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GREEN ANALYTICAL CHEMISTRY IN PHARMACEUTICAL METHOD DEVELOPMENT: SUSTAINABLE APPROACHES

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ABSTRACT

Green Analytical Chemistry (GAC) has emerged as a sustainable approach in pharmaceutical method development, aiming to minimise environmental impact while maintaining analytical efficiency and reliability. Conventional analytical techniques often rely on toxic solvents, high energy consumption, and generate significant chemical waste, necessitating the adoption of greener alternatives. This review highlights the principles of GAC, including reduction of hazardous reagents, minimisation of solvent use, energy efficiency, waste management, and the use of renewable materials. The application of green solvents such as water, ethanol, supercritical CO_2, ionic liquids, and deep eutectic solvents is discussed. Various green analytical techniques, including green HPLC, UPLC, SFC, spectroscopic methods, electroanalytical techniques, and microextraction approaches, are explored for sustainable pharmaceutical analysis. Additionally, green sample preparation methods and evaluation tools such as Analytical Eco-Scale, GAPI, and AGREE are emphasised for assessing method greenness. Despite significant advancements, challenges such as limited green alternatives, validation complexities, and cost constraints remain. The integration of green principles with modern analytical technologies is essential for achieving environmentally sustainable pharmaceutical practices.

Keywords: *Green Analytical Chemistry, Pharmaceutical analysis, Green solvents, Sustainable methods, HPLC, GAPI, AGREE.*

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INTRODUCTION

Green Analytical Chemistry (GAC) has emerged as a progressive and sustainable approach in analytical sciences, focusing on minimising the environmental footprint of analytical procedures while maintaining high standards of accuracy, precision, and reliability. It represents an extension of green chemistry principles into analytical methodologies, emphasising the reduction of hazardous substances, energy consumption, and waste generation throughout the analytical lifecycle. In recent years, GAC has gained significant importance due to increasing global awareness of environmental protection, occupational safety, and sustainable development in scientific research and industrial practices [1]. In pharmaceutical method development, conventional analytical techniques often rely on large volumes of toxic organic solvents such as acetonitrile, methanol, and chloroform, which pose serious environmental and health hazards. Additionally, these methods frequently involve energy-intensive instrumentation and generate substantial chemical waste, contributing to environmental pollution and increased operational costs. Such concerns have driven the need for greener alternatives that can deliver equivalent or improved analytical performance while minimising ecological impact [2].

GAC addresses these challenges by promoting the use of safer solvents, reducing solvent consumption through miniaturisation, and implementing energy-efficient analytical techniques. Approaches such as

solvent-free analysis, microextraction methods, and the use of renewable and biodegradable reagents are increasingly being adopted. Furthermore, the development of rapid and high-throughput analytical techniques, such as ultra-performance liquid chromatography (UPLC) and supercritical fluid chromatography (SFC), contributes to reduced analysis time and lower resource utilisation [3].The integration of green principles into pharmaceutical analysis not only enhances environmental sustainability but also improves laboratory safety and cost-effectiveness. Regulatory agencies and international organisations are increasingly encouraging the adoption of environmentally friendly analytical practices as part of quality-by-design (QbD) and lifecycle management strategies. Tools such as Analytical Eco-Scale, Green Analytical Procedure Index (GAPI), and AGREE metrics are now widely used to evaluate and compare the greenness of analytical methods [4].The scope of this review is to provide a comprehensive overview of green analytical approaches in pharmaceutical method development, highlighting sustainable techniques, green solvents, evaluation tools, and future perspectives. Emphasis is placed on balancing analytical performance with environmental responsibility to support the advancement of sustainable pharmaceutical sciences [5].

PRINCIPLES OF GREEN ANALYTICAL CHEMISTRY

Green Analytical Chemistry (GAC) is founded on a set of principles aimed at reducing the environmental and health impact of analytical procedures while maintaining high analytical quality. These principles, derived from the broader concept of green chemistry, provide a systematic framework for designing safer, more efficient, and sustainable analytical methods in pharmaceutical and environmental analysis[6].

