Pharmacy Education (2025) 25(4) 1 - 5
https://doi.org/10.46542/pe.2025.254.ips.14

CONFERENCE ABSTRACTS

FIP COPENHAGEN 2025

83rd FIP World Congress of Pharmacy and Pharmaceutical Sciences in Copenhagen, Denmark, 31 August to 3 September 2025

Industrial pharmacy

Development of a quantitative near-infrared spectroscopy method for Lisinopril analysis during the blending stage of tablet manufacturing

Alexander Gamboa[1], Thamara Hidalgo[1]

[1]Facultad de Química y Biología. Departamento Ciencias del ambiente. Universidad de Santiago, Santiago, Chile

Introduction: Lisinopril is a long-acting angiotensin-converting enzyme inhibitor used primarily for the treatment of hypertension. Its pharmaceutical form is available in oral tablet form in strengths ranging from 2.5 mg to 40 mg. Issues related to tablet strength arise primarily from inadequate blending uniformity, particularly in low-dose pharmaceuticals such as lisinopril. In the United States Pharmacopoeia (USP), the uniformity of lisinopril content is assessed using high-performance liquid chromatography (HPLC), a time-consuming and labor-intensive technique for evaluating and ensuring this parameter during the manufacturing process. Near-infrared spectroscopy is proposed as an effective technique for analyzing the large number of samples generated during the assessment of blending time. However, this approach necessitates the application of chemometric methods to extract quantitative information from the samples.

The aim of this study was to develop a near-infrared spectroscopy (NIRS) method for quantifying lisinopril to evaluate content uniformity during the blending stage of pharmaceutical tablet production.

Method: A placebo was formulated with excipients in proportions equivalent to those used in the product mixture, including Avicel PH102, spray-dried lactose, and Explotab. This was supplemented with proportional amounts of lisinopril, corresponding to a 5 mg dosage, within a range of 80 to 120% of the declared amount. A set of 41 calibration samples was utilized to develop a multivariate partial least squares (PLS) calibration model. Each sample was placed in a glass vial and positioned in the reflectance module of a PerkinElmer Spectrum 400 spectrophotometer for analysis. A total of 10 scans per sample were acquired within the spectral range of 4000 to 10,000 cm^{-1}. The averaged spectral data were utilized for model development, validation, and quantification of the active pharmaceutical ingredient. The manufacturing process was conducted using a V- blender operating at 19 rpm, with samples collected at 15, 20, 25, 30 and 35 minutes and analyzed using NIRS. The product was subsequently compressed into tablets, which were then analyzed using the compendial HPLC method.

Results: Analysis of the spectra obtained from the calibration set identified four absorption regions with regression coefficients exceeding 0.95, indicating adequate correlation. The spectral range of 5898–6586 cm^{-1} was selected based on optimal validation parameters, including a prediction error of 0.1904, an estimation error of 0.06346, and a correlation coefficient of 0.9919. The evaluation of samples from the manufacturing process revealed a coefficient of variation of 3.83% at 35 minutes, indicating the optimal blending time. The analysis of tablets obtained after the compression process demonstrated an assay result of 97.27% of the declared value, with a coefficient of variation (CV) of 2.84%. All units remained within the 85–115% range, and the acceptance value was 6.75, complying with the specifications of the United States Pharmacopoeia.

Conclusion: A method for the direct determination of lisinopril in solid samples from the blending stage of a pharmaceutical process was successfully developed. This method enabled the evaluation of the optimal blending time, which was subsequently validated through the analysis of tablets that met compendial standards.

Monitoring of solid-liquid systems during pharmaceutical processing using Electrical Resistance Tomography (ERT) as Process Analytical Technology (PAT)

Riccardo Pellicari[1], Stephen Luckham[2], Andrea Albano[2]

[1]*Università Degli Studi di Bologna, Bologna, Italy*

[2]*Global Drug Product Development, Technical R&D – R&D, GSK Siena, Italy*

Background: Pharmaceutical processes require strict control to maintain the highest quality standards. To achieve this, various techniques have been developed to monitor industrial processes. However, most of these methods are intrusive and provide only localized measurements. Understanding the homogeneity of a suspension or identifying sedimentation in a solid-liquid system is essential, yet it cannot be achieved with local measurements alone. Similarly, detecting air entrapment is a critical aspect of process monitoring that remains challenging with standard sensor technology. Therefore, implementing an in-line, non-intrusive measurement technique would offer a valuable tool for optimizing pharmaceutical process conditions.

