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Analytical Methods for Imeglimin Hydrochloride: A Comprehensive Review of Current Approaches and Advances

Kadambari S. Wagh[1], Tejashri R. Dugaje[2], Priyanka B. Jadhav[3], Chetna Y. Gavit[4], Revati A. Khairnar[5].
Final year B pharmacy Students, Department of pharmacy, Mahavir institute of pharmacy, Nashik

Abstract: ***Imeglimin hydrochloride is a unique anti-diabetic medication that is primarily used to treat type 2 diabetes. The rising frequency of this chronic illness needs the development of effective analytical methods for precise measurement and characterisation of imeglimin hydrochloride in pharmaceutical formulations and biological systems. This comprehensive analysis investigates existing approaches and recent advances in the analytical techniques used to determine imeglimin hydrochloride. Key technologies such as high-performance liquid chromatography (HPLC), mass spectrometry (MS), spectrophotometry, and electrochemical analysis are evaluated for sensitivity, specificity, and applicability. Furthermore, the paper discusses current trends in the creation of more dependable and cost-effective procedures, such as downsized systems and the incorporation of newer technology. The review also covers advances in technique development, such as the adoption of novel stationary phases, mobile phase optimizations, and sensitivity enhancements.***
Keywords: Analytical methods, Force degradation, Imeglimin hydrochloride, Method development, Validation.

I. INTRODUCTION

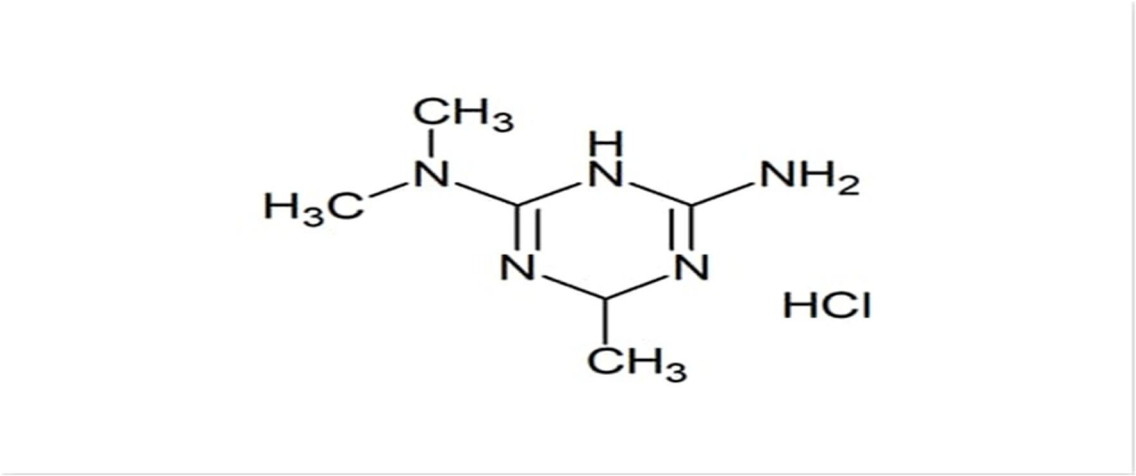
The current focus of the pharmaceutical industry and drug research lies in the rapid advancement of analytical techniques. The need for these developments is driven by several factors, such as increasingly strict quality control demands for pharmaceutical products, the necessity of managing impurities in these products, the high cost of testing, and the push from all parties involved in drug research and production for faster drug development. Clinical trials for Imeglimin hydrochloride, an oral antidiabetic agent intended for treating type 2 diabetes, have been underway. Reports indicate that it is capable of reducing fasting blood sugar levels in patients and enhancing insulin functionality by increasing insulin superexpression and reducing the expression and phosphorylation of glucotoxicity and or lipoatalin, along with reducing the expression of glucokinase-6-phosphatase and hepatic phosphoenolpyruvate carboxykinase. Additionally, it has been observed to enhance the activity of glycogen synthase 2 to improve relative hemoglobin levels in patients and lower left mass-to-body weight ratios while also reducing histone 3 acetylation levels, thus disrupting the inhibitory feedback regulation of mTOR. Furthermore, Imeglimin hydrochloride has been accepted as a beneficial oral antidiabetic agent [1]. The increasing use of Imeglimin hydrochloride in the market has led to the need for more efficient and rapid analytical methods. Rapid advancements have been made in biomolecule separation, particularly in chiral separation for studying trace interactions between drug candidates and chiral targets, as well as in impurity profiling of drug candidates. Because Imeglimin hydrochloride is often used as racemate mixtures of two enantiomers, accurately calculating the concentration of the enantiomers is crucial, given their differing bioactivity [2].