The reduction or elimination of toxic reagents is a fundamental principle of GAC. Traditional analytical methods often rely on hazardous chemicals such as organic solvents and strong acids, which pose risks to both human health and the environment. GAC promotes the substitution of these toxic substances with safer and less hazardous alternatives, thereby reducing exposure risks and environmental contamination.

Another key principle is the minimisation of solvent consumption, as solvents constitute a major source of waste in analytical laboratories. Techniques such as microextraction, solid-phase extraction, and miniaturised chromatographic systems are increasingly employed to reduce solvent usage without compromising analytical performance. In some cases, solvent-free analytical approaches are also being developed to further enhance sustainability [7,8].

Energy efficiency is also an important consideration in green analytical method development. Conventional analytical techniques often require high energy input due to long analysis times and energy-intensive instrumentation. GAC encourages the use of rapid, high-throughput, and low-energy techniques, such as ultra-performance liquid chromatography (UPLC) and microwave-assisted methods, to minimise energy consumption.

The principle of waste prevention and management focuses on reducing the generation of chemical waste at the source rather than treating it after formation. This includes optimising analytical procedures to produce minimal waste and implementing proper waste management strategies to ensure safe disposal. Reducing waste not only benefits the environment but also lowers operational costs. The use of renewable and safer materials is another critical aspect of GAC. This involves selecting reagents and materials that are biodegradable, non-toxic, and derived from renewable sources. For example, replacing petroleum-based solvents with bio-based alternatives such as ethanol contributes to sustainability [9,10].

Finally, the development of miniaturised and automated methods plays a significant role in green analytical practices. Miniaturisation reduces sample and reagent consumption, while automation enhances precision, reproducibility, and efficiency. Techniques such as lab-on-a-chip systems and microfluidics exemplify this principle by enabling high-performance analysis with minimal resource usage. Collectively, these principles provide a comprehensive framework for designing environmentally friendly analytical methods that balance analytical performance with sustainability. Their implementation in pharmaceutical analysis supports the development of safer, cost-effective, and eco-friendly analytical practices [11,12].

IMPORTANCE IN PHARMACEUTICAL ANALYSIS

Green Analytical Chemistry (GAC) plays a crucial role in modern pharmaceutical analysis by addressing environmental, economic, and safety concerns associated with conventional analytical practices. One of the primary advantages of GAC is its ability to reduce environmental pollution and laboratory hazards. Traditional analytical methods often generate large volumes of toxic chemical waste, which can pose serious risks to ecosystems and human health. By minimising the use of hazardous reagents and solvents, GAC significantly decreases the environmental burden of pharmaceutical analysis. Another important aspect is the enhancement of operator safety. Exposure to toxic solvents such as acetonitrile, chloroform, and methanol can lead to adverse health effects in laboratory personnel. The adoption of safer and less toxic alternatives reduces occupational risks and promotes a healthier working environment. In addition, green analytical methods often involve simplified procedures and reduced handling of dangerous chemicals, further improving safety [13-15].

GAC also contributes to the reduction of operational costs. Lower solvent consumption, reduced energy requirements, and decreased waste disposal expenses

result in cost-effective analytical processes. This is particularly beneficial for large-scale pharmaceutical industries, where routine analysis can incur significant expenses. Furthermore, green analytical practices support regulatory compliance, as regulatory agencies such as ICH and FDA increasingly emphasise sustainable and quality-by-design (QbD) approaches. The implementation of environmentally friendly methods aligns with global regulatory expectations and corporate sustainability goals. Finally, GAC promotes sustainable pharmaceutical development by integrating environmental considerations into the entire analytical lifecycle. This ensures that pharmaceutical research and manufacturing processes are not only efficient but also environmentally responsible, contributing to long-term sustainability [16-18].

