iJRASET
International Journal For Research in
Applied Science and Engineering Technology

INTERNATIONAL JOURNAL
FOR RESEARCH
IN APPLIED SCIENCE & ENGINEERING TECHNOLOGY

Volume: 13 Issue: IX Month of publication: September 2025

DOI: https://doi.org/10.22214/ijraset.2025.74214

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Review on Niosomes as a Novel Drug Delivery

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***Abstract: Targeted drug administration, also known as smart drug delivery, is a method of administering medication to a patient in which the concentration of the drug is higher in some parts of the body than in others. a particular way of administering drugs. Targeting, localizing, extending, and establishing a secure pharmaceutical contact with the ill tissue are the system's goals. As a result of review and investigation, articles about niosomes have been published in the last decade. This suggests that niosomes' advantages over other vesicular carrier systems are what have scientists interested. The formation of niosomes occurs when non-ionic surfactant vesicles self- assemble. This article examines how niosomes are currently gaining more and more attention throughout a wide range of scientific fields, especially in relation to their use in medicine*.**
Keywords: Structure of niosomes, Composition of niosomes, Characterization of niosomes, Factors affecting the formation of niosomes, Application of niosmes

I. INTRODUCTION

In the 1970s, cosmetics companies started to use niosomes as a delivery mechanism (Waddad et al., 2013; Moghassemi and 2014; Hadjizadeh). They are vesicles composed of one or more bilayers containing non-ionic surfactants (Nasir et al., 2012). In the process of making the niosomes, cholesterol and its derivatives were used multiple times (Moghassemi and Hadjizadeh, 2014). Concentrated bilayer vesicles that can transport both hydrophilic and lipophilic molecules are formed when non-ionic surfactant layers spontaneously unite in the aqueous phase (Sankhyan and Pawar, 2012, Patil and Jadhav, 2014).(1) One of the 21st century's most promising technologies, nanotechnology presents prospects for scientific research across many fields, including health, pharmaceutical and cosmetic sciences, medicinal chemistry, bioengineering, genetic engineering, and food science. technology.(2)(3) Concentrating the drug in the targeted tissues while trying to lower the medication's relative concentration is the aim of targeted drug delivery. in the tissues that are left. The medication is thereby localized to the intended location. As a result, the medication has no effect on the surrounding tissues. Additionally, by avoiding medication loss, the treatment's localization optimizes its efficacy. Numerous drug delivery methods, such as niosomes, serum proteins, immunoglobulin, liposomes, erythrocytes, and synthetic polymers, have been used.

.(4) Niosomes are among the best of these carriers. Non-ionic surfactants' ability to self-assemble into vesicles was initially discovered by researchers working in the cosmetics sector in the 1970s. When cholesterol and non- ionic surfactants of the alkyl or dialkyl polyglycerol ether family are combined, microscopic lamellar structures known as niosomes, or non-ionic surfactant vesicles, are created.(5)

II. STRUCTURE OF NIOSOMES

Since niosomes are small and have a unique shape and composition, they can stabilize the drug molecule at the desired site. Because niosomes are both hydrophilic and hydrophobic, they are a suitable vesicle for encapsulating medicinal substances that are hydrophilic, lipophilic, and amphiphilic and have a wide range of solubility.(6). According to Usman et al. (2017), niosomes are an amphiphile vesicle. Agents, chemicals that induce charges, bilayer-inducing nonionic surfactants (surface active substances), and the necessary components comprise the amphiphile vesicles.(7) Five categories of surfactants can be distinguished based on the union of their hydrophilic and hydrophobic components: amides, fatty acids, amino acids, alkyl esters, and alkyl ether surfactants. Alkyl ethers are the most common type of nonionic surfactant. Moreover, these were used to produce cosmetic The hydrophilic heads of repeat ethylene oxide subunit groups and the hydrophilic heads of repeat glycerol subunits, similar isomers, or larger sugar molecules are the two classes into which L'OrSal. Ijeoma et al. (1995) in France classified alkyl ethers.(8). Each alkyl ether's molecular weight was determined by Rajera et al., who also suggested an extra classification: Surfactant I includes C16 monoalkyl glycerol and has a molecular weight of 473. Diglycerol ether, which has an average molecular weight of seven glycerol units, is present in surfactant II, which has a molecular weight of 972; surfactant III is an ester-linked surfactant, which has a molecular weight of 393. (9)