A. Overview of Imeglimin Hydrochloride

Imeglimin hydrochloride (IMEG) is a novel, first-in-class oral antidiabetic compound that alleviates hyperglycemia in patients inadequately controlled by metformin. IMEG activates an increased utilization of glucose [3]. IMEG acts through a unique mechanism of action that targets the key defects of type 2 diabetes. This innovative treatment will offer a more comprehensive coverage and combination with other antidiabetic drugs, ensuring that patients are addressing the underlying cause of their disease. By treating both insulin resistance and insulin secretory defects, a new paradigm in the treatment of type 2 diabetes is opening, imitating the effects of combination therapy. In contrast to most of the drugs with antidiabetic properties that are available now, imeglimin increases insulin action in the liver, muscle, and adipose tissues, and β-cell activity. Due to these distinct effects, researchers believe that imeglimin can hold promise in treating diabetes on a long-term basis and be an improvement over the current treatments. This review provides an overview of imeglimin with various details about the chemical aspects, mechanism of action, pharmacokinetics and pharmacodynamics, solubility, and method of estimation [4].

B. Structural Characteristics

Figure 1. Basic Structure of Imeglimin Hydrochloride



Imeglimin hydrochloride is a relatively new antidiabetic medication with a distinctive chemical structure. Its structure influences its method of action, which differs from that of other types of antidiabetic drugs [5]. Imeglimin hydrochloride's structural features the benzoxazole core, the benzyl group, the guanidine moiety, and the salt form are all interrelated and contribute to its distinct pharmacological effects. The unique arrangement of these groups enables it to target mitochondrial activity and improve metabolic regulation in a way that distinguishes it from other diabetic treatments [6].

C. Mechanism of action of imeglimin hydrochloride

Imeglimin's mechanism of action consists of two effects: (a) increased insulin action, which may include inhibition of hepatic glucose output and improvement of insulin signaling in both the liver and skeletal muscle; and (b) amplification of glucose-stimulated insulin secretion (GSIS) and preservation of β-cell mass [7] [8].

Pharmacokinetics: Imeglimin is rapidly absorbed, with a median time to maximum plasma concentration (Tmax) of 1-2 hours. It has a relatively long half-life of around 24 hours, which allows for once-daily dosing. Imeglimin is largely metabolized by the liver enzyme CYP3A4, and its metabolites are mostly eliminated through the kidneys. Food and renal impairment have no substantial effect on the drug's pharmacokinetics [9]. Pharmacodynamics: Imeglimin improves glucose-dependent insulin production and β-cell activity in type 2 diabetic patients. It also increases insulin sensitivity, which lowers glucose levels and improves glycemic management. Imeglimin preserves islet β-cell mass in type 2 diabetes patients, supporting pancreatic function throughout time. The drug's mode of action involves increasing glucose-stimulated insulin release from diabetic islets through a unique pathway [10].

D. Indication and Uses (Approved uses)

Imeglimin Hydrochloride's principal indication is the treatment of type 2 diabetes in adults. It is commonly used to improve glycemic control in conjunction with other diabetic drugs when those therapies alone are ineffective. Specifically, it is authorized for usage in

Monotherapy: Used as a stand-alone treatment for people with type 2 diabetes who do not respond well to diet and exercise. Combination therapy: When other oral antidiabetic medications, such as metformin, sulfonylureas, or SGLT2 inhibitors, or insulin therapy alone are unable to manage blood glucose levels [11].

E. Off Label uses

Imeglimin hydrochloride has not been formally licensed for usage other than diabetes therapy, and its off-label applications are unknown. Based on its mechanisms, it may have therapeutic effects in the following areas:

Metabolic Disorders: Because of its ability to improve insulin sensitivity and mitochondrial activity, it could be used to treat metabolic disorders such as metabolic syndrome.

