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A Review on RP-HPLC Method Development and Validation of Bilastine and Montelukast in Bulk and its Dosage Form

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Abstract: ***Bilastine, a second-generation antihistamine, is recognized for its effectiveness and favorable tolerability in treating allergic rhinitis and chronic urticaria. It offers a safety profile similar to other second-generation antihistamines, such as levocetirizine and desloratadine, but with significantly less sedation when compared to cetirizine due to its inability to cross the blood-brain barrier readily. Montelukast has been reviewed as an effective treatment for controlling symptoms associated with allergic rhinitis and asthma. However, its efficacy when compared to other treatments such as inhaled corticosteroids varies significantly. A major concern regarding montelukast is its potential for serious neuropsychiatric side effects, leading to the issuance of a black box warning by the FDA in 2020. This alert highlights an increased risk of mood alterations, behavioral changes, and cognitive issues, including suicidal ideation. Therefore, patients need to thoroughly evaluate the benefits against these potential risks and communicate any observed changes to their healthcare provider. The future of RP-HPLC method development and validation for the analysis of Bilastine and Montelukast in both bulk and dosage forms is marked by several pivotal trends and advancements. Key among these is the shift towards Ultra-High Performance Liquid Chromatography (UHPLC) or Ultra-Performance Liquid Chromatography (UPLC), which utilize smaller particle size columns, enhancing analytical speed, sensitivity, and resolution while also reducing solvent consumption. Further developments will be guided by the Quality by Design (QbD) framework, a proactive and systematic approach that emphasizes a comprehensive understanding of key parameters. This methodology aims to create robust analytical methods from the beginning, rather than relying on adjustments after the development phase. There is also a strong focus on developing highly selective stability-indicating methods (SIMs) that can effectively separate and measure active ingredients from their degradation products and impurities across various stress conditions, including acid/base hydrolysis, oxidation, thermal, and photolytic stress. In conclusion, the analytical methods for Bilastine and Montelukast are set to advance significantly, moving towards faster, more efficient, and environmentally friendly protocols that leverage technology to enhance data management and regulatory conformity.***
Keywords: Bilastine; montelukast; RP-HPLC methods; stability-indicating methods.

I. INTRODUCTION

Bilastine (Figure 1), a second-generation antihistamine, is recognized for its effectiveness and favorable tolerability in treating allergic rhinitis and chronic urticaria. It offers a safety profile similar to other second-generation antihistamines, such as levocetirizine and desloratadine, but with significantly less sedation when compared to cetirizine due to its inability to cross the blood-brain barrier readily (1).

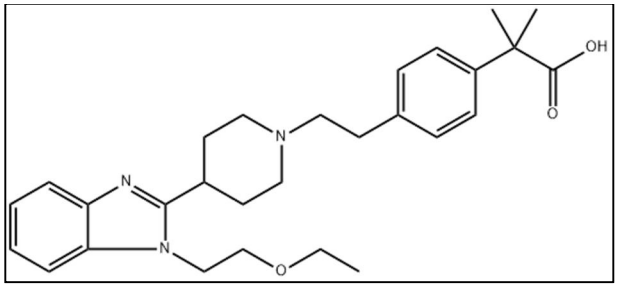

Figure 1: Bilastine

Clinical evidence indicates that bilastine successfully alleviates symptoms associated with allergic rhinitis, such as nasal congestion and ocular discomfort, and provides relief for chronic spontaneous urticaria, with noticeable improvement in symptoms beginning as early as the second day of treatment (2). Research underscores the positive impact of bilastine on quality of life, demonstrating substantial enhancements for patients in these conditions. The medicament is noted for its low incidence of sedation and fatigue, attributed to its pharmacological properties (3). Importantly, bilastine does not exhibit cardiotoxic effects nor prolong the QT/QTc interval at therapeutic doses. The side effects reported predominantly include headaches, yet overall, it is considered well-tolerated across different demographics, including elderly patients, due to its minimal potential for drug interactions (4, 5). In terms of administration, bilastine should ideally be ingested on an empty stomach, as food intake may disrupt its absorption process. Long-term studies validate bilastine's safety and efficacy for ongoing use, reinforcing its role in maintaining symptom control. However, despite robust support from clinical trials, there is a call for further long-term, real-world studies to better understand its effectiveness in a wider array of patient situations (6).

