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The Use of *Opuntia Ficus Indica* Mucilage Powder as a Novel Excipient Used in Transdermal Patch

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Abstract: The application of powdered Opuntia ficus-indica (OFI) mucilage as a natural excipient in transdermal drug delivery systems is investigated in this work. Excellent mechanical characteristics, regulated drug release, and improved skin penetration were demonstrated by transdermal patches made with different amounts of OFI mucilage. Its biocompatibility with human skin fibroblasts was validated by in vitro experiments. For transdermal patches, the results indicate that OFI mucilage is a viable, sustainable substitute for synthetic excipients; nevertheless, more in vivo and long-term stability research is required.
Index Words: Opuntia ficus-indica mucilage, Transdermal drug delivery, Natural excipient, Controlled drug release, Skin permeation, Biocompatibility

I. INTRODUCTION

A. Applications of Opuntia ficus-indica Mucilage Powder

1) Natural Film-Forming Agent

The mucilage extracted from *Opuntia ficus-indica* posses excellent film-forming ability, which is essential for developing transdermal patches. It forms thin, uniform, and flexible films that can easily adhere to the contours of the skin. These films create a semi-permeable barrier, allowing drug diffusion while protecting the site of application. Moreover, its natural bio adhesive properties promote prolonged retention on the skin surface without causing irritation or discomfort, making it ideal for topical applications.

2) Sustained Drug Release

Due to its high viscosity and gel-forming capacity, *Opuntia* mucilage acts as an effective matrix for the controlled release of active pharmaceutical ingredients. When incorporated into transdermal patches, it slows the rate of drug diffusion, resulting in sustained and consistent release over an extended period. This controlled delivery minimizes the need for frequent reapplication, enhances patient compliance, and maintains therapeutic levels of anti-inflammatory agents such as diclofenac for chronic inflammatory conditions.

3) Biocompatibility and Biodegradability

As a naturally derived polysaccharide, *Opuntia* mucilage is inherently biocompatible and biodegradable. It does not provoke immune responses, making it suitable for repeated or long-term use. Its non-toxic and non-sensitizing nature reduces the risk of adverse skin reactions, especially important for transdermal systems intended for chronic treatment, such as in osteoarthritis, rheumatoid arthritis, or muscle pain. Furthermore, its biodegradability aligns with eco-friendly pharmaceutical development and supports sustainable product design.

4) Hydrophilic Nature

The mucilage exhibits strong hydrophilicity, which plays a crucial role in enhancing the performance of transdermal patches. Its ability to retain water maintains a moist environment at the site of application, softening the stratum corneum (outer skin layer) and facilitating better drug penetration. Improved skin hydration directly contributes to increased permeability and enhanced absorption of the incorporated drug. This property is especially beneficial when delivering water-soluble anti-inflammatory compounds through the skin barrier.

B. Historical and Current Use of Opuntia Ficus Indica

Opuntia Ficus Indica has a long history of use across various fields, ranging from traditional medicine to cosmetic formulations. Its mucilage is particularly valued for its polysaccharide content, which confers unique gel-forming and film-forming abilities.

The plant's abundance in arid regions and its economic viability make it an attractive material for industries seeking sustainable resources. Historically, it has been used in medicinal applications such as wound healing, where its moisture retention and protective properties were recognized. In pharmaceutical applications, these characteristics can be leveraged to create coatings that safeguard APIs and optimize drug delivery.

C. Adhesion and Biocompatibility

Opuntia ficus-indica mucilage exhibits excellent adhesion, moisture retention, and film-forming properties, making it an effective natural excipient for transdermal patches. Its bio adhesive strength is due to its polysaccharide composition, which allows strong skin contact without irritation. When combined with polymers, it enhances mechanical strength and flexibility. The mucilage is also biocompatible, non-toxic, and hypoallergenic, with added anti-inflammatory and antioxidant benefits. Studies confirm its safety, compatibility with drugs, and ability to improve drug permeation and retention, supporting its potential in anti-inflammatory transdermal therapies.

D. Role in Sustained and Controlled Drug Release

Opuntia ficus-indica mucilage powder serves as a natural polymer matrix in transdermal patches, enabling sustained and controlled drug release. Its high polysaccharide content allows it to form a gel-like structure upon hydration, which regulates drug diffusion and maintains consistent drug levels in the bloodstream. The mucilage exhibits excellent swelling, film-forming, and viscosity properties, contributing to a slow, controlled release over extended periods (e.g., 12–24 hours). Additionally, it is biodegradable, biocompatible, and responsive to skin moisture and pH, making it ideal for safe, prolonged dermal application. These features enhance therapeutic effectiveness, reduce dosing frequency, and improve patient compliance in anti-inflammatory therapy.

