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A Review on Development and Validation for the Simultaneous Estimation of Lansoprazole and Domperidone in Bulk and Capsule Dosage Form

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Abstract: ***Lansoprazole is an effective proton pump inhibitor utilized for managing various acid-related disorders, such as ulcers and gastroesophageal reflux disease (GERD), by significantly reducing stomach acid production. It has demonstrated a general tolerance among users, with common side effects including headaches, nausea, and diarrhea, while serious side effects are comparatively rare. Importantly, lansoprazole may provide superior healing results for conditions like ulcers and esophagitis compared to alternative medications such as ranitidine. Furthermore, it plays a key role in eradicating Helicobacter pylori bacteria when used in combination with antibiotics. Domperidone is a dopamine antagonist primarily used to treat nausea, vomiting, and gastrointestinal motility disorders. It functions both as an antiemetic, alleviating symptoms of nausea and vomiting, and as a prokinetic agent, enhancing gastric emptying. Notably, it is regarded as safer compared to metoclopramide due to its limited ability to cross the blood-brain barrier, thus minimizing central nervous system side effects. However, its safety profile is under scrutiny, particularly concerning potential cardiac effects and its impact on mental health during lactation. The future scope for the simultaneous estimation of Lansoprazole (LAN) and Domperidone (DOM) emphasizes the development of efficient, sustainable, and high-throughput analytical methods. Key areas of focus include minimizing hazardous solvent use through green chemistry principles, potentially utilizing supercritical fluid chromatography (SFC) or aqueous- based mobile phases in reverse-phase high-performance liquid chromatography (RP-HPLC). Research is anticipated to concentrate on ultra-high performance liquid chromatography (UHPLC) and chip-based microfluidic systems, offering faster analysis and reduced solvent consumption compared to traditional HPLC. There is a trend towards integrating analytical methods to enhance specificity and sensitivity, such as liquid chromatography-mass spectrometry (LC-MS/MS) for trace analysis, pharmacokinetic studies, and impurity profiling essential for regulations. The development of automated sample preparation and analysis systems aims to boost efficiency in quality control during manufacturing. Additionally, the use of chemometrics and multivariate calibration methods, including Partial Least Squares (PLS) and Principal Component Regression (PCR), alongside UV-spectrophotometry is expanding to improve accuracy and reduce analysis times, particularly in complex samples. Emphasis is also placed on creating robust methods that can accurately differentiate and quantify active pharmaceuticals from degradation products under various stress conditions, including acidic, basic, thermal, oxidative, and photolytic environments. Future methods will require thorough validation according to the International Conference on Harmonization (ICH) guidelines regarding accuracy, precision, linearity, specificity, limits of detection (LOD), limit of quantification (LOQ), and robustness, ensuring compliance with major regulatory bodies like the***
U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Future validation strategies may also incorporate real-time release testing (RTRT) principles for in-line or online process monitoring, advancing beyond conventional post-manufacturing testing. In conclusion, the trajectory is towards more sophisticated, rapid, environmentally friendly, and highly specific analytical methods that adhere to rigorous global regulatory standards.
Keywords: Lansoprazole (LAN); Domperidone (DOM); RP-HPLC methods; Validation.

I. INTRODUCTION

Lansoprazole (Figure 1) is an effective proton pump inhibitor utilized for managing various acid- related disorders, such as ulcers and gastroesophageal reflux disease (GERD), by significantly reducing stomach acid production. It has demonstrated a general tolerance among users, with common side effects including headaches, nausea, and diarrhea, while serious side effects are comparatively rare. Importantly, lansoprazole may provide superior healing results for conditions like ulcers and esophagitis compared to alternative medications such as ranitidine.

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Furthermore, it plays a key role in eradicating Helicobacter pylori bacteria when used in combination with antibiotics (1, 2).