Polycystic Ovary Syndrome (PCOS): Because insulin resistance is a crucial feature in PCOS, imeglimin may help manage the condition, albeit clinical testing is required.

Neurodegenerative Diseases: There is growing interest in mitochondria-targeting therapy for diseases such as Alzheimer's and Parkinson's, as mitochondrial dysfunction is linked to their development. Imeglimin's possible effect on mitochondrial function may prompt exploratory research in this area.

It is vital to highlight that any off-label use should only be evaluated with the guidance of a healthcare professional and would necessitate additional clinical research to determine safety and efficacy [12].

F. Dosage and Administration

Initial dose: 1000 mg twice daily (2000 mg per day). Administration: Take it orally, with or without food. The tablets are commonly taken in the mornings and evenings.

Special Considerations: Patients with renal impairment may require dosage adjustments. For patients with moderate renal impairment (eGFR 30-59 mL/min/1.73 m^2), dosage may be lowered and monitoring is indicated.

Elderly patients: Adjustments may be required in elderly people depending on individual tolerance and renal function. Patients with liver impairment should proceed with caution, while there is no specific dosage advice for severe hepatic dysfunction. Monitoring for side effects is critical [13].

Imeglimin is taken orally, and the tablet must be consumed whole with water.

Imeglimin absorption is not greatly affected by meals, therefore the medicine can be taken with or without it. Missed Dose: If a dose is missed, the patient should take it as soon as they remember, unless it is almost time for their next dose. Don't double the dose to compensate for a missing one. Long-Term Use: Imeglimin is frequently used for the long-term control of type 2 diabetes. Patients should continue to take the medication as recommended, and routine follow-up visits should involve monitoring for adverse effects and reviewing treatment effectiveness, such as blood sugar levels and kidney function [14].

G. Clinical Efficacy

Several clinical trials have examined the efficacy of imeglimin hydrochloride in patients with T2DM:

Phase II and III Trials:

In a Phase II research released in 2018, imeglimin demonstrated promising outcomes in improving glycemic control in T2DM patients. Compared to the placebo, the medication considerably lowered HbA1c levels.

In Phase III trials, imeglimin significantly reduced HbA1c and fasting plasma glucose (FPG) levels in patients who were either drug-naïve or insufficiently controlled on existing oral anti-diabetic medications. The reduction in HbA1c was typically between 0.5% and 0.9%.

Imeglimin was particularly well tolerated by patients who experienced relatively minor side effects, such as nausea or diarrhea, which are typical with many anti-diabetic medications.

Comparative studies: A head-to-head comparison with metformin (the first-line treatment for T2DM) revealed that imeglimin was just as effective at controlling HbA1c while having less gastrointestinal side effects. Some trials have also investigated combination therapy, in which imeglimin was added to current metformin or other oral medications, resulting in complimentary effects on glycemic control [15].

H. Recent Advances in Formulation Technology

Nanotechnology has been used to increase the solubility and bioavailability of imeglimin formulations, similar to other poorly soluble medicines. Imeglimin could be encapsulated in nanoparticles or nanocarriers such as lipid nanoparticles or polymeric nanoparticles, allowing for better solubility and targeted distribution to the site of action.

Nanocrystals: This technique includes decreasing medication particles to nanometer size in order to improve solubility.

Formulations containing imeglimin nanocrystals could aid in quicker absorption and increased bioavailability.

Modified Release Formulations include extended- or controlled-release formulations. One of the difficulties with many oral diabetic treatments is maintaining consistent blood glucose levels throughout the day. Imeglimin modified release formulations may help to maintain therapeutic medication concentrations for longer periods of time, eliminating the requirement for frequent dosing. This is being investigated using matrix tablets and osmotic release techniques. These formulations gradually release the medicine over time, providing a more constant impact.

Patient-Centric Formulation Developments: Progress is being made in developing patient-friendly formulations. For example, combining imeglimin hydrochloride with other antidiabetic medicines such as metformin or SGLT2 inhibitors as combination tablets could simplify patients' treatment regimens and improve compliance.

Combination medicines are increasingly significant in the treatment of type 2 diabetes. Oral thin films and orally disintegrating tablets (ODTs) may be considered for easier administration, especially in geriatric and pediatric patients [16].

