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Green Analytical Chemistry in Pharmaceutical Quality Control

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Abstract:
This review article summarizes the opportunities for utilizing the green analytical chemistry (GAC) techniques and principles in the field of quality control (QC) of pharmaceuticals. Green analytical chemistry is considered a branch of the green chemistry based on the principles overlapping with the goals of sustainable development. General definitions of quality and quality control, the principles of GAC, proposals for greener sample pretreatment and greener chromatographic method of analysis applied in QC laboratories are discussed herein. The main goal is to achieve more eco-friendly analysis in QC laboratories through different strategies and techniques, replace toxic reagents, and modify or replace analytical methods and/or techniques with safer ones, making it possible to dramatically reduce the amounts of reagents consumed and waste generated.

Keywords: Green Analytical Chemistry, Pharmaceuticals Quality Control, HPTLC /UHPLC Method, Principle, types**,** Green Sample Preparation, Technique, Key strategies, solvents.

1. INTRODUCTION

1. Green analytical chemistry

Green chemistry has become a fundamental aspect of modern scientific research and industrial practice, promoting the development of sustainable technologies that minimize environmental impact and improve safety for both humans and ecosystems. Integrating green chemistry principles into various branches of chemistry, including analytical chemistry, underscore the importance of sustainability in all chemical processes. Green analytical chemistry (GAC) is defined as the optimization of analytical processes to ensure they are safe, nontoxic, environmentally friendly, and efficient in their use of materials, energy, and waste generation. The GAC field is guided by 12 principles that prioritize sustainability, such as waste prevention, the use of safer solvents and reaction conditions, and energy efficiency. These principles serve as a framework for developing methodologies that are both effective and environmentally friendly (1).

2. Quality control in pharmaceutical industries field:

One instance area that is making an effort to incorporate green chemistry ideas into equipment and analytical procedures is analytical chemistry. Creating more effective and resilient sample preparation protocols is one of the biggest concerns in analytical chemistry [11–13]. Therefore, as shown in Table 1, the first principle specifies that introducing the sample with minimal or no preparation is the most viable approach to decrease waste. However, most analyses require matrix extraction prior to analysis. The second, fifth, seventh, ninth, tenth, eleventh, and twelve principles may and should be used in situations when sample preparation is required. Techniques for preparing samples should be improved to the greatest extent feasible to decrease the amount of energy needed, solvent usage, waste output, and employee contact. Tis may be done in an assortment of manners, such as by limiting the amount and quantity of representative, using utile sample extraction equipment, and staying away from organic solvents that are hazardous [14]. Chromatographic strategies,

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which are used for distinguishing between the components of complicated mixtures in diverse matrices, are one of the topics of chemical analysis that GAC is passion at about. In the procedure of chromatographic analysis, the detrimental effects of harmful solvents to the health of humans and the environment must be ignored. Te trash produced by a traditional chromatographic process, that demands a lot of organic solvent and can produce 1–1.5 L of scrap per day, must be dismissed of [15]. Since the majority of utilized organic solvents are volatile, they can quickly disperse and damage the surroundings. Thus, it is the duty of analytical scientists to reduce the detrimental impact produced by their work and to prevent, or at the at least, minimize it.This systemic analysis review will give information on implementation of sustainable practices analytical chemistry as well as details on using green solvents and sample preparation methods. Additionally, we have described the execution of GAC principles for the validation and development of analytical methods utilizing HPLC, UHPLC, Ultraviolet–Visible spectroscopy (Uv–Visible Spectroscopy), HPTLC, and TLC