E. Environmental Impact and Sustainability

There is growing concern about the environmental impact of synthetic polymers used in pharmaceuticals. Natural polymers such as Opuntia Ficus Indica mucilage are biodegradable and environmentally friendly, making them an attractive alternative. Their use significantly reduces the environmental footprint of pharmaceutical production. Moreover, sustainable harvesting and processing of Opuntia plants further enhance their appeal, contributing to the eco-conscious manufacturing practices currently being adopted in the industry.

F. Optimization and Areas for Improvement

While OFI mucilage shows considerable promise, there is potential for further optimization. The addition of plasticizers like glycerol or polyethylene glycol (PEG) could improve the flexibility and durability of the mucilage-based film, reducing the risk of cracking during storage. Furthermore, the incorporation of preservatives such as sorbic acid could extend the shelf life by preventing microbial contamination. Formulating the mucilage with other natural or synthetic excipients may also enhance its film strength.

II. LITERATURE REVIEW

1) *Maqsood, A., & Hussain, S. (2021). "Utilization of Opuntia Ficus Indica as a Natural Excipient in Pharmaceutical Formulations."*

This study investigates the potential of Opuntia Ficus Indica mucilage as a natural excipient in pharmaceutical formulations. The authors highlight its properties, including binding, film-forming, and stabilizing capabilities, which enhance tablet characteristics. Experimental results indicate that transdermal patch formulated with Opuntia mucilage exhibit improved dissolution rates and mechanical properties, suggesting its effectiveness as a substitute for synthetic excipients.

2) *Jabeen, F., et al. (2022). "Characterization of Opuntia Ficus Indica Mucilage for Pharmaceutical Applications."*

This research focuses on the extraction and characterization of mucilage derived from Opuntia Ficus Indica. The study elaborates on its physicochemical properties, such as viscosity and gelling capacity. Findings reveal that Opuntia mucilage significantly enhances drug release profiles and provides stability to pharmaceutical formulations.

3) *Alkhalaf, M. I., & Moustafa, M. F. (2020). "The Potential of Opuntia Ficus Indica in Drug Delivery Systems: A Review."*

This review explores the applications of Opuntia Ficus Indica mucilage in drug delivery systems. The authors summarize various studies demonstrating the mucilage's ability to enhance the bioavailability of active pharmaceutical ingredients while protecting sensitive compounds during storage, showcasing its significance in modern formulations.

4) *Pérez-Flores, L. J., et al. (2020). "Mucilage from Opuntia Ficus Indica: A Natural Alternative for Tablet Coatings."*
This study examines the effectiveness of Opuntia Ficus Indica mucilage as a tablet coating agent. The authors found that the transdermal patch with this natural mucilage exhibited improved drug release kinetics and enhanced mechanical strength. They also emphasized the environmental advantages of using natural polymers over synthetic alternatives, aligning with current trends in sustainable pharmaceuticals.

5) *Zubair, M., & Bhatia, A. (2021). "Opuntia Ficus Indica: A Review of its Pharmacological and Pharmaceutical Applications."*
This comprehensive review discusses the diverse applications of Opuntia Ficus Indica, particularly its role as a adhesive material in pharmaceutical formulations. The authors underscore the natural mucilage's capacity to enhance drug solubility, stability, and release profiles, providing valuable comparisons to traditional synthetic excipients.

6) *Ravi Kumar, M., et al. (2022). "Application of Natural Polymers in Pharmaceutical Formulations: The Case of Opuntia Mucilage."*
This study focuses on the utilization of natural polymers, with a particular emphasis on Opuntia Ficus Indica mucilage, in various pharmaceutical formulations.

7) *Mohammed, A. A., et al. (2023). "Innovative Uses of Opuntia Ficus Indica Mucilage in Modern Pharmaceutics."*
This article reviews recent advancements in the use of Opuntia Ficus Indica mucilage in the pharmaceutical sector. The authors explore its multifunctional roles, including its application as an adhesive and topical delivery formulation, emphasizing the mucilage's benefits in enhancing drug delivery systems and minimizing the side effects commonly associated with synthetic additives.

III. PLANT PROFILE

Opuntia ficus Indica is a succulent plant characterized by its flat, paddle-shaped stems (or pads) covered in spines or glochids (small, hair-like spines). It can grow as a shrub or small tree, reaching heights of up to 5 meters (16 feet) in ideal conditions. The plant features bright yellow or red flowers that can bloom in spring and summer, followed by edible fruit known as "tunas," which are typically sweet and juicy.

Fig No. 1 Opuntia Ficus Indica

Opuntia ficus-indica typically grows as a sprawling bush or small tree, reaching heights between 1 and 5 meters (approximately 3 to 16 feet) under ideal conditions. The plant's branching structure allows it to spread extensively, often forming a dense canopy that offers shelter to various wildlife species.
During the spring and summer seasons, *Opuntia ficus-indica* produces striking flowers in vibrant shades ranging from yellow to deep red or magenta. Although each individual bloom is short-lived, lasting only about a day, the plant continuously generates new flowers throughout its flowering period. Following pollination, these flowers develop into oval-shaped fruits known as "tunas," which vary in color from green and yellow to reddish-purple. The fruits are sweet, juicy, and covered in tiny spines called glochids, necessitating careful handling before consumption.