I. Analytical method development

UV visible spectroscopy : UV visible spectroscopy refers to the analytical examination of several sorts of chemicals. The analysis involves measuring the absorbance of a monochromatic light by a colourless chemical in the UV visible range (200-400 nm). Imeglimin hydrochloride is an oral, first-class glimin derivative used to treat type 2 diabetes. Poxel created them in various Asian countries (Esser et al. and Kahn et al.) [17].

High performance liquid chromatography: The RP-High Performance Liquid Chromatography (HPLC) method is widely used in analysis due to its simplicity, specificity, sensitivity, and ability to analyze complicated samples. To develop HPLC method for the analysis of Imeglimin hydrochloride, many factors need to be optimized to ensure accuracy, precision of the method. Using HPLC involve the optimization of mobile phase, column, flow rate and detection condition. Various quality control parameters is crucial to ensure it's reliability for pharmaceutical analysis [18].

Ultra performance liquid chromatography: UPLC, an upgraded variant of HPLC, provides shorter analysis times, improved resolution, and increased sensitivity. This approach is gaining popularity for imeglimin analysis, especially in clinical pharmacology and bioanalysis. UPLC is suitable for:

Imeglimin concentrations in bodily fluids can be rapidly determined. Quality control laboratories conduct high-throughput testing.This method was found to be fast, affordable, robust, precise and specific for estimation of imeglimin hydrochloride.

Mass spectrometry

Mass spectrometry, commonly combined with HPLC (LC-MS), is a potent tool for: Imeglimin can be precisely quantified, particularly in complicated biological matrices.

The measurement of imeglimine hydrochloride in plasma and urine sample was performed by using liquid chromatography with tandem mass spectrometry method plasma sample were centrifuged within 30 min. at about 4 degree celsius and 1500g for 10 min and store at -20 degree celsius . Developing a Mass Spectrometry (MS) method for imeglimin hydrochloride involves several critical phases, including selecting acceptable ionization techniques, adjusting chromatographic conditions, and configuring the mass spectrometer for accurate measurement. The key objectives are to achieve high sensitivity, specificity, and resolution for imeglimin hydrochloride in a variety of matrices (such as formulations and biological samples). where low levels of the medication must be evaluated in plasma or urine.

J. Force Degradation Study (Stability Testing)

A force degradation study is required to determine the chemical stability of imeglimin hydrochloride under conditions that promote degradation. These investigations aid in identifying probable degradation pathways, drug stability under different conditions, and the generation of degradation products.

Force degradation studies are critical for determining Imeglimin Hydrochloride's stability profile and ensuring that it meets regulatory and safety requirements. Pharmaceutical companies can assure Imeglimin-based formulations' long-term efficacy, safety, and quality by subjecting them to various stress conditions and monitoring the degradation products. Analytical advances continue to increase the precision and efficiency of these research, thereby facilitating the production of robust, stable pharmaceutical products.

The ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) guidelines suggest subjecting the drug substance to forced degradation under various stress conditions to assess its stability. Acidic Conditions: Exposure to acidic environments (e.g., 0.1 N HCl) at elevated temperatures can simulate acidic degradation. Basic Conditions: Alkaline degradation (e.g., using 0.1 N NaOH) helps study hydrolytic breakdown. Oxidative Degradation: Subjecting imeglimin hydrochloride to oxidative conditions using agents like hydrogen peroxide (H2O2) or other oxidizing agents. Thermal Degradation: Heating the compound at high temperatures to simulate thermal stress. Photodegradation: Exposing the drug to light (UV or visible) to simulate photolytic degradation.

Long term stability study : A Long-Term Stability Study is an important part of pharmaceutical research since it evaluates a drug's stability over time under typical storage settings. Long-term stability studies are required for Imeglimin Hydrochloride, a new oral medication for the treatment of type 2 diabetes, in order to understand its shelf life, degradation behavior, and the generation of potentially dangerous degradation products. It is essential to ensuring that the medicine stays effective and safe during its shelf life.

Pharmaceutical businesses can monitor medication deterioration and identify appropriate storage conditions by using advanced analytical technologies such as HPLC, mass spectrometry, UV spectroscopy, UPLC. These studies are critical for regulatory approval and providing healthcare practitioners and patients with a safe and dependable product. Long-term stability testing is becoming more accurate and efficient as analytical technology advances [19].