A. Advantages :-(10,11)

1) Drugs' bioavailability is increased by nanobodies because they shield them from enzymatic and acidic breakdown in the gastrointestinal system.
2) Its amphipathic structure allows us to mix different medications and employ them in different medications.
3) By employing nanobodies, we can enhance the permeability of the skin.
4) By delaying the removal of medication molecules from the bloodstream, their therapeutic efficacy can be increased.
5) Surfactants are usable and don't need to be stored in a certain way.

B. Disadvantages :-(12)

1) It contains greater drug aggregation.
2) Drugs that are encapsulated have a shorter shelf life due to vesicle hydrolysis.
3) The vesicles will release the medication within.
4) lengthy preparation period

III. TYPES OF NIOSOMES

Niosomes can be divided into three groups based on their size:

1) Small unilamellar vesicles (SUVs), which range in size from 10 to 100 nm
2) Range of sizes generally referred to as large unilamellar vesicles (LUV) at 100–3000 nm.

The existence of multiple bilayers is referred to as "multilamellar vesicles" (MLV). A few other distinct niosomes are also identified in the literature in addition to the already mentioned. A few of the most important ones are discussed below..(13,14,15)

A. Aspasomes

These are the water-soluble lamellar vesicles of acorbyl palmitate. A highly charged lipid called diacetylphosphate is added to the mixture to stabilize it and make the bilayer more rigid.(16) Following preparation, the aspasomes are hydrated with an aqueous solution before being sonicated. Aspasomes may accelerate skin penetration. Aspases have a variety of medical and cosmetic applications. Because aspasomes are naturally antioxidants, they are used to treat diseases brought on by reactive oxygen species. Aspasomes of magnesium ascorbyl phosphate were created by Aboul-Einien to treat melasma. Lecithin was utilized in the procedure instead of the charged molecule dicetyl phosphate..(17,18,19-23)

B. Proniosomes

A dehydrated niosome is called a proneosome. It is recommended to soak proneosomes prior to use. When they get wet, they form an aqueous niosome dispersion. Because they are dry, proneosomes have advantages to niosomes, including simpler transportation and distribution, less caking, and reduced aggregation and fusion..(17,24,25,26,27,28) There are three methods for producing proneosomes: spray coating, coacervation phase separation, and the slurry process.(29)

C. Bola-surfactant niosomes

Omega-hexadecyl-bis-(1-aza-18-crown-6):span-80:cholesterol in a molar ratio of 2:3:1 is used to create bola- surfactant niosomes. where the bola surfactant omega-hexadecyl-bis-(1-aza-18-crown-6).(17,25,30,31)

D. Elastic niosomes

These are made with water, ethyl alcohol, and a non-ionic surfactant. They have the ability to flow through the larger-sized holes found in the stratum corneum than vesicles.(24,32,33) Ethyl alcohol, water, and a non-ionic surfactant are used to make them. Compared to vesicles, they can pass through the bigger openings in the stratum corneum.(34,35,36)

IV. COMPOSITION OF NIOSOMES

The bilayered structure of niosomes, which are thermodynamically stable, is composed of non-ionic surface-active compounds that are only produced when cholesterol and surfactants are mixed at temperatures higher than the gel liquid transition point in the proper ratio. It contains a hollow area in the middle that contains both hydrophilic and hydrophobic medications(37). Conventional niosomal vesicles can be made up of vesicles that generate a nonionic, or amphiphilic, surfactant such as Span60, which is frequently sustained by a combination of cholesterol.

