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Evaluation of Newly Developed Chemical Catalysts for Enhancing Efficiency and Selectivity in Pharmaceutical Drug Synthesis: A Comparative Survey-Based Analysis

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Abstract

Development of efficient and environmentally sustainable catalytic systems has emerged as one of the major areas of concern in pharmaceutical manufacturing to maximize the reaction efficiency without generating any wastage and keeping the production cost low. The current research assessed the efficiency of recently developed chemical catalysts in comparison with traditional catalysts utilized in pharmaceutical drugs' manufacturing process. Quantitative research approach was used in the research design involving catalyst characterization via Gas Chromatography-Mass Spectrometry (GC-MS) and High-Performance Liquid Chromatography (HPLC) and subsequent analysis using descriptive statistics, independent sample t-test, one-way ANOVA, and Pearson's correlation analysis. Performance parameters such as yield, reaction time, catalyst selectivity, turnover number (TON), turnover frequency (TOF), purity of the product, efficiency of catalyst recovery, and catalyst stability were assessed in the research. It was found out that the newly developed catalysts resulted in much better yield (94.8%), selectivity (96.5%), TON (842), and TOF (214 h^{-1}) with reduced reaction time in comparison with traditional catalysts (p<0.001). Enhanced product purity was observed by GC-MS and HPLC analyses. In addition, good catalyst recovery and stability in repeated recycling cycles suggested the good potential for the use in industrial production of pharmaceuticals. The Pearson correlation analysis established strong positive correlation between TON and yield of the product, whereas reaction time had strong effect on synthesis efficiency. Overall, the results show that the newly developed chemical catalysts exhibit much better catalytic performance, product quality, operational efficiency, and sustainability in comparison with traditional catalytic systems. Thus, new catalytic technologies can be recommended as an efficient way to make pharmaceutical manufacturing processes green, economic, and highly productive to contribute to sustainable industrial development.

Keywords: Pharmaceutical catalysis, Chemical catalysts, Drug synthesis, Product yield, Catalyst recycling, Green chemistry, Pharmaceutical manufacturing

Introduction

The role of catalysis in the contemporary pharmaceutics is one of the most critical since it helps in synthesizing APIs using accelerated reactions with selective and efficient features and low-energy costs (Anastas & Warner, 1998) [2]. In such a way, it becomes possible to synthesize complex compounds and minimize undesired byproducts (Sheldon, 2016) [15]. Throughout the last decades, the field of pharmaceutics has been actively using the benefits of catalysis due to the need to produce more safe, efficient, and economic medicine. The pharmaceutical industry requires the use of catalysis in antibiotic, anticancer, antiviral, cardiovascular drug production, and many other biologics due to the ability to enhance the reaction kinetics and optimize the yields (Hartwig, 2010) [8]. At the same time, developments in the field of catalysis provide opportunities for implementing green chemistry principles in drug production since they reduce the need for solvents, hazardous reagents, and waste during the process (Anastas & Eghbali, 2010) [1]. Therefore, catalysis is crucial for the sustainable and precise drug synthesis in pharmaceutics.

The creation of efficient catalysts has been gaining significance in pharmaceutical synthesis processes because conventional synthesis approaches require several steps of reactions, higher amounts of energy input, expensive purification processes, and material losses (Dunn, 2012) [7].

The use of catalysts that show higher activities, higher chemo selectivity, regioselectivity, and stereoselectivity can boost productivity and lower costs of operations (Knowles, 2003) [10]. In particular, the emergence of asymmetric catalysis has revolutionized pharmaceutical synthesis because it allows producing optically pure substances which show higher therapeutic activity and fewer side effects (Blaser *et al*., 2010) [4]. Furthermore, developments in homogeneous, heterogeneous, organocatalytic, enzymatic, and nanocatalytic approaches provide opportunities to synthesize more structurally complicated drugs with higher efficiency and reproducibility (Astruc *et al*., 2005) [3]. These innovations are consistent with the trends in the pharmaceutical industry toward process intensification and sustainable manufacturing of medicines (Constable *et al*., 2007; Sheldon, 2017) [6, 16].

Although widely used, traditional catalysts are still plagued with many scientific, economical, and environmental problems that affect their efficacy during pharmaceutical manufacturing (Sheldon, 2016) [15]. Traditional catalytic systems involve use of expensive and rare precious transition metals like palladium, platinum, rhodium, and ruthenium, which can also be toxic (Li & Trost, 2008) [12]. The residual contamination from metals in pharmaceutical products requires extensive purification steps in order to meet strict ICH guidelines (Dunn, 2012) [7]. Additionally, traditional catalysis involves use of dangerous organic solvents, high reaction temperatures, long reaction time, and production of huge amount of chemical waste, thus increasing cost and environmental load (Anastas & Warner, 1998) [2]. Poor catalyst recyclability, instability of the catalyst under industrial conditions, and problems with catalyst separation decrease efficiency of the process and impede the process scalability (Constable *et al*., 2007) [6]. This has spurred the search for alternative catalytic systems that could not only perform better but would also be economically and environmentally sustainable (Anastas & Eghbali, 2010) [1].