Montelukast (Figure 2) has been reviewed as an effective treatment for controlling symptoms associated with allergic rhinitis and asthma. However, its efficacy when compared to other treatments such as inhaled corticosteroids varies significantly. A major concern regarding montelukast is its potential for serious neuropsychiatric side effects, leading to the issuance of a black box warning by the FDA in 2020. This alert highlights an increased risk of mood alterations, behavioral changes, and cognitive issues, including suicidal ideation. Therefore, patients need to thoroughly evaluate the benefits against these potential risks and communicate any observed changes to their healthcare provider (7, 8).

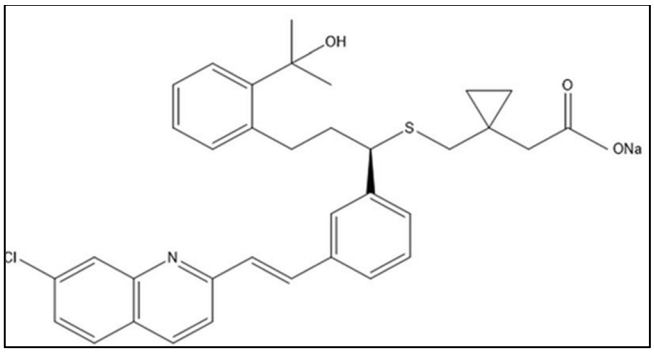

Figure 2: Montelukast

In terms of efficacy, studies demonstrate that montelukast is significantly more effective than a placebo for alleviating allergic rhinitis and asthma symptoms. When compared to other treatment options, its effectiveness for allergic rhinitis is largely comparable to that of antihistamines, although it tends to be less effective than intranasal corticosteroids. In pediatric patients with asthma, montelukast is effective but typically not as effective as inhaled corticosteroids, especially for nocturnal symptoms. However, when used in conjunction with other treatments such as antihistamines or inhaled corticosteroids, montelukast may enhance overall effectiveness (9, 10). Safety concerns primarily revolve around neuropsychiatric events, which encompass a range of issues from mood fluctuations and nightmares to enhanced anxiety, depression, and suicidal thoughts. The FDA's black box warning necessitates vigilant monitoring of patients for such symptoms, underscoring the importance of physician supervision. Additional adverse effects can involve allergic reactions characterized by swelling in the face, lips, tongue, or throat, which demand immediate medical intervention. Individuals with a history of depression or other mental health disorders should approach montelukast usage cautiously, as it may exacerbate existing conditions. It is also important to note that montelukast is not recommended for the treatment of acute asthma attacks (11, 12).

II. REVIEW ON RP-HPLC METHOD DEVELOPMENT AND VALIDATION OF BILASTINE AND MONTELUKAST IN BULK AND ITS DOSAGE FORM

Sahitya LL et al., 2025 developed a simple, precise, sensitive, and rapid reverse phase high-performance liquid chromatography method was developed and validated for simultaneous estimation of bilastine and montelukast in bulk as well as in tablet formulation according to ICH guidelines. The chromatographic phase consisted by methanol and acetonitrile (70:30) at pH 3 adjusted by 0.1% orthophosphoric acid. The flow rate was adjusted to 1 ml/min and ultraviolet detection was carried out at 260 nm. The retention time for of bilastine and montelukast were found to be 3 and 7 min, respectively.

The detector was showed linear responses over the concentration range 25–150 µg/ml for bilastine and 5–30 µg/ml for montelukast a good correlation coefficient of 0.999. This proposed method is highly sensitive, precise, and accurate which reduces cost of analysis, hence recommended for routine quality analysis in laboratories (13).