Purpose: This research employs Electrical Resistance Tomography (ERT) as an innovative Process Analytical Technology (PAT) to enable real-time monitoring of a solid-liquid system and air entrapment.

Method: By injecting a small current through a pair of 16 electrodes positioned on the tank wall, differential potentials are measured by the remaining electrodes. These potentials are then used to reconstruct a conductivity map, providing a real-time representation of the system's state. The electrodes can be arranged in various probe configurations—circular, linear, or dual—along the tank walls to optimize system evaluation. For this study, two stirred vessels with a semispherical bottom were used:
-A 250 mL vessel (T = 73.3 mm; D = 38.8 mm);
-A 7 L scale-up version (T = 231 mm; D = 122 mm).
Each vessel was equipped with two planes of circular probes located in the tank walls and one linear probe placed along the bottom. A removable dual probe was designed for both vessel scales and used as needed to insert closer to the wall's tank.

Results: During data acquisition, the re-suspension of the fine solids was analyzed at different agitation speeds using a linear probe positioned at the bottom to determine the minimum speed required for complete solid suspension (Njs). This procedure was performed on two different vessel scales to enable a comparative analysis. Additionally, the speed at which vortices formed, their depth, and the impeller speed at which air bubbles entered in the system were assessed. This was done for various liquid levels in both vessels using ERT measurements and taking pictures. The Froude number ($N^2 * D/g$, where D is the impeller diameter, N impeller speed in rps and g the gravitational acceleration) versus the normalized liquid level (HL/T, where T is the tank diameter and HL is the liquid level) showed three distinct operating zones: no bubbles or vortex formation, vortex and bubble formation, and complete dispersion.

Conclusion: Such information allows better understanding of the system in terms of time and energy to homogenize the solid-liquid suspension and identify the optimal operating conditions.

Quality control of radiopharmaceuticals: Case of Fluorodeoxyglucose (FDG)

Sarah Neggazi[1,2], Manel Belkhatir[1,2], El Mansouria Nebchi[1,2]

[1]*University of Algiers 1, Faculty of Pharmacy, Algiers, Algeria*

[2]*Ali Ait Idir Neurosurgery Hospital, Algiers, Algeria*

Introduction: The Quality Control (QC) of Radiopharmaceuticals is a critical aspect in ensuring patient safety and the efficacy of diagnostic and therapeutic applications. Fluorodeoxyglucose's (FDG) short half-life and its combined pharmaceutical and nuclear properties require stringent and precise quality control measures to meet regulatory standards. This study looks into quality control procedures of radiopharmaceuticals with a particular emphasis on Fluorodeoxyglucose (FDG), the most widely used radiopharmaceutical in positron emission tomography (PET) and the first radiopharmaceutical set to be locally produced in Algeria in the near future. It provides a descriptive comparative overview of different quality control processes and guidelines relating to radiopharmaceuticals used in various corners of the world to serve as a resource to outline key recommendations that inform the local production of FDG as well as the development of a regulatory framework for quality control of radiopharmaceuticals produced in Algeria (i.e. FDG) or imported from other countries.

Method: In this literature review, we have compiled and analysed journal articles (2018-now) accessible to the Algerian researchers' community as well as resources from the International Atomic Energy Agency (IAEA) to detect the main challenges and solutions encountered in QC of Radiopharmaceuticals as well as to provide a comparative overview of FDG quality control procedures in various pharmacopoeia: US pharmacopoeia (USP), British Pharmacopoeia (BP), European Pharmacopoeia (Ph.Eur), and International Pharmacopoeia (Ph.Int) with the aim of creating recommendations to ease potential local production processes of Fluorodeoxyglucose.

