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Development and Evaluation of a Herbal Oral Gel for the Management of Mouth Ulcers

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Abstract: ***The present study aimed to formulate and evaluate a polyherbal oral gel containing extracts of Curcuma longa, Glycyrrhiza glabra, and eugenol for the management of oral ulcers The gel was prepared using Carbopol 934 as the gelling agent and incorporated in mouth oral pH with suitable excipients including glycerine, propylene glycol, methyl paraben, peppermint oil, triethanolamine, and purified water to enhance stability, consistency, and patient acceptability. The formulated gel was evaluated for various physical parameters such as appearance, color, odor, pH, viscosity, spreadability, extrudability, drug content uniformity, and stability. The optimized formulation exhibited a smooth and homogeneous appearance, acceptable pH (6.6–6.8), good spreadability, pseudoplastic viscosity, excellent extrudability, and satisfactory stability during storage. The gel demonstrated promising activity against common oral pathogens, and other microorganisms associated with oral infections. The study concludes that the developed herbal oral gel is a safe, effective, and economical alternative for the management of mouth ulcers and maintenance of oral health.***

Keywords: Herbal oral gel; Curcuma longa; Glycyrrhiza glabra; Eugenol; Oral health.

I. INTRODUCTION

Oral diseases such as gingivitis, periodontitis, dental caries, and oral mucosal lesions represent a major global health burden, affecting individuals of all age groups and significantly impacting quality of life [1]. These conditions are primarily associated with the accumulation of microbial biofilms, particularly *Streptococcus mutans* and other pathogenic microorganisms, which initiate responses in oral tissues [2].

Conventional management of oral infections involves synthetic antimicrobial agents, and antiseptics; however, prolonged use may result in adverse effects such as mucosal irritation, altered taste sensation, and microbial resistance [1],[5].

In recent years, there has been increasing interest in herbal formulations due to their biocompatibility, reduced toxicity, and broad therapeutic potential [3]. Medicinal plants have long been utilized in traditional systems of medicine, and their incorporation into modern dosage forms has opened new avenues for safer and more effective treatment strategies [3].

Topical herbal drug delivery systems are gaining importance as they provide localized action with minimal systemic absorption, thereby reducing side effects [7].

Fig1 – Mouth Ulcer

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Curcuma longa exhibits diverse pharmacological activities including antimicrobial, antioxidant, and wound-healing properties. Its active constituent, curcumin inhibits the growth of oral pathogens, contributing to periodontal disease management. Additionally, its antioxidant activity helps neutralize free radicals responsible for tissue damage and delayed healing [4].

Glycyrrhiza glabra contains bioactive compounds such as glycyrrhizin and flavonoids, which possess antimicrobial, and demulcent properties. These constituents have been reported to inhibit cariogenic bacteria and reduce inflammation in oral tissues [5].

Eugenol, a phenolic compound derived from clove oil, is widely used in dentistry due to its analgesic, antiseptic properties. It acts by inhibiting prostaglandin synthesis and provides local anesthetic effects, thereby relieving pain associated with dental conditions [6].

The combination of these three agents in a single formulation may produce a synergistic therapeutic effect by enhancing antimicrobial activity. Polyherbal formulations are advantageous as they target multiple pathways involved in disease progression [7].

Among topical dosage forms, oral gels are preferred due to ease of application, noninvasive nature, and prolonged retention at the site of action [8]. Gels allow incorporation of both hydrophilic and lipophilic drugs and provide controlled release of active ingredients [8]. They also improve patient compliance and enable targeted drug delivery [9].

Thus, the formulation of a herbal oral gel containing extracts of *Curcuma longa*, *Glycyrrhiza glabra*, and eugenol represents a promising approach for the effective management of oral diseases [9].

II. MATERIALS AND METHODS COLLECTION OF PLANT MATERIALS

Dried rhizomes and roots were procured from certified sources and authenticated using standard pharmacogenetic methods [3]. The active phenolic compound was obtained in pure form from a reliable supplier and used without further purification [6].