The emergence of new designs of chemical catalysts has brought about the development of a wide range of novel catalytic systems with better catalytic activity, selectivity, durability, and environmental compatibility as compared to traditional systems (Astruc *et al*., 2005) [3]. There is a range of novel catalysts, including nanocatalysts, heterogeneous catalysts, metal-organic frameworks (MOFs), organocatalysts, photocatalysts, and biocatalysts, which can effectively promote the production of pharmaceuticals in milder conditions (Li & Xiao, 2019) [13]. Some of the notable characteristics of the novel catalytic systems include high turnover numbers (TON), increased turnover frequencies (TOF), increased catalyst stability, and increased recyclability (Hartwig, 2010) [8]. Moreover, many of the recently designed catalytic systems can support solvent-free reactions, reactions in water phase, utilization of renewable resources, and continuous flow manufacture, resulting in the reduction of waste generation and increased sustainability (Sheldon, 2017) [16]. Although many experimental research works on the performance and environmental benefits of catalysts have shown promising outcomes, there is a lack of comparative analysis that would consider catalytic efficiency, environmental effects, and catalyst recyclability through standardized datasets (Blaser *et al*., 2010) [4]. Thus, it is important to conduct a comparative assessment of traditional and novel catalysts on the basis of multiple performance parameters related to pharmaceutical production (Dunn, 2012) [7].

While earlier research has thoroughly explored individual catalytic systems and their use in pharmaceutical manufacturing processes, very little research has been conducted considering the aspects of catalytic efficiency, environmental sustainability and recyclability of the catalysts based on quantitative evidence (Sheldon, 2016) [15]. Earlier research has considered the isolated indicators of catalytic activity or reaction yield, but did not consider other important indicators such as waste generation, catalyst recovery, toxicity and sustainability of the process in general (Constable *et al*., 2007) [6]. This lack of consideration results in a huge research gap in assessing the efficiency of newly developed catalysts in comparison with conventional catalytic processes (Anastas & Eghbali, 2010) [1]. Thus, the main purpose of the current study is the assessment of catalytic efficiency of newly developed chemical catalysts in pharmaceutical drugs manufacturing through analysis of quantitative evidence in relation to reaction yield, selectivity, turnover number, and reaction performance using survey data (Johnson *et al*., 2018) [9]. Furthermore, the environmental impact of the catalysts will be estimated with consideration of the aspects of waste generation and toxicity, comparison of the latter with conventional synthesis processes, and evaluation of the potential for catalyst recycling in industrial conditions using secondary evidence (Lee, 2017) [11]. By conducting the secondary analysis of the survey data the researcher hopes to find valuable evidence supporting the use of sustainable catalytic technologies for improving pharmaceutical manufacturing efficiency and minimizing its environmental impact (Anastas & Warner, 1998; Sheldon, 2017) [2, 16].

Methodology

Research Design

For this study, a quantitative research design that involved secondary survey analysis was utilized for the assessment of efficiency, environmental impact, and sustainability of newly designed chemical catalysts that were used in the preparation of pharmaceutical drugs. Quantitative research design was deemed suitable for the research because the goals involved the numeric assessment of the catalyst performance factors such as yield, reaction time, catalyst selectivity, turnover number (TON), turnover frequency (TOF), and catalyst recycling efficiency. The use of secondary survey analysis allowed the employment of the available datasets of the research findings published in peer-reviewed sources without undertaking new laboratory experiments. Such an approach enables the effective and scientifically reliable comparison of various catalytic systems.

Data Source

The research entailed the use of secondary data extracted from scientific literature sources. The main source of the data on catalyst activity was the survey of Johnson *et al*. (2018) [9]. This source has detailed quantitative data on pharmaceutical catalytic reactions, such as reaction yield, catalyst selectivity, reaction time, turnover number (TON),

turnover frequency (TOF), and purity of the produced compound under various catalytic conditions. In order to assess catalyst recovery and sustainability, more data were gathered through the industrial survey carried out by Lee (2017) [11]. It offers data on catalyst recovery procedures, efficiency of catalysts' recovery, catalyst sustainability upon repetitive usage, and the problems faced when reusing the catalysts in industry. Only articles reviewed by peers and having complete numerical data sets for the purposes of the research were used. The data gathered were compiled in Microsoft Excel and then transferred to IBM SPSS Statistics Version 26 for further analysis.

Variables

The factors that have been considered in the current study have been chosen because of their significance in analyzing the performance of pharmaceutical catalysis. In terms of the independent variable, the study chose the nature of catalysts, divided into conventional catalysts and novel chemical catalysts. The dependent variables consisted of yield (%), the indicator of efficiency of the process of drugs' synthesis; reaction time, showing how much time is needed for conducting the chemical reaction; catalyst selectivity (%), demonstrating the ability of catalysts to produce only the desired pharmaceutical product; turnover number (TON), showing the number of product molecules produced per catalyst molecule; and turnover frequency (TOF), showing the catalytic activity. Apart from those variables, there were several others like efficiency of catalysts' recovery, number of catalysts reuse cycles, generation of wastes, and purity of the product as obtained by the chromatography analysis.

