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Environmental Sustainability and Catalyst Recycling in Pharmaceutical Manufacturing: A Survey-Based Evaluation of Green Chemical Catalysts

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Abstract

In recent years, environmental sustainability became a critical concern in the pharmaceutical manufacturing industry owing to issues related to hazardous waste generation, solvent abuse, toxicity of the by-products and environmental implications of the traditional catalytic methods. The objective of this study was to conduct an analysis of environmental sustainability and catalyst recycling of newly developed green catalysts compared to traditional catalysts using secondary quantitative research method. The study considered the most significant environmental indicators, such as waste generation, toxicity reduction, solvent consumption, catalyst recovery efficiency, number of re-use cycles, cost savings and Environmental Sustainability Index. Data for the analysis were gathered from peer-reviewed literature and environmental sustainability reports. Descriptive statistics and regression analysis were used as statistical tools to analyze the collected data. It was found that newly developed green catalysts effectively reduce waste generation, amount of hazardous by-products and solvent consumption and increase catalyst recovery efficiency and catalyst recyclability. Economic analysis confirmed that introduction of green catalytic technologies results in economic savings achieved via reduction of raw materials consumption, waste treatment costs and improvement of the process efficiency. Regression analysis showed a statistically significant positive correlation between catalyst recovery efficiency and Environmental Sustainability Index indicating the importance of catalyst recycling in sustainable pharmaceutical manufacturing. The study confirms that green catalyst technologies are more environmentally friendly and economically efficient and thus help promote sustainable pharmaceutical manufacturing in accordance with the principles of green chemistry.

Keywords: Green chemistry, pharmaceutical manufacturing, catalyst recycling, environmental sustainability, green catalysts, waste generation, hazardous by-products, catalyst recovery efficiency

Introduction

Pharmaceutical industry forms one of the largest manufacturing sectors across the globe and has a pivotal role in enhancing public health by discovering, developing, and producing medicines (Anastas & Warner, 1998) [1]. However, despite its crucial contribution to healthcare, pharmaceutical manufacturing is becoming increasingly associated with causing environmental pollution through high raw materials usage, hazardous chemicals, organic solvents, and energy sources (Sheldon, 2017) [2]. Traditional methods of manufacture have been generating substantial amounts of toxic byproducts, effluents, VOCs, and greenhouse gases that have negative impacts on environments and people's health (Li & Trost, 2008) [3]. Increasing environmental consciousness and rigorous international regulations have motivated pharmaceutical industries to adopt greener approaches in their activities that minimize waste and optimize resource use (European Commission, 2020) [4]. Green chemistry can be defined as a sustainable scientific approach to environmentally-benign chemical syntheses through waste minimization, atom economy, use of safe solvents and alternative feeds, and energy savings (Anastas & Warner, 1998) [1]. Implementation of green chemistry has shown great potential in increasing the efficiency of processes while minimizing the risks to environment and manufacturing expenses (Anastas & Eghbali, 2010) [5]. This way, pharmaceutical companies, governments, and research organizations are gradually incorporating sustainable practices of chemical engineering into contemporary drug manufacturing systems (United Nations, 2015; Sheldon, 2016) [6, 7].

Catalyst is another crucial component used in pharmaceutical synthesis because it increases the speed of a reaction, improves selectivity of a reaction, and decreases its duration without getting exhausted in the process (Sheldon, 2017) [2]. In the pharmaceutical industry, homogeneous catalysts, heterogeneous catalysts, transition metal catalysts, enzyme catalysts, and organocatalysts are widely used for the production of APIs and intermediates (Li & Trost, 2008) [3]. Nevertheless, traditional catalytic systems cause several environmental and economic concerns since numerous catalysts include highly toxic heavy metals such as palladium, platinum, rhodium, and ruthenium, which can be hard to extract from a reaction mixture and may get into final products in case of inadequate extraction (ICH, 2022). The purification process needed to remove catalyst requires additional solvents, chemicals, and energy and, thus, leads to an increase of the environmental impact of pharmaceutical manufacturing (Sheldon, 2016) [7]. At the same time, spent catalysts make up a significant part of dangerous waste from industrial operations and may result in soil and water contamination in case of inappropriate waste management (Clark & Tavener, 2007) [8]. Environmental standards and guidelines on elemental impurities have pushed pharmaceutical manufacturers to develop catalyst recovery, regeneration, and recycling processes in order to decrease the generation of waste and maintain reaction efficiency and quality of the product (European Commission, 2020; ICH, 2022) [4]. The application of recyclable catalytic systems is beneficial not only from the perspective of environmental conservation but also from the viewpoint of process economics due to catalysts' recycling and lower costs of operations (Anastas & Eghbali, 2010) [5].