Sahoo S et al., 2025 developed a simple, accurate, precise method was developed for the simultaneous estimation of the Bilastine and Montelukast in bulk and pharmaceutical dosage form. Chromatogram was run through Agilent C18 150 x 4.6 mm, 5mm. Mobile phase containing Buffer :Acetonitrile taken in the ratio 70:30 was pumped through column at a flow rate of 1.0 ml/min. Buffer used in this method was 0.01N Na2Hpo4 buffer. Temperature was maintained at 30°C. Optimized wavelength selected was 265.0 nm. Retention time of Bilastine and Montelukast were found to be 2.141 min and 2.605 min. %RSD of the Bilastine and Montelukast were and found to be 0.4% and 0.2% respectively. %Recovery was obtained as 99.47% and 99.55% for Bilastine and Montelukast respectively. LOD, LOQ values obtained from regression equations of Bilastine and Montelukast were 0.1, 0.03 and 0.03, 0.10 respectively. % Assay was obtained as 99.74% and 99.72% for Bilastine and Montelukast respectively. Regression equation of is Montelukast y = 45726x + 6306.9, y = 43360x + 810 of Bilastine (14).

Bhandari D et al., 2025 developed an easy and cost-effective analytical methods for simultaneous quantification of BLN and MLS. A C18 column (25 cm × 0.46 cm, 5 µ) as a stationary phase and methanol:0.5% orthophosphoric acid (80:20, v/v) as an eluent with a flow rate of 1.0 mL/min were used for HPLC separation, while a stationary phase, readymade silica gel G60F254 plate and mobile phase, Chloroform:Benzene:Methanol:Ammonia (3:5:2:0.2, v/v/v/v) with chamber equilibrium time of 40 min were used for HPTLC separation. Validation of both methods was performed according to ICH quality guidelines (Q2R1). BLN and MLS were eluted at 3.303 min and 5.570 min, respectively, and the retardation factor was observed, respectively, to be 0.29 and 0.45. Both methods passed validation parameters and were used for the assessment of BLN and MLS in commercial tablets. The given HPLC and HPTLC methods were simple, sensitive, accurate, robust and can be applied for regular quality analysis of dosage forms containing BLN and MLS (15).

Kodishala RK et al., 2025 introduced a novel ultra-performance liquid chromatography (UPLC) method for the rapid, simple, and accurate detection of contaminants in bilastine (BLS) and montelukast (MTK) tablet formulations. In a runtime of just 20 minutes, 13 analytes were successfully separated. The retention times for the target compounds and impurities were as follows: BLS impurity-A: 1509 min, BLS impurity-B: 3435 min, BLS: 5668 min, MTK impurity-A: 8137 min, MTK: 9784 min, MTK impurity-B: 11,853 min. The unspecified impurities in the degradation samples were detected at retention times of 2174, 2657, 3368, 4143, 8239, 11,722, and 12,436 minutes, and were characterized using liquid chromatography-mass spectrometry (LC-MS). The UPLC-based analytical method demonstrated in this study is an effective and efficient technique for the quantification of BLS, MTK, and their associated impurities in tablet formulations. This method has been validated in accordance with ICH Q2(R2) and USP <1225> guidelines (16).

Rathod SM et al., 2025 carried out a study in which the degradation products (DPs) of Bilastine and Montelukast sodium have been identified and characterized utilizing a unique liquid chromatography-tandem mass spectrometry (LC–MS/MS) technique. Both medications are anti-allergic, and they were subjected to hydrolysis, oxidation, photolysis, and heat stimuli in accordance with International Council for Harmonisation guidelines. The drug products were stable under thermal and photolytic stress. Six DPs were found and resolved. The drug and its breakdown products were separated chromatographically on an Agilent Zorbax C18 (150 × 4.6 mm, 5µm) column with an eluent of 10 mM ammonium acetate (pH 4): acetonitrile (25:75, v/v). The hypothesized structure of DPs and their corresponding routes are based on precise mass and MS/MS fragmentation patterns; obtained using LC-ESI-TQ-MS/MS. The suggested degradant structures and pathways will be crucial for optimizing the production and quality control parameters of the pharmaceuticals under consideration (17).