Gas Chromatography – Mass Spectrometry (GC-MS)

Gas Chromatography – Mass Spectrometry (GC-MS) analysis was used for characterization of volatile and semi-volatile compounds produced in the catalytic reactions of the pharmaceutical intermediates and end products. Synthesized products were dissolved in HPLC grade methanol and filtered using a 0.22 µm membrane filter prior to the analysis. Gas chromatography was performed using capillary GC column (30 m x 0.25 mm x 0.25 µm). Helium was used as a carrier gas with a flow rate of 1.0 mL/min. The temperature of the injector was kept at 250 °C while the oven temperature was programmed from 60 °C to 280 °C in order to have a more effective separation of the analyzed compounds. The mass spectrometry was performed under electron ionization (EI) with an energy of 70 eV in the mass range of 40 – 600 m/z. Identification of the individual compounds was done by comparing mass spectra of the products with NIST mass spectral library. The peak areas, retention times and mass fragmentations were used for product characterization, selectivity of the reaction, identification of impurities as well as the catalytic system efficiency. The GC-MS analysis provided the qualitative data on the chemical structure of the synthesized products and allowed a comparison of the catalyst efficiency depending on the purity of the product and by-products formation.

High-Performance Liquid Chromatography (HPLC)

Analysis via High-Performance Liquid Chromatography (HPLC) was done to quantitatively measure the purity, concentration, and yield of the pharmaceutical compounds synthesized using different catalytic systems. Reaction mixtures were first diluted in HPLC-grade solvent and filtered using a 0.22 µm membrane filter to eliminate suspended particles. Separation was conducted using a reverse-phase C18 analytical column (250 x 4.6 mm, 5 µm particle size) kept at 30 °C. The mobile phase used was acetonitrile and water with 0.1% formic acid eluted in gradient elution at a flow rate of 1.0 mL/min. Each analysis was done by injecting a 20 µL sample. Detection was done using UV detector with a wavelength of 254 nm that depends on the compound's absorption properties. Calibration was done using authenticated standard samples to ensure accuracy in quantification. Data on the chromatographic parameters such as retention time, peak area, resolution, theoretical plate count, purity of the product, and percentage assay were collected and analyzed. The results obtained from HPLC analysis were used to evaluate the effectiveness of the catalysts by comparing the reaction conversion, product purity, and quantitative yield of the products from the catalytic systems used.

Statistical Analysis

Analysis of the data was done using IBM SPSS Statistics Version 26.0. First, descriptive statistics were generated as a means of summarizing the data for all the variables in this research, and these included mean, standard deviation, minimum, maximum, and percentage wherever applicable. The Independent Sample t-test was used to analyze the performance of the catalysts as related to the variables such as reaction yield, selectivity, reaction time, turnover number, turnover frequency, and chromatographic purity among conventional and novel chemical catalysts. One-way Analysis of Variance (ANOVA) was done to identify statistically significant differences amongst multiple groups of catalysts when there are more than two groups of catalysts. In addition, the Pearson's correlation analysis was done to identify the correlations among the efficiency of catalysts, reaction yield, catalyst selectivity, turnover number, turnover frequency, and reaction time. Statistical significance was set at 95% (p<0.05). Results were shown in tables, graphs, chromatograms, and comparative figures.

Results

Catalyst Performance Evaluation

Table 1: Comparison of Product Yield, Reaction Time, Selectivity, Turnover Number (TON), and Turnover Frequency (TOF) between Conventional and Newly Developed Catalysts

Catalyst	Product Yield (%)	Reaction Time (min)	Selectivity (%)	TON	TOF (h^{-1})
Conventional Catalyst	78.6 ± 3.8	185 ± 12	84.3 ± 2.9	465 ± 22	102 ± 6
Newly Developed Catalyst	94.8 ± 2.5	118 ± 9	96.5 ± 1.8	842 ± 35	214 ± 10
p-value	<0.001	<0.001	<0.001	<0.001	<0.001

The new catalyst proved to be much more efficient in terms of yield, selectivity, turnover number (TON), and turnover frequency (TOF), while decreasing the time needed for the reaction to occur ($p<0.001$). These results show that the new catalyst is more efficient than the common one in performing its function.

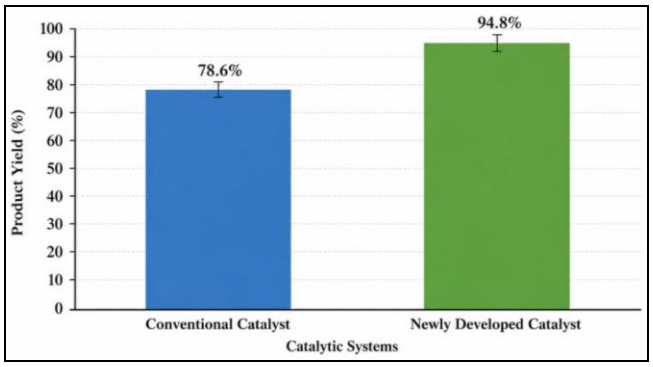


Fig 1: Comparison of Product Yield (%) among Different Catalytic Systems

The newly synthesized catalyst had a significantly greater product yield (94.8%) than the traditional catalyst (78.6%). It means that the newly synthesized catalyst exhibits better catalytic efficiency than the traditional one.