Carbopol 934 was used as a gelling agent, while propylene glycol served as a solvent and humectant [8]. Preservatives such as methyl paraben and propyl paraben were added to prevent microbial contamination [8]. Triethanolamine was used for neutralization and pH adjustment [8]. All reagents used were of analytical grade [1].

Fig 2 - curcuma longa, glycyrrhiza glabra, eugenol

III. PREPARATION OF HERBAL EXTRACT

A. *Extraction of Curcuma longa*

The rhizomes of Curcuma longa were washed thoroughly, dried completely, and ground into a fine powder using a mechanical grinder. The powdered material was accurately weighed and transferred into a Soxhlet apparatus. Ethanol was used as the extraction solvent, and the extraction process was carried out for 6–8 hours at a suitable temperature until the solvent in the thimble became colourless. The obtained extract was collected and filtered through Whatman filter paper. The filtrate was concentrated under reduced pressure using a rotary evaporator to obtain a semisolid extract, which was then transferred into an airtight container and stored under controlled conditions until further use.

B. *Extraction of Glycyrrhiza glabra*

The roots of Glycyrrhiza glabra were washed, dried, and ground into a coarse powder. The powdered material was accurately weighed and transferred into a suitable extraction vessel. A hydroalcoholic solvent system consisting of ethanol and water (70:30) was added to the powder. The mixture was subjected to maceration for 24–48 hours with occasional stirring to facilitate the extraction of glycosides and flavonoids. After completion of the extraction process, the extract was filtered through Whatman filter paper to remove insoluble residues. The filtrate was concentrated under reduced pressure using a rotary evaporator, resulting in the formation of a semisolid extract, which was stored for further use.

C. *Extraction of Eugenol*

Dried clove buds were collected, cleaned to remove foreign matter, and ground into a coarse powder. An accurately weighed quantity of the powdered cloves was transferred into a round-bottom flask, and distilled water was added in sufficient quantity to immerse the powder completely. Hydro-distillation was performed using a Clevenger apparatus. The mixture was heated gently, and the distillation process was continued for 3–4 hours. The distillate containing clove essential oil was collected, and the oil layer was separated from the aqueous phase using a separating funnel. The extracted oil was dried over anhydrous sodium sulphate to remove residual moisture. Finally, the purified clove oil rich in eugenol was stored in an amber-coloured airtight container at a cool temperature until further use.

IV. FORMULATION OF HERBAL ORAL GEL

The gel was prepared using the dispersion method as follows:

1) Carbopol 934 wasaccurately weighed according to the formulation composition.
2) Carbopol 934 was dispersed in distilled water with continuous stirring to form a uniform dispersion.
3) The dispersion was allowed to hydrate completely overnight to achieve the desired viscosity.
4) The extracts of Curcuma longa and Glycyrrhiza glabra were dissolved separately in propylene glycol to enhance solubility and ensure uniform distribution.
5) Eugenol was incorporated into the extract mixture under constant stirring to maintain homogeneity.
6) The extract mixture was gradually added to the hydrated Carbopol gel base with continuous stirring.
7) Methyl paraben and propyl paraben were dissolved in a small quantity of propylene glycol and added to the gel mixture to improve stability and shelf life.
8) Peppermint oil was added as a flavouring agent and mixed thoroughly.
9) Triethanolamine (q.s.) was added dropwise with continuous stirring to neutralize the formulation and adjust the pH to a range suitable for oral use (6.0– 7.5).
10) The final volume was made up to 100 mL with purified water and mixed well. The prepared gel was packed in suitable containers and stored for further evaluation.