Sasikala L et al., 2025 proposed a particular, accurate, simple, and speedy HPLC approach for detecting impurities in Bilastine (BLS) tablet formulations. A gradient mode elution buffer solution (10 mm Potassium dihydrogen phosphate and 10 mm Di-Potassium hydrogen phosphate) employed as mobile phase-A, acetonitrile used as as mobile phase-B, facilitating optimized chromatographic separation with X Bridge Shield RP18 (150 × 4.6 mm) 3.5 µm column. The detection was performed at 254 nm using a 10 µL injection volume, 40 °C column temperature, and 1.0 mL/min flow rate. The method was validated using the current regulatory guidelines. The recovery for impurities found between 94.4 and 107.2, with precision data ranging from 0.53 to 1.97. The impurities were linear, with correlation coefficient values greater than 0.999. Specificity was proven with degradants and the method stability indication nature was proven by forced degradation studies in-line with regulatory guidelines. Quality by design concept was utilized to demonstrate the method robustness. Solution stability established up to 72 h for using the solutions for longer times. The validation results show that the suggested approach is specific, accurate, linear, precise, rugged, and resilient for quantifying impurities in tablet formulation (18).

Pethani T eta l., 2025 developed a new and reliable LC-ESI-MS method to identify Dextromethorphan, Phenylephrine, and Bilastine in a fixed dose combination and mass-spectrally characterise each degradation product. Chromatographic conditions were carefully adjusted using a gradient elution with 20Mm ammonium acetate as mobile phase-B and methanol:acetonitrile (8:2 v/v) as mobile phase-A. Separation took 20 minutes using an Enable C18 column. Regression coefficients (R2) for all analytes above 0.999, indicating that the technique exhibited high linearity across concentration ranges of 3.3-66 µg/mL for bilastine, 5-100 µg/mL for phenylephrine, and 10-200 µg/mL for dextromethorphan. Phenylephrine, bilastine, and dextromethorphan were found to have limits of detection (LOD) of 0.202, 0.0785, and 0.110, respectively, and limits of quantification (LOQ) of 0.612, 0.238, and 0.334. A range of stress conditions, including acidic, basic, oxidative, thermal, and photolytic, were utilised to conduct forced deterioration studies. According to the ICH (Q2) R2 Guideline, the validation parameters-precision, robustness, accuracy, and recovery-performed exceptionally well, with the relative standard deviation (RSD) being less than 2%. For quality control analysis and stability evaluation of the designated combination medication product, this approach provides a reliable instrument (19).

Pachauri AD et al., 2024 developed and validated RP-HPLC method for the estimation of Bilastine and Montelukast sodium in tablet dosage from. Ofloxacin was used as an internal standard. The HPLC system used for analysis was JASCO, PU 2075plus, UV 2080 plus with a column Qualisil 5 BDS-C18 (250 mm x 4.6 m, 5 µm). Acetonitrile: potassium dihydrogen phosphate buffer (pH adjusted to 6.2 with TEA) in the ratio of 38:82 was used as mobile phase. The optimized conditions were: flow rate (1.2 ml/min), wavelength (254 nm), injection volume (20 µl), working time was 10 minutes. The retention times of Bilastine, Ofloxacin, and Montelukast sodium were found to be 3.017min, 4.367min, and 7.342min respectively. % Assay was found to be 101.13% for Bilastine and 99.67% for Montelukast sodium. The linearity range of Bilastine and Montelukast sodium were found to be 2-14 µg/ml and 4-28 µg/ml with a correlation coefficient (r2) of 0.9994 and 0.9998 respectively. % Recovery was obtained as 99.91%-100.56% and 99.45%-100.38% for Bilastine and Montelukast sodium respectively. LOD and LOQ was found to be 0.107µg/ml and 0.325µg/ml for Bilastine and 0.412µg/ml and 1.248µg/ml for Montelukast sodium. The analytical method was validated as per ICH guidelines. The method was robust and rugged as observed from insignificant variation in the results of analysis by changes in flow rate and mobile phase composition separately and analysis being performed by different analysts (20).