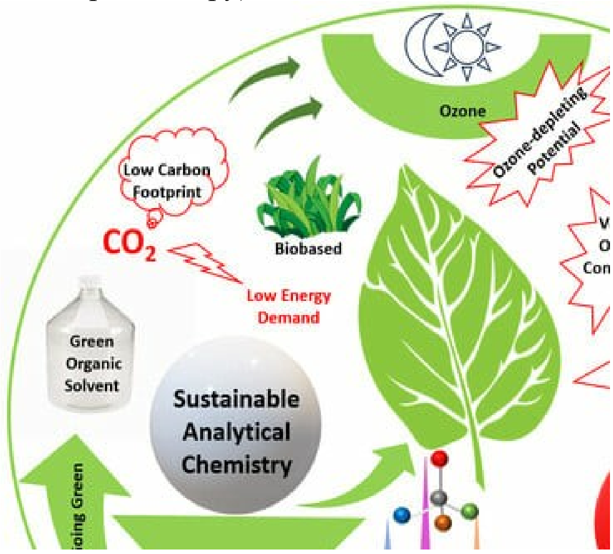

Fig-1 Green analytical chemistry

3. Green analytical chemistry principles

The present paper provides a comprehensive review of the analytical methods employed in South Africa, a developing nation, for the analysis of pharmaceuticals in the environment. The published South African literature was searched through the Google Scholar platform. The main terms used in searching the literature were "Pharmaceuticals in South African waters". The articles retrieved were examined on their adherence to the 12 green analytical chemistry principles which are already in existence [5,26]. These 12 green analytical chemistry principles are:

1. Apply direct analytical techniques to avoid sample pre-treatment which eliminates the excessive volumes of solvents.
2. Reduce sample size and use a minimum number of samples.
3. Perform in situ measurements
4. Integrate analytical methods to save energy and reduce the use of reagents.
5. Automate the analytical processes and use the miniaturized methods.
7. Circumvent the production of large volumes of waste and establish proper protocols for analytical waste management.
8. Multi-analytic analysis must be performed as opposed to performing the analysis of single substances at a time.
9. Minimize the energy use.
10. Use renewable resources such as reagents if possible.
11. Avoid using toxic reagents.
12. Prioritize the safety of the operator. (2)

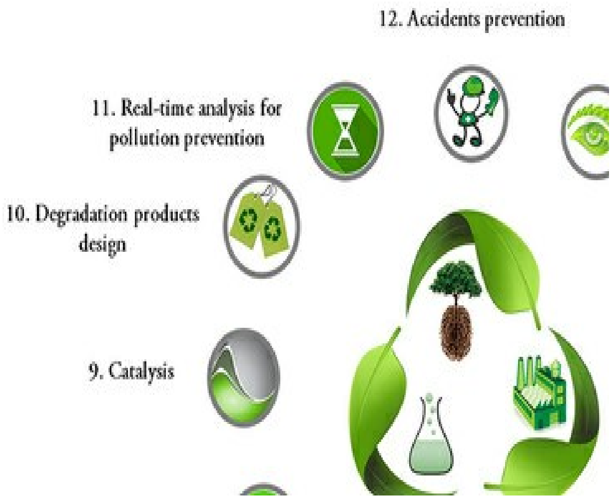

Fig -2 Eco-Friendly Sample Preparation Techniques

4. Comparative table of different types GAC metrics 20, 21,23,25,28
Table-1

Tool	Output type	Perception	Quantitative score	Advantages	Disadvantages
Analytical Eco-Scale	Score in numbers	Text based score	✔	Simple and easy	No visualization
GAPI	Pictogram	Pentagram	❌	Visual	No output in numbers
NEMI	4 Quadrants	Circle(Quadrant)	❌	Very simple	Lack of information
AGREE	Colour graded pictographs(0-1)	Score	✔	Uses 12 Principles	Software is needed
RGB Model	RGB colour(0-1)	Blended colour	✔	Use multiple tools	Complex

5. ECO-FRIENDLY SAMPLE PREPARATION TECHNIQUES

Sample preparation is a critical step in pharmaceutical analysis, and its greening can significantly reduce solvent consumption and waste generation. Conventional techniques, such as liquid-liquid extraction and solid phase extraction, often require large amounts of solvents and generate hazardous waste. Green sample preparation methods aim to enhance efficiency while reducing environmental impact.[9]

The design and validation of analytical techniques include the enhancement of some critical analytical variables. Nevertheless, other factors of user safety and the effect of analytical techniques on the environment are not frequently mentioned. A counterintuitive condition arose because of the negative effects of analytical methodologies established to analyze various types of samples, such as environmental samples, which produce an enormous quantity of chemical waste, which leads to significant environmental and human effects. In several cases, the substances used for analysis were significantly more dangerous than the analyte being defined [1].