Results: This study allowed us to outline and compare various quality control tests required for FDG production across

pharmacopoeia standards such as those of the Ph.Int, Ph.Eur, BP, and USP, including but not limited to radionuclidic identity and purity, radiochemical purity, pH, sterility, bacterial endotoxins, residual solvents, and osmolality. It also explores the challenges associated with the real-time quality assessment of FDG due to its rapid decay, as well as the necessary validation procedures for each test to ensure reliability and accuracy.
Some differences between pharmacopoeia exist in terms of norms and required tests:

- BP does not include ethanol residual test,
- BP and USP don't list membrane integrity test,
- Radio-nucleidic identity and radiochemical identity are considered the same in BP compared to USP,
- Radionuclidic and radiochemical purity are also considered the same in BP compared to Ph.Eur. Algeria, as an IAEA member state, could follow the guidelines of the agency to produce and control radiopharmaceuticals with adjustment tailored to the local standards and daily practices.

Conclusion: The findings underscore the need for harmonisation of quality control standards through international guidelines. The four major pharmacopoeia, although in agreement regarding most quality attributes, do include certain differences. The test methods applied should be formulated into Standard Operating Procedures through validation and qualifying studies. In addition to the QC procedures, investments in infrastructure, and continuous improvement of regulatory frameworks is also critical to ensure the safety and effectiveness of PET imaging and support the advancement of other radiopharmaceutical technologies.

Excipient and process sustainability in the manufacture of oral solid dosage forms - Targeted literature review as complementary method to life cycle assessment

Anja Autzen Virtanen[1], Satu Lakio[2], Atif Madi[3], Mia Sivén[1,4]

[1]Division of Pharmaceutical Chemistry and Technology, Faculty of Pharmacy, University of Helsinki, Helsinki, Finland

[2]Orion, Espoo, Finland

[3]SK biotek Ireland, Dublin, Ireland

[4]Helsinki Institute of Sustainability Science, HELSUS, Helsinki, Finland

Background information: The pharmaceutical industry is rapidly approaching a green transition. As the negative environmental impacts of pharmaceutical manufacture are uncovered, significant efforts have been made to reduce the environmental footprint of pharmaceuticals. These efforts have, however, thus far focused on the optimization of active pharmaceutical ingredient manufacture e.g. with respect to the principles of green chemistry. Still, pharmaceutical dosage forms exert their impact on the environment throughout all stages of their life cycle: from raw material acquisition to waste disposal. Addressing this interdependent complexity, life cycle assessments are inherently intricate, requiring extensive knowledge in the generation and application of life cycle inventory data.

Purpose: Despite the extensive variety of active pharmaceutical ingredients employed in the manufacture of oral solid dosage forms, only a limited selection of excipients and processes are routinely used. Focusing on generic excipients and common manufacturing processes, this study aims to investigate the environmental impact of these throughout the life cycle of a model tablet formulation of a poorly water-soluble active pharmaceutical ingredient. Thereby, emphasizing what can be discerned about its environmental impact without specific empirical data or software calculations. Throught the identification of environmental hotspots, the goal is to inform pharmaceutical product development and enable the targeting of sustainability optimization efforts to areas in which the greatest impact can be achieved.

Method: The study is based on previous work detailing the direct compression manufacture of minitablets from a spray-dried amorphous solid dispersion of indomethacin (BCS II) in polyvinylpyrrolidone or hydroxypropylmethylcellulose acetate succinate with the use of lactose, microcrystalline cellulose and magnesium stearate as tablet excipients. Our study employs a mixed-method methodology using the PRISMA -framework to conduct a systematic literature review and comprehensive analysis of literature describing the environmental impacts of these excipients and manufacturing processes throughout the life cycle of the formulation.