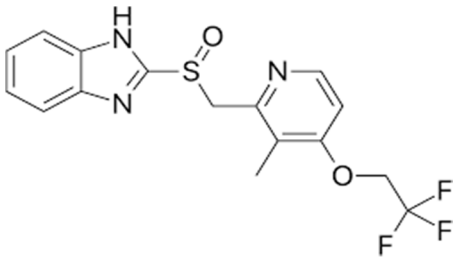


Figure 1: Lansoprazole

The efficacy of lansoprazole extends across multiple acid-related conditions. It effectively treats duodenal ulcers, NSAID-related gastric ulcers, and erosive esophagitis, and it is particularly beneficial for providing symptom relief in GERD, often yielding quicker healing of reflux esophagitis compared to older treatment options. Additionally, lansoprazole is indicated for long- term maintenance therapy to prevent GERD relapse and is employed in treating hypersecretory conditions such as Zollinger-Ellison syndrome (3, 4). Despite its efficacy, users may experience common side effects, including headaches, diarrhea, nausea, vomiting, stomach pain, and dizziness. Management strategies for these side effects involve resting and staying hydrated for headaches, consuming bland foods for nausea, and taking small sips of water to alleviate diarrhea. Although serious side effects are rare, they can include severe allergic reactions, liver issues, or persistent diarrhea. Notably, lansoprazole may inhibit the absorption of essential nutrients such as folic acid and vitamin B12, suggesting that supplementation could be necessary for individuals on long-term therapy. Patients are advised to take lansoprazole as prescribed by their healthcare provider, typically before meals. Long-term users may require folic acid supplementation to counteract potential deficiencies. It is crucial for patients to seek medical advice tailored to their individual health needs when considering or using lansoprazole (5, 6).

Domperidone (Figure 2) is a dopamine antagonist primarily used to treat nausea, vomiting, and gastrointestinal motility disorders. It functions both as an antiemetic, alleviating symptoms of nausea and vomiting, and as a prokinetic agent, enhancing gastric emptying. Notably, it is regarded as safer compared to metoclopramide due to its limited ability to cross the blood-brain barrier, thus minimizing central nervous system side effects. However, its safety profile is under scrutiny, particularly concerning potential cardiac effects and its impact on mental health during lactation (7, 8).

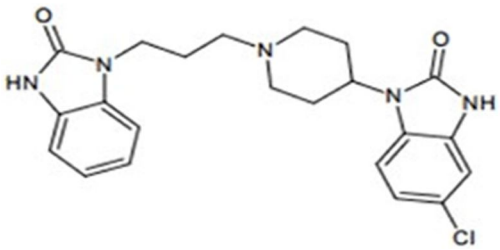


Figure 2: Domperidone

Domperidone acts as a peripheral dopamine antagonist with its effects largely outside the central nervous system. It promotes gastric contractions and accelerates gastric emptying, thereby improving gastrointestinal motility. Additionally, it modifies the activity in the chemoreceptor trigger zone to exert its antiemetic effects (9). Domperidone's peripheral action limits central nervous system-related side effects, such as extrapyramidal symptoms associated with other antiemetics like metoclopramide. However, possible cardiac risks have emerged, particularly concerning heart rhythm disturbances, including a prolonged Q-T interval linked to higher dosages. Reports of severe mental health effects, including anxiety and depression following withdrawal, have led to regulatory reviews in various regions. Additional side effects can encompass irritability, fatigue, headaches, and gastrointestinal discomforts (10). Domperidone is less frequently utilized in the United States in comparison to its availability in other countries, where it may be provided under investigational new drug protocols. Regulatory bodies are particularly focused on its cardiac risks, evaluating its utility during lactation. Furthermore, due to its gastrointestinal effects, there is concern regarding protopathic bias, suggesting that the drug might be incorrectly attributed as the cause of outcomes relating to other underlying conditions, such as heart disease (11, 12).