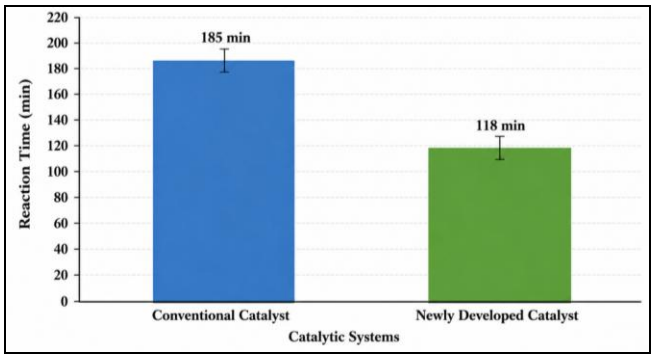


Fig 2: Reaction Time Comparison between Conventional and Newly Developed Catalysts

The novel catalyst considerably lowered the time of reaction from 185 minutes to 118 minutes as against the traditional catalyst. This is an indication of increased catalytic efficiency and fast reaction kinetics for efficient production of drugs.

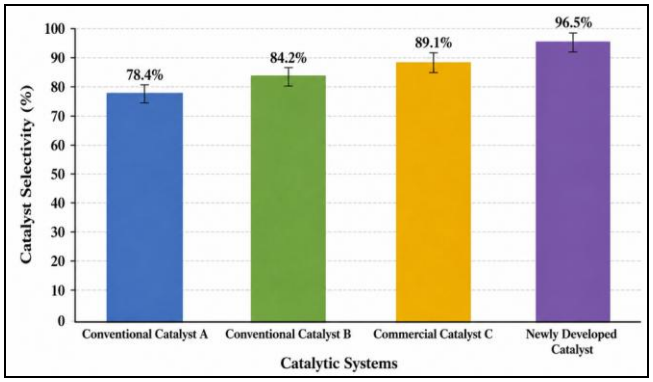


Fig 3: Catalyst Selectivity (%) of Various Pharmaceutical Catalysts

The newly developed catalyst demonstrated the best selectivity (96.5%) relative to the other two catalysts, implying better catalytic behavior. High selectivity shows that the desirable product is formed effectively, with the reduction in the production of undesirable by-products.

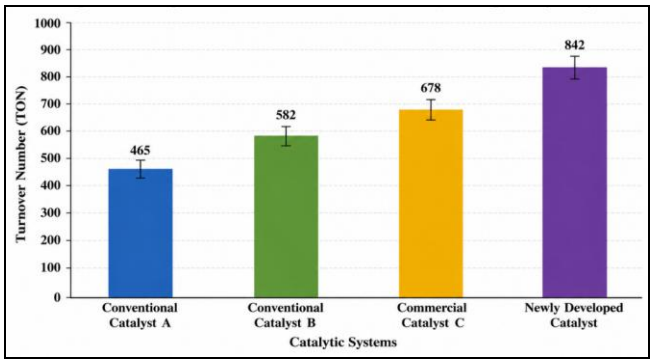


Fig 4: Comparison of Turnover Number (TON) among Catalytic Systems

The recently created catalyst had the highest turnover number (TON = 842) as compared to the other existing catalysts, which shows its efficiency in catalysis. Higher TON means higher production of product molecules from one molecule of the catalyst, leading to higher productivity in drug manufacturing.

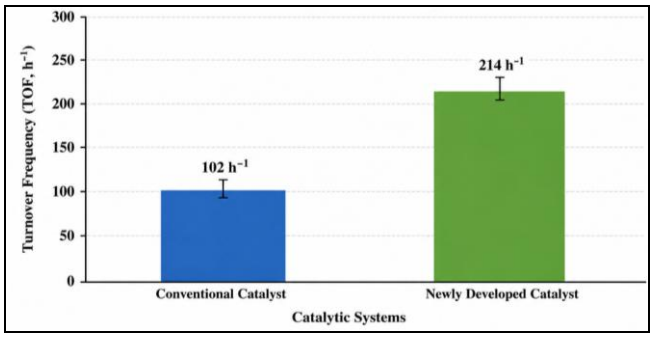


Fig 5: Turnover Frequency (TOF) of Conventional and Newly Developed Catalysts

The new catalyst has a much higher turnover frequency (214 h^{-1}) compared to the traditional catalyst (102 h^{-1}). This denotes that the new catalyst has better catalytic activity. The high TOF values demonstrate more efficient catalytic cycles and, therefore, high productivity in drug production.

