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Design and Characterization of a Mushroom-Enriched Chewable Supplement for PCOS Management

Ms. Varsha Rane[1], Mr. Yash Thakur[2], Ms. Utkarsha Shinde[3], Mr. Chinmay Parab[4], Ms. Neha Dhumal[5], Mr. Aryan Keer[6], Mr. Atharv Patil[7]
[1, 2, 3, 4, 5]*V P College of Pharmacy, Madkhol-Swantwadi*

Abstract: ***polycystic ovarian syndrome, is a common reproductive illness which impacts several metabolic processes along with a number of relate Type 2 diabetes, obesity, cardiovascular disease, and insulin resistance (IR) are all made more likely by it. A consensus diagnosis among physicians is challenging because to the subjective phenomenology and the disease's unknown aetiology. A mix of genetic and environmental variables seems to be the root cause of this familial genetic condition. The medical disorders. Anovulation, polycystic ovaries, and hyperandrogenism are signs of PCOS. In first-degree relatives, it has been correlated with issues with metabolism. Nutraceuticals—natural bioactive compounds with health benefits— have emerged as promising adjuncts in the management of PCOS. This study focuses on the formulation and evaluation of nutraceuticals gummies designed to support hormonal balance, metabolic function, and overall reproductive health in women with PCOS. Key active ingredients including Vitamin D, Terpenoids, Curcumin, Cinnamon aldehyde, inositol. The gummy dosage form was chosen for enhanced patient compliance, palatability, and ease of consumption. Preliminary evaluations demonstrated good organoleptic properties, stability, and efficacy potential. This novel delivery system may serve as an effective, user-friendly alternative to conventional supplements, potentially improving adherence and outcomes in PCOS care.***
Keywords: PCOS, Anovulation, Hyperandrogenism, Chewable gummies, Genetic mutation

I. INTRODUCTION

The common reproductive disorder referred to as polycystic ovarian syndrome (PCOS) alters a number of metabolic processes, increasing an individual's risk of developing Type 2 diabetes, obesity, cardiovascular disease, and resistance to insulin. Because of the wide range of symptoms and the unknown underlying reasons of PCOS, diagnosing the disorder can be challenging for healthcare professionals [(1)]. PCOS is believed to be a hereditary disorder, resulting from a combination of environmental and genetic factors. Anovulation (absence of ovulation), polycystic ovaries, and hyperandrogenism (high levels of male hormones) are among the main markers for PCOS [(2)]. In accordance to research, relatives in the first degree of those with PCOS are more likely to have problems with metabolism. In fact, as much as 30% of cases of infertility in couples seeking therapy have been attributed by PCOS. Although PCOS is becoming more prevalent, there is presently no FDA-approved therapy for it [(3)]. There hasn't been much comprehensive study on the syndrome, therefore this review will look at what we now know about PCOS and consider prospective future approaches for management and treatment [(1,3)]. Up to 30% of infertility cases in couples seeking treatment are caused by PCOS, thus making it one of the leading causes of infertility. Even though PCOS is becoming more and more common, there is presently no treatment for the disorder.

II. PATHOPHYSIOLOGY

PCOS has a complex and unknown pathophysiology. PCOS is a long-term condition. Stein and Leventhal presented the first overview of it in 1935. PCOS is a metabolic, heterogeneous, and reproductive illness. Ovulatory dysfunction1, gonadotropin release, and insulin resistance are some of the pathogenic mechanisms that cause PCOS. [(7)]

A. Excessive Androgen Secretion

Adrenal, Ovarian, and Androgen Excess: PCOS is typified by an excess of androgen generated by either the adrenal glands or the ovaries. Excess levels of adrenal androgens, especially dehydroepiandrosterone sulphate (DHS), are observed in more than 50% of patients with polycystic ovarian syndrome (PCOS). However, the exact mechanism underlying the excess of adrenal androgen is yet unknown. [(7,8)]