Usha K et al., 2024 developed an easy-to-use, precise method was developed for the simultaneous estimation of bilastine and montelukast in bulk and tablet dose form. Chromatogram was run through Inertsil C18 150 x 4.6 mm, 5µm. mobile phase comprising 0.01N disodium hydrogen phosphate and in the ratio of (70:30) was pumped through column at a flow rate of 1.0ml/min. 30°C was kept as the temperature. The chosen optimized wavelength was 230.0 nm. Retention time of Bilastine & Montelukast were 2.523 min & 3.140 min respectively. Bilastine &Montelukast %RSD were determined to be 1.2 and 0.6% respectively. %Recovery of Bilastine & Montelukast were 99.55% & 99.51 %respectively. Bilastine & Montelukast ’s regression equation yielded LOD and LOQ values of 0.16,0.48ppm and 0.12,0.36ppm. Bilastine regression equation is y = 62266x + 12857 and Montelukast regression equation is 72927x + 8987. Stability experiments of Bilastine & Montelukast under distinctive environments of stress were also performed. As a result of shorter retentions durations and shorter run times, the method was created to be straightforward and cost-effective, and it may be used for routine Quality Control Tests in Industries (21).

Kunala A et al., 2024 developed and validated a new RP-HPLC method for estimation of Bilastine and Montelukast in bulk and in their combined tablets. A good separation of both analytes in various types solutions was attained by using a Ascentis C18 (150 x 4.6mm, 2.6µ) column with a solvent or mobile phase of 0.1% OPA: acetonitrile (50:50 v/v) at a flow rate of 1ml/min and a detection wavelength of 230nm. To test the stability of the analytes, the drug substance was put in an environment with a lot of stress, such as hydrolysis with acid and base, peroxide oxidation, and thermal degradation. At at 2.25min and 2.78 min, Bilastine and Montelukast were eluted with isocratic elution. The method is expected to show a linear response from 2.5 to 15µg/ml for Bilastine and from 5 to 30 µg/ml for Montelukast. Bilastine's LOD and LOQ were establishe to be 0.1and 0.31µg/ml, while Montelukast's were 0.3 and 0.91µg/ml. From the Bilastine and Montelukast peaks, the degradant peaks that were made were easy to tell apart (22).

Kolekar BD et al., 2024 carried out a study in which the simultaneous equation method was chosen based on the spectral characteristics. A 50% alcohol solvent was utilized, with absorbance measurements taken at wavelengths of 274.5 nm for bilastine and 351.5 nm for montelukast sodium. Various input variables affecting spectrum characteristics were analyzed to determine critical parameters, and the method was validated according to the ICH Q2 R1 regulatory guidelines. The linearity for BSE was confirmed over a concentration range of 1-32 mcg/ml, while for MKS, it ranged from 1-20 mcg/ml. Results indicated a percentage purity of assay at 98.09% for BSE and 103.62% for MKS. The accuracy data showed variations between 0.2523 to 0.5221 for BSE and 0.2512 to 1.2515 for MKS. Precision studies yielded acceptable standard deviation values ranging from 0.1902 to 0.5773 for BSE and from 0.2828 to 0.5458 for MKS.

In conclusion, the developed analytical method is robust, reliable, and efficient for estimating BSE and MKS in their dosage form compositions. The implementation of QbD facilitated the creation of a stable method through early risk assessment and the definition of design space in later stages of development (23).

Swathi L et al., 2023 developed a simple, accurate, precise method was developed to estimate Bilastine and Montelukast in bulk and tablet form. Chromatogram was run on Std Inertsil C18 150 x 4.6 mm, 5m. Mobile phase with Buffer 0.01N Na2HPO4: Acetonitrile 70:30 was pumped through column at 1.0ml/min. Method buffer was 0.01N Na2hpo4. The temperature was 30°C. The optimal wavelength was 218nm. Bilastine and Montelukast had 2.524 and 3.153min retention times. Bilastine and Montelukast had 0.9 and 1.2 %RSD. Recovery was 99.98% for Bilastine and 99.48% for Montelukast. Bilastine and Montelukast regression equations yielded LOD, LOQ values of 0.32, 0.97, and 0.24, 0.72. Montelukast regression equation is y = 36464x + 8987, while Bilastine is y = 31133x + 12857. The method developed was simple and economical for regular quality control tests in industries because retention and run times were reduced (24).