Nowadays, analytical laboratory wastes tend to be less distributed, but they could be more dispersed than industrial pollutants, making them more challenging to control. Although analytical waste cannot be eliminated, its quantity can be reduced. As a result, green analytical chemistry should be explored further in the future. Green analytical chemistry involves principles, such as direct analytical techniques, small sample sizes, in-situ measurements, integration of analytical, automated, and miniaturized methods, no derivatization, less waste and proper waste management, multi analyst or multi parameter methods, minimal energy consumption, use of renewable source reagents, elimination or replacement of toxic reagents, and good operator safety [1–6]. Nevertheless, analytical methods are difficult to identify as being environmentally friendly. In the context of green chemistry, evaluation necessitates an in-depth investigation of frequently complicated analytical methodologies. Green analytical chemistry requires specific metrics to assess the level of

greenness of analytical techniques. Several methods have been established, including the National Environmental Method Index (NEMI). NEMI allows users to obtain both method overviews and the full method document. Methods in the database
are easily searchable, sortable, and compared [7]. Another method is the Analytical Eco-Scale. This method involves penalizing components of an analytical procedure that do not correspond to the ideal green analysis [8]. Multicriteria Decision Analysis (MCDA) could be another option. MCDA incorporates social, environmental, economic, and technological standards into the decision-making process [9]. Furthermore, the Green Analytical Procedure Index (GAPI) assesses the environmental friendliness of an entire analytical methodology, from collecting samples to the final result. In GAPI, a particular symbol with five pentagrams can be utilized for assessing and calculating the environmental effects associated with every stage of an analytical procedure [10]. Additionally, the Analytical Greenness (AGREE) calculator could be used to assess greenness. This method is a thorough, adaptable, simple evaluation method that yields an easily comprehensible and valuable outcome. The assessment parameters are derived from the 12 principles of green analytical chemistry and converted into a standardized 0–1 scale. Identical tools for evaluating the greenness of the sample preparation process are known as AGREE prep, which relies on ten indicators of effect with 0–1 scale sub-scores [6,11].

Green Sample Preparation Techniques :-

1. Microwave-assisted extraction: Uses microwave energy to enhance solvent penetration and extraction efficiency, reducing time and solvent consumption.
2. Supercritical fluid extraction: Employs CO_2 as an extraction solvent, eliminating organic solvents.
Utilizes ultrasonic waves to improve extraction efficiency and reduce solvent volume.
4. Solid-phase microextraction: Eliminates solvent use by directly adsorbing analytes onto a fiber coating.
5. Dispersive liquid-liquid microextraction: Minimizes solvent usage by employing dispersing agents to enhance phase separation.[10]

comparative analysis of green sample preparation techniques.

Advantages of Green Sample Preparation :-

- Reduction in hazardous waste due to decreased solvent use
- Lower energy consumption due to efficient extraction techniques
- Improved selectivity and sensitivity in analytical

Table2: Comparative analysis of green sample preparation techniques [11]

Technique	**Solvent requirement**	**Advantages**	**Applications in pharma**
Microwave-assisted extraction	Minimal	Rapid extraction, energy efficient	Herbal and natural products
Supercritical fluid extraction	No organic solvents	High-purity extracts, non-toxic	Drug formulation analysis
Ultrasound-assisted extraction	Low solvent usage	Fast process, mild conditions	Bioactive compound extraction
Solid-Phase microextraction	No solvents	Solvent-free, automated	Pharmaceutical residue analysis
Dispersive liquid-liquid microextraction	Very low	High enrichment factor	Trace drug analysis

7. Future perspectives: Where should green ecotoxicology go next ?

The studies in this VSI clearly show that green analytical chemistry can improve how we assess the impact of pollutants on the environment. Still, important steps remain to make these approaches common practice. One of the main challenges is the need for standardization and validation of green methods. New analytical techniques must be tested and approved by regulatory agencies to ensure they are reliable and produce comparable results across different laboratories. This is crucial for making green methods part of official environmental monitoring programs.