B. Development Of Insulin Resistance

The primary pathogenic factor in PCOS is insulin resistance. Women with PCOS often suffer from hyperinsulinemia and insulin resistance. The insulin resistance in PCOS has been detected in adipocytes by post binding damage in the insulin receptor mediated transmission of signals in skeletal muscle, which is caused by an excess of androgen that enhances insulin resistance in peripheral tissues. Obesity contributes to the insulin resistance caused by PCOS and causes hyperandrogenism, hirsutism, infertility, and irregular menstruation. With a BMI of over 30 kg/m2, obesity impacts 30–60% of PCOS patients and is linked to hyperinsulinemia. Insulin resistance occurs in even thin women with PCOS, and it becomes worse as their body- mass index (BMI) increases. (7,9)

C. Hirsutism

Different cultures and ethnic populations have various opinions regarding hirsutism, which is frequently seen as a clinical sign of hyperandrogenism. Depending on these variables, the views of individuals of hirsutism as a problem may differ significantly. The Ferriman-Gallwey score is a commonly employed method for clinical evaluation; a score of eight or higher is typically considered as diagnostic. It's necessary to keep in mind that this evaluation is highly personalised and subjective. The prevalence of hirsutism ranges from 60–70% among Caucasian women and about 30% among Japanese women. Because hyperinsulinism boosts the body's sensitivity to the hormone ACTH, it can give rise to an elevated level of adrenal androgens in women with PCOS, worsening the condition. [8,9,10]

D. Infertility

Chronic anovulation, a condition where the ovaries fail to regularly release eggs, is the main cause of fertility issues in women with PCOS. However, research studies have additionally shown that women with PCOS who are normo-ovulatory—that is, they ovulate—but still infertile, as well as those who fail to have pregnancies repeatedly, frequently develop polycystic ovaries on ultrasound technology. Elevated luteinizing hormone (LH) levels throughout the follicular phase of the menstrual cycle may be responsible for this subfertility. This can lead to an early resumption of the oocyte's second meiotic division, which may result in prematurely releasing of the egg. [6,8] Even though the precise mechanism relating PCOS to miscarriage still remains unidentified it is believed that a number of factors associated with oocyte maturation, folliculogenesis (the growth of ovarian follicles), steroidogenesis (the production of hormones), and decreased endometrial receptivity all serves an essential role in the cycle that links PCOS to an increased probability of miscarriage. Additionally, the persistent chronic anovulation and elevated oestrogen levels in women with PCOS over time may increase the risk of endometrial hyperplasia (thickening of the uterine lining) and even endometrial cancer. Women with PCOS are found to have a higher incidence of these conditions. Moreover, obesity and type II diabetes, which are common among women with PCOS, further elevate the risk of endometrial cancer. [9,11]

III. HERBAL DRUG

Medicinal preparations containing active compounds derived from one or more plant components (leaves, flowers, seeds, roots, bark, or stems) are known as herbal medications. These medications come in a variety of forms, including teas, extracts, ointments, tablets, powders, and capsules [12,13]. Compared to traditional medications, herbs are generally thought to be safe and have fewer adverse effects. Ayurvedic medicine has a longer duration of action and can help women with PCOS heal naturally (14). According to research on the use of medicinal plants in polycystic ovarian syndrome, the herbal extracts were found to be beneficial in treating PCOS and to enhance ovulation, insulin resistance, sex hormone levels, and PCOS symptoms [14,15].

Medications made from plants and plant extracts are referred to as herbal pharmaceuticals, botanical medicines, or phytomedicines. Herbal medicines have been a mainstay of traditional healthcare for thousands of years in a variety of civilizations, including Native American healing methods, Traditional Chinese Medicine, and Ayurveda in India. Herbal remedies are once again in the news around the world due to the renewed interest in natural and holistic health methods [16,17]. One well-known form of complementary treatment is herbal medicine Grifols frondosa is an herbal remedy that improves ovarian function and irregular menstrual cycles, which increases fertility and ovulation. However, a very small percentage of PCOS patients who took Grifols frondosa experienced mild epigastric pain and distention [18]. Herbal drugs represent a valuable fusion of traditional knowledge and modern science. While they offer significant benefits as natural remedies, their effective use requires proper education, regulation, and research. With increasing awareness and integration into modern medicine, herbal drugs have the potential to contribute significantly to global healthcare in a safe and sustainable manner [19].