K. Regulatory Consideration

The European Medicines Agency (EMA) has not yet approved Imeglimin in the European Union. However, it is currently undergoing clinical trials in Europe, with continuing research evaluating its safety, efficacy, and potential for usage in combination therapy for Type 2 diabetes.

Imeglimin will most likely go through a centralized marketing authorization process with the European Medicines Agency (EMA) once sufficient clinical trial data is available. The decision will be made after thorough consideration of data on long-term safety, efficacy in various subgroups (elderly, renally impaired, etc.), and a risk-benefit analysis in comparison to other anti-diabetic medications.

United States Food and Drug Administration (FDA): Imeglimin has not yet been approved by the FDA. Clinical trials are now underway, and after the data are collected and reviewed, the pharmaceutical company may submit a New Drug Application (NDA) to the FDA. The FDA will review all available information, including Phase III trial data, safety profiles, and benefits in real-world populations.

FDA's considerations: The FDA will evaluate imeglimin to other first-line medicines, such as metformin, in terms of efficacy, safety (e.g., risk of lactic acidosis, cardiovascular consequences), and tolerability (particularly gastrointestinal side effects, which are frequent with anti-diabetic medications).

Orphan Drug Designation: Given imeglimin's innovative mechanism of action and potential to meet an unmet need, there may be debates about its eligibility for Orphan Drug Designation, albeit this is normally reserved for more rare illnesses.

L. Method Validation Parameters

Method validation is an important step in pharmaceutical development because it ensures that the analytical methods used to analyze medicinal ingredients and products are reliable, accurate, and reproducible. Imeglimin hydrochloride, like any other pharmaceutical product, requires method validation to evaluate its quality, safety, and efficacy in both preclinical and clinical stages. To be recognized for regulatory reasons, analytical methods must be rigorously validated in accordance with guidelines established by the(ICH) International Conference on Harmonization and the (USFDA) United States Food and Drug Administration. The following validation parameters are generally evaluated:

Accuracy:

Definition: Accuracy refers to how well the measured value (using the analytical procedure) matches the true value or the established reference standard.

Validation for Imeglimin: The procedure should yield findings that are within an acceptable range of known criteria for imeglimin hydrochloride. This could include injecting known doses of imeglimin into a sample and monitoring the recovery rate.

Precision:

Definition: Precision is the reproducibility or consistency of a process when repeated under the same conditions. It consists of both repeatability (same operator, same instrument, small time intervals) and intermediate precision.

Validation for Imeglimin: Precision testing for imeglimin entails taking repeated measurements under different settings and confirming that the results are consistent. This can be measured using intra-day and inter-day variability and must fall within a specific range (e.g., relative standard deviation <2%).

Specificity (selectivity):

Definition: Specificity relates to the analytical method's capacity to assess the analyte (imeglimin hydrochloride) without interference from other compounds such as excipients, contaminants, or degradation products.

Validation in Imeglimin entails demonstrating that the method can specifically identify imeglimin in the presence of probable interfering components in the formulation or matrix (for example, tablet excipients, metabolites, or contaminants).

Linearity:

Linearity is defined as the method's capacity to deliver findings that are directly proportional to the concentration of analyte within a certain

range.

Validation for Imeglimin: The approach should be linear across the concentration range predicted in pharmaceutical formulations (e.g., trace levels to maximum dose). This would entail testing several concentrations of imeglimin hydrochloride and graphing the results to establish a straight-line association.

Limits of detection (LOD) and quantification (LOQ) are as follows:

Definition: The detection limit is the lowest concentration of imeglimin that can be consistently detected, whereas the quantitation limit is the lowest concentration at which imeglimin can be precisely measured.

Validation in Imeglimin: These limits are obtained by testing the method with progressively decreasing concentrations of imeglimin hydrochloride and establishing the point at which the chemical cannot be consistently recognized or quantified.

Robustness:

Definition: Robustness relates to the method's ability to stay unaffected by minor alterations in experimental settings (e.g., temperature, pH, reagent concentration).