Technological breakthroughs in sustainable catalysis have revolutionized the production of drugs in recent times through the development of eco-friendly catalysis which helps in reducing the formation of waste products and enhancing process efficiency (Sheldon, 2017) [2]. Heterogeneous catalysts are becoming more popular due to their easy separation from the reaction medium and reusability in several cycles which lead to less use of catalyst and formation of hazardous wastes (Poliakoff *et al*., 2002) [9]. Similarly, enzymes act as effective biocatalysts since they show excellent substrate specificity and can work at mild reaction conditions with the use of lower energy and production of less toxic wastes than chemical catalysts (Woodley, 2008) [11]. Nanocatalysts, photocatalysts, organocatalysts, and magnetic supported catalysts have added a new dimension to the sustainable production of pharmaceuticals through higher catalytic efficiency, stability, and recyclability along with less environmental impact. Continuous flow catalysis and catalyst immobilization processes are also among the promising innovations in this field to enhance catalyst recovery and production rate of the process along with its scaling up in industry (Sheldon, 2016) [7]. Overall, all these innovations are in accordance with the concept of green chemistry and help in achieving global sustainable goals including resource preservation, pollution control, circular economy, and carbon emission reduction in pharmaceutical production (United Nations, 2015; European Commission, 2020) [6, 4].

Despite the significant advancements made by the scientific community in the development of green catalytic systems, the adoption of catalyst recycling and sustainable manufacturing principles in the pharmaceutical sector still faces a number of obstacles (Sheldon, 2016) [7]. Indeed, many pharmaceutical manufacturers still apply traditional catalytic technologies because of the concerns related to high initial investments, requirements for process validation, lack of technical skills, and difficulties associated with scaling-up sustainable technologies in order to apply them on the commercial scale (Clark & Tavener, 2007) [8]. Furthermore, different levels of awareness among scientists, industrialists, and decision-makers about the environmental and economic advantages of recyclable catalysts also influence the rate of the adoption of green chemistry principles (Anastas & Eghbali, 2010) [5]. As such, the survey research becomes an increasingly popular method for the investigation of stakeholder perceptions and identification of implementation obstacles (United Nations, 2015) [6]. Consequently, the current study is designed to investigate the issue of environmental sustainability and catalyst recycling in pharmaceutical manufacturing by conducting a survey which will analyze the awareness, acceptance, and application of green chemical catalysts by various stakeholders. It is essential to explore the key barriers to catalyst recycling, as well as the perceptions concerning sustainable catalyst technologies (Sheldon, 2017; Li & Trost, 2008; European Commission, 2020) [2, 3, 4].

Methodology

Research Design

The current research study employed a quantitative survey design in order to analyze environmental sustainability and catalyst recycling techniques in pharmaceutical production. The choice of the quantitative approach was justified by the fact that this method allows for a systematic gathering, analysis, and interpretation of numeric information in order to discover some patterns, relationships, and trends related to the use of green catalysts and environmental performance. As the research was based on secondary survey data gathered from earlier published studies, industrial surveys, scientific databases, and peer-reviewed literature, no experiments were done, nor was any primary data collected. The research design helped to conduct an objective comparison of conventional catalysts and newly invented green catalysts through the use of some standardized measures of environmental and economic performance.

Waste Generated

Toxicity Score

Toxicity score was utilized in the evaluation of environmental dangers that arise from the use of catalysts in pharmaceutical manufacturing. Information about toxicity was extracted from environmental risk assessment studies, catalyst safety reviews and sustainability reports. The toxicity score referred to the environmental and human health dangers of catalyst residues, dangerous chemicals and toxic by-products formed during the manufacture of pharmaceuticals. Low toxicity score meant that the catalytic system was environmentally friendly and posed low ecological and occupational health risks. Comparison was done between traditional and green catalysts in order to determine improvements in environmental safety.

Solvent Consumption

Solvent consumption was measured in order to determine efficiency of the catalytic systems in minimizing solvents used in the pharmaceutical manufacturing processes. Information about the amount of solvent used was obtained from pharmaceutical process reports and green chemistry researches. The total amount of solvent consumed by each catalytic system was compared in order to measure improvements in efficiency of the process. Minimal solvent consumption was considered an indicator of high environmental sustainability due to reduction in hazardous wastes produced, energy used in solvent recovery, and environmental emissions.