Here are some herbal ingredients used in treatment of PCOS:

A. Maitake Mushroom

The Maitake mushroom (Grifols frondosa), an edible fungus belonging to the Polyocracies family and Aphyllophorales order, has been traditionally valued in Asian medicine for its potential health benefits. Modern research has begun to validate some of these traditional uses, particularly its role in blood sugar regulation. Scientists have identified a specific extract from Maitake, known as *SX-fraction*, as the component responsible for lowering blood glucose levels. SX-fraction is a glycoprotein with an approximate molecular weight of 20,000 Daltons and has shown promise in reducing insulin resistance and related conditions, such as polycystic ovary syndrome (PCOS).

In our recent pilot study, we explored SX-fraction as a potential natural treatment for PCOS. Encouragingly, the extract was effective in promoting ovulation, a key concern for individuals affected by this condition. These findings were presented at the 22nd Annual Meeting of Traditional Medicines in Tokyo, highlighting SX-fraction's potential as a complementary therapeutic option. Given Maitake's long-standing use in traditional medicine, its growing recognition in scientific communities is significant. Recent studies have supported its beneficial properties—particularly its ability to reduce inflammation, regulate hormonal balance, and improve insulin sensitivity. These qualities make it a promising natural approach for managing PCOS symptoms and improving reproductive outcomes.

B. Button Mushroom

The common mushroom (Agaricus bisporus) is the most widely cultivated, harvested and consumed edible mushroom in the United States. Apart from being good for cooking, it is rich in bioactive compounds such as phenols, polysaccharide, vitamins, traces minerals and sterols such as ergosterol (26). These substances possess several pharmacological properties, including immunomodulation, anti-inflammatory, antioxidant, anticancer, and metabolic activities (27). PERSPECTIVE This review presents the most recent studies in the field of biological research and applications in chronic diseases, and synthesizes the knowledge of nutritional profile, therapeutics benefits and therapeutic potential of button mushroom (26,28).

C. Turmeric

One type of yellow polyphenol is curcumin. It is taken from the rhizome of turmeric, a plant native to tropical Southeast Asia. Recent research in obese and diabetic mice models demonstrated curcumin's anti-inflammatory, anti-diabetic, and anti-obesity properties. Numerous female reproductive illnesses, including PCOS, ovarian diseases, and endometriosis, can benefit from curcumin [31]. According to Mohammadi et al., curcumin's anti-inflammatory and antioxidant properties for PCOS may be due to its inhibitory effect on serum interleukin-6 (IL-6), tumour necrosis factor-alpha (TNF α), and C-reactive protein (CRP) expression levels [32]. Body weight, glycaemic control, blood lipids (except from triglycerides and VLDL cholesterol), and the expression of the genes for the low-density lipoprotein receptor (LDLR) and peroxisome proliferated-activator receptor gamma (PPAR-γ) were all improved after 12 weeks of PCOS. In PCOS patients, curcumin even decreased oxidative stress and problems linked to apoptosis [32,33,34]. Curcumin's impact on lipid profiles and glycaemic management in PCOS was examined in recent research. In this study, however, we examined the information regarding curcumin's inherent processes and protective benefits against the pathophysiology of PCOS [35].