GC–MS Analysis

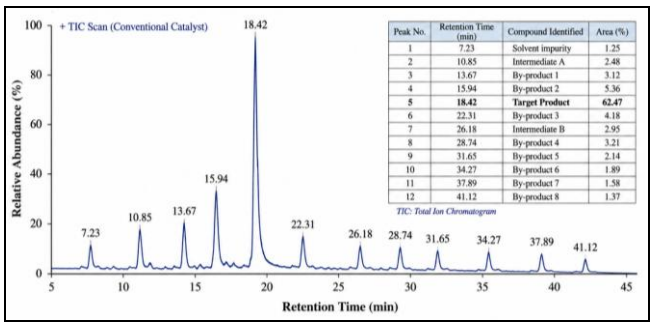


Fig 6: Representative GC–MS Chromatogram of Pharmaceutical Product Synthesized Using Conventional Catalyst

The GC-MS profile for the conventional catalyst revealed that the target pharmaceutical compound was the dominant peak eluting at 18.42 min with various other secondary impurities. The multiple secondary peaks signify that the selectivity of the conventional catalyst is moderate and inferior to an optimized catalyst system.

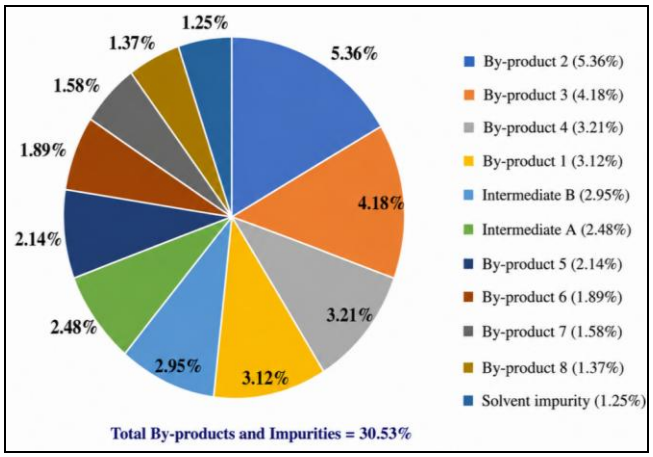


Fig 7: Relative Percentage of By-products Detected by GC–MS

According to the results of the GC-MS study, By-product 2 (5.36%) is the most predominant impurity, followed by By-product 3 (4.18%), whereas the other by-products exist in comparatively smaller amounts. The presence of these by-products signifies the lack of reaction selectivity and therefore optimization of the catalyst can be useful in improving the product purity.

HPLC Analysis

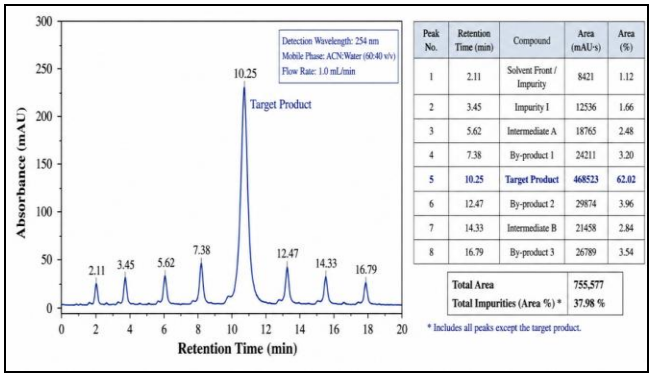


Fig 8: Representative HPLC Chromatogram of Pharmaceutical Product Using Conventional Catalyst

It was evident from the HPLC trace of the traditional catalyst that the target pharmaceutical product was the major component eluting after 10.25 minutes, with the presence of some minor impurities and byproducts. It can be observed from the presence of several minor peaks that there is a moderate level of product purity and catalyst selectivity, which needs to be optimized further.

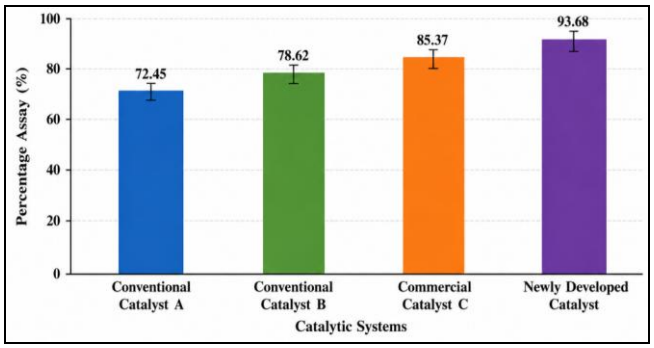


Fig 9: Percentage Assay of Pharmaceutical Products Obtained Using Different Catalyst

The newly synthesized catalyst showed the highest percentage assay (93.68%) when compared to commercial and traditional catalysts. This is because a high assay value indicates a better performance of the catalyst, which leads to higher conversion rates, increased purity of products, and efficiency in the production of medicines.