Results: Environmental hotspots related to manufacture of excipients and tablets, and the end-of-life scenarios were identified. Despite identical nomenclature, from a sustainability viewpoint, excipients provided by different suppliers are not always created equal. Typically, two or more commercial scale manufacturing methods are available, which may differ significantly in resource and energy consumption. These findings highlight the need for transparency in the sustainability metrics of excipients. Moreover, process level energy consumption significantly affects the environmental profile of the formulation. This observation notwithstanding, energy expenditure comparisons between direct compression and wet granulation were found inconclusive, which can be indicative of the lack of energy performance indexes in the industry. Lastly, when considering the end-of-life scenario of the formulation, excipients generally regarded as safe (GRAS) are not necessarily harmless to the environment. For example, issues regarding accumulation and biodegradation were identified in the cases of polyvinylpyrrolidone and hydroxypropylmethylcellulose acetate succinate, respectively.

Conclusion: Targeted literature reviews focusing on specific excipients and processes are a useful complementary method

to full life cycle assessment of the environmental impacts of pharmaceuticals. Being a quick and low barrier method, it provides valuable insights that can provide perspectives on choices in formulation development or product review, thereby promoting sustainable product development.

Optimizing the pharmaceutical supply chain in Qatar's primary healthcare centers: A data driven forecasting approach

Manal Alzaidan[1], Laoucine Kerbache

[1]*Phcc, Al Kheesa, Qatar*

Introduction: Ensuring an efficient pharmaceutical supply chain in Qatar's Primary Healthcare Centers (PHCC) is critical for medication availability, cost control, and patient safety. However, challenges such as inconsistent order fulfillment, fluctuating demand, medication wastage, and delivery delays hinder operational efficiency. Addressing these inefficiencies requires a structured, data-driven approach to optimize procurement, distribution, and inventory management.

Methods: This study analyzes PHCC's supply chain performance using real-time dashboard data from 2024. Key performance indicators (KPIs) such as ordered versus shipped quantities, fulfillment rates, and delivery timeliness were examined across different regions. The analysis informed the development of a demand forecasting-based framework designed to improve supply chain operations.

Results: Findings reveal that 259,945,427 medication units were requested, yet fulfillment rates varied significantly across regions: the Northern region ordered 91,444,138 units, the Central region 94,064,383 units, and the Western region 7,439,906 units, indicating disparities in supply allocation. Additionally, only 44% of shipments were delivered on time, and 38% of orders met the perfect order criteria, highlighting inefficiencies in logistics. Monthly demand fluctuations were evident, with peaks in May (27,141,892 units) and October (27,116,880 units), and lower procurement in April (15,446,451 units) and December (17,102,161 units), underscoring the need for better demand planning.

To address these challenges, we propose a three-pronged solution:
1. Demand Forecasting Modeling: Utilizing historical and statistical data to predict medication demand and minimize stock imbalances.
2. Dynamic Inventory Optimization: Implementing real-time stock monitoring and allocation strategies to improve supply balance across PHCC facilities.
3. Integrated Supply Chain Coordination: Establishing a centralized digital system to enhance procurement planning, supplier management, and inventory visibility.

Conclusion: PHCC can enhance medication availability, reduce waste, and improve overall supply chain resilience. This study provides valuable insights for policymakers, pharmacists, and healthcare administrators seeking to optimize pharmaceutical logistics in primary healthcare settings.

Impact of Soft Skills on Employee Performance in Saudi Pharmaceutical Industry

Khaled Halawany[1], Mutaz Qashlan, Zeyad Halawani

[1]*Ministry Of Defense - Health Services, Madina, Saudi Arabia*

Introduction/Background: Soft skills (e.g., communication, emotional intelligence, problem-solving) are increasingly recognized as critical for employee success in modern industries. In the pharmaceutical sector, particularly in Saudi Arabia, medical representatives (MPs) play a pivotal role in client interactions, relationship building, and sales performance. Despite the growing focus on soft skills globally, there is limited research on their impact. This study aims to assess the significance of soft skills on employee performance, identify key skills required, and explore effective training methods to enhance these skills.

Methods: A survey was designed to explore pharmaceutical industry leaders' (from various departments including sales, marketing, medical affairs, HR) perspectives on the importance of soft skills, their impact on employee performance, metrics used to evaluate soft skills, and effective training methods. It was distributed to potential participants across the kingdom using purposive non-probability sampling.