GREEN SOLVENTS AND REAGENTS

The selection of solvents and reagents is a critical factor in the development of green analytical methods. Conventional analytical techniques often rely on toxic organic solvents such as acetonitrile, methanol, and chloroform, which are hazardous to both human health and the environment. GAC emphasizes the replacement of these toxic solvents with greener alternatives, such as water, ethanol, and other biodegradable solvents. These alternatives are less toxic, more sustainable, and often readily available, making them suitable for routine pharmaceutical analysis.

The use of supercritical fluids, particularly supercritical carbon dioxide (CO_2), has gained considerable attention as a green alternative in analytical chemistry. Supercritical CO_2 exhibits unique properties such as low viscosity and high diffusivity, enabling efficient extraction and separation without the need for harmful organic solvents. It is non-toxic, non-flammable, and can be easily removed from the system, making it an environmentally friendly option.

In addition, ionic liquids and deep eutectic solvents (DES) are emerging as promising green solvents due to their low volatility, high thermal stability, and tunable physicochemical properties. These solvents can be designed to meet specific analytical requirements while minimizing environmental impact. Their application in extraction and separation processes has shown significant potential in green pharmaceutical analysis.

Another important strategy is the reduction of solvent volume through micro-scale techniques. Miniaturised analytical methods, such as microextraction and microfluidic systems, significantly decrease solvent consumption and waste generation. These approaches not only enhance sustainability but also improve analytical efficiency and reduce costs [19-21].

Table 01: Green Solvents and Reagents in Pharmaceutical Analysis

Category	Conventional Solvent/Reagent	Green Alternative	Example
Organic solvents	Acetonitrile	Ethanol, Water	Ethanol–water mixture for drug analysis
Organic solvents	Methanol	Ethanol, Propanol	Ethanol in UV/HPLC analysis
Chlorinated solvents	Chloroform, Dichloromethane	Ethyl acetate, Water	Ethyl acetate for drug extraction
Non-polar solvents	Hexane	Supercritical CO_2	Supercritical CO_2 in SFC
Volatile solvents	Benzene	Toluene alternatives, Green solvents	Replacement with safer aromatic solvents
Extraction solvents	Petroleum ether	Bio-based solvents	Limonene-based extraction
Advanced solvents	—	Ionic liquids	Imidazolium-based ionic liquids
Advanced solvents	—	Deep eutectic solvents (DES)	Choline chloride–urea DES
Aqueous systems	Organic solvent mixtures	Water-based systems	Water as mobile phase
Micro-scale usage	Large solvent volumes	Microextraction techniques	SPME, micro-LLE methods

GREEN ANALYTICAL TECHNIQUES

Green analytical techniques are central to the implementation of Green Analytical Chemistry (GAC), aiming to minimize environmental impact while maintaining analytical efficiency and reliability. These techniques emphasize reduced solvent consumption, energy efficiency, waste minimization, and safer

operational conditions. In pharmaceutical analysis, the adoption of green techniques has significantly improved sustainability without compromising analytical performance [22].

Chromatographic Techniques

Chromatographic methods are among the most widely used analytical tools in pharmaceutical analysis, and their transformation into greener approaches has been a major focus of recent research. Green High-Performance Liquid Chromatography (HPLC) involves replacing hazardous organic solvents such as acetonitrile and methanol with environmentally benign alternatives like water, ethanol, or buffer systems. Additionally, the use of shorter columns, reduced flow rates, and optimized gradients contributes to lower solvent consumption and reduced waste generation.

Ultra-Performance Liquid Chromatography (UPLC) represents a significant advancement in green chromatography. By utilizing columns packed with sub-2 µm particles, UPLC enables faster separations with higher resolution and sensitivity while consuming significantly less solvent. This not only reduces environmental impact but also enhances laboratory productivity.

Supercritical Fluid Chromatography (SFC) is another promising green technique that employs supercritical carbon dioxide as the primary mobile phase. CO_2 is non-toxic, non-flammable, and easily recyclable, making it an ideal green solvent. SFC offers high efficiency, rapid analysis, and minimal organic solvent usage, making it particularly suitable for pharmaceutical applications such as chiral separations [23,24].

