4(3): 112-117.
22. Humeera Rafeeq*, Osman Ahmed, Sohail Ali, Mohd Younus, Mohd Bilal. A Review on MowatWilson Disorder, International Journal of Pharmaceutical Research Scholars, 2015; V-4, I-3: 176-181.
23. Humeera Rafeeq*, Osman Ahmed, Fayeeza Ameen, Amreen Sultana, Maryam Fatima. A Review on Harlequin Ichthyosis. International Journal of Pharmaceutical Research Scholars, 2015; 4(3): 189-193.
24. Anees Begum*, Osman Ahmed. An Assay Method for the Simultaneous Estimation of Albuterol and Ipratropium Bromide using RP- HPLC Technology. International Journal of Pharmaceutical Research Scholars, 2016; 5(4): 33-37.
25. Anas Rasheed*, Osman Ahmed. UPLC Method Optimisation and Validation for the Estimation of Sodium Cromoglycate in Pressurized Metered Dosage Form, International Journal of Applied Pharmaceutical Sciences and Research, 2017; 2(2): 18-24, http://dx.doi.org/10.21477/ijapsr.v2i2.7774
26. Anas Rasheed*, Osman Ahmed. UPLC Method Development and Validation for the Determination of Chlophedianol Hydrochloride in Syrup Dosage Form. International Journal of Applied Pharmaceutical Sciences and Research, 2017; 2(2): 25-31, http://dx.doi.org/10.21477/ijapsr.v2i2.7775
27. Anas Rasheed*, Osman Ahmed. Validation of a Forced Degradation UPLC Method for Estimation of Beclomethasone Dipropionate in Respules Dosage Form. Indo American Journal of Pharmaceutical Research, 2017; 7(05).
28. Anas Rasheed*, Osman Ahmed. Validation of a UPLC method with diode array detection for the determination of Noscapine in syrup dosage form, European Journal of Pharmaceutical and Medical Research, 2017; 4(6): 510-514.
29. Anas Rasheed*, Osman Ahmed. Stability indicating UPLC method optimisation and validation of Triamcinolone in syrup dosage form. World Journal of Pharmaceutical and Life Sciences, 2017; 3(4): 200-205.
30. Anas Rasheed*, Osman Ahmed. Stability indicating UPLC method optimisation and validation of Pholcodine in bulk dosage form. European Journal of Biomedical and Pharmaceutical Sciences, 2017; 4(6): 572-579.
31. Anas Rasheed*, Osman Ahmed. Analytical method development and validation for the determination of Codeine in syrup dosage form using UPLC technology. World Journal of Pharmaceutical and Life Sciences, 2017; 3(5): 141-145.
32. Anas Rasheed*, Osman Ahmed. Analytical stability indicating UPLC assay and validation of Fluticasone propionate in nasal spray inhaler dosage form. World Journal of Pharmaceutical and Life Sciences, 2017; 3(5): 168-172.
33. Anas Rasheed*, Osman Ahmed. Stability indicating UPLC method optimisation and validation of Acetylcysteine in syrup dosage form. European Journal of Pharmaceutical and Medical Research, 2017; 4(7): 485-491.
34. Anas Rasheed*, Osman Ahmed. Analytical stability indicating UPLC assay and validation of Ciclesonide in dry powder inhaler dosage form. European Journal of Pharmaceutical and Medical Research, 2017; 4(7): 523-529.

35. Anas Rasheed*, Osman Ahmed. Analytical stability indicating UPLC assay and validation of Dextromethorphan in syrup dosage form. European Journal of Pharmaceutical and Medical Research, 2017; 4(7): 548-554.
36. Anas Rasheed*, Osman Ahmed. Analytical Development and Validation of a StabilityIndicating Method for the Estimation of Impurities in Budesonide Respules Formulation, International Journal of Applied Pharmaceutical Sciences and Research, 2017; 2(3): 46-54. http://dx.doi.org/10.21477/ijapsr.v2i3.8100.
37. Anas Rasheed*, Osman Ahmed, Analytical Separation and Characterisation of Degradation Products and the Development and Validation of a Stability-Indicating Method for the Estimation of Impurities in Ipratropium Bromide Respules Formulation, International Journal of Applied Pharmaceutical Sciences and Research, 2017; 2(3): 55-63. http://dx.doi.org/10.21477/ijapsr.v2i3.8101.
38. Neha Naaz*, Khaja Uzair ul Hasan, Aaminah Najmus Sahar, Prof. Dr. Osman Ahmed. Plights and Predicaments in the Pharmacy Industry. Indo American Journal of Pharmaceutical Research, 2017; 7(11).
39. Syed Vakeeluddin*, Osman Ahmed, Kauser Fathima, Analytical Method Development and Validation for the Simultaneous Estimation of Budesonide and Formoterol in Bulk and Dosage Form Using RP-HPLC Method, Indo Am. J. P. Sci, 2017; 4(07).
40. Dr. Osman Ahmed*, Syed Vakeeluddin, Kauser Fathima. A Stability Indicating Method for the Simultaneous Estimation of Budesonide and Formoterol in Bulk and Dosage Form. Indo American Journal of Pharmaceutical Research.