Hyperglycaemia Type 2 diabetes mellitus (DM2) is associated with PCOS, a metabolic disorder that starts with hyperglycaemia and gradually progresses to insulin resistance [50,85]. Up to 70% of women with PCOS have insulin resistance [61]. Women with PCOS may go from impaired glucose tolerance (IGT) to DM2 more quickly and experience impaired glucose metabolism earlier in life [86]. As a compensatory mechanism, endogenous insulin production frequently rises in conjunction with insulin resistance. High levels of endogenous insulin are associated with insulin resistance, and weight increase exacerbates insulin resistance [87,88]. This vicious cycle keeps going until hyperglycaemia occurs because pancreatic beta-cell activity is unable to keep up with the elevated insulin demand brought on by insulin resistance. When there is a persistent mismatch between insulin production and demand, known as hyperglycaemia, glucose levels rise to levels compatible with DM2. Curcumin's ability to prevent hyperglycaemia. By inducing the glucose, HBA1c, FIS, FBG, and HOMA-IR and suppressing insulin synthesis, stressors raise insulin resistance. The stage of hyperglycaemia is established. However, in curcumin-induced animals, the hyperglycaemia stage is downregulated and insulin production is elevated.

D. Cinnamon

Cinnamon is one of the world's most popular medicinal plants, with a range of potential health benefits. Through activation of phosphatidylinositol 3-kinase in the insulin signalling pathway and up regulation of sensitivity to insulin, cinnamon might offer a potential therapy for women with PCOS (38). Consistent with this, there is also increasing evidence suggesting inositol is necessary for insulin sensitivity and activity, a possible key target for PCOS sufferers. Moreover, inositol has a beneficial effect on several aspects of the metabolic syndrome (e.g. blood pressure, the concentration of triglycerides and glucose tolerance). Sequentially, they are intermediaries of insulin- mediated glucose consumption in the cell. In oocytes and follicular cells, myo-inositol functions as an inositol and is a second messenger of the luteinizing hormone (LH) and follicle-stimulating hormone (FSH) signalling pathways. Human follicular fluid myo-inositol concentrations determine follicular maturity and oocyte quality. In addition to being one of the most widely used spices worldwide, this kind of herbal remedy is also overused in PCOS (40). There isn't a comprehensive systematic review that summarizes the results of the numerous studies that have already assessed the possible effects of cinnamon on weight fluctuations, glycaemic control, dyslipidaemia, ovarian hormones, androgen levels, biomarkers of inflammation, oxidative stress, and other metabolic variables in PCOS (41).

E. Aloe vera

Aloe vera, a plant of the family Liliaceae, possesses another secondary metabolite including anthraquinone derivatives, flavonoids, phytosterols and polyphenols. Barbaloin and aloe emodin are the two major constituents of aloe vera (42). The women treated with aloe vera gel exhibited enhanced steroidogenic activity and a partial restoration of oestrous cyclicity. Similarly, in rat preclinical studies, in vivo treatment with aloe vera reduced ovary weight, and inhibited both 3β-HSD and 17β-HSD activity, thereby implicating diminished androgen secretion in general (42,43). It also increased oestrogen synthesis by augmenting the flow of steroidogenesis pathway.

F. Gummies

Gummies investigate the covert advantages of a quick-acting and potent lozenge form. In addition to being used for taste masking, gummies can be used by children, the elderly, and those in the palliative care. Every year, more than 700,000 people lose their lives to self- murder. The fourth most common cause of mortality for people aged 15 to 29 is self-murder. 1 Medicated chewing epoxies are solid, one-time-use drugs that contain one or more active ingredients that are released when the bite occurs. Compared to tablets or liquid formulations, this medication delivery system offers new patient benefits and compliance, with the remedial system not being swallowed, which improves patient adherence, particularly in elderly and young patients with swallowing disorders; also, the product is portable [(46)].

Since CGTs are simpler to chew or swallow than other dose forms like tablets or capsules, they have recently been created as nutraceuticals. As a result, they are frequently utilized in elderly, paediatric, and swallowing disorder patients. Chewable gummy tablets (CGTs), sometimes referred to as confectionery gel or gummy candy, are made of sucrose or syrup with a gelling ingredient such pectin, gum, or gelatine. This formulation can also contain other excipients, such as flavouring, colouring, and acidulant [(47)].