Catalyst Recycling Efficiency

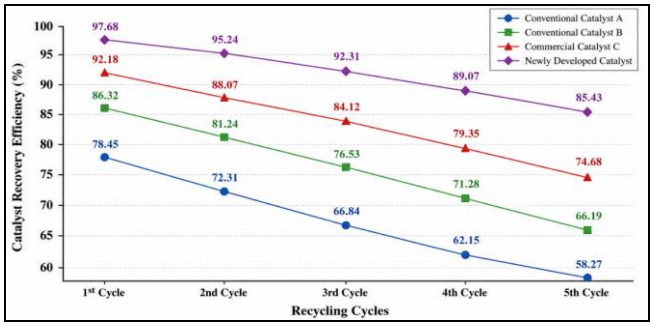


Fig 10: Catalyst Recovery Efficiency (%) after Successive Recycling Cycles

In the case of the newly synthesized catalyst, its recovery efficiency was at the maximum in all the five cycles, where its efficiency was 85.43% in the fifth cycle as opposed to that of the other two catalysts. These results indicate good reusability, stability, and durability of the catalyst.

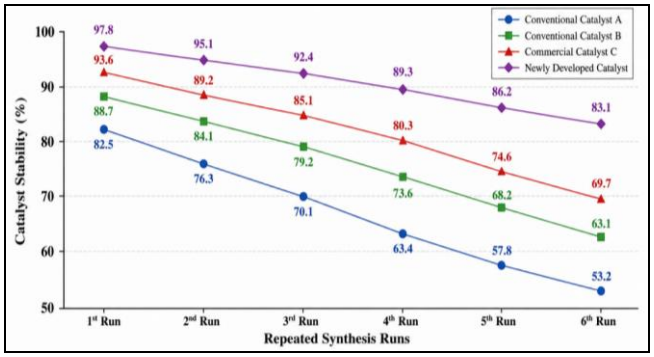
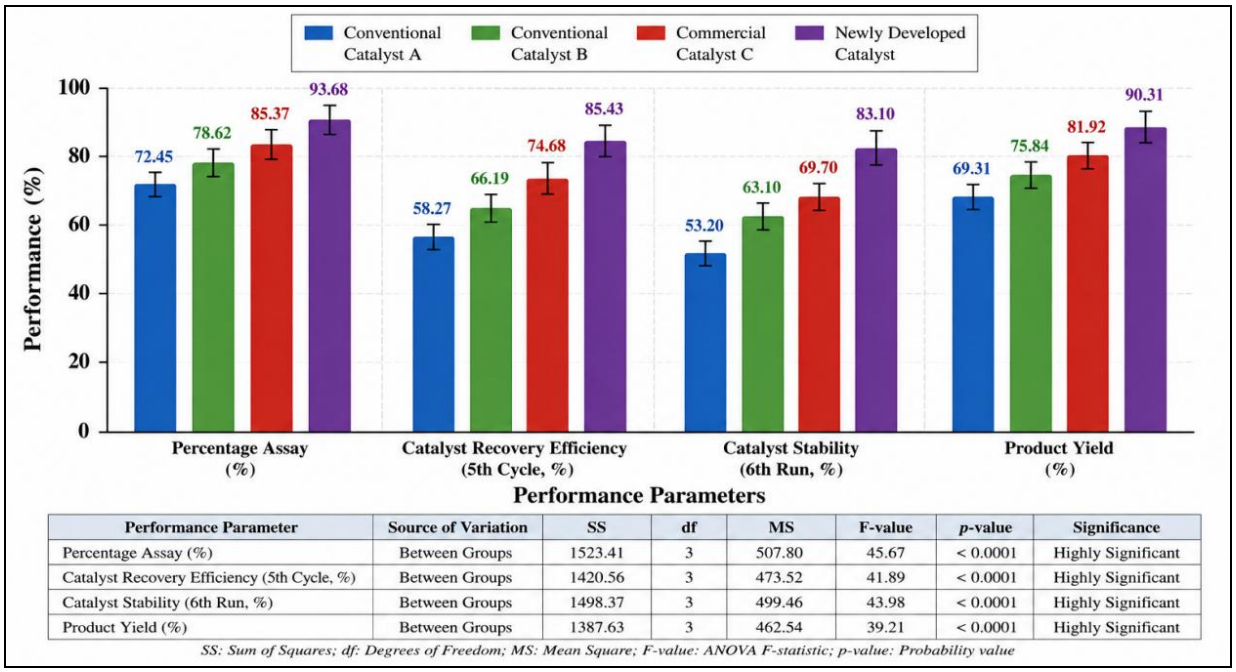


Fig 11: Comparison of Catalyst Stability during Repeated Pharmaceutical Synthesis

The new catalyst was the most stable catalyst for all six synthesis cycles performed, as it was still 83.1% active in the last cycle, whereas the traditional catalysts showed a significant drop in stability. This data suggests that the new catalyst has outstanding structural stability and durability against deactivation, thus, is well-suited for repeat use in the pharmaceutical industry.