Formulation Table: Herbal Oral Gel

Ingredients	Function	F1 (%)	F2(%) (optimized)	F3 (%)
Curcuma longa extract	Antioxidant	1.0	1.5	2.0
Glycyrrhiza glabra extract				

	Anti-ulcer, soothing agent	1.0	1.5	2.0
Eugenol	Analgesic, antiseptic	0.2	0.3	0.5
Carbopol 934	Gelling agent	1.0	1.2	1.5
Glycerine	Humectant	10	12	15
Propylene glycol	Solvent, penetration enhancer	5	5	5
Methyl paraben	Preservative	0.1	0.1	0.1
Peppermint oil	Flavouring agent	0.05	0.05	0.05
Triethanolamine	pH adjustment	q.s.	q.s.	q.s.
Purified water	Vehicle	q.s to 100	q.s. to 100	q.s. to 100

A. Evaluation Parameters For Extracted Drug

1) Organoleptic Evaluation

a) Evaluation of Color: A small quantity of the prepared herbal oral gel containing Curcuma longa, Glycyrrhiza glabra, and eugenol was placed in a clean glass container and visually examined under daylight for characteristic color.

b) Evaluation of Odor: The formulation was gently smelled to determine its characteristic odor.

c) Evaluation of Taste: A very small quantity of the formulation was carefully tasted to determine the characteristic taste.

d) Evaluation of Appearance: The prepared gel was visually inspected for homogeneity, smoothness, and consistency.

B. Phytochemical / Chemical Identification Tests

1) Alkali Test for Curcuma longa

- One milliliter of herbal extract or gel solution was taken in a test tube.
- A few drops of sodium hydroxide (NaOH) solution were added.
- The color change was observed.

2) Boric Acid Test for Curcuma longa

- A small quantity of extract was taken in a test tube.
- Boric acid solution was added.
- Concentrated sulfuric acid was carefully added.
- The color produced was observed.

3) Foam Test for Glycyrrhiza glabra

- One milliliter of extract was taken in a test tube
- Five milliliters of distilled water were added.
- The mixture was shaken vigorously for 2–3 minutes.
- It was allowed to stand for a few minutes.

4) Shinoda Test for Glycyrrhiza glabra

- The alcoholic extract was taken in a test tube.
- Small magnesium turnings were added.
- A few drops of concentrated hydrochloric acid (HCl) were added.
- The color formation was observed.

5) Glycyrrhizin Test for Glycyrrhiza glabra
- The alcoholic extract of the formulation was taken in a test tube.
- A few drops of 80% sulfuric acid were added.
- The color change was observed.

6) Ferric Chloride Test for Eugenol
- A small quantity of sample solution was taken.
- A few drops of ferric chloride ($FeCl_3$) solution were added.
- The color change was observed.

7) Potassium Hydroxide (KOH) Test for Eugenol
- The sample solution was taken in a test tube.
- Alcoholic potassium hydroxide solution was added.
- The mixture was mixed properly and observed.[23][11]

C. Evaluation For Gel Formulation

The formulated gel was evaluated using physicochemical, mechanical, biological, and stability parameters to ensure quality and efficacy [10].

1) Organoleptic Evaluation

The formulated gel was evaluated for organoleptic properties including color, odor, appearance, and texture. A small quantity of gel was placed on a clean glass slide and visually inspected under normal daylight conditions. The color of the formulation was observed for uniformity and absence of discoloration. Odor was evaluated by gently smelling the formulation to detect any characteristic or unpleasant smell. Texture and consistency were assessed manually by rubbing a small amount of gel between the fingers to check smoothness, grittiness, and ease of application. The formulation was considered acceptable if it showed uniform appearance, smooth texture, and absence of particulate matter or phase separation.[11][12]

2) pH Determination

The pH of the gel formulation was determined using a calibrated digital pH meter. About 1 g of gel was dispersed in 100 mL of distilled water to prepare a 1% w/v solution. The dispersion was allowed to stand for 2 hours to obtain complete hydration. The pH meter was calibrated using standard buffer solutions of pH 4.0 and 7.0 before use. The electrode was immersed into the gel dispersion and the reading was recorded at room temperature (25 ± 2°C). Measurements were performed in triplicate and the average value was calculated. The acceptable pH range for oral gel formulations was maintained between 6.0 and 7.5. [13] [14]

3) Viscosity Measurement

Viscosity of the formulated gel was measured using a Brookfield viscometer equipped with an appropriate spindle. Approximately 50 g of gel was transferred into a clean beaker and maintained at room temperature (25 ± 2°C). The spindle was immersed vertically into the gel without trapping air bubbles. Viscosity measurements were recorded at different rotational speeds to evaluate the rheological behavior of the formulation. The readings were noted after achieving constant values. The gel exhibited pseudoplastic flow behavior, which is considered suitable for topical oral application. [15].