A. Habitat and Distribution

Originally native to Mexico, *Opuntia ficus-indica* flourishes in arid and semi-arid climates and has successfully adapted to a variety of environments, including the southwestern United States, Mediterranean regions, and parts of Africa and South America. It thrives in well-drained sandy or rocky soils and is highly drought-resistant, making it a valuable crop for sustainable agriculture in challenging climates.

B. Cultural Significance

Prickly pear holds deep cultural and culinary importance, particularly in Mexican traditions, where both the pads (nopalitos) and the fruits (tunas) are widely utilized. Nopalitos are typically grilled, sautéed, or added to salads, tacos, and soups, while the fruit is consumed fresh, juiced, or used in making jams and jellies. Beyond its role in cuisine, *Opuntia ficus-indica* has longstanding applications in traditional medicine, where it is valued for treating various ailments, highlighting its enduring relevance in indigenous cultural practices.

C. Medicinal Uses

The medicinal value of *Opuntia ficus-indica* stems from its rich nutritional content and abundance of bioactive compounds. Both the mucilage-rich pads and the fruit offer a range of health benefits, including:

- Antioxidant Properties: High levels of vitamin C, flavonoids, and polyphenols help neutralize oxidative stress and protect cells from damage.
- Anti-Inflammatory Effects: Traditionally used to alleviate inflammation and manage chronic conditions such as arthritis.
- Digestive Health: The plant’s high fibre content supports digestive function, promotes gut health, and assists in managing gastrointestinal disorders.

D. Blood Sugar Regulation

Research indicates that prickly pear may contribute to lowering blood glucose levels, making it potentially beneficial for individuals with diabetes or insulin resistance.

E. Weight Management

Due to its rich fibre content, *Opuntia ficus-indica* can promote feelings of fullness, supporting weight management strategies by reducing overall calorie intake.

F. Phytochemical Composition:

The mucilage derived from the pads contains a diverse mix of polysaccharides, vitamins, and minerals, key components including:

- Mucilage: Functions as a natural thickener and stabilizer, offering gel-like properties advantageous for digestive health and product formulation.
- Vitamins: Particularly rich in vitamin C, with additional contributions from B vitamins (B6 and B12) important for energy metabolism.
- Minerals: Supplies essential minerals such as calcium, magnesium, potassium, and iron, supporting various physiological functions.
- Phytochemicals: Includes a variety of antioxidants, flavonoids, and betalains that enhance the plant’s health-promoting profile.

G. Applications in Pharmaceutical Formulations

The functional properties of *Opuntia ficus-indica* mucilage powder, such as its film-forming, binding, and stabilizing abilities, make it a promising natural excipient for pharmaceutical use:

- Natural Origin: Helps reduce dependence on synthetic additives, aligning with the growing demand for natural, clean-label products.
- Biocompatibility: Offers a favourable safety profile, minimizing risks of adverse effects in pharmaceutical formulations.
- Enhanced Drug Delivery:Capable of improving the stability and controlled release of active pharmaceutical ingredients, leading to better therapeutic performance.
- Sustainability: The cultivation of prickly pear is environmentally sustainable, requiring fewer resources and making it an attractive option for eco-friendly agriculture and manufacturing practices.

IV. PHARMACOLOGICAL POTENTIAL

1) Nutritional Composition: Opuntia Ficus Indica is rich in essential nutrients, including vitamins (such as vitamins C and E), minerals (such as magnesium, potassium, and calcium), and dietary fibre. This nutritional profile contributes to its overall health benefits.
2) Antioxidant Activity: The fruit and pads of Opuntia Ficus Indica contain various phenolic compounds and flavonoids, which exhibit significant antioxidant properties. These antioxidants help neutralize free radicals in the body, potentially reducing oxidative stress and lowering the risk of chronic diseases such as cancer and cardiovascular disorders.
3) Anti-Inflammatory Effects: Several studies have reported that extracts of Opuntia Ficus Indica possess anti-inflammatory properties. The bioactive compounds, such as betalains and polyphenols, may help mitigate inflammation in various conditions, including arthritis and metabolic syndrome.
4) Hypoglycaemic Properties: Research suggests that Opuntia Ficus Indica may aid in regulating blood sugar levels. Its extracts have been shown to improve insulin sensitivity and reduce blood glucose levels, making it a potential therapeutic agent for managing type 2 diabetes.
5) Lipid-Lowering Effects: The consumption of Opuntia Ficus Indica has been associated with reductions in lipid levels in the bloodstream. Studies indicate that its extracts may help lower total cholesterol and triglyceride levels, contributing to improved cardiovascular health.
6) Weight Management: Due to its high fibre content, Opuntia Ficus Indica may promote feelings of fullness, potentially aiding in weight management and appetite control. Some studies suggest that its extracts can reduce fat absorption in the intestines.
7) Hepatoprotective Activity: Preliminary studies indicate that Opuntia Ficus Indica may offer protective effects on the liver. Its antioxidant properties may help mitigate liver damage caused by toxins or excessive alcohol consumption.
8) Antimicrobial Activity: Extracts from Opuntia Ficus Indica have demonstrated antimicrobial properties against various pathogenic bacteria and fungi. This suggests its potential use in preventing infections and promoting skin health.
9) Wound Healing Properties: Traditionally, Opuntia Ficus Indica has been used for wound healing in folk medicine. Studies have shown that its extracts can accelerate the healing process, possibly due to their anti-inflammatory and antioxidant effects.
10) Digestive Health: The high fibre content of Opuntia Ficus Indica supports digestive health by promoting regular bowel movements and preventing constipation. Additionally, its mucilage content may soothe gastrointestinal inflammation.