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II. A REVIEW ON DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF LANSOPRAZOLE AND DOMPERIDONE IN BULK AND CAPSULE DOSAGE FORM

Ertekin ZC et al., 2025 explored that the UV–Vis spectroscopy remains essential in pharmaceutical research and quality control due to its accessibility, simplicity, and effectiveness. However, overlapping spectra resulting from multicomponent drug formulations present challenges. Here, we describe a signal processing strategy using continuous wavelet transform (CWT) to resolve overlapping spectra of domperidone (DMP) and lansoprazole (LSP) for simultaneous quantification. Three different wavelet functions (Symlets 3, Coiflets 1, Daubechies 10), were found to be suitable for this purpose. Linear calibration curves were constructed using the CWT zero-crossing technique and the methods were validated by analyzing a set of synthetic mixtures, intra- and inter-day samples, and standard addition samples. The assay results of commercial capsule samples were compared with those obtained by derivative spectroscopy, and no significant statistical difference was observed. The proposed CWT methods demonstrated good compliance with the label claims and proved to be reliable, versatile, fast, and cost-efficient analytical methods without the need for preliminary separation procedures (13).

Dangariya AV et al., 2025 conducted a study with a objective of stability and related substance studies is to assess how the quality of pharmaceutical substances changes over time under various environmental factors, with a particular focus on impurities that can significantly affect the stability and pharmacological action of active pharmaceutical ingredients (API) and drug products. This is particularly critical in the context of vaccine formulation development. Analytical techniques such as UV spectrophotometric methods (including simultaneous equation methods and Vierodts) and liquid chromatography tandem mass spectrometry (LC MS-MS) are recognized as reliable for the simultaneous estimation of pharmaceutical combinations. The principles of Analytical Quality by Design (AQbD) and Central Composite Design (CCD) are vital for regulatory compliance and are instrumental in developing stability-indicating methods. Despite the availability of Flunarizine and Domperidone in the market for migraine treatment, existing literature indicates a gap: while various analytical methods have been documented for estimating these drugs individually or in combination with others—specifically using UV and RP-HPLC—there is no reported stability-indicating analytical method for the simultaneous estimation of Flunarizine and Domperidone via RP-HPLC. Therefore, it is essential to develop and validate such a method for their combined estimation in synthetic mixtures using RP-HPLC (14).

Kurt Cucu A et al., 2025 Pantoprazole sodium a substituted benzimidazole derivative is an irreversible proton pump inhibitor and was developed for the treatment of acid-related gastrointestinal disorders. As with other drugs of its class (omeprazol or lansoprazole), pantoprazole reduces gastric acid secretion through inhibition of the portion on the gastric parietal cell. Analytical methods for the determination of the active drug ingredient pantoprazole sodium are available in many manuscripts. Pantoprazole sodium, alone or in combination with other drugs, in different pharmaceutical forms, industrial wastewater, and plasma samples using spectroscopic, chromatographic, electroanalytical and thermal analysis methods have been made by many researchers analyzed. Manuscripts were identified that included analytic methods developed to analyze pantoprazole sodium alone or in the presence of other drugs included. In this review, an overview of the analytical methods developed for the determination of Pantoprazole sodium and their validation will be given (15).

Varshini M et al., 2025 developed a simple, precise, and accurate reverse-phase high- performance liquid chromatography (RP-HPLC) method was developed and validated for the simultaneous estimation of pantoprazole and ondansetron in bulk and pharmaceutical dosage forms (16).