Another key area for development is the life cycle assessment of analytical methods themselves. Scientists should not only evaluate the environmental impact of the pollutants they study but also consider how much energy, chemicals, and waste their own testing methods produce.

This would help identify and promote truly sustainable research practices.

In the future, computational toxicology, artificial intelligence, and machine learning will play a bigger role. These tools can speed up chemical risk assessments, reduce the need for animal testing, and help predict the toxicity of substances based on their structure.The integration of genomics, proteomics, and metabolomics (the socalled omics technologies) will also improve our understanding of how pollutants affect organisms at the molecular level. This will lead to better predictions of long-term and sub-lethal effects that are often missed in traditional tests.

Collaboration between scientists from different fields (i.e., chemistry, biology, eco-toxicology, data science, and policy) will be vital. Working together will help develop practical solutions that can be applied by industries and environmental agencies worldwide.Finally, green analytical chemistry must be ready to face new and emerging pollutants. These include advanced pharmaceuticals, engineered nanomaterials, micro- and nanoplastics, and chemicals related to climate change. New methods must be able to detect complex mixtures of pollutants and assess their combined effects.

This VSI presents valuable examples of how sustainability and scientific quality can go hand in hand in environmental research. The studies show that greener methods are not only possible but necessary to improve environmental monitoring and reduce the negative impacts of the testing itself. Looking ahead, green analytical chemistry will continue to grow and adapt, offering better tools to understand and solve environmental problems. The goal is clear: to protect ecosystems and human health while making scientific research as sustainable and responsible as possible.

8.Key strategies towards greener contaminant analysis

The progress of GAC brings considerable challenges due to conflicting priorities in the evaluation of analytical methods. Researchers worldwide are actively seeking ways to harmonize the rigorous demands of validation—such as sensitivity, accuracy, and precision—with sustainable principles. Balancing the enhancement of analytical performance with the reduction of environmental impact has become a key obstacle in the field [28]. Nonetheless, the integration of sustainable approaches in contaminant analysis has gained increasing recognition, with numerous studies highlighting both their feasibility and advantages. These investigations provide practical examples of how GAC principles can be seamlessly incorporated into analytical workflows without compromising performance. Recent findings underscore the variety of green methodologies applied to diverse contaminants, showcasing innovative solutions tailored to specific challenges. Furthermore, multiple approaches are being adopted in contaminant monitoring to embrace more eco-friendly GAC practices (see Fig. 2). To provide a clear and organized perspective, Table 3 summarizes representative studies that have successfully implemented green strategies in contaminant analysis.

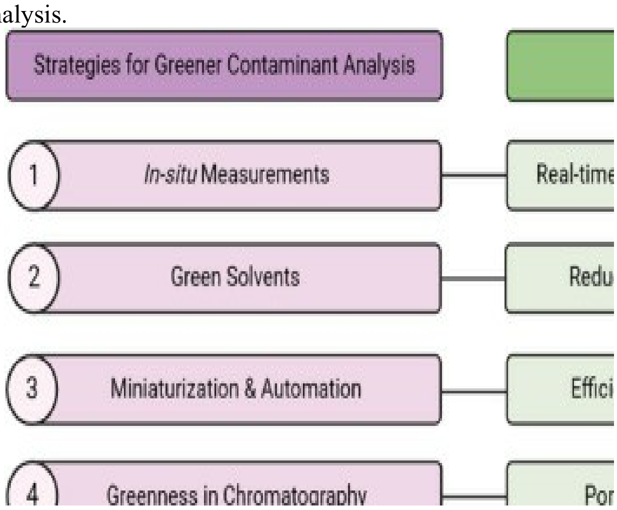

Fig. 3. Key strategies towards greener contaminant analysis.