Validation in Imeglimin is testing the method under slightly different settings to determine whether the results are still accurate. For example, in chromatography, changing parameters such as column temperature, flow rate, or mobile phase composition and assessing the impact on imeglimin quantification [20].

Table 1: Side Effects and Adverse Reaction :

Common Side Effects	Serious Adverse Reaction
Nausea	Hypoglycemia
Diarrhea	Renal Impairment
Abdominal discomfort or pain	Allergic Reaction
Headache	Liver Issues
Fatigue	Anaphylaxis

M. Contraindications and Precautions

Imeglimin hydrochloride should be avoided in the following situations:

Severe renal impairment:

Imeglimin is not recommended for those with severe renal impairment (e.g., eGFR < 30 mL/min/1.73 m^2).

Hypersensitivity to Imeglimin or its components:

Imeglimin is not recommended for people who are known to be allergic to imeglimin hydrochloride or any of the excipients used in its formulation.

Pregnancy (category C):

Imeglimin is not recommended during pregnancy unless the possible benefits outweigh the dangers.

N. Precautions

Renal impairment (moderate): Caution is advised for people with moderate renal impairment (eGFR between 30 and 59 mL/min/1.73 m^2).

Imeglimin has not been demonstrated to have severe hepatotoxicity, however caution is nevertheless suggested in patients with liver disease or reduced liver function.

Risk of hypoglycemia: Imeglimin does not normally cause hypoglycemia since it does not directly stimulate insulin secretion. However, when coupled with other anti-diabetic medications that lower blood glucose levels (such as insulin or sulfonylureas), there is a risk of hypoglycemia.

Gastrointestinal disorders: Imeglimin may produce gastrointestinal symptoms such as nausea, diarrhea, and stomach pain.

O. Drug Interactions

Other antidiabetic medications:

Imeglimin may interact with other blood glucose-management drugs, including insulin, sulfonylureas (e.g., glibenclamide), and metformin. Combining these drugs may raise the risk of hypoglycemia (low blood sugar).

Blood sugar levels should be closely monitored and dosages adjusted as needed.

Renal impairment:
Imeglimin is mostly eliminated through the kidneys. In patients with renal impairment, it may accumulate, increasing the risk of side effects. Close monitoring of renal function is required, and dose modifications may be needed in these patients.
Cytochrome P450 Enzyme Inhibitors and Inducers:
Imeglimin does not appear to be appreciably metabolized by the CYP450 enzyme system, making interactions with CYP450 inhibitors or inducers improbable. However, this has not been fully proven, and it is still crucial to monitor for any unexpected side effects when used with other drugs that influence the CYP450 system.

P. Patient Counseling Information
Lifestyle and dietary recommendations:
Diet: Stick to a balanced, healthy eating plan specifically created for diabetics. This involves eating at regular intervals, focusing on nutritious grains, lean meats, healthy fats, and plenty of veggies. Limiting high-sugar and high-fat diets is critical for blood sugar management.
Exercise: Get regular physical activity (at least 150 minutes of moderate-intensity exercise each week, such as brisk walking). Exercise helps to enhance insulin sensitivity and blood sugar regulation.
Weight Management: Maintaining a healthy weight can help with blood sugar control. Even minor weight loss (5-10% of body weight) can have a major impact on diabetes management.
Hydration: Stay hydrated throughout the day, especially if you're physically active.
Avoid Alcohol: Excessive alcohol use might cause variations in blood sugar. Drink in moderation and regularly monitor your blood sugar levels.
Quit Smoking: Smoking increases the risk of diabetes complications such as heart disease, kidney difficulties, and nerve damage.

II. CONCLUSION

The invention and refinement of analytical procedures for imeglimin hydrochloride have helped to ensure its purity, safety, and efficacy in clinical use. Techniques such as UV,HPLC, UPLC, MS, and spectroscopy have various advantages, including high sensitivity, adaptability, and the capacity to handle complicated biological material. These approaches are critical for drug discovery, clinical pharmacology, and real-time monitoring of Type 2 diabetic patients. However, some technologies, particularly those using multidimensional approaches or advanced instrumentation, continue to present cost, time, and complexity issues. Furthermore, bioanalysis in complex matrices requires careful management of potential mistakes caused by matrix effects. Despite these hazards, the ongoing improvement of analytical tools promises to resolve these limits while also improving imeglimin hydrochloride monitoring and application.
In the future, the integration of emerging technologies such as portable biosensors and rapid diagnostic tools may improve imeglimin's real-time analysis and therapeutic monitoring, potentially revolutionizing its clinical application and contributing to the larger diabetes management landscape.