Includes a very small quantity of anions, such as dicetyl phosphate, which are used as a surfactant to stabilize vesicles..(38) Niosomes are produced using the following three ingredients:

1) Cholesterol
2) Non-ionic surfactants
3) Charged molecule

Cholesterol is a precursor to steroids that gives niosomes their proper form and stiffness while also enhancing their strength and enabling the production of niosome compounds. The use of steroids affect the bilayer's permeability and fluidity, making them crucial elements.

A common addition to nonionic surfactants to give them rigidity and orientational order is cholesterol, a waxy steroid metabolite. In large molar ratios, it can be absorbed and has little effect on the bilayer. As an amphiphilic molecule, cholesterol faces the aqueous phase with its OH group and the hydrocarbon chain of the surfactant with its aliphatic chain. A stiff steroidal backbone is alternately positioned inside the bilayer with the surfactant molecules to provide rigidity by limiting the movement of hydrocarbon carbons.(39)

A surfactant is a non-ionic hydrophilic surfactant that does not contain charged groups. They are less dangerous, more stable, more biocompatible than their cationic, amphoteric, or anionic cousins. Thus, they are preferred for the formation of stable niosomes both in vitro and in vivo. Nonionic surfactants are amphiphilic substances with two different regions: one that is hydrophilic (soluble in water) and the other that is hydrophobic (soluble in organic substances). In niosome emulsions, fatty acids, alkyl ethers, alkyl esters, and different alkyl amides are the primary nonionic surfactant types used. While selecting surfactant molecules for niosome production, the critical packing parameter (CPP) and hydrophilic-lipophilic balance (HLB) values are crucial factors to take into account..(40)

Charged molecule is the stability of the vesicles is increased by the addition of charged groups to the vesicle bilayer. By raising its surface charge, they lessen vesicle aggregation density. Because of repulsive forces of the same charge, they prevent vesicle fusion, which raises the potential's zeta values. While stearylamine and stearyl pyridinium chloride are well-known positively charged chemicals, diethyl phosphate and phosphatidic acid are the most often used negatively charged molecules during niosome synthesis.(41)

V. CHARACTERIZATION OF NIOSOMES.(42)

A. *Measurement Of Angle of Repose*

The angle of repose of dry powder niosomes can be measured using the funnel method. The funnel is filled with niosome powder. 5 cm above a smooth black surface was the precise location of the funnel's 13mm exit hole. The angle of repose was then ascertained by taking measurements of the mountain's height and base diameter. A little, mountain-like structure will appear on the surface as the powder flows down from the full.

B. *Scanning Electron Microscopy*

One of the most crucial features of niosomes is their particle size. the appearance of the surface (roundness, smoothness, and forming aggregate) and niosome size distribution were examined using scanning electron microscopy (SEM). Onto the double-sided tape that was attached to the aluminum stubs, scatter the niosomes. The scanning electron microscope's vacuum chamber was filled with the aluminum stub. Using gaseous secondary electron detectors, the sample was examined for morphological characterization.(43)

C. *Osmotic Shock*

The osmotic studies can identify any changes in the vesicle size. The niosome formulation is incubated with the hypotonic, three hours in an isotonic and hypertonic solution. When the formulation's vesicles are examined under optical microscopy after the time period, we can observe changes in their size.(43)

D. *Stability Studies*

The optimized batch was stored at different temperatures in airtight, sealed vials to assess the niosomes' stability. The one that has proportion and surface characteristics Medicines retained in niosomes and niosome-derived niosomes were selected as the metrics for the stability evaluation. Leakage of the drug could be a sign of an unstable formulation.(44)

E. Zeta Potential analysis

The colloidal properties of the formulation we have created must be ascertained by zeta potential investigation. The dilute The lasser doppler velocimetry method and a zeta potential analyzer based on electrophoretic light scattering were used to identify niosomes that are produced from proniosome dispersion. Straight from the measurements of the temperature set at 25°C charge on vesicles, the mean zeta potential values with standard deviations of measurement were extracted.(45)