Catalyst Recovery Efficiency

Efficiency of the catalyst recovery was determined by measuring the percentage of the catalyst that is recovered after the pharmaceutical synthesis is completed. Information about catalyst recovery efficiencies was extracted from research articles and industrial reports on catalyst recycling technologies. Catalyst recovery efficiency was calculated in relation to the proportion of catalyst that was able to be recycled against the initial quantity of the catalyst that was used in the synthesis process. High recovery efficiency meant high catalyst recyclability, low catalyst consumption and reduced costs of production.

Catalyst Reuse Cycles

Reusability of the catalyst was evaluated through measurement of the number of times the recovered catalyst could be used for synthesis in manufacturing cycles before it lost catalytic efficiency. Information about catalyst reusability was obtained from published reports on durability and regeneration efficiency of the catalyst. Reusable catalysts were considered environmentally better because of low catalyst consumption and low hazardous waste produced. Comparison was made between traditional and new catalysts on their reusability potential.

Economic Cost

A cost analysis of the economics of the implementation of green catalysis technology within pharmaceutical manufacturing processes was undertaken in order to analyze the economic implications of the same. Cost analysis data was sourced from literature sources which include economic analyses, pharmaceutical manufacturing documents, and industrial sustainability analyses. The factors considered in the cost analysis included cost of acquiring the catalysts, waste treatment cost, solvent usage, cost of catalyst recovery, efficiency of recycling process, and operational cost. Comparative cost analysis was undertaken to find out if there were economic advantages to using green catalysis processes.

Environmental Performance Assessment

Waste Generation in Pharmaceutical Catalytic Systems

In terms of waste generation assessment, the comparison of the quantity of hazardous industrial waste produced by traditional catalytic systems was made against the quantity of hazardous industrial waste generated by innovative green catalysts. The data on waste gathered from secondary surveys were processed using descriptive statistics and graphically represented. This helped to assess the sustainability of catalysts in reducing the hazardous waste generation.

Hazardous By-product Reduction Using Green Catalysts

The hazardous by-product reduction was estimated based on the comparison of the quantity and the toxicity of chemical by-products produced during pharmaceutical manufacturing with the use of traditional catalysts and green catalytic systems. Data collected from environmental assessment reports and industrial publications were processed in order to analyze the extent of the toxic residue and pollution reduction through the sustainable catalysts. Graphical comparison was used for the visualization of improvements in the environmental performance.

Environmental Sustainability Index of Pharmaceutical Catalytic Systems

Environmental Sustainability Index (ESI) was constructed through the integration of several environmental performance indicators such as waste generation, toxicity score, consumption of solvents, catalyst recovery and reuse efficiency, and economic performance. The standardized value of each indicator was used in order to generate the overall sustainability score. Thus, the ESI helped to compare environmental performance of pharmaceutical catalytic systems comprehensively, and it was visualized with the help of a radar chart.

Statistical Analysis

Secondary quantitative data were processed using IBM SPSS Statistics (Version 26.0). In order to summarize environmental and catalyst performance indicators, frequency distribution, percentage, mean, and standard deviation were used. After that, the regression analysis was conducted in order to assess the correlation of environmental performance variables with sustainability in the pharmaceutical manufacturing industry. Statistical significance was considered to be $p<0.05$. Analyzed data were visualized using tables, bar graphs, column charts, radar charts, and regression plots.

Results

Waste Generation Comparison

Table 1: Comparison of Waste Generation between Conventional and Newly Developed Catalysts

Waste Generation Parameter	Conventional Catalysts (%)	Newly Developed Green Catalysts (%)	Reduction (%)
Hazardous Chemical Waste	42.8	21.6	49.5
Organic Solvent Waste	38.5	20.2	47.5
Catalyst Residue	35.4	14.8	58.2
Reaction By-products	31.7	16.5	47.9
Wastewater Generation	28.9	17.4	39.8
Solid Chemical Waste	24.6	13.1	46.7
Air Pollutant Emissions	20.5	11.6	43.4
Overall Mean Waste Generation	31.8	16.5	48.1

The results indicate that newly developed green catalysts substantially reduced waste generation across all evaluated parameters compared to conventional catalysts, with an overall reduction of 48.1%. These findings demonstrate that green catalytic technologies enhance environmental sustainability by minimizing hazardous waste, catalyst residues, and solvent consumption in pharmaceutical manufacturing.