3.1. In situ measurements

A critical advancement in the pursuit of greener contaminant analysis is the adoption of in situ measurements, a strategy that aligns with the principles of GAC [29]. Traditional contaminant analysis often requires extensive sample collection, transportation, and preparation before laboratory analysis, which can contribute significantly to resource consumption, time delays, and environmental impact. In contrast, in situ measurement techniques enable direct detection and quantification of contaminants at the source, reducing the need for sample transport and pre-treatment.

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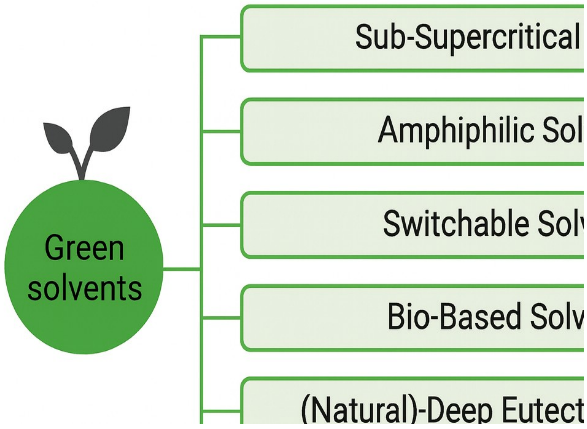
In situ measurements not only minimize the use of solvents and consumables but also enhance the efficiency of analytical workflows by providing real-time data. Techniques such as portable spectrometers [30], electrochemical sensors [31], and field-deployable chromatographi systems [32] have been successfully employed for the rapid analysis of contaminants in water, soil, and air matrices. These methods are particularly valuable for monitoring pollutants in remote or environmentally sensitive locations, where conventional laboratory-based analysis may be impractical or resource-intensive. In this context, it is essential to highlight the use of direct analysis methods, which eliminate the need for extensive sample preparation. These methodologies are typically suitable for analyzing contaminants in clean aqueous matrices. Nonetheless, they have been successfully applied in both gas and liquid chromatography (GC, LC), utilizing techniques such as on-column injection, programmed temperature vaporizers, and injectors equipped with sorbent-packed liners [33]. Direct injection (DI), a key approach within this category, involves introducing filtered, diluted, or centrifuged samples directly into the chromatographic system. This technique reduces costs associated with extraction materials and labor-intensive pre-treatment processes. In the literature, two main types of DI are described [34]. The first involves injecting large sample volumes (100–5000 µL) [35–37]. While this approach is widely used, it requires pre-columns or complex LC systems to handle such high volumes, as standard LC systems are generally not designed to accommodate them. The second method involves the injection of smaller sample volumes (10–20 µL), which is compatible with most LC instruments and avoids the need for additional system modifications [38]. Main applications are based on the analysis of various compounds in water samples, such as halogenated and volatile organic compounds [39,40].Thus, it is evident that remote sensing [41] and direct methods without any chemical sample preparation [42] represent some of the most promising approaches for addressing analytical challenges accurately and safely. However, the complexity of certain samples and the high sensitivity required for many analytes often necessitate the inclusion of a sample pretreatment step, as detailed in the following section [23].