The world is well aware of how delicious gummies are and how much people love them. Gummies are soft, sugary, chewable candies that, as we all know, make us happy when we eat them. These days, gummies come in a wide range of forms, hues, tastes, and types. In addition to the confectionery industry, the pharmaceutical and nutraceutical sectors have also embraced them to promote lucrative ventures through the incorporation of nutritional and therapeutic components into gummies. Today stores are crowded with assortments of gummy-based products in the form of substitution for nutritional inadequacies. They can be referred to as health promoters [(46,48)].

Types of gummies [(48)]

1. Based on application
   a. Medicated gummies (Health gummies)
   b. Candy gummies
2. Based on ingredients
   a. gelatine gummy
   b. Pectin gummy
   c. Starch based gummies
   d. Fructose based gummies

Medicated Chewable Gummies

Gummy confections, sometimes referred to as confectionary gel or chewable gummy tablets (CGTs), are made of sucrose or syrup with a gelling ingredient such pectin, gum, or gelation. These formulations can also contain other excipients, such as flavouring, colouring and acidulants. Since CGTs are simpler to chew or swallow them other dosage forms like tablet or capsule, they have recently been created as nutraceutical goods. As a result, they are frequently utilised in elderly, paediatric, and swallowing disorder patients. A gelling agent is use in the formulation of CGTs as the products vehicle. A variety of hydrocolloid materials, including gum, sodium alginate, pectin, and gelatine, function as gelling agents.

Because it has a major impact on the physiochemical characteristics of these products, the choice of gelling agent is an essential component of CGT formulation. The chewable gummy formulation enables the dispersion or dissolution of the active chemicals in the gels soft, elastic, and supple matrix. Water molecules readily enter the gel structure of the matrix – structured tablet, causing the active component to dissolve in the salivary fluid and requiring less force to chew in the oral cavity.

IV. METHODS

Cinnamon and Turmeric extract was added to the gelatin and it is allowed to swell for 5 minutes at room temperature.The swelled gelatin mixture was heated at 60 degree celcius in a water bath until a uniform viscous liquid is formed.Then mushroom powder was then added to the mixture and then other ingredients like mannitol, glycerine, polyethelyne glycol , peppermint was added to the heated mixture.Mix it thoroughly for 5-10 min and apply glycerine inside the molds. later pour the mixture into the molds. Place the molds in refrigerator for the settling of gummies.

Fig 1: Medicated Chewable Gummies

Table No 1: Formulation Table

Ingredients	F1	F2	F3	F4	F5	Role of Ingredients
Button Mushroom	250mg	250mg	250mg	250mg	250mg	API
Maitake Mushroon	250mg	250mg	250mg	250mg	250mg	API
Cinnamon Extract	250mg	250mg	2.5ml	2.5ml	2.5ml	API
Turmeric Extract	250mg	250mg	2.5ml	2.5ml	2.5ml	API
Gelatin	10g	6g	8g	6.5g	5.5g	Gelling Agent
Agar	-	4g	2g	-	-	Gelling Agent
Propylene Glycol	2ml	4ml	1ml	-	-	Texture Enhancer

Polyethylene Glycol	-	-	-	2ml	3ml	Texture Enhancer
Mannitol	-	-	0.50mg	0.50mg	0.50mg	Increase Elasticity
Glycerin	-	-	-	1ml	1ml	Texture Modifier
Jaggery Powder	-	-	2.5g	-	-	Increase Elasticity
Pippermint oil	-	-	-	q.s	q.s	Sweetener & Firming Agent
Purified Water	10ml	8ml	5ml	-	-	Vehicle

V. EVALUATION RESULTS

Table No 2: Determination of Physical Characteristics

Parameter	F1	F2	F3	F4	F5
Colour	Dark brown	Dark brown	Dark brown	Light Brown	Light Brown
Odour	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant
Taste	Mint	Mint	Mint	Mint	Mint
Shape	Square	Square	Square	Square	Square
Texture	Smooth, sticky, Poorly Elastic	Smooth, non- sticky, Hard texture	Smooth, highly sticky, non-elastic	Smooth, Slightly sticky, elastic	Smooth, non-sticky, Elastic