Results: Fifty-five responses were received. Communication skills and emotional intelligence were ranked as the most critical soft skills, followed by negotiation, problem-solving, and time management. All agreed that MPs with strong soft skills perform better, particularly in areas such as client interaction, relationship building, and customer satisfaction. Managerial performance reviews and sales growth were identified as the primary metrics for evaluating soft skills. Training methods such as communication workshops, role-playing sessions, and mentoring programs were deemed most effective, though challenges such as time constraints and employee resistance to change were noted.

Conclusion: This study highlights the crucial role of soft skills in enhancing employee performance and driving business success in the Saudi pharmaceutical industry. It emphasizes the need for structured training programs during onboarding and continuous development to equip MPs with essential soft skills. The findings provide actionable insights for leaders and HR professionals and pave the way for further research in this domain.

Anesthetic and antinflammatory effects of benzydamine hydrochloride 3mg lozenges in 6 to 11 years of age children with pharyngotonsillitis measured through WBFPRS scale and infrared thermography

Martina Barcaroli[1], Enrica Salvatori[1], Giorgio Di Loreto[1], Elisa Fioravanti[1], Daniela Pierucci[1], Agnese Cattaneo[1]

[1]Global Medical Department, Angelini Pharma S p A, Rome, Italy

Introduction: Acute sore throat is among the most common causes of healthcare professional consultation during the colder months of the year, especially in younger age groups, and it represents one of the main causes of antibiotic overprescription in children, despite evidence that the majority of self-limiting pharyngotonsillitis is caused by viruses. There is no common approach among general practitioners and paediatricians regarding the diagnosis and treatment of sore throat, but the shared goal is to alleviate pain as quickly as possible and restore children's well-being. Benzydamine hydrochloride (B.H.) is a nonsteroidal anti-inflammatory drug, available as OCT (Over the Counter) drug without requirement of prescription for local treatment in many Countries. A phase IV, open-label, single-arm study has been set up to confirm the pain-relieving effect of B.H. lozenges 3 mg in non-streptococcal pharyngotonsillitis. The study Sponsor is Angelini Pharma SpA and EU CT number: 2025-521526-15-00. It will be a multicenter clinical study, involving ten pediatricians in Italy.

Methods: The primary objective is to assess the clinical efficacy of B.H. in reducing pain in 120 children with sore throat measured by the Wong-Baker Faces Pain Rating Scale (WBFPRS) at different timepoints from the lozenge assumption. Responders will be defined as patients who reached pain relief of at least 2 points on the WBFPRS. Additionally, as an exploratory objective, the study aims to verify if the anti-inflammatory effect of the drug can be indirectly demonstrated through far infrared thermal imaging, as local temperature reduction after intake. The child will be asked to report the intensity of the pain on the Wong-Baker smiley scale, the oral temperature will be measured, and a duplicate image of the throat will be taken with the thermal camera, similar to a normal photograph. Drug safety will also be evaluated.

An ancillary web-based app will be available to collect parents'/caregivers' opinions about the impact of the child's sore throat on the child's and caregiver's daily activities (e.g., lost days at school or work).

Expected Results: The study aims to demonstrate that B.H. is an and effective treatment for non-bacterial sore throat in children, as it helps to quickly alleviate pain, as well as having with an effect on inflammation. This effect may also be beneficial in reducing the impact of the child's condition on family/caregivers' activities.

Conclusions: No studies are available on thermographic variations during anti-inflammatory therapy. In the proposed clinical trial, the possibility of evidencing a effect of benzydamine hydrochloride in changing the local pharyngotonsillar region temperature, as a result of its action on inflammation, will be explored through repeated far infrared thermography at different timepoints from the administration of a 3 mg lozenge, over a period of 72 hours from the administration of a 3 mg lozenge. Further, the aim is to show a correlation between the amount of reduction in surface temperature and the extent of pain relief as measured by the WBFRPS.

The aim is also to confirm the safety profile of B.H. over the entire duration of the study in the pediatric population