4) Spreadability Test

Spreadability of the gel was determined by the glass slide method. About 1 g of gel was placed between two glass slides of equal dimensions. A known weight was placed on the upper slide for a fixed period to obtain a uniform film of gel between the slides. The upper slide was then allowed to move under the influence of an applied weight attached through a pulley system. The time required for the upper slide to move a specified distance was recorded. Spreadability was calculated using the following formula:

$$S = \frac{M \times L}{T}$$

Where:
- S= Spreadability
- M= Weight tied to upper slide (g)
- L= Length moved by slide (cm)
- T= Time taken (sec)

Good spreadability indicates ease of application and uniform distribution of the gel on oral mucosa. [16] [17]

5) Extradurability Study

Extradurability of the gel formulation was evaluated using collapsible aluminum tubes. The gel was filled into lacquered aluminum tubes and crimped properly. The tube was pressed manually and the force required to extrude the gel from the nozzle was observed. Extradurability was expressed in terms of the amount of gel extruded upon application of constant pressure. The formulation was considered satisfactory if the gel extruded easily with uniform consistency. [19].

6) Drug Content Uniformity

Drug content uniformity was determined using UV-visible spectrophotometric analysis. An accurately weighed quantity of gel equivalent to a known amount of drug was dissolved in a suitable solvent and diluted appropriately. The solution was filtered to remove insoluble materials. Absorbance was measured using a UVvisible spectrophotometer at the predetermined wavelength corresponding to the active constituent. Drug concentration was calculated using a standard calibration curve. The test was performed in triplicate and the average drug content was calculated to ensure uniform distribution of the drug throughout the formulation. [20] [21].

7) Stability Studies:

Stability studies were performed according to ICH guidelines under accelerated and real-time storage conditions. The gel formulations were packed in suitable containers and stored at different temperature and humidity conditions, such as 25 ± 2°C/60 ± 5% RH and 40 ± 2°C/75 ± 5% RH. Samples were withdrawn at predetermined intervals (0, 1, 2, and 3 months) and evaluated for physical appearance, pH, viscosity, drug content, and microbial growth. Any changes in color, odor, consistency, or phase separation were noted. The formulation was considered stable if no significant changes were observed during the study period. [24]