Spectroscopic Techniques

Spectroscopic methods are inherently aligned with green chemistry principles due to their minimal requirement for solvents and reagents. UV-Visible spectroscopy is widely used in pharmaceutical analysis because it requires small sample volumes, simple preparation, and generates negligible waste. It is particularly useful for routine quality control and quantitative analysis.

Fourier Transform Infrared (FTIR) spectroscopy enables direct analysis of solid, liquid, and semi-solid samples without the need for solvents, thereby eliminating chemical waste. It is highly effective for studying functional groups, drug–excipient interactions, and compatibility. Similarly, Raman spectroscopy provides molecular fingerprinting with minimal or no sample preparation. It is a non-destructive technique that can analyse samples through transparent containers, reducing contamination and waste. These spectroscopic techniques contribute significantly to green analytical practices by offering rapid, solvent-free, and energy-efficient analysis [25].

Electroanalytical Methods

Electroanalytical techniques, including potentiometry and voltammetry, are considered environmentally friendly due to their low reagent consumption, minimal waste generation, and high sensitivity. These methods are particularly useful for trace-level detection of pharmaceutical compounds and impurities.

Potentiometric methods rely on ion-selective electrodes, which allow direct measurement of analytes without extensive sample preparation. Voltametric techniques, on the other hand, provide detailed information about redox behaviour and are highly sensitive for detecting low concentrations of analytes. Their simplicity, cost-effectiveness, and reduced environmental impact make electroanalytical methods attractive alternatives to conventional techniques [26].

Miniaturised and Microextraction Techniques

Miniaturisation is a key strategy in GAC aimed at reducing resource consumption while improving analytical efficiency. Solid-Phase Microextraction (SPME) is a solvent-free technique that integrates sampling, extraction, concentration, and injection into a single step. This significantly reduces solvent usage and simplifies the analytical workflow.

Microfluidics and lab-on-a-chip systems represent cutting-edge advancements in miniaturised analysis. These systems handle extremely small volumes of samples and reagents, enabling high-throughput analysis with minimal waste generation. They also offer enhanced automation, precision, and reproducibility. The integration of such technologies is expected to revolutionise pharmaceutical analysis by providing sustainable and efficient analytical solutions [27,28].

Green Sample Preparation

Sample preparation is often the most resource-intensive stage in analytical procedures, contributing significantly to solvent consumption, energy usage, and waste generation. Therefore, the application of green principles in sample preparation is essential for achieving sustainable analytical practices.

One of the primary strategies is the reduction of sample size, which directly decreases the number of reagents and solvents required. Advances in analytical instrumentation have made it possible to obtain accurate and precise results from very small sample quantities, thereby minimising environmental impact. The development of solvent-free extraction techniques has further enhanced the sustainability of analytical methods. Techniques such as headspace analysis and solid-phase extraction eliminate or significantly reduce the need for organic solvents. These methods are particularly advantageous for volatile and semi-volatile compounds [29,30].

Modern extraction techniques such as microwave-assisted extraction (MAE) and ultrasound-assisted extraction (UAE) have gained popularity due to their ability to enhance extraction efficiency while reducing extraction time and solvent consumption. Microwave-assisted extraction uses electromagnetic radiation to rapidly heat the sample and solvent, improving extraction efficiency. Ultrasound-assisted extraction utilises acoustic cavitation to enhance mass transfer, leading to faster and more efficient extraction. Another important approach is the use of solid-phase

extraction (SPE) with reusable and environmentally friendly sorbents. SPE reduces solvent usage, improves selectivity, and generates cleaner extracts compared to traditional liquid–liquid extraction methods. The reusability of sorbents further contributes to waste reduction and cost savings [31].