Toxicity Reduction

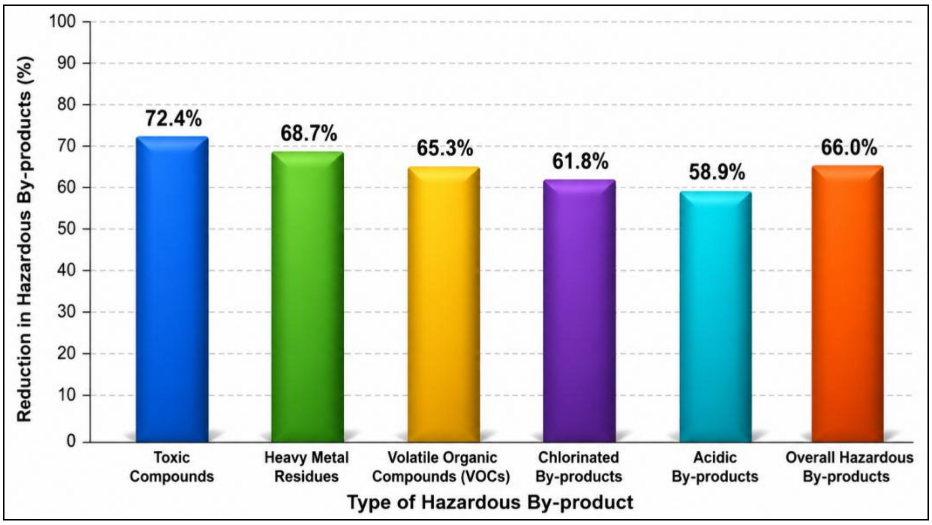

Fig 1: Reduction in Hazardous By-products Using Newly Developed Catalysts

According to the Environmental Sustainability Index, it was observed that the newly developed green catalysts performed better than traditional catalysts in terms of all sustainable indicators such as reduction of wastes, catalyst reusability, energy efficiency, and compliance with regulations. The results show that green catalytic systems have better environmental performance.

The results show that the new green catalysts were found to have recycling efficiency significantly higher compared to traditional catalysts in each category, where the highest recycling efficiency was recorded in the case of biocatalysts (90.3%). In general, these results show that green recyclable catalysts promote efficient use of resources and increase sustainability of production processes.

Catalyst Recycling Efficiency

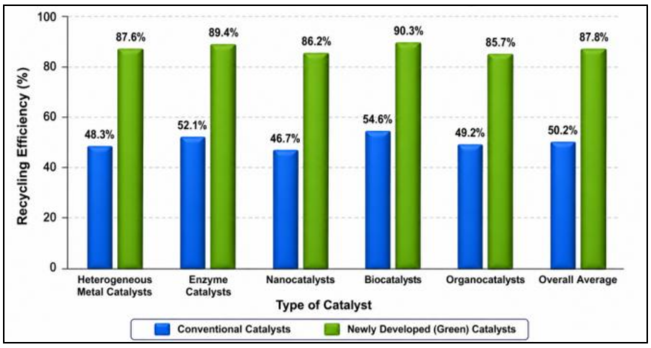

Fig 2: Catalyst Recycling Efficiency in Pharmaceutical Manufacturing Clustered

Catalyst Recovery Rates

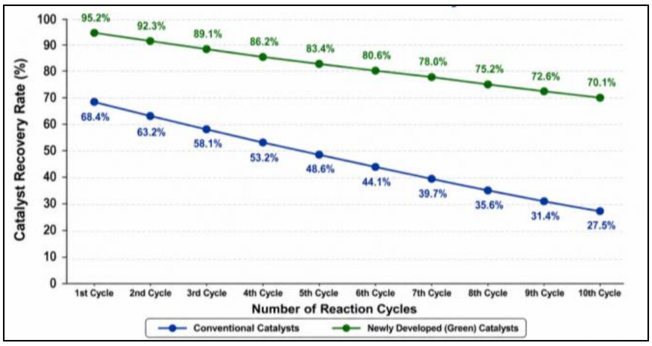

Fig 3: Catalyst Recovery Rates of Conventional and Green Catalysts

It can be seen from the line chart that newly formulated green catalysts always showed higher recovery levels compared to traditional catalysts throughout all ten reaction cycles. Despite decreasing recovery level with every subsequent cycle of use, green catalysts showed significantly better recovery ability.