Ahmed A et al., 2023 proposed to develop and validate the RP-HPLC method for Bilastine (BIL) and Montelukast (MKT) by QbD to substantiate the RP-HPLC analysis as per ICH validation guidelines. Quality by Design (QbD) allows the accomplishment of specific unsurprising quality with a predetermined and wanted determination. The simultaneous estimation of BIL and MKT was performed with C18 (4.6×250 mm, 5-µm particle size) with an LC-10AD pump and PDA detector. The mobile phase employed methanol and ammonium acetate buffer pH-3.6 at 85:15 v/v. The flow rate was maintained at 1.0 ml/min, and BIL and MKT were detected at 249nm and 293 nm by UV detector, respectively. The HPLC method provided linear responses found in the 200–600 µg/ml range. The correlation coefficient was 0.9995 for BIL and 0.9991 for MKT. The LOD and LOQ for BIL and MKT were found to be 0.493, 1.495 µg/ml, and 0.693, 2.100, respectively. The percentage recovery for BIL was 95.33 to 102.06, and for MKT was 96.31 to 104.05, respectively. Calculated information acquired for both the preliminaries roughly coordinates with the information given by Design expert programming, showing the chromatographic condition's genuineness. Design-Expert version 10 ("DX10") software has calculated this calculation, setting a composite design of significant parameters. A new selective, rapid, accurate, precise, and sensitive RP-HPLC method was developed and evaluated for the simultaneous determination of Bilastine (BIL) and Montelukast sodium (MKT) in a bulk and pharmaceutical dosage form. This method is useful in the routine quality analysis of combinations of BIL and MKT in bulk and its tablet formulations (25).

Roshdy A et al., 2023 employed the Quality by Design (QbD) approach, which facilitated accelerated method development and robustness testing. A full factorial design was utilized to assess the impact of variable factors on chromatographic responses. The separation was conducted via isocratic elution using a C18 column, with the mobile phase composed of 92% methanol, 6% acetonitrile, and 2% phosphate buffer containing 0.1 (v/v) triethylamine, adjusted to pH 3. The flow rate was maintained at 0.8 mL/min with an injection volume of 20 µL. Additionally, this method demonstrated stability-indicating capabilities, particularly for Montelukast (MNT), which underwent rigorous evaluation under various stress conditions including hydrolytic (acid-base), oxidative, thermal, and photolytic stress. Each stress condition revealed significant degradation pathways for MNT, which exhibited pseudo-first-order kinetics under the experimental setup. Consequently, the kinetic parameters for degradation, such as rate constant and half-life (t1/2), were determined, and a degradation pathway was proposed based on the findings (26).

III. FUTURE SCOPE

The future scope for the development and validation of the RP-HPLC method for analyzing Bilastine and Montelukast in both bulk and dosage forms is characterized by several key trends and advancements. A significant advancement is the transition to Ultra-High Performance Liquid Chromatography (UHPLC) or Ultra-Performance Liquid Chromatography (UPLC), which employs smaller particle size columns to enhance speed, sensitivity, and resolution while minimizing solvent usage. This shift represents a fundamental move from traditional HPLC techniques. Future method development will increasingly leverage the Quality by Design (QbD) approach, a systematic and risk-based methodology that promotes a profound understanding of critical parameters, thereby ensuring more robust methods from the outset instead of relying on post-development optimizations. Additionally, there is a strong emphasis on creating highly selective stability-indicating methods (SIMs) capable of separating and quantifying active ingredients from degradation products and impurities under various stress conditions, including acid/base hydrolysis, oxidation, thermal, and photolytic stress. The future landscape will also witness the integration of RP-HPLC with mass spectrometry techniques (LC-MS or LC-MS/MS), which will enhance analytical capabilities, allowing for definitive identification and quantification of impurities or degradation products, essential for complying with stringent regulatory standards. Moreover, automation in sample preparation and injection, coupled with artificial intelligence (AI)-integrated software for method optimization and predictive analytics, will significantly streamline analytical workflows, improving consistency and decreasing the time and costs associated with analyses.

Prioritizing green chemistry principles will guide future methodologies, focusing on minimizing hazardous solvent use, reducing waste, and developing techniques that align with environmental and safety regulations. Furthermore, advancements in miniaturization technology, such as micro- or nano-LC systems, will facilitate the reduction of sample sizes and solvent consumption, enhancing efficiency and portability in analytical processes.