Barseem A et al., 2024 developed an environmentally friendly RP-HPLC method for the simultaneous determination of pantoprazole (PAN) and domperidone (DOM). Chromatographic separation was performed using isocratic elution on CORTECS® Shield RP18 column maintained at 25 °C. The mobile phase consisted of ethanol and potassium phosphate buffer (50.0 mM, pH 6.0) in a 30:70 (v/v) ratio, delivered at a flow rate of 1.0 mL/min, with UV detection at 286 nm. The method demonstrated excellent linearity within the concentration ranges of 1.0–25.0 μg/mL for PAN and 3.0–30.0 μg/mL for DOM. It was successfully applied to the analysis of both drugs in bulk and pharmaceutical dosage forms. The greenness of the proposed method was evaluated using the Analytical Eco-Scale, yielding a total score of 83, which indicates minimal environmental impact. The method "whiteness" was assessed using the RGB 12 model, resulting in a high total score of 89.2, reflecting a well-balanced combination of analytical performance, environmental sustainability, and practical implementation. Its "blueness," representing practical applicability, was measured using the BAGI tool and achieved a total score of 82.5. Compared to a previously reported HPLC method, the proposed method offers comparable practical applicability while exhibiting enhanced greenness through the use of ethanol as the organic modifier, rather than environmentally hazardous solvents such as acetonitrile and methanol. The method was fully validated according to ICH Q2(R1) guidelines, confirming its accuracy, precision, specificity, and robustness. Furthermore, the proposed method was statistically compared with a previously reported HPLC method using Student's *t*- test and F-test (17).

Prajapati R et al., 2024 condcuted a study in which a novel bilayer tablet formulation combining itopride, a gastroretentive agent, with domperidone, an immediate release agent, was developed to enhance gastric motility in patients suffering from gastroesophageal reflux disease. The formulation aims to leverage the synergistic antidopaminergic and antiacetylcholine properties of these medications. The optimization of the bilayer tablet was conducted using a quality by design approach, analyzing product performance rigorously. The itopride layer was specifically designed to be gastroretentive, allowing for prolonged retention within the stomach and enabling sustained drug release. To optimize the domperidone layer, an empirical hit-and- trial method was employed, while the itopride layer optimization utilized the Box Behnken experimental design. The study considered three independent variables, which included hydroxypropyl methyl cellulose K 100 M, xanthan gum, and Carbomer 974. The dependent variables analyzed included floating lag time, swellable index, and the percentage of drug released after 24 hours. The formulation process aimed at developing an effective bilayer tablet, supported by the evaluation of quality target product profiles and critical quality attributes. The excipients were selected based on the appropriate timing for drug release, and their quantities were determined in accordance with guidelines set forth in the Handbook of Pharmaceutical Excipients. The resulting optimized compositions were identified as DF5 for domperidone and IH2 for itopride layers of the bilayer tablet. The physical dimensions of the bilayer tablets were formulated into an oblong plain biconcave die and punch, measuring 16 × 8.26 mm. In vitro drug release studies demonstrated that domperidone achieved a release of 99.39% within 30 minutes, whereas itopride exhibited cumulative release percentages of 27.50%, 53.45%, and 93.65% at intervals of 4, 16, and 24 hours, respectively. This advanced formulation offers promising therapeutic benefits in managing gastroesophageal reflux disease through its tailored release characteristics (18).

Taha AS et al., 2023 presented the development and validation of three spectrophotometric techniques—ratio difference (RD), first derivatives (1DD), and mean centering (MC)—for the determination of PAN and DOM in combined pharmaceutical formulations. These methods effectively manipulate the ratio spectra to resolve spectral overlaps, with DOM being measured using the RD method at specific wavelengths (209 and 233 nm) and PAN at 254 and 223 nm. The first derivatives approach allowed for selective determination of DOM and PAN at 215 nm and 249 nm, respectively. Meanwhile, PAN was quantified at 254 nm using the mean centering method, and DOM was quantified specifically at 209 nm. The validation of these procedures adhered to ICH regulations, demonstrating effective analysis of PAN and DOM in pharmaceutical formulations through linear correlations over concentration ranges of zero–52 µg/mL for PAN and 1–18 µg/mL for DOM. These techniques offer accessible, cost-effective, and reliable alternatives to standard chromatographic methods, serving as dependable substitutes for quality control of these medications in combination dosage forms (19).