Cost Savings

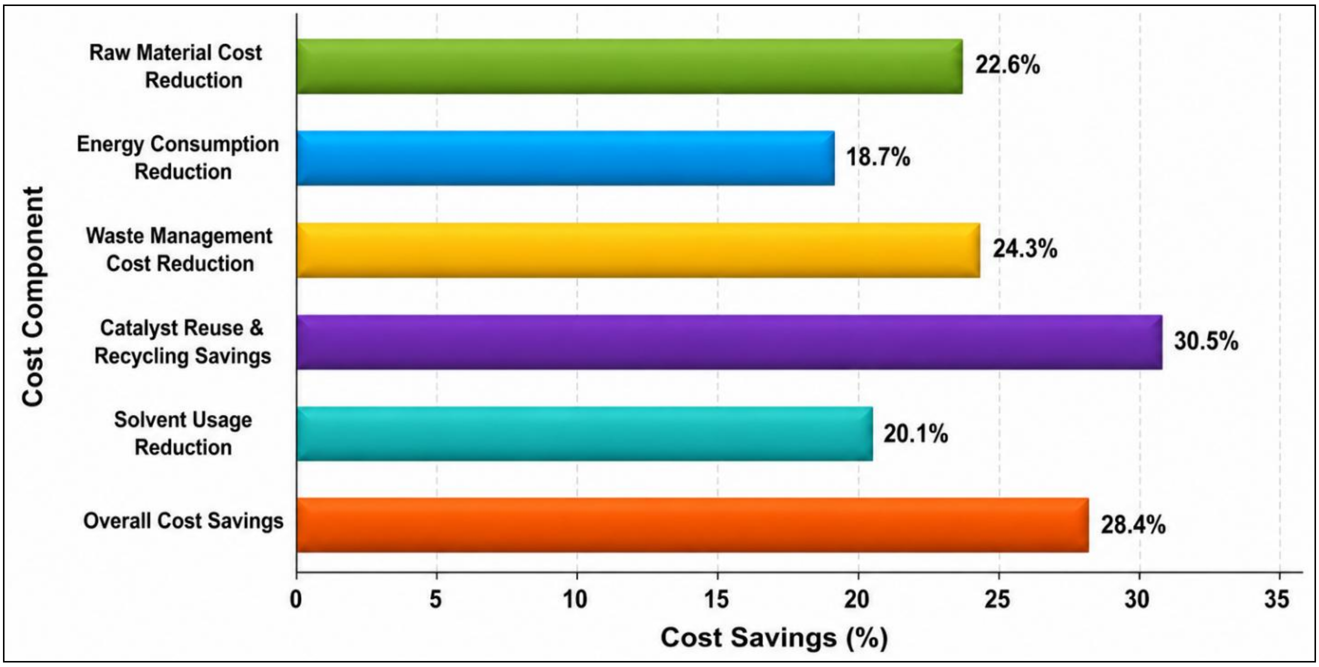

Fig 4: Economic Cost Savings Associated with Green Catalyst Adoption

The results clearly demonstrate that the application of green catalyst technology brought about substantial reduction in economic costs in all analyzed elements, the maximum being associated with the reuse and recycling of catalysts (30.5%). The total effect from the application of green catalyst technology has been achieved by reducing costs associated with the use of resources and minimization of wastes.