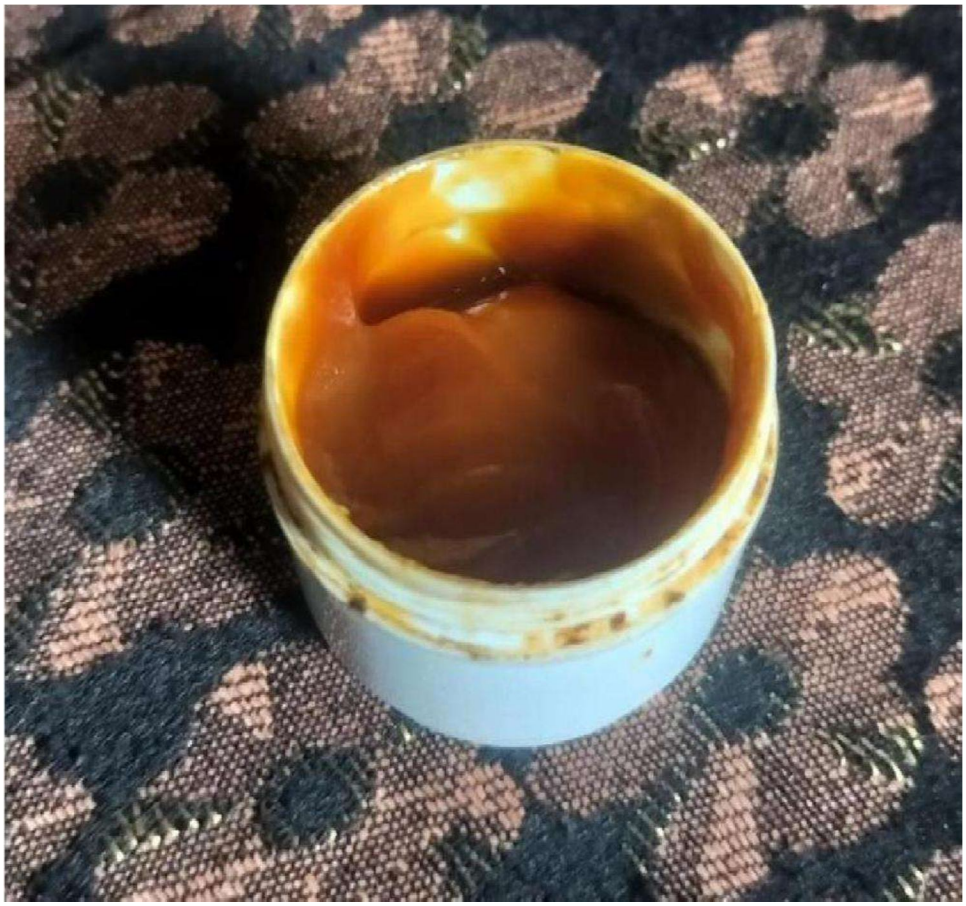

Fig 3 – Prepared Herbal gel for mouth Ulcer

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V. RESULTS AND DISCUSSION

A. *Identification of Extracted Drug*

1) *Organoleptic Evaluation*

Parameter	*Curcuma longa*	*Glycyrrhiza glabra*	Eugenol
Color	Yellow to orange-yellow	Brownish yellow	Pale yellow
Odor	Aromatic	Mild characteristic odor	Strong clove like odor
Taste	Slightly bitter	Sweet	Pungent and spicy
Appearance	Smooth homogeneous gel	Smooth homogeneous gel	Homogeneous gel

The organoleptic evaluation confirmed the characteristic properties of the herbal ingredients used in the formulation. The observed color, odor, taste, and appearance were consistent with reported standards for *Curcuma longa*, *Glycyrrhiza glabra*, and eugenol, indicating their authenticity and suitability for formulation development.

2) *Phytochemical / Chemical Identification Tests*

Extract	Test	Procedure	Observation
Curcuma longa	Alkali Test	Add NaOH solution to sample	Reddish-brown coloration appears
Curcuma longa	Boric Acid Test	Add boric acid and conc. H_2SO_4	Reddish-brown color develops
Glycyrrhiza glabra	Foam Test	Shake with distilled water	Persistent foam formation indicates saponins
Glycyrrhiza glabra	Shinoda Test	Add Mg turnings and HCl	Pink/red coloration confirms flavonoids
Glycyrrhiza glabra	Glycyrrhizin Test	Add 80% H_2SO_4	Yellow coloration observed
Eugenol	Ferric Chloride Test	Add $FeCl_3$ solution	Blue-green/dark coloration observed
Eugenol	KOH Test	Add alcoholic KOH	Yellow coloration appears

The phytochemical identification tests showed positive results for the characteristic constituents present in *Curcuma longa*, *Glycyrrhiza glabra*, and eugenol. The observed colour changes and foam formation confirmed the presence of curcuminoids, flavonoids, saponins, glycyrrhizin, and phenolic compounds, supporting the authenticity and quality of the selected herbal ingredients.

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3) Formulation of Herbal Gel

The formulated herbal oral gel containing extracts of *Curcuma longa*, *Glycyrrhiza glabra*, and eugenol was evaluated for physicochemical, rheological, and biological parameters. The results obtained are summarized below.

a) Organoleptic Properties

The prepared gel showed acceptable aesthetic characteristics.