Dash SK et al., 2022 deals with a detailed discussion of different reported analytical procedures along with their pros and cons and their relevant criteria for quantifying the drug. Various analytical techniques like UV-Visible spectrophotometry, HPLC, HPTLC, hyphenated techniques, etc., are developed to assess the esomeprazole magnesium trihydrate in bulk materials, different pharmaceutical formulations, and biological matrices. Literature survey confirmed that the hyphenated techniques and chromatographic techniques are the best tools for biological matrices. Spectroscopic methods like UV and visible techniques are widely used for pharmaceutical matrices. All of the reported methods are accurate, precise, costeffective, and sensitive (20).

Rajput RS et al., 2022 developed a simple, selective and well-defined stability indicating method for the quantitative estimation of esomeprazole in tablet dosage form using XBridge BEH Shield RP18 (4.6 x 250 mm), 5µm with phosphate buffer pH 7.3 and acetonitrile (740:260%v/v) as a mobile phase and successfully validated as per the ICH guideline. The method was found to be specific, linear, accurate, rugged, and robust. Stress degradation studies were performed by exposing the esomeprazole magnesium delayed release capsules into acidic, alkaline, oxidative, thermal, humidity and photolytic stress conditions as per ICH guidelines. In separate in-vitro experiments, esomeprazole pallets dispersion passed through feeding tubes using gentle syringe pressure to develop a clog-free dispersion-delivery method. Nasogastric tube (8-French [Fr]) and diluents (different pH of water used i.e. pH 5.5, 7.0 and 8.5) were tested. The results showed excellent delivery of esomeprazole pellets using water as a medium for tube delivery. Recovery of esomeprazole pallets dispersion in different pH of water i.e. pH 5.5, 7.0 and 8.5 at “0 and 15” minutes incubation time were nearly 100% in 8-Fr nasogastric tubes (21).

III. FUTURE SCOPE

The future scope for the simultaneous estimation of Lansoprazole (LAN) and Domperidone (DOM) emphasizes the advancement of efficient, sustainable, and high-throughput analytical methods. Key areas of development include: A shift towards developing methods that minimize the use of hazardous solvents, in line with green chemistry principles. This may involve the adoption of supercritical fluid chromatography (SFC) or aqueous-based mobile phases in reverse-phase high-performance liquid chromatography (RP-HPLC).

Research is likely to focus on ultra-high performance liquid chromatography (UHPLC) and chip-based microfluidic systems. These innovations promise faster analysis times and diminished sample/solvent consumption, presenting significant advantages compared to traditional HPLC. Integrating various analytical methods to enhance specificity and sensitivity. This trend includes techniques such as liquid chromatography-mass spectrometry (LC-MS/MS) for trace analysis, pharmacokinetic studies in biological matrices, and impurity profiling, which is essential for regulatory submissions. The development of automated systems for sample preparation and analysis aims to increase efficiency in quality control processes in manufacturing. There is an expansion in using chemometrics and multivariate calibration methods (like Partial Least Squares (PLS) or Principal Component Regression (PCR)) coupled with UV-spectrophotometry to improve accuracy and decrease analysis times, especially in complex sample matrices. A significant focus is on developing robust methods that can accurately separate and quantify active pharmaceuticals from degradation products under various stress conditions, including acidic, basic, thermal, oxidative, and photolytic environments. Future methods will require stringent validation in accordance with international regulatory guidelines to ensure reliability and acceptance: Validation parameters must comply with the International Conference on Harmonization (ICH) guidelines covering aspects like accuracy, precision, linearity, specificity, limits of detection (LOD), limit of quantification (LOQ), and robustness. Validation efforts must align with requirements set forth by major regulatory bodies, including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), with a focus on data integrity and quality by design (QbD) frameworks. Future validation strategies might integrate RTRT principles to facilitate in-line or online monitoring of the manufacturing process, moving beyond conventional end-product testing.

IV. CONCLUSION

In conclusion, the future trajectory is towards more sophisticated, rapid, environmentally friendly, and highly specific analytical methods that comply with rigorous global regulatory standards.