Table No 3: Determination Of Moisture Content

Parameters	Button Mushroom	Maitake Mushroom	Cinnamon	Turmeric
Moisture Content (%)	40	43	12	11

Table No 5 : Determination of Dimension of Gummies

Batch F4	Batch F5
Diameter: 1.9cm	Diameter: 1.9cm
Thickness mm:	Thickness mm:
0.6	0.7
0.7	0.6
Average: 0.35	Average: 0.35

Table No 6: Determination of Swelling Ratio

Batches	Initial Weight (mg)	Final Weight (mg)	Swelling Ratio %
F4	4.49	4.90	2.3%
F5	4.52	4.95	2.9%

Table No 7: Determination of pH

Batches	pH
F4	6.23
F5	6.17

Table No 8: Determination of % Drug release of Chewable Gummies

Time (Min)	% Drug Release	
	F4	F5
0	0	0
10	23.55	25.16
20	40.34	45.20
30	62.81	65.13
45	83.67	85.04
60	94.21	95.10

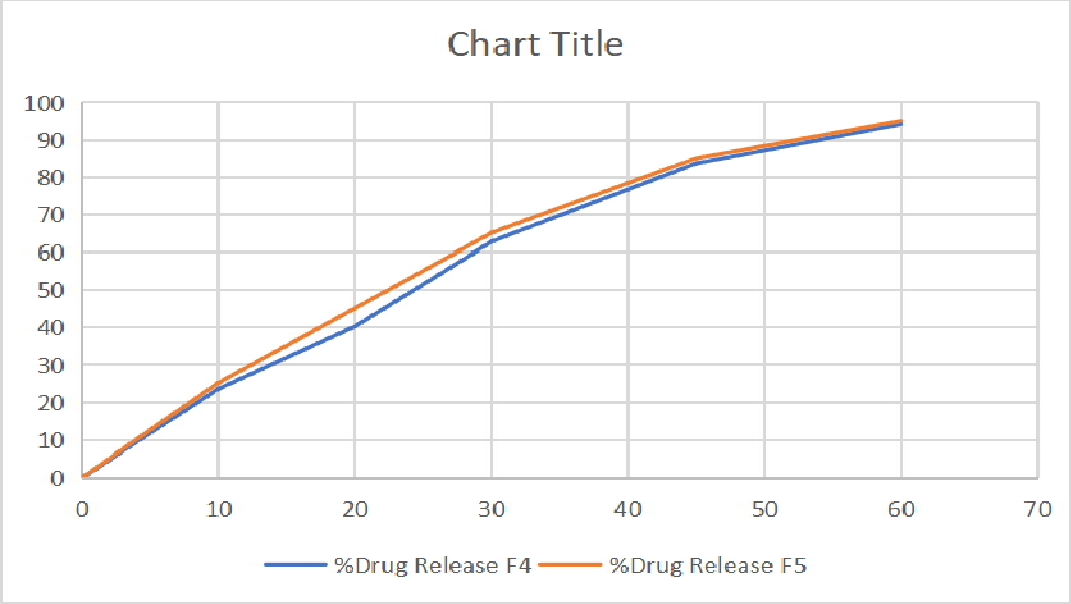

Fig 2: Determination of % Drug release of Chewable Gummies

VI. CONCLUSION

Polycystic Ovary Syndrome (PCOS) is the most common endocrine disorder among young women, presenting with symptoms like insulin resistance, hormonal imbalances, hirsutism, hyperandrogenism, and menstrual irregularities (oligo/amenorrhea). While pharmacotherapy for PCOS often carries a risk of side effects, herbal medicines have emerged as a promising alternative due to their lower adverse effects. These herbal treatments show potential in improving insulin resistance, modulating hormone levels (FSH and LH), and supporting ovarian function, including the reduction or dissolution of cysts, follicular development, and ovulation, possibly leading to pregnancy. Despite these promising findings, further research is essential to validate the efficacy of herbal remedies in treating PCOS. This review highlights the potential of herbal supplements as a beneficial alternative treatment option for PCOS.