V. EXTRACTION PROCESSES

Extraction is the process of separating a desired substance from a mixture, usually by using a solvent or mechanical means. In the context of natural compounds, it refers to the process of isolating bioactive compounds, such as mucilage, from plant materials. For Opuntia Ficus Indica, the extraction of mucilage involves separating this gelatinous substance from the cactus pads using specific techniques aimed at preserving its integrity and bioactivity.

The following steps outline a detailed procedure for the extraction of mucilage from Opuntia Ficus Indica:

1) *Extraction Process of Mucilage from Opuntia Ficus-Indica*

a) *Harvesting and Preparation*
- Begin by harvesting the cladodes (cactus pads) of Opuntia ficus-indica. It's essential to choose healthy, mature pads to ensure a good yield of mucilage.
- Wash the cladodes thoroughly to remove any dust, dirt, and spines. This step is crucial to ensure the purity of the extracted mucilage.

b) *Cutting and Homogenization*
- Chop the washed cladodes into small pieces to increase the surface area for extraction. This helps in releasing the mucilage more efficiently.
- Blend the chopped pieces with an appropriate amount of distilled water using a blender or homogenizer. This creates a homogeneous slurry.

c) *Heating and Filtration*
- Heat the slurry to around 60-80°C for about 30-60 minutes. Heating helps to break down the cellular structure, releasing the mucilage into the water.
- After heating, allow the mixture to cool to room temperature.

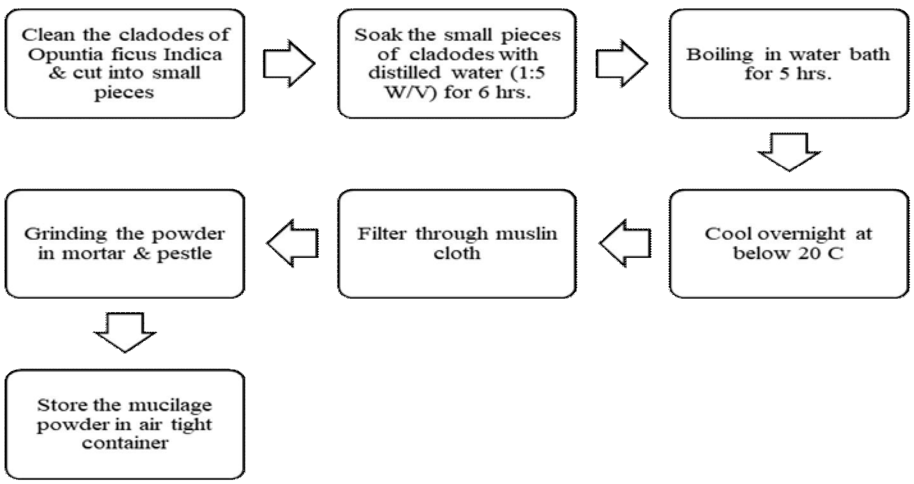
- Filter the cooled slurry using a fine mesh or cheesecloth to separate the solid residues from the mucilage solution. You can use vacuum filtration for more efficient separation.

d) *Precipitation and Drying:*
- To concentrate the mucilage, add a precipitating agent such as ethanol to the filtered mucilage solution. This causes the mu cilage to precipitate out of the solution.
- Collect the precipitated mucilage by centrifugation or filtration.
- Wash the precipitated mucilage with ethanol to remove any impurities.
- Dry the washed mucilage at room temperature or in a drying oven at a controlled temperature (below 50°C) to prevent degr adation.