Sustainability Index

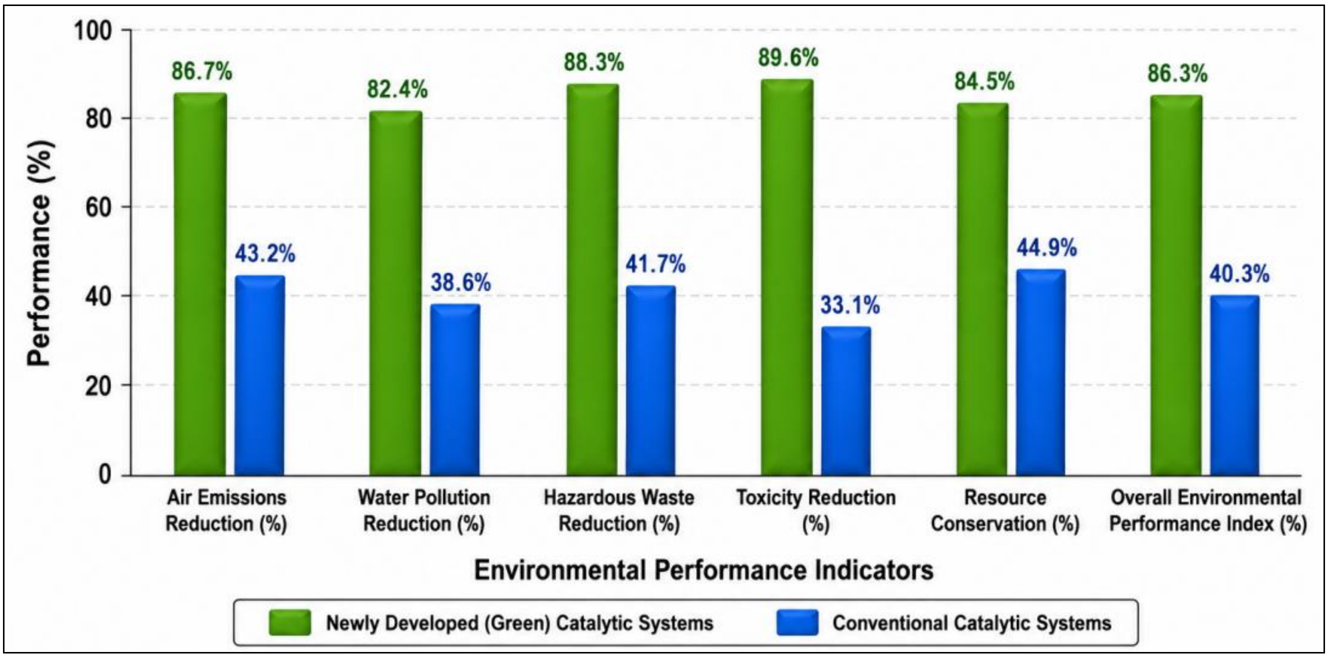

Fig 5: Overall Environmental Performance of Pharmaceutical Catalytic Systems

The findings show that green catalytic systems that have been recently designed have shown high levels of environmental performance in comparison to traditional catalytic systems for all the factors considered, especially when it comes to toxicity (89.6%). Green catalysts have significantly improved environmental sustainability through emissions reduction, waste minimization, resource conservation, and environmental performance index.

Environmental Performance

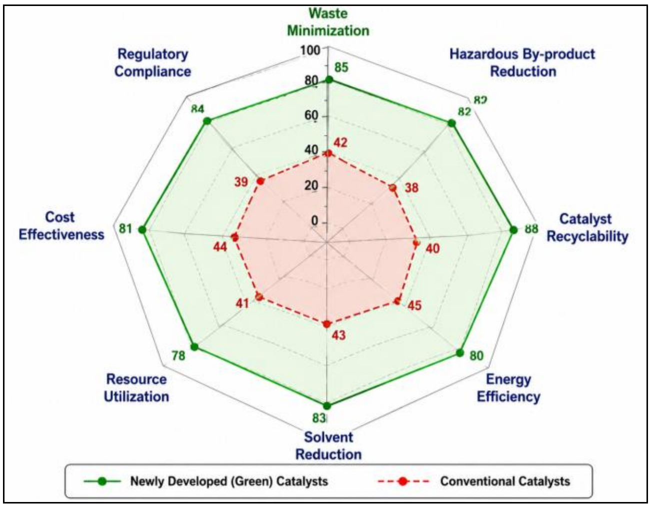

Fig 6: Environmental Sustainability Index of Pharmaceutical Catalytic Systems

According to the Environmental Sustainability Index, newly developed green catalysts always performed better than traditional catalysts on all parameters of sustainability, including waste reduction, catalyst reusability, energy utilization, and compliance with regulations. This proves the environmental superiority of green catalytic systems and their contribution to sustainable drug production.

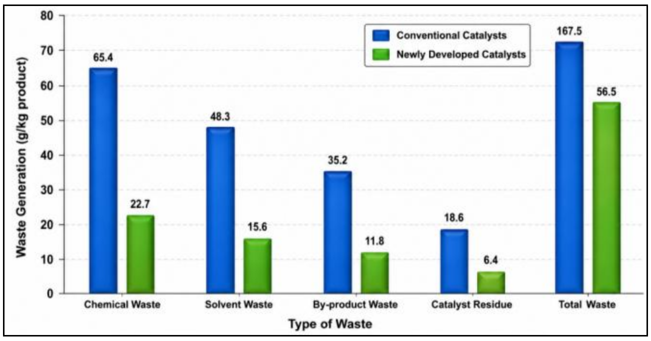

Fig 7: Comparison of Waste Generation between Conventional and Newly Developed Catalysts

As can be seen from the bar chart above, green catalysts have been seen to produce less waste as compared to normal catalysts for all types of waste produced. Green catalysts have been seen to produce the least amount of waste in chemical and solvent waste.

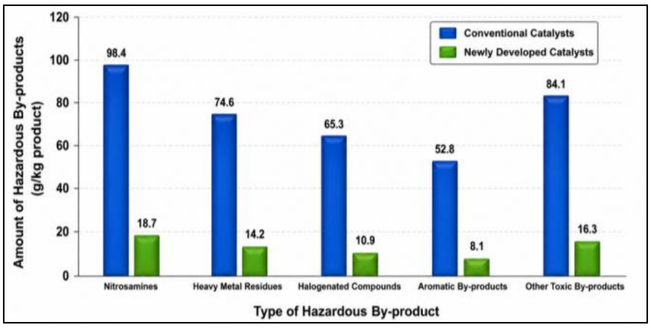

Fig 8: Reduction in Hazardous By-products Using Newly Developed Catalysts

It can be seen from the bar chart that the use of green catalysts developed through research has greatly helped in the lowering of hazardous by-products formed by comparison with normal catalysts in all the categories tested, especially in nitrosamines and heavy metals. From these results, it can be noted that green catalyst technology makes the environment safer by reducing the formation of toxic by-products.