VI. FACTORS AFFECTING THE FORMATION OF NIOSOMES

A. Nature of Surfactant

Ester-type non-ionic surfactants are less stable and less dangerous than ether-type ones. The HLB value of niosomes is particularly significant in the synthesis of surfactants. The crucial packing parameter of the surfactant dictates the shape of the resulting vesicles. The following equation is used to determine it. where the volume of hydrophobic groups is the critical packing parameter (CPP) and A0 times v/Ic equals CPP. The critical length of the hydrophobic group is Vlc. The hydrophilic head group's area (a0) The stability of the Niosome suspension decreases as the hydrophilic chain of the surfactant lengthens because the phase transition temperature decreases and more low molecular weight medicine leaks into the aqueous compartment. The stability of the Niosome suspension is enhanced by the rise in the transition temperature, decrease in low molecular weight drug leakage from the aqueous compartment, and increase in drug encapsulation caused by the surfactant's hydrophobic chain length.(46)

B. Nature of Encapsulated Drug

The physicochemical characteristics of the drug affect the charge and stiffness of the Niosome bilayer. Compared to hydrophilic medications, hydrophobic pharmaceuticals are less likely to leak from the bilayer. Drugs that are hydrophobic have superior transdermal penetration and are more stable in formulation. Because hydrophilic drugs are more likely to leak from the bilayer, they reduce the formulation's stability. Niosomes effectively encapsulate amphiphilic medications.(46)

C. Cholesterol Contents

It can be found using the equation below. The critical packing parameter (CPP), which is equal to A0 times v/Ic, is the volume of hydrophobic groups. Vlc stands for the hydrophobic group's critical length. The area (a0) of the hydrophilic head group As the hydrophilic chain of the surfactant lengthens, the phase transition temperature drops and more low molecular weight medication percolates into the aqueous compartment, decreasing the stability of the Niosome suspension. The increase in the transition temperature affects the stability of the niosome suspension, the reduction of low molecular weight drug leakage from the aqueous compartment, and the increase in drug encapsulation caused by the hydrophobic chain length of the surfactant.(46)

D. Temperature of Hydration

This should be below the gel to liquid phase transition temperature of the system. Niosome size and form could be affected.(46)

VII. METHODS OF PREPARATION

A. The Bubble Method

It should be higher than the system's gel to liquid phase transition temperature. It might have an impact on niosome size and shape.(47)

B. Ether for Injection Method

In essence, the ether injection method involves injecting niosomal components into diethyl ether into a heated aqueous phase maintained at 60°C at a rate of 14–roughly 0.25 milliliters per minute using a gauge needle. The delayed vaporization of the solvent, which produces an ether gradient that stretches towards the aqueous– nonaqueous border, is probably what causes the formation of larger unilamellar vesicles. The former might have contributed to the formation of the bilayer structure. One of the disadvantages of this approach is that the vesicle suspension typically contains a very small quantity of ether, which is difficult to remove.(48)

C. Sonication Method

One common method for producing Niosome vesicles is sonication. The medication, cholesterol, and surfactants are taken out of a 10-ml glass vial and combined with buffer. After that, the liquid is sonicated for about three minutes using a titanium probe to create niosomes.

There are minuscule, unilamellar vesicles in the final product. The creation of tiny particles is the most common use for this method. The two types of sonicators utilized in the sonication process are probe and bath types. The situation determines whether any kind is used.(49)

D. *Multiple Membrane Extrusion Method*

A thin film is created by evaporating a solution containing cholesterol, diacetyl phosphate, and surfactant in chloroform. The suspension is then extruded through a sequence of polycarbonate membranes with a maximum of eight passages using an aqueous pharmacological solution. This is an effective way to manage loud sizes.(48)

VIII. IN VITRO METHOD FOR NIOSOMES(50)

The following methods can be used to study in vitro drug release:

A. *Dialysis Tubing*

With dialysis tubing, in-vitro medication release can be accomplished. Placed in a pre-washed dialysis tubing, the niosomes can be closed off hermetically. After dialyzing the dialysis sac against an appropriate dissolving liquid at room temperature for a few intervals, the sample can be removed from the medium. Sink condition maintenance is crucial.(51)

B. *Reverse Dialysis*

Proniosomes are filled using this method using a tiny dialysis device that can store one milliliter of dissolving solution. Following that, the proniosomes entered the disintegration medium. This technique allows us to directly dilute the proniosomes. This technique, however, cannot guarantee the timely release.(52,53)

C. *Franz Diffusion Cell*

Using a tiny dialysis device that can accommodate one milliliter of dissolving solution, proniosomes are filled using this method. Next, the proniosomes entered the disintegration medium. This approach allows us to directly dilute the proniosomes. Nevertheless, this approach cannot guarantee the timely release..(54,55)

IX. APPLICATION OF NIOSOMES

There are several therapeutic uses for niosomes as a delivery method.

A. *Delivery of Anticancer Drugs*

With nanobodies, antibodies can be delivered to specific locations. Such a target may be supplied to the body (delivered to a certain environment, such pH or magnetic fields), failed (releasing cysts in the tumor due to unique qualities of tumor cells not found in the normal body), or active type (forcing liposomes into tumor cells). The main objective is is possible by altering the nanosomes' surface characteristics or by incorporating ligands into them. To facilitate ligand binding, cholesterol-PEG-ligand conjugates can be joined to the ends of polyethylene glycol or cholesterol chains or added to liposomes.(56)

B. *Neoplasia*

The antibiotic doxorubicin has a wide range of effects and unrestricted anti-inflammatory and anti-tumor properties. The drug's circulation, metabolism, and half-life are all extended when it is encapsulated in vesicles.(57)

C. *Carrier for haemoglobin*

Because nanobodies absorb oxygen, they can also be utilized as blood transporters for hemoglobin. In order to use the vesicle suspension as a hemoglobin carrier, its visible spectrum can be superimposed on the spectrum of free hemoglobin. Additionally, vesicles take up oxygen, therefore their heme dissociation curve will resemble heme that is not encased(57)

D. *Delivery of peptide drug*

The stability of the peptide was enhanced by vesicle-encapsulated oral delivery of 9-desglycinamide, 8-arginine vasopressin, according to tests conducted in an in vitro intestinal model.(58)

E. Dignostic imaging with niosomes

One possible diagnostic test is niosomes. According to MRI study, liposomal formulations that combined PEG and NPG, gadobenate dimethicamide, and [Npalmitoylglucosamine (NPG)] were more effective than encapsulated paramagnetic medications. Blistering techniques have a wide range of uses and can be used to treat a variety of illnesses.(59)

X. CONCLUSION

Niosomes, a recent technological advancement, exhibit potential in the realms of cancer and infectious disease treatments. Serving as an alternative to liposomes, they offer advantages such as increased chemical stability, enhanced purity, and reduced cost. Niosomes, which are non-ionic surfactant vesicles, influence drug plasma clearance, tissue distribution, metabolism, and cellular interaction. Already employed in cosmetic products, they hold promise for diverse drug delivery applications, such as targeting, ophthalmic, topical, and parenteral. Advanced targeted niosomal systems utilizing active, passive, and magnetic mechanisms have been devised for precise macromolecular drug delivery. Since niosomes don't need particular handling or storage conditions, they are thought to be safer and more useful than ionic drug carriers. The Potential for effectively delivering medications to tumor locations is emphasized, especially with activated macrophage support. Even though the current research is restricted to animal studies, more clinical studies are necessary to fully utilize niosomes as efficient medicine carriers for infections, cancer, and other illnesses. Niosomes have a great deal of potential for encapsulating a variety of medications, such as toxic antiviral, anti-inflammatory, anti-infective, and anti-cancer compounds.