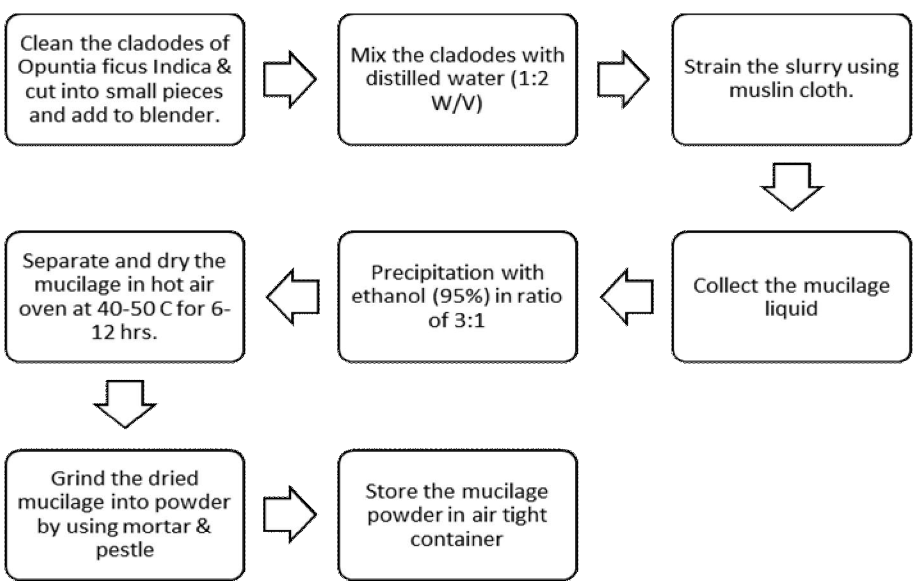
e) *Grinding and Storage:*
- Once dried, grind the mucilage into a fine powder using a mortar and pestle or a mechanical grinder.
- Store the mucilage powder in an airtight container, protected from moisture and light to maintain its quality.

2) *Different methods have been used for the extraction of mucilage from Opuntia ficus Indica:*

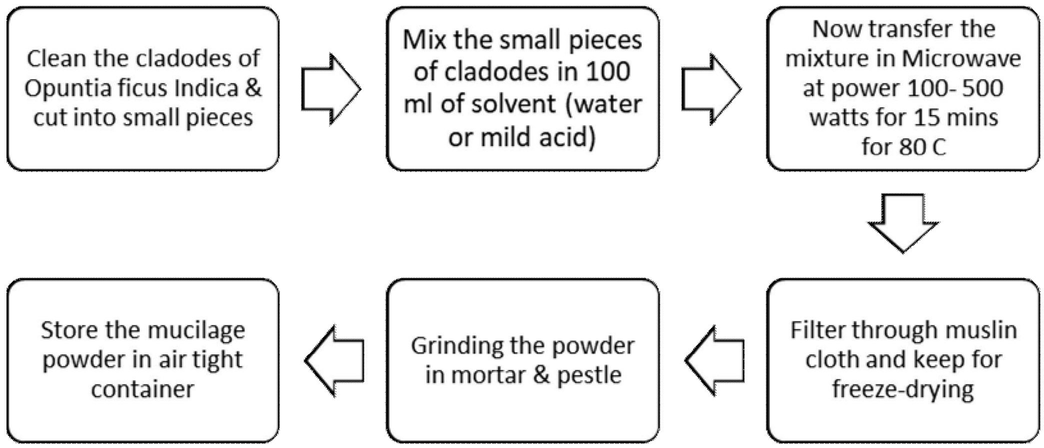
A. *Hot Water Extraction Process*



B. *Extraction Process by using Ethanol*



C. Microwave Assisted Extraction Process



D. Centrifugation Method of Extraction

Centrifugation is a technique used to separate particles from a solution based on their size, shape, density, and the viscosity of the m edium. Here's a detailed description about the process:

1) Principle of Centrifugation

Centrifugation works on the principle of centrifugal force, which is the force exerted on an object moving in a circular path1. When a mixture is spun at high speeds, the denser particles move outward to the bottom of the tube (forming a pellet), while the less dense particles remain in the liquid (supernatant)1.

2) Steps Involved in Centrifugation Extraction

- Preparation of Sample: Mix the sample with a suitable solvent to create a homogeneous solution1.
- Loading the Centrifuge: Place the sample in centrifuge tubes and balance them in the rotor to ensure even distribution of centrif ugal force1.
- Spinning: Set the centrifuge to the desired speed (RPM) and duration2. The speed and time depend on the type of particles you want to separate.
- Separation: During spinning, denser particles sediment at the bottom of the tube, forming a pellet2.
- Collection of Supernatant: Carefully remove the supernatant, which contains the less dense particles, without disturbing the pell et2.
- Washing: If necessary, wash the pellet with a fresh solvent to remove any impurities.
- Repetition: For finer separation, repeat the centrifugation process at higher speeds or for longer durations2.