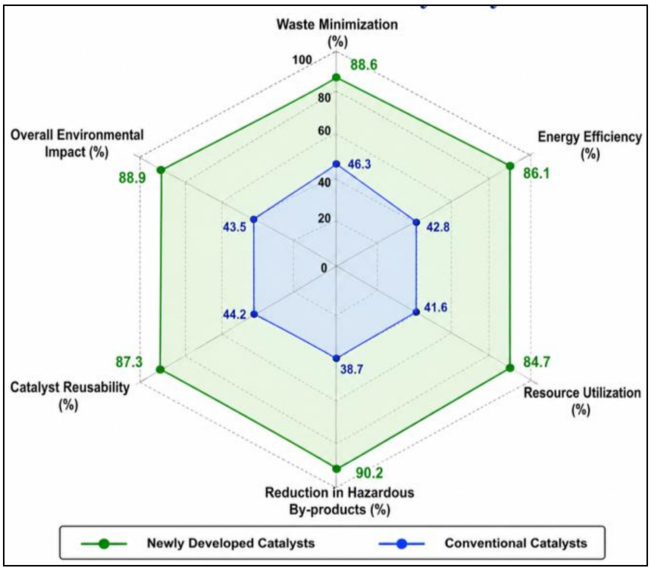

Fig 9: Environmental Sustainability Index of Pharmaceutical Catalytic Systems

As seen in the radar diagram, green catalysts, which were recently developed, attained much better Environmental Sustainability Index ratings than traditional catalysts with respect to all measured parameters, with their best performance in reducing toxic by-products (90.2%). It is thus evident that green catalytic systems are more sustainable environmentally in terms of minimizing wastes, saving energy, using resources effectively, reusing the catalyst, and improving environmental sustainability.

Statistical Analysis

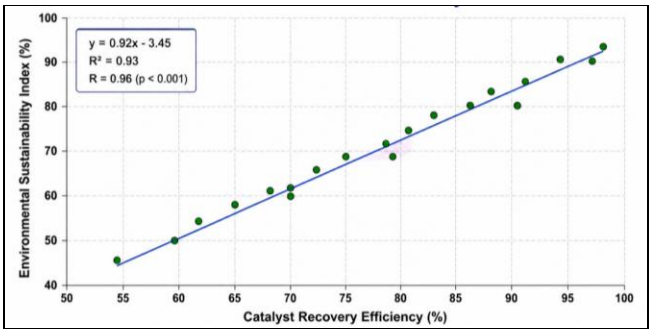

Fig 10: Regression Analysis between Catalyst Recovery Efficiency and Environmental Sustainability Index

The results of the regression analysis showed a significant positive correlation between catalyst recovery efficiency and the Environmental Sustainability Index, which shows that an improvement in catalyst recovery efficiency greatly increases environmental sustainability. This is due to the high coefficient of determination ($R^2 = 0.93$).

Discussion

The results obtained in this study confirm that the introduction of new green catalysts substantially decreases the amount of waste produced in the pharmaceutical industry in comparison with the use of traditional catalytic systems. The comparative analysis shows that the introduction of sustainable catalyst technology leads to a significant reduction in the volume of hazardous chemical waste, solvent waste, waste from catalysts, wastewater and total industrial waste. These results correspond to the main postulates of green chemistry since the latter claims that it is necessary to prevent the appearance of waste rather than treat it via designing environmentally-friendly chemical processes (Anastas & Warner, 1998) [1]. Similar conclusions have been made by Sheldon (2017) [2], who found out that sustainable catalytic technology leads to a significant reduction in E-factor by reducing the volume of waste produced and improving process efficiency. Similarly, Li and Trost (2008) [3] state that atom-economical catalytic reactions produce less by-products and need smaller amounts of hazardous reagents in comparison with traditional synthesis methods. Moreover, Poliakoff *et al.* (2002) [9] show that sustainable catalyst technologies lead to a decrease in solvent usage and chemical waste as well as an improvement in resource utilization in industrial chemical manufacturing. The current research adds more information to the existing evidence proving that pharmaceutical manufacturing can be made less wasteful by introducing sustainable catalyst technologies.