EVALUATION OF GREENNESS

The assessment of environmental sustainability in analytical methods is a crucial aspect of Green Analytical Chemistry (GAC). To ensure that analytical procedures align with green principles, several evaluation tools have been developed to quantitatively and qualitatively assess their environmental impact. These tools enable researchers to compare different analytical methods and optimize them for improved sustainability without compromising analytical performance.

One of the most widely used tools is the Analytical Eco-Scale, which evaluates the greenness of an analytical method based on penalty points assigned to factors such as the use of hazardous reagents, energy consumption, waste generation, and occupational hazards. The final Eco-Scale score reflects the overall environmental friendliness of the method, with higher scores indicating greener procedures. This tool is simple, practical, and highly useful for routine laboratory assessments.

Another important metric is the Green Analytical Procedure Index (GAPI), which provides a comprehensive visual representation of the environmental impact of an analytical method. GAPI evaluates all stages of the analytical process, including sample collection, preparation, reagents, instrumentation, and waste generation. The results are typically presented in a colour-coded pictogram (green, yellow, and red), allowing easy identification of areas requiring improvement. This holistic approach makes GAPI particularly effective for method comparison and optimization.

The AGREE (Analytical GREEnness metric approach) is a more recent and advanced tool that integrates all 12 principles of green analytical chemistry into a single, unified evaluation system. It provides a numerical score along with a circular graphical representation, offering a clear and comprehensive assessment of method greenness. AGREE is considered one of the most reliable and standardized tools for evaluating analytical sustainability [32,33].

CHALLENGES IN GREEN ANALYTICAL METHOD DEVELOPMENT

Despite significant advancements in Green Analytical Chemistry, several challenges hinder its widespread implementation in pharmaceutical analysis. One of the primary limitations is the limited availability of green alternatives. Although many eco-friendly solvents and techniques have been developed, they may not always provide the same level of efficiency, selectivity, or compatibility as conventional methods, restricting their applicability in certain analytical scenarios.

Another critical challenge is the trade-off between sensitivity and sustainability. Highly sensitive analytical methods often require complex instrumentation, higher energy consumption, or the use of specific reagents that may not be environmentally friendly. Balancing analytical performance with sustainability remains a key concern in method development. Method validation complexities also pose significant challenges. Green analytical methods must meet stringent regulatory requirements for accuracy, precision, specificity, and robustness. However, modifying conventional methods to make them greener may affect these validation parameters, requiring additional optimisation and validation efforts.

The high initial cost of green technologies is another barrier to adoption. Advanced instrumentation such as UPLC systems, supercritical fluid chromatography, and microfluidic devices often requires substantial investment, which may not be feasible for all laboratories, particularly in developing regions.

Finally, resistance to change in traditional laboratories can slow the adoption of green practices. Established analytical protocols and regulatory familiarity with conventional methods often discourage the transition to newer, greener alternatives. Training, awareness, and regulatory support are essential to overcome this challenge [34,35].

CONCLUSION

Green Analytical Chemistry represents a vital advancement in pharmaceutical method development by promoting environmentally sustainable and safer analytical practices. The adoption of green principles, including reduced solvent usage, energy efficiency, and waste minimization, has significantly improved the environmental profile of analytical methods. Techniques such as green chromatography, spectroscopic methods, electroanalytical approaches, and microextraction have demonstrated their potential in achieving high analytical performance with minimal ecological impact. Additionally, the use of green solvents and innovative sample preparation strategies further enhances sustainability. Evaluation tools like Eco-Scale, GAPI, and AGREE provide effective means to assess and optimize analytical methods. However, challenges such as limited availability of green alternatives, high initial costs, and validation complexities must be addressed. Future advancements in technology, automation, and regulatory support will play a crucial role in overcoming these limitations. Overall, GAC offers a promising pathway toward sustainable pharmaceutical analysis and environmentally responsible scientific practices.

AUTHOR CONTRIBUTIONS

Kiran Kumar Byram: Conceptualisation, literature review, data curation, writing – original draft

preparation, writing – review and editing, and final approval of the manuscript.

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