3) Types of Centrifugations

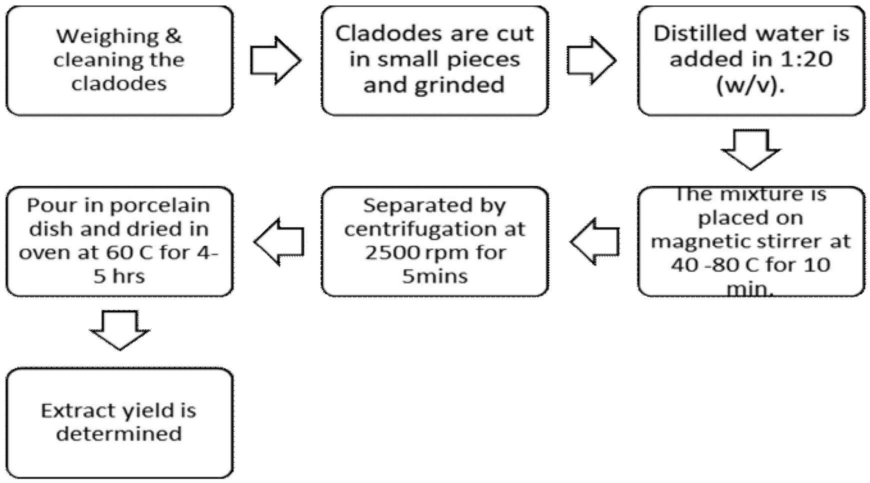
- Differential Centrifugation: Separates particles based on their size and density by using a series of increasing centrifugal forces.
- Density Gradient Centrifugation: Uses a gradient of increasing density to separate particles more precisely based on their buoya nt density1.

4) Applications

Centrifugation is widely used in biological research, clinical laboratories, and industrial processes to isolate cells, viruses, proteins, nucleic acids, and other particles1.

5) Advantages

- Efficiency: Rapid separation of particles based on density.
- Precision: Ability to separate particles with very small differences in density.
- Scalability: Can be used for small-scale laboratory experiments or large-scale industrial processes.



VI. CHEMICAL TESTS

SR NO.	TEST	OBSERVATION	INFERENCE
1.	State	Solid	High molecular weight
2.	Colour	Coloured solid -Deep colour: Brown	Nitro compounds: Nitroanilines, Nitrophenols, Azocompounds, Nitroso compounds: Aminophenol, Higher aminophenols, Higher aromatic amines
3.	Odour	Sweet and pleasant odour	Esters, alcohols, aromatic hydrocarbons, alkyl halides.
4.	Effect of heat	i) Sharp melting ii) Gives out water and chars with caramel odour	i) Pure organic compounds present. ii) Carbohydrates present.
5.	Solubility	Soluble in water A) Test with litmus i) Acidic B) No evolution on CO2	A) Carboxylic acid, acid anhydrides, acid salts, acid chlorides, phenols. B) Phenols
6.	A) Action of cold NaOH B) Action of hot NaOH	A) i) Evolution of ammonia ii) Change in colour Colourless to deep yellow B) darkens	A) m- and p- Nitrophenol. B) Carbohydrates, polynitro compounds.
7.	Action of Sodium carbonate solution	Effervescence	Acids

8.	Action of Hot conc. Sulfuric acid	Blackening with effervescence of CO_2, CO, SO_2	Carbohydrates such as cane sugar, higher hydroxy acids.
9.	Action of potassium permanganate	1) Neutral medium 2) Acidic medium 3) Basic medium	1) No change 2) No change 3) No change
10.	Action of Bromine Water	Decolourization with precipitate	Phenols, aromatic amines.
11.	Action of Bromine in Chloroform	Decolourization with evolution of HBR fumes	Saturated compounds easily brominated.
12.	Action of ferric chloride solution	Green colouration changing through blue and violet to red by Na_2CO_3	Catechol
13.	Heating on copper gauze	Charring and smell of burnt Sugar	Carbohydrates
14.	pH	6.58- 6.62 (Alkaline)	Slightly Acidic

A. Test for Carbohydrates

SR NO.	TEST	IF PRESENT
1.	Fehling's Test	Brick red ppt is observed
2.	Benedict's Reagent	Green coloured is observed
3.	Barford's Reagent	Red coloured is observed
4.	Selvinoff Reagent	Red coloured is observed
5.	Tollen's Reagent	Reddish yellow colour is observed
6.	Iodine Test	No change is observed

VII. DRUG AND EXCIPIENT PROFILE

A. Diclofenac Sodium: Overview

1. Chemical Information
- Name: Diclofenac Sodium
- Molecular Formula: $C_{14}H_{10}Cl_2NNaO_2$
- Molecular Weight: 318.13 g/mol
- Structure: A phenylacetic acid derivative with two chlorine atoms
- Appearance: White to slightly yellowish, crystalline powder

2. Pharmacological Properties
- Class: Non-Steroidal Anti-Inflammatory Drug (NSAID)

- Mechanism of Action: Inhibits cyclooxygenase enzymes (COX-1 and COX-2), thereby decreasing the synthesis of prostaglandins responsible for inflammation, pain, and fever. Diclofenac exhibits anti-inflammatory, analgesic, and antipyretic (fever-reducing) activities.