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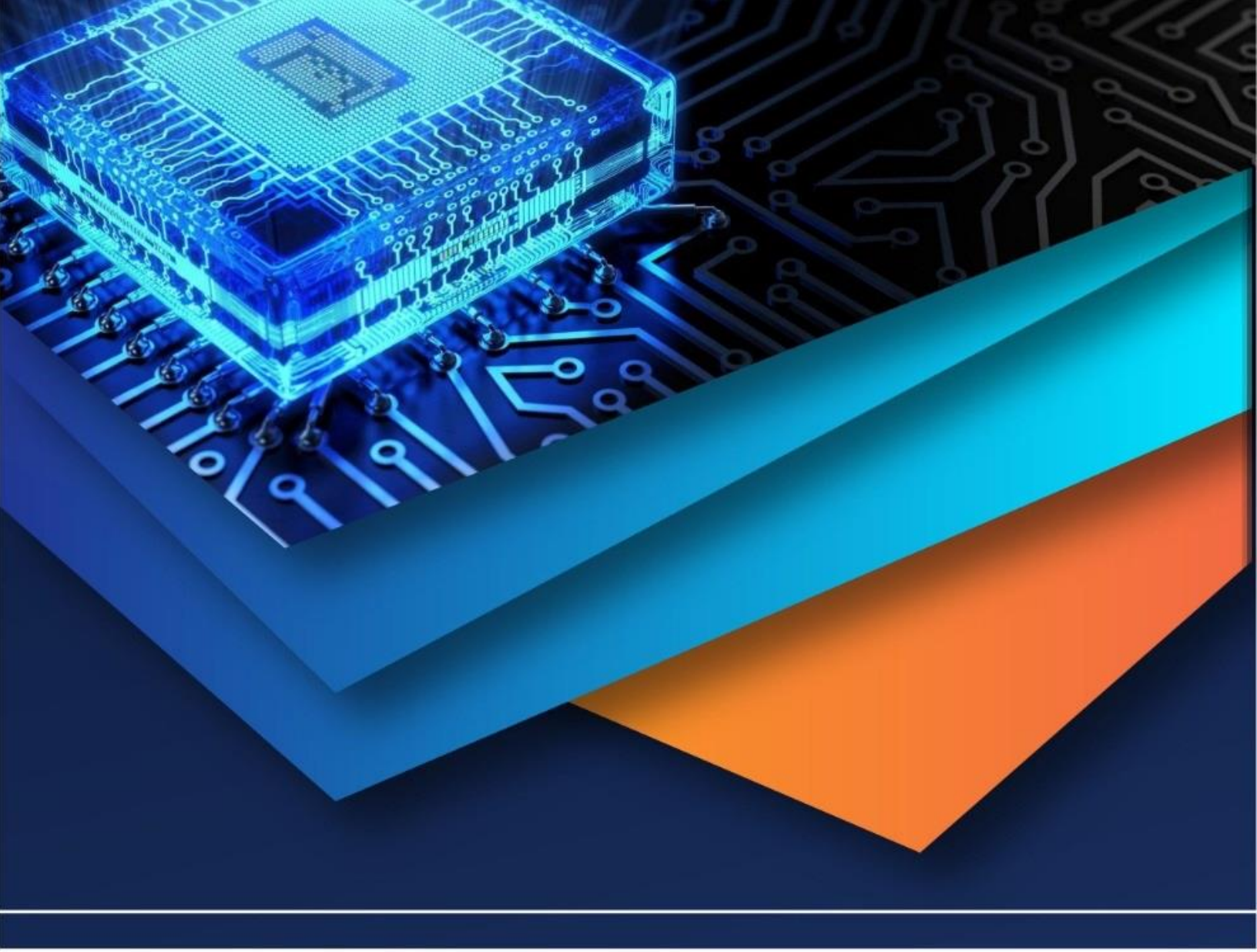

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