IV. CONCLUSION

In conclusion, the analysis of Bilastine and Montelukast is poised to evolve towards methodologies that are faster, more efficient, environmentally friendly, and highly specific, harnessing advanced technologies to improve data management and ensure regulatory compliance.

Conflict of Interest
None

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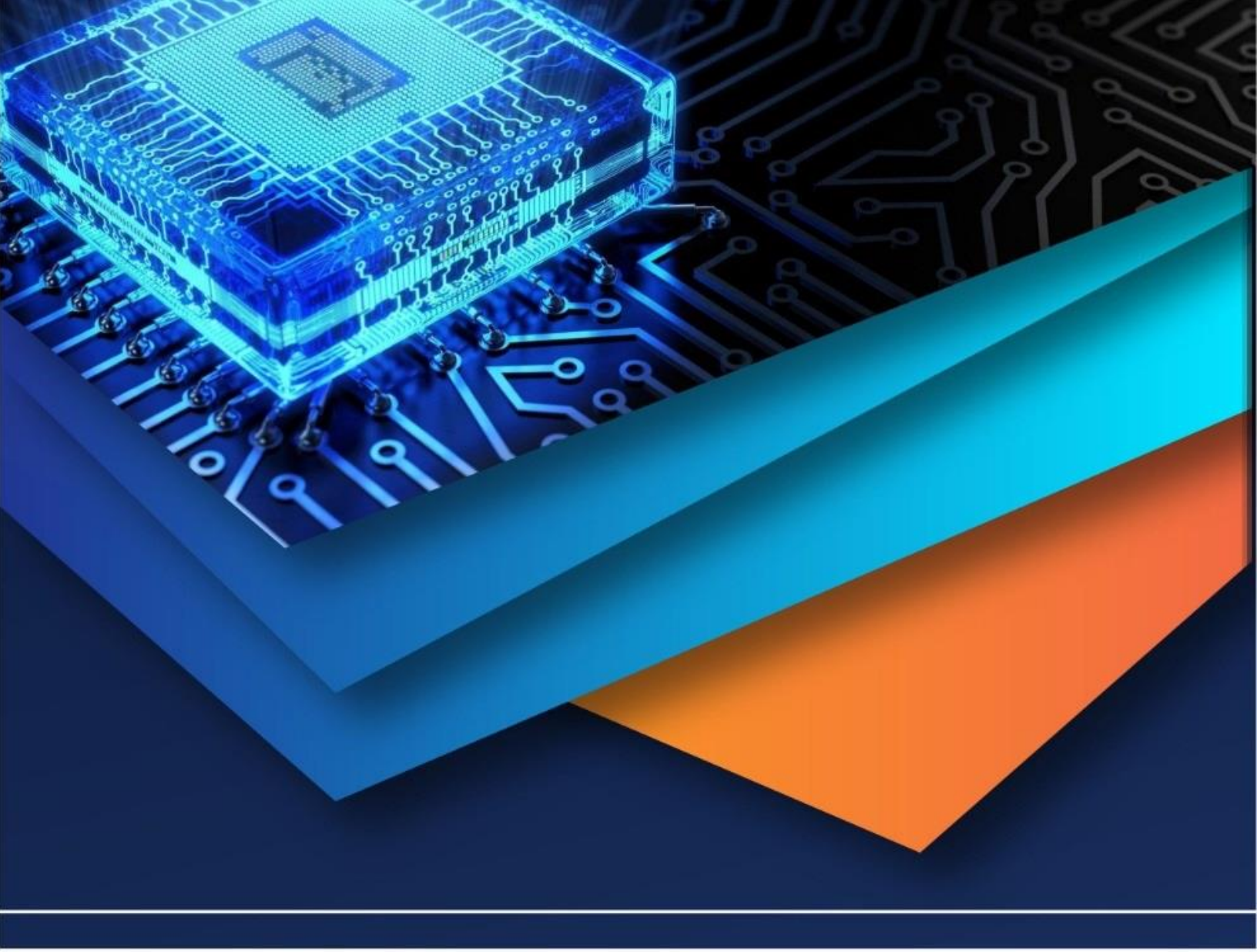

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