3.2. Green solvents



Transitioning to greener methodologies in contaminant analysis hinges largely on addressing one of the most impactful components of traditional methods: the use of solvents. Solvents are indispensable in many analytical workflows, from sample preparation to chromatographic separations, but their extensive use poses significant environmental an safety challenges. Most conventional organic solvents used for extraction in analytical chemistry are highly volatile, flammable, corrosive, toxic, and carcinogenic [43,44]. Reducing their use, or replacing them with greener alternatives, is a critical step towards aligning analytical chemistry practices with the principles of sustainability. However, certain restrictive criteria are required for a solvent to qualify as "green", such as availability, low toxicity, biodegradability, and low cost. So far, the number of green solvents available has been increasing, but it remains quite limited, as there is still no ideal solvent, since all have their advantages and disadvantages [45]. By modifying chemical structures and adjusting the molar ratios of constituents, sustainable green solvents have been effectively integrated with microextraction techniques as both extraction solvents and sorbent modifiers. This versatility enables their application in the analysis of a wide range of organic and inorganic contaminants across environmental, food, and biological sample preparation methods [46,47]. Recent advances in the 5prominent sustainable green solvents applied to contaminant analysis compromise ionic liquids (ILs), deep eutectic solvents (DES), natural deep eutectic solvents (NADES), amphiphilic solvents, sub-/supercritical fluids, switchable solvents (SSs), and bio-based solvents [48] (see Fig. 3). ILs are liquids entirely composed of ions, with melting points below 100 ◦C. They are typically formed from large organic cations paired with inorganic or organic anions [49]. Due to their unique and tunable physicochemical properties, ILs have been widely utilized as solvents. However, their green credentials remain a topic of debate, as some studies have raised concerns about their limited biodegradability, high cost, and complex synthetic processes [50,51]. The application of ILs has primarily focused

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on their combination with sample preparation techniques, such as liquid–liquid and solid-phase extraction (LLE, SPE), particularly in the analysis of food and environmental samples [52]. Various studies have been conducted using ILs in matrices such as water, milk, tea, honey, vegetables, fruits, and sediments, with special emphasis on the determination of pesticides [53,54], antibiotics [55]and inorganic cations [56,57]. To address the challenges associated with ILs, DES have emerged as a promising alternative due to their high atom economy, low cost, and reduced toxicity [47]. DES are formed by simply mixing a hydrogen bond acceptor and a hydrogen bond donor in specific molar ratios, resulting in a eutectic mixture with a melting point significantly lower than that of the individual components [58]. DES have recently been applied for the extraction of trace-level chemical contaminants in food and water [47]. L´opez-Ruiz et al. [59] developed a thymol:vanillin (1:1) DES deposited on cellulose paper strips for isolating selected triazine herbicides in environmental water samples. In this context, NADES, a subclass of DES derived exclusively from natural components (e.g., primary metabolites such as sugars, alcohols, amino acids, organic acids, and choline derivatives), offer enhanced sustainability. NADES have been used in combination with advanced extraction techniques, such as dispersive liquid-liquid microextraction (DLLME)-solidification of the floating organic droplet, for the extraction of mycotoxins in apple juice using a glucose:lactic acid (3:1) NADES with dodecanol [60]. Additionally, NADES have been applied to extract ECs from human urine, wastewater, and seawater, employing fenchol:acetic acid NADES in 2:1 and 1:1 molar ratios [61].

Amphiphilic solvents are also regarded as sustainable and environmentally friendly alternatives. Their unique structure, featuring hydrophobic heads and hydrophilic tails, enables them to dissolve in both organic and aqueous phases through a combination of dispersion, dipole-dipole, and dipole-induced dipole interactions [62].

Amphiphilic solvents include ionic surfactants and SUPRAS. Ionic surfactants have shown remarkable applications, particularly in wastewater management and heavy metal removal [63], while SUPRAS have been extensively used for studying bisphenols [25,64], perfluorinated compounds [65], pesticides [66,67], and polycyclic aromatic hydrocarbons (PAHs) [68] in food and environmental matrices. Despite their numerous advantages, amphiphilic solvents face two key challenges: (a) they are unsuitable for extracting solid samples and encounter matrix effect issues induced by other ions or metals when used for trace-level heavy metal extraction [69]; (b) their low volatility and high viscosity restrict the use of surfactants in GC systems [70,71].