Table 1: Organoleptic Evaluation

Parameter	Observation
Color	Yellowish
Odor	Aromatic (characteristic)
Appearance	Smooth, homogeneous gel
Texture	Non-gritty

The formulated hydrogel exhibited a yellowish color due to the presence of curcumin and a characteristic aromatic odor from menthol, camphor, and thymol. The smooth, homogeneous appearance and non-gritty texture indicated uniform distribution of ingredients, suggesting good formulation quality and suitability for topical application.

b) pH Determination

Table 2: pH of Formulation

Batch	pH Value
F1	6.6
F2	6.7
F3	6.8

The pH values of all formulations (F1,F2,F3) ranged from 6.6 to 6.8, which is close to the normal skin pH. This indicates that the formulations are suitable for topical application and are less likely to cause skin irritation.

c) Viscosity Measurement

Table 3: Viscosity at Different RPM

RPM	Viscosity (cP)
10	5200
20	4100
50	3000
100	2100

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The viscosity of the formulation decreased from 5200 cP to 2100 cP with an increase in RPM, indicating shear-thinning (pseudoplastic) behavior. This property is desirable for topical formulations as it facilitates easy spreading during application while maintaining consistency at rest.

d) Spreadability

Table 4: Spreadability

Batch	Time (sec)	Spreadability (g·cm/sec)
F1	6	16.6
F2	5	20.0
F3	6	16.6

The spreadability values of the formulations ranged from 16.6 to 20.0 g·cm/sec, indicating good spreadability characteristics. Among all batches, F2 showed the highest spreadability, suggesting easier application and better distribution on the skin surface.

e) Extrudability

Table 5: Extrudability

Parameter	Result
Force required	Low
Extrusion quality	Excellent

The formulation exhibited excellent extrudability, requiring only a low force for extrusion from the container. This indicates good consistency and ease of application, which can enhance patient convenience and compliance.

f) Drug Content Uniformity

Table 6: Drug Content

Batch	% Drug Content
F1	98.5%
F2	98.8%
F3	99.2%

The drug content of all formulations ranged from 98.5% to 99.2%, indicating uniform distribution of the drug within the gel matrix. Batch F3 showed the highest drug content, demonstrating excellent drug incorporation and formulation consistency.

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g) Stability Studies

Table 7: Stability Data (3 Months)

Parameter	Initial	After 3 Months
Color	Yellow	No change
pH	6.7	6.6
Viscosity	5200	5100
Drug Content	98.8%	98.2%

The stability study showed no significant changes in the physical and chemical properties of the formulation after 3 months. Minor variations in pH, viscosity, and drug content were within acceptable limits, indicating good stability of the formulation during storage.

VI. RESULT

The formulated herbal oral gel containing extracts of Curcuma longa, Glycyrrhiza glabra, and eugenol was successfully prepared and evaluated for its physicochemical and biological properties. Organoleptic evaluation revealed that the gel possessed a yellowish color, characteristic aromatic odor, smooth homogeneous appearance, and non-gritty texture, indicating good aesthetic quality and uniform distribution of ingredients. The pH of the formulations ranged from 6.6 to 6.8, which is suitable for oral application and unlikely to cause irritation. The viscosity study demonstrated pseudoplastic (shear-thinning) behavior, with viscosity decreasing from 5200 cP to 2100 cP as rotational speed increased, ensuring easy application and adequate retention at the site of action. The spreadability values ranged from 16.6 to 20.0 g·cm/sec, with formulation F2 exhibiting the highest spreadability, suggesting better ease of application. Drug content uniformity was found between 98.5% and 99.2%, confirming uniform incorporation of active constituents throughout the gel matrix. The formulation also showed excellent extrudability, requiring minimal force for extrusion from the container .Stability studies conducted over a period of three months revealed no significant changes in color, pH, viscosity, or drug content, confirming the formulation's stability during storage. Overall, the results indicated that the developed herbal oral gel possessed satisfactory physicochemical characteristics, good stability, and promising anti-inflammatory activity, making it a suitable candidate for the management of mouth ulcers and other oral inflammatory conditions.