3. Clinical Uses
Diclofenac Sodium is used in the treatment of inflammatory disorders such as:
- Rheumatoid arthritis
- Osteoarthritis
- Ankylosing spondylitis
- Acute pain (e.g., muscle injuries, sprains)
- Post-operative pain

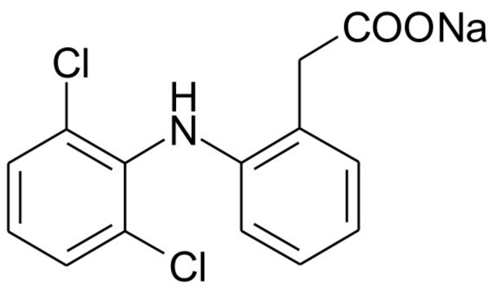


Fig no. 2: Diclofenac Sodium

B. Xanthum Gum
1. Chemical Information
- Name: Xanthan Gum
- Chemical Formula: $(C_{35}H_{49}O_{29})_n$ *(repeating polysaccharide unit)*
- Molecular Weight: ~933.75 g/mol per repeating unit
- Structure: A high molecular weight extracellular polysaccharide composed of a cellulose backbone (β-D-glucose) with trisaccharide side chains containing mannose and glucuronic acid
- Appearance: Cream-colored to white, odourless, fine powder

2. Functional and Physicochemical Properties
- Class: Natural polysaccharide; hydrophilic polymer
- Mechanism of Action / Function:
  - Acts as a thickening, stabilizing, suspending, and film-forming agent
  - Forms viscous solutions and hydrogels upon hydration
  - Exhibits shear-thinning behaviour (viscosity decreases under shear stress)
- Solubility: Soluble in both cold and hot water
- Stability: Stable over a wide pH range (4–10) and resistant to temperature fluctuations and enzymatic degradation

3. Industrial and Clinical Uses
A. Food Industry:
- Used as a thickener, emulsifier, and stabilizer in salad dressings, sauces, beverages, and desserts

B. Pharmaceutical Applications:
- Used as a suspending agent in liquid formulations
- Functions as a tablet binder, controlled-release matrix former, and viscosity enhancer

C. Cosmetics and Personal Care:
- Thickening agent in creams, gels, and lotions

D. Other Uses:
- Used in oil drilling, agriculture, and industrial formulations

4. Use in Transdermal Patch Systems

Role in Transdermal Delivery:

- Film-Forming Agent: Xanthan gum helps form a uniform and flexible film, essential for drug-loaded patches
- Matrix Former: Acts as a polymeric matrix that controls the release rate of the drug through the skin
- Bio adhesive Properties: Exhibits moderate bio adhesion, helping the patch adhere to the skin for sustained delivery
- Hydration and Swelling: Upon contact with skin moisture, xanthan gum swells to form a gel-like layer, facilitating controlled drug diffusion
- Combination Use: Often used in combination with other polymers like HPMC, PVA, or Carbopol to enhance mechanical properties and drug release behaviour

Advantages in Transdermal Systems:

- Non-toxic, biodegradable, and biocompatible
- Provides sustained drug release and improves patient compliance
- Useful for both hydrophilic and lipophilic drugs (in combination with other excipients)

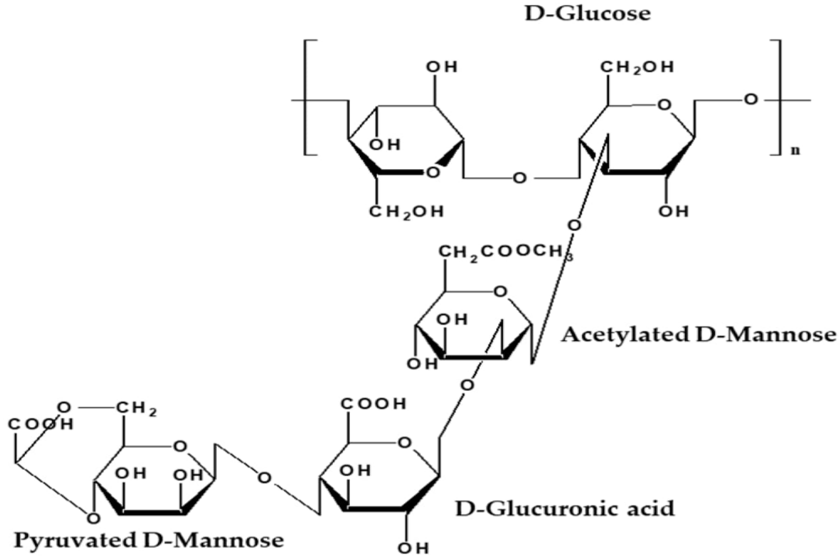


Fig no 3: Xanthum Gum

C. Glycerine

1. Chemical Information

- Name: Glycerine (also known as Glycerol)
- IUPAC Name: Propane-1,2,3-triol
- Molecular Formula: $C_3H_8O_3$
- Molecular Weight: 92.09 g/mol
- Structure: A three-carbon alcohol with three hydroxyl (-OH) groups
- Appearance: Colorless, odorless, viscous liquid with a sweet taste