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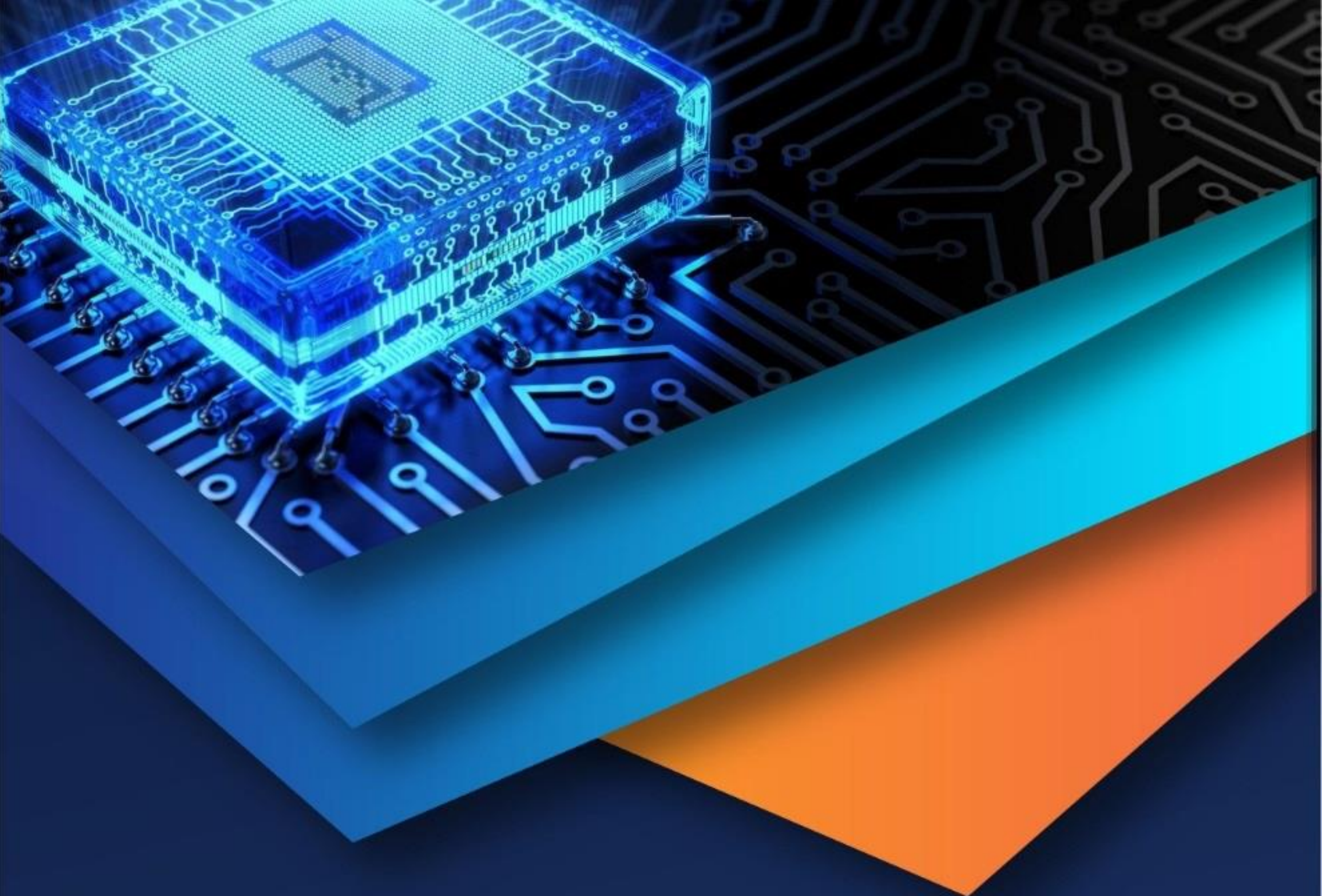

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