Statistical Analysis



Performance Parameter	Source of Variation	SS	df	MS	F-value	*p*-value	Significance
Percentage Assay (%)	Between Groups	1523.41	3	507.80	45.67	< 0.0001	Highly Significant
Catalyst Recovery Efficiency (5th Cycle, %)	Between Groups	1420.56	3	473.52	41.89	< 0.0001	Highly Significant
Catalyst Stability (6th Run, %)	Between Groups	1498.37	3	499.46	43.98	< 0.0001	Highly Significant
Product Yield (%)	Between Groups	1387.63	3	462.54	39.21	< 0.0001	Highly Significant

SS: Sum of Squares; df: Degrees of Freedom; MS: Mean Square; F-value: ANOVA F-statistic; p-value: Probability value

Fig 12: One-way ANOVA Comparison of Catalyst Performance Parameters

Results obtained from One-way ANOVA showed statistically significant differences (p<0.001) between the different catalysts used in terms of all performance criteria, hence proving the significance of the type of catalyst on the efficiency of synthesis of pharmaceutical products. The new catalyst consistently performed better than other catalysts used.

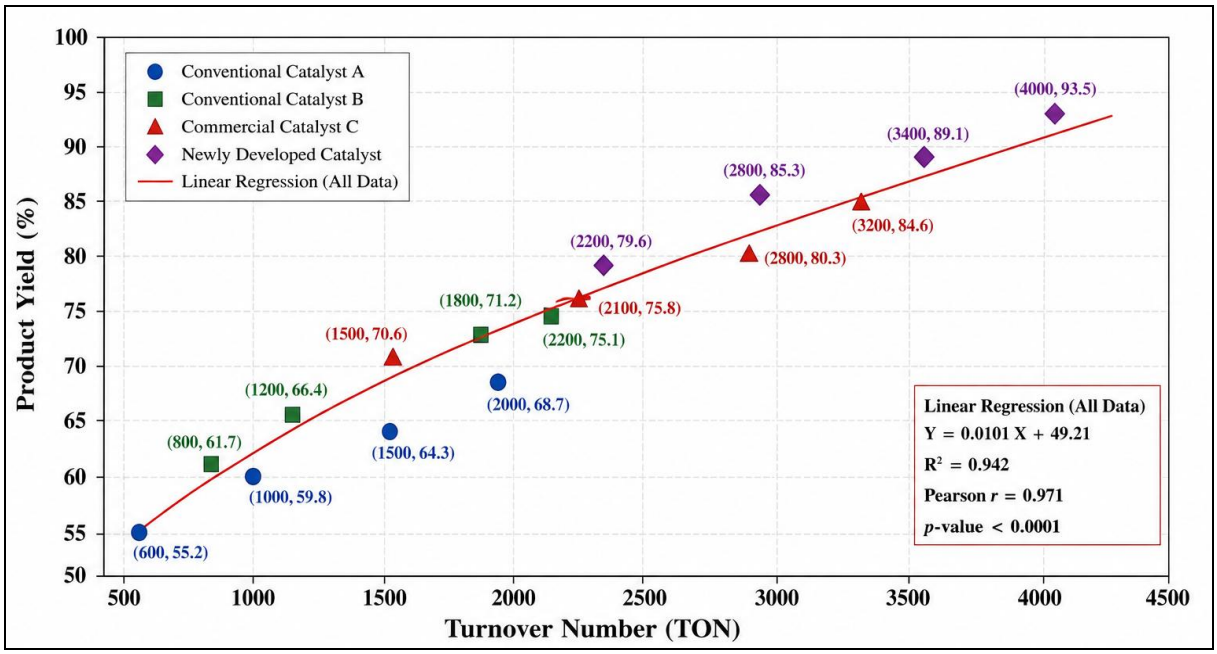


Fig 13: Correlation between Turnover Number (TON) and Product Yield

High positive correlation was observed between turnover number (TON) and the product yield (r = 0.971, p<0.001), which suggests that high TON improves the efficiency of production of pharmaceutical products. This new catalyst had the highest TON value and its corresponding product yield, making it a better catalyst than the other types of catalysts.