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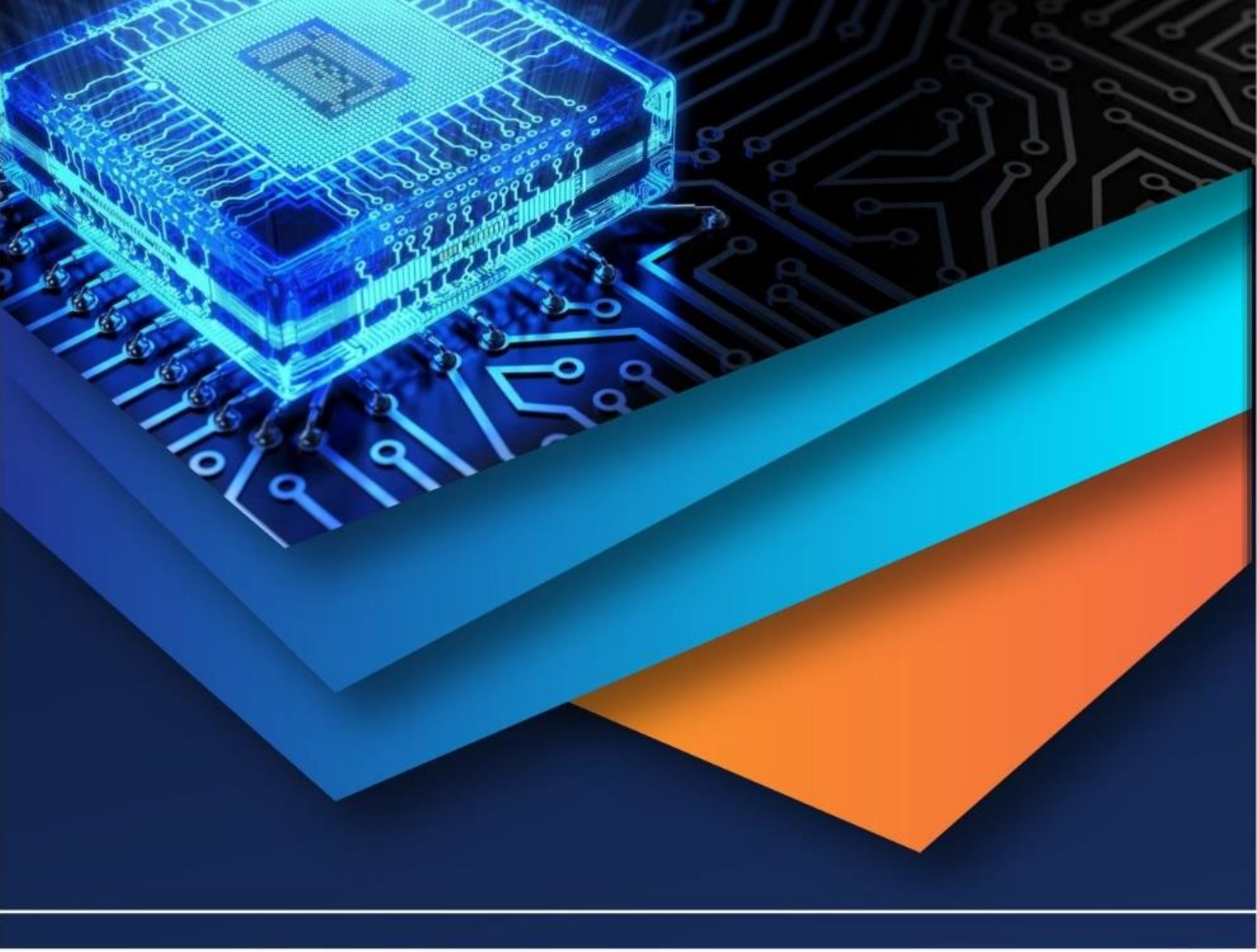

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