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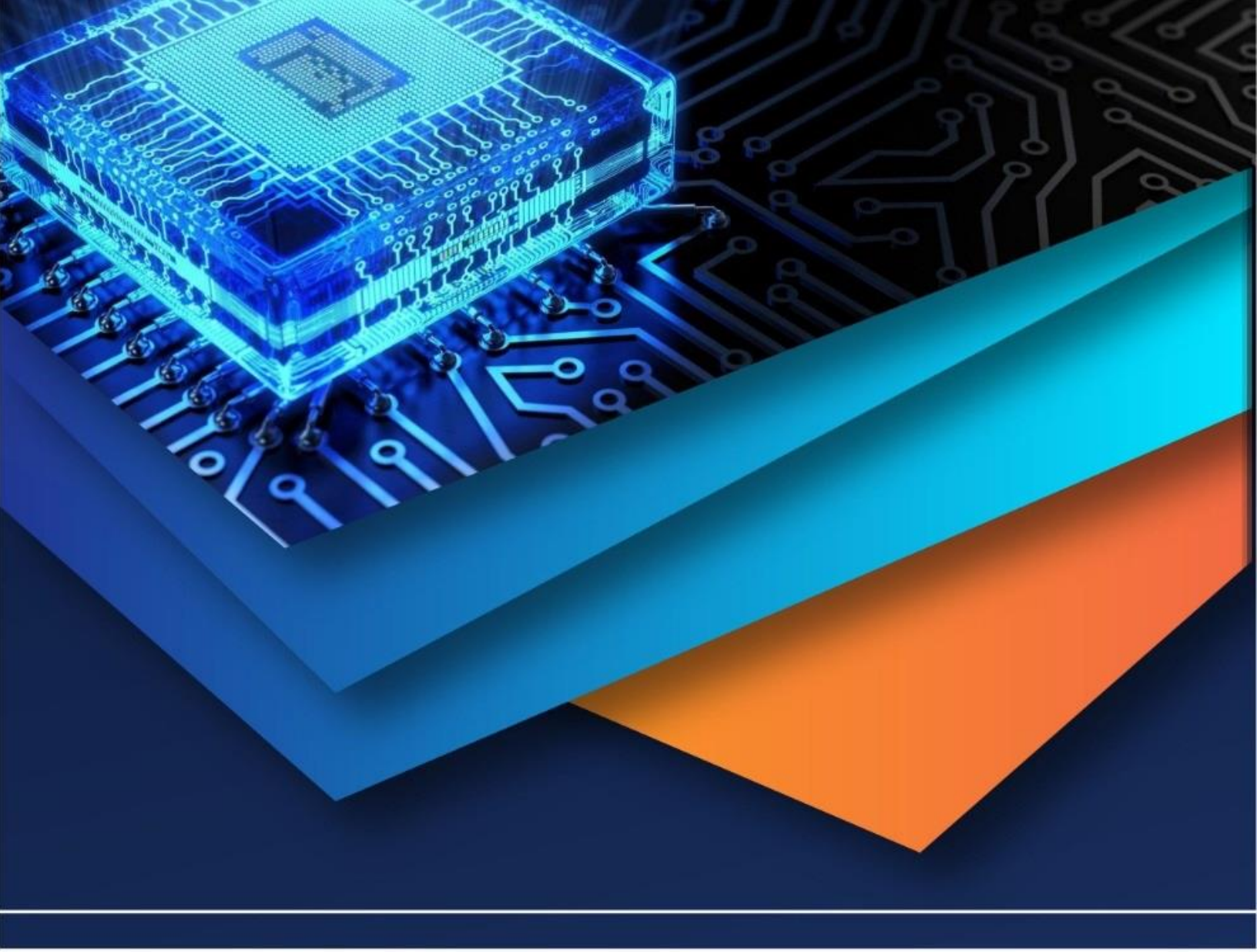

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