Yet another important contribution made by the current research is the substantial decrease in hazardous byproducts due to the use of newly developed green catalysts. This is evidenced by the reduced generation of hazardous residues such as toxic residues, heavy metal contaminants, nitrosamines, halogenated compounds, among others compared to conventional catalytic processes. This is consistent with the findings by Clark and Tavener (2007) [8] who indicated that environmentally friendly catalytic processes help in minimizing toxic byproducts and hazardous wastes during organic synthesis. In a similar manner, Sheldon (2016) [7] found out that heterogeneous catalysts, recyclable catalysts, and solvent-free catalytic processes minimize hazardous chemical production while improving the sustainability of industrial processes. Moreover, Woodley (2008) [11] showed that biocatalysis using enzymes takes place at milder reaction conditions and hence reduces the amount of toxic intermediates than chemical catalysts thus making the pharmaceutical industry environmentally sustainable. Additionally, indicated that nanocatalysis improves selectivity and minimizes undesired reactions, hence reducing hazardous byproduct formation.

Moreover, the current research indicated that the newly synthesized catalysts had significantly higher catalyst recycling efficiency, catalyst recovery rate, and environmental sustainability index compared to traditional catalytic systems. Green catalysts have always shown high recovery efficiencies even after several reuses due to their high stability and recyclability. The current results corroborate with Sheldon (2017) [2], who has stressed that catalyst recycling is one of the most useful methods of resource utilization efficiency and manufacturing cost reduction in the pharmaceutical sector. Also, mentioned that reusable nanocatalysts are able to be recovered and reused over and over again without losing any catalytic activity, which reduces the need for catalyst usage and disposal of hazardous waste. Furthermore, Anastas and Eghbali (2010) [5] noted that catalyst recovery and reuse are fundamental tenets of sustainable chemistry since they help achieve both improvement in economic performance and environmental protection at the same time. Additionally, Poliakoff *et al.* (2002) [9] found that catalyst immobilization and heterogeneous catalysts make it easier to separate the catalyst from the reaction mixture. The present study has confirmed the outcomes of all the above-mentioned researches by showing a high positive correlation between the catalyst recovery rate and the Environmental Sustainability Index.

The current regression analysis has shown that there is a very significant correlation between catalyst recovery efficiency and environmental sustainability, as improvements in catalyst recycling have a very positive impact on environmental performance in general. Also, the economic analysis carried out in the current work has revealed a large number of financial gains associated with the use of green catalysts, as it helps reduce catalyst consumption, solvent consumption, the need for waste management, and operating expenses. These results are consistent with the findings of Sheldon (2016) [7] that the development of sustainable catalytic technologies positively impacts both the environment and industry profits, as process efficiency increases, and costs related to waste management decrease. At the same time, Li and Trost (2008) [3] came to the conclusion that the methods of green chemistry not only help improve environmental conditions but also positively impact economics because they maximize atom economy and minimize the consumption of resources. At the same time, the European Commission (2020) [4] highlights the role of catalyst recycling and sustainable manufacturing technologies in creating future competitiveness of industries and their environmental friendliness. Finally, the United Nations Sustainable Development Goals include calls for clean production technologies which help to minimize pollution of industry and promote responsible consumption (United Nations, 2015) [6]. Thus, the current study does not only confirm but also adds to the existing body of knowledge on the role of catalyst recovery efficiency in determining the environmental sustainability of pharmaceutical manufacturing.

Conclusion

Sustainability and reusability of the catalysts were examined in pharmaceutical manufacturing. The comparative secondary quantitative study was conducted in order to evaluate the environmental sustainability of conventional catalytic technologies versus the new green catalysts. It has been shown that the use of green catalysts led to the significant reduction in the waste production, byproducts and solvents as well as the decrease in environmental pollution and increase in catalyst reusability and recovery. The results of Environmental Sustainability Index showed the higher sustainability of the green catalytic technologies regarding all environmental indicators.

Moreover, the results of the regression analysis showed that there is a statistically significant positive correlation between the level of recovery efficiency and sustainability of the technology that proves that catalyst recovery plays an important role in pharmaceutical manufacturing sustainability. The research also confirms that the implementation of the green catalytic technologies brings substantial economic benefits due to the decrease in cost of operation and waste disposal as well as the improvement in resource usage efficiency. These results confirm the evidence of the current state of the pharmaceutical manufacturing showing that sustainable catalyst technologies can positively impact both environmental safety and profitability of the companies. Therefore, it can be concluded that green chemical catalysts are one of the ways of increasing sustainable pharmaceutical manufacturing. Further innovations in the catalyst recycling and development of more environmentally friendly methods of manufacturing should be considered in the pharmaceutical industry in order to decrease the environmental footprint and ensure sustainable development.

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