Similarly, subcritical water is non-toxic, readily available, and highly versatile, making it an appealing option for various analytical applications. However, water also has limitations, including a low solubilizing capacity for nonpolar compounds and the high energy demands associated with its use in extraction processes [39]. Subcritical water extraction (SWE) addresses these challenges by utilizing superheated water as an alternative to organic solvents. Operating below water's critical point, SWE allows for the extraction of polar analytes at lower temperatures, while higher temperatures are required for the efficient extraction of moderately polar or nonpolar organic compounds. SWE has been successfully applied to remove ECs such as human and veterinary pharmaceuticals, hormones, personal care products, pesticides, PAHs, polychlorinated biphenyls, organic dyes, heavy metals, and more from various environmental matrices [72,73]. Similarly, supercritical fluids have gained popularity as sustainable alternatives. Carbon dioxide is the most widely used solvent in supercritical fluid extraction (SFE) due to its non-corrosive, non-explosive nature, easy availability, and low cost. SFE minimizes or completely eliminates the need for hazardous organic solvents, solidifying its green credentials [39]. It has been applied to extract PAHs in soils and sediments [74,75].

SSs have garnered significant attention as sustainable green alternatives due to their unique ability to rapidly and reversibly switch between two distinct conformations with different physicochemical properties under atmospheric pressure (1 bar) [76]. Since their introduction in 2005, SSs have been widely used in extractions because of their greenness, speed, simplicity, repeatability, and low cost. As with amphiphilic solvents, the number of publications utilizing SSs combined with microextraction techniques has increased significantly in recent years, focusing on the extraction of pollutants in food, biological, and environmental samples [77,78]. Special attention has been given to applications involving pesticides [79–81] and inorganic cations [82,83].

Bio-based solvents (e.g., d-limonene, menthol), derived from a wide range of renewable biomass sources such as plants, animals, microbes, and agricultural waste, have emerged as promising alternatives to traditional petroleum-based solvents [48]. These solvents are abundant, biodegradable, and easy to recycle, significantly reducing their environmental impact [48]. For instance, menthol has been used as a bio-based extraction solvent in DLLME for five phthalate esters [84], diethyl carbonate has been applied to extract chlorophenols from water [85], and several bio solvents have been tested for the extraction of biocides from fish tissue samples [86]. Although the use of bio-based solvents in contaminant analysis is still relatively limited, a practical strategy to expand their applications is to combine them with other chemicals to formulate task-specific composite bio-based solvents for GAC purposes [48]. Recently, supramolecular bio-based solvents, such as chitosan solutions and bio-derived p-cymene solvents, have been utilized as extractants in bio-microextractions for polar toxic dyes [87,88], paracetamol [89], Cu(II) [90], and carbofuran [91], demonstrating their versatility and potential in sustainable analytical chemistry.

Conclusions

Green Analytical Chemistry (GAC) plays a vital role in modern pharmaceutical quality control by promoting environmentally sustainable, safe, and cost-effective analytical practices without compromising data quality or regulatory compliance. By minimizing the use of hazardous chemicals, reducing solvent consumption, lowering energy requirements, and decreasing waste generation, GAC aligns pharmaceutical analysis with global sustainability goals.

The adoption of green techniques such as miniaturized methods, solvent-free or solvent-reduced sample preparation, eco-friendly solvents, and advanced instrumental approaches enhances laboratory efficiency while ensuring accurate, precise, and reliable results. In pharmaceutical quality control, these methods support routine testing, stability studies, and regulatory submissions while improving worker safety and reducing environmental impact.

Despite certain challenges related to method development, validation, and regulatory acceptance, continuous technological advancements and increased awareness are accelerating the implementation of green analytical approaches. Overall, integrating Green Analytical Chemistry into pharmaceutical quality control is not only an environmental responsibility but also a strategic advancement toward sustainable pharmaceutical manufacturing and analysis.

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