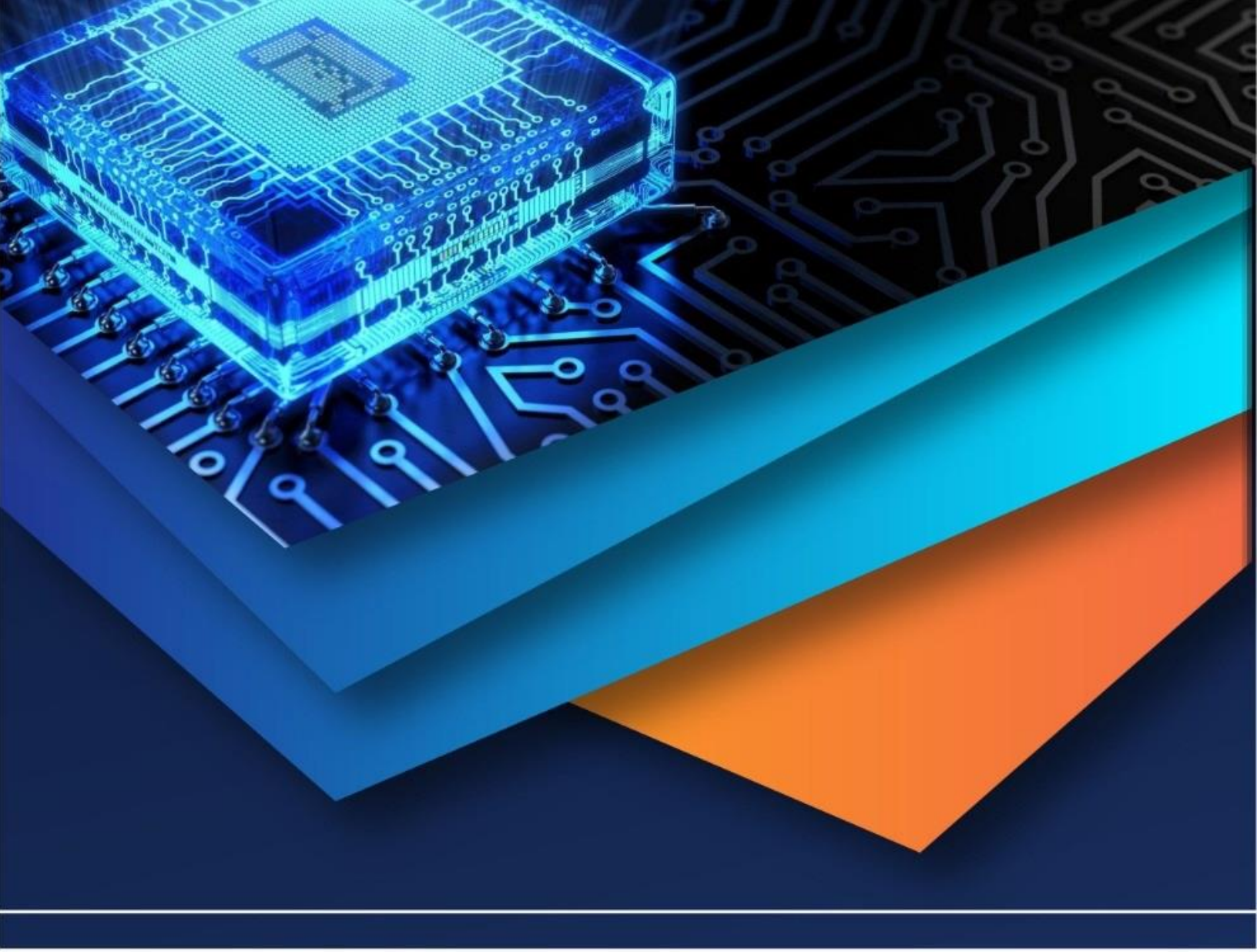
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