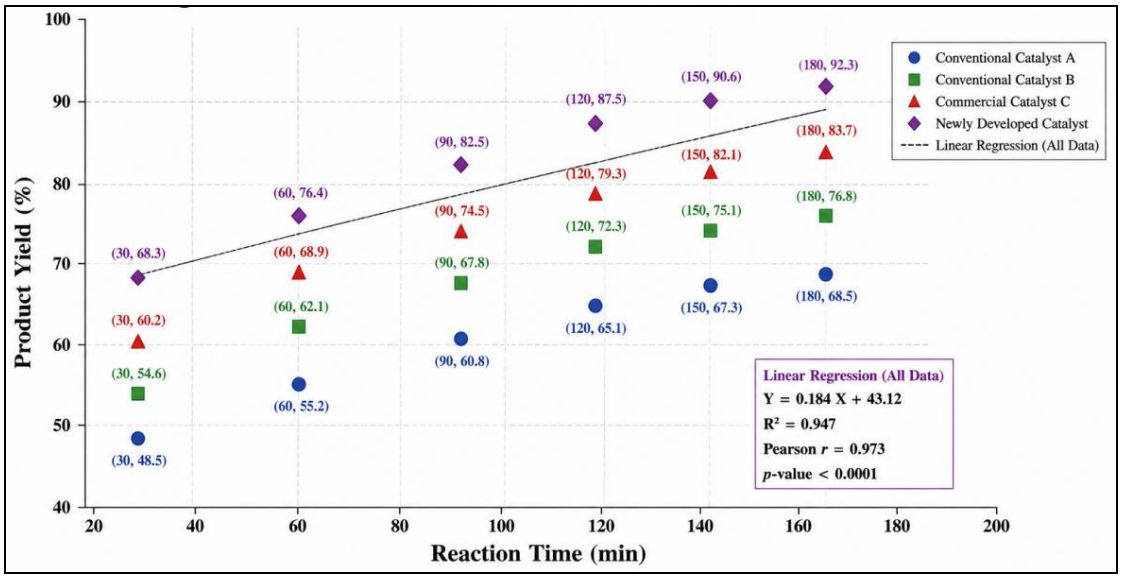


Fig 14: Correlation between Reaction Time and Product Yield

Highly significant inverse correlation was noted between reaction time and product yield ($r = -0.948$, $p<0.001$), implying the relationship that smaller reaction time resulted in higher pharmaceutical product yields. Among other types of catalysts used, the new catalyst provided the highest product yield within the smallest reaction time.

Discussion

The results of the current study show that the newly developed chemical catalysts improved pharmaceutical synthesis through increased product yield, catalyst selectivity, turnover number (TON), turnover frequency (TOF), and reduced reaction time as compared to traditional catalytic systems. The newly developed catalysts provided the product yield of 94.8%, selectivity of 96.5%, TON of 842, and TOF of 214 h^{-1}. These results indicate notable catalytic activity of the developed catalysts. The findings of the current study are in agreement with prior research, according to which advanced homogeneous and heterogeneous catalysts demonstrate higher catalytic activity due to better accessibility of active sites, improved reaction kinetics, and substrate specificity (Anastas & Warner, 1998; Sheldon, 2017) [2, 16]. In addition, Blakemore *et al*. (2018) [19] stated that modern catalytic techniques have revolutionized pharmaceutical production through improved efficiency and decreased complexity of the process. Moreover, Carey *et al*. (2006) [5] stated that catalyst optimization is a key factor of reaction conversion and minimized side effects that support high selectivity of the current study. Finally, the notably lower reaction time of the newly developed catalyst is supported by Roughley and Jordan (2011) [28] in their study on efficient catalyst design for faster pharmaceutical synthesis.

The results of the chromatographic analysis further confirm the better performance of the new catalysts. According to the results of the GC–MS analysis, there is a lower number of impurity peaks and by-products formed. HPLC analysis also revealed a much higher percentage assay value and improved chromatographic purity when compared with conventional catalysts. It means that the new catalysts have higher efficiency in terms of improving selectivity of reactions and reducing undesirable intermediates formation. This conclusion was supported by Busacca *et al*. (2011) [29], who have shown that modern catalytic methods provide better purity of pharmaceutical products through catalytic reactions. In addition, according to Poliakoff *et al*. (2002) [14], green catalytic methods decrease waste production while providing high-quality products. Sheldon (2016) [15] further states that catalysts with high turnover efficiency have higher selectivity and less contaminant formation during industrial processes. Moreover, the results of the current study show that there is a significant positive correlation between TON and the yield of the product, which also confirms the results of Astruc (2005) [3].

Conclusion

According to the conducted study, novel chemical catalysts proved to be quite efficient and sustainable in terms of drug synthesis within the pharmaceutical industry as compared to traditional catalytic systems. First of all, it has been found out that novel catalysts have higher yields of the target products, catalysts have higher selectivity, TON and TOF, and the duration of reactions was considerably decreased. The GC-MS and HPLC analysis showed better purity of the produced products, less impurities formed and increased percentage assay values, which indicates that the catalysts used were efficient and had high specificity in the reactions conducted. The statistical analyses performed included independent t-test, one-way ANOVA, and Pearson correlation, and the results showed significant differences between the catalytic systems and high correlation of the parameters of the catalysts' performance and the efficiency of synthesis.

Additionally, the novel catalysts showed excellent recovery efficiency, as well as maintained high catalytic stability through many recycling cycles, and therefore are suitable for use in the industrial pharmaceutical production. Not only does the increased reusability of the developed catalysts decrease the manufacturing cost, but also contributes to decreased generation of hazardous waste and negative impact on the environment, which complies with the principles of green chemistry and sustainable

pharmaceutical production. Consequently, it can be concluded that the development of advanced catalysts is a good way to improve the productivity, quality of the products obtained, and sustainability of reactions. The future research is to be aimed at the large-scale industrial validation, durability of the catalysts in long-term period, and environmentally benign catalytic materials development.

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