2. Physicochemical and Functional Properties

- Class: Polyol / Humectant / Solvent
- Solubility: Miscible with water and alcohol; insoluble in oils
- Viscosity: Highly viscous
- Boiling Point: 290 °C (554 °F)
- Melting Point: 18 °C (64 °F)
- pH: Neutral to slightly acidic (pH ~5–7)
- Stability: Chemically stable and non-volatile at room temperature

3. Industrial and Clinical Uses

A. Pharmaceutical Applications:
- Used as a humectant, plasticizer, co-solvent, lubricant, and preservative
- Found in oral liquids, suppositories, topical creams, and ointments
- Serves as a vehicle for drug delivery, especially for hydrophilic drugs

B. Cosmetic and Personal Care:
- Common in moisturizers, lotions, and hair care products due to its hydrating properties

C. Food Industry:
- Used as a sweetener, humectant, and preservative in food and beverages

D. Industrial Applications:
- Found in antifreeze, plastics, and e-liquids for vaping

4. Use in Transdermal Patch Systems

Role in Transdermal Delivery:
- Plasticizer: Glycerin improves the flexibility and elasticity of polymeric films used in transdermal patches
- Humectant: Helps retain moisture in the patch, maintaining a hydrated environment that enhances drug permeation through the skin
- Solubilizer / Co-solvent: Enhances the solubility of the active pharmaceutical ingredient (API) within the polymer matrix
- Permeation Enhancer (minor role): May contribute to improving skin permeability when used with other enhancers

Common Combinations:
- Frequently used with polymers like HPMC, PVA, carbopol, and xanthan gum
- Acts synergistically with propylene glycol, PEG, or ethanol to enhance patch performance

Advantages in Transdermal Systems:
- Non-toxic, biocompatible, and readily available
- Provides softness and smoothness to the patch
- Helps maintain drug stability within the matrix

D. Opuntia ficus Indica Mucilage Powder

1. Botanical and Chemical Information

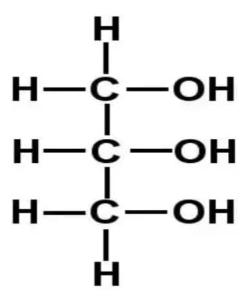


Fig no.: 4 Glycerine

- Name: Opuntia indica Mucilage Powder
- Common Name: Prickly pear cactus mucilage
- Source: Extracted from the cladodes (pads) of *Opuntia indica*, a species of the cactus family
- Main Constituents:
    - Polysaccharides (mainly arabinose, galactose, rhamnose, and galacturonic acid)
    - Pectins, cellulose, and mucopolysaccharides
- Appearance: Off-white to light beige, amorphous or fine powder
- Solubility: Swells in water; forms a viscous gel
- Taste/Odor: Neutral to slightly earthy odor; bland taste

2. Functional and Physicochemical Properties
- Class: Natural polysaccharide; hydrocolloid
- Viscosity: High water-holding capacity; forms gels at low concentrations
- pH Stability: Stable in a range of pH 4–8
- Biodegradable and biocompatible
- Non-toxic and renewable source

3. Traditional and Industrial Uses

A. Food Industry:
- Used as a thickener, emulsifier, and stabilizer in beverages and jellies
- Acts as a fiber supplement due to its high mucilage content

B. Pharmaceutical and Cosmetic Applications:
- Employed as a natural binder and disintegrant in tablets
- Used in moisturizing and soothing skin products due to hydrating properties
- Has antioxidant and anti-inflammatory potential

4. Use in Transdermal Patch Systems

Role in Transdermal Drug Delivery:
- Film-Forming Agent: The mucilage forms flexible, bioadhesive films, suitable for use in transdermal patches
- Polymeric Matrix: Serves as a natural polymer matrix that can entrap and control the release of drugs through the skin
- Hydration and Swelling: Upon contact with skin moisture, it swells to form a gel-like layer, aiding sustained drug diffusion
- Bioadhesive Properties: Provides good adhesion to the skin, helping patches remain in place for extended periods
- Permeation Enhancement (minor): Its hydrating effect may soften the stratum corneum, improving drug absorption

Advantages:
- Natural, biodegradable, and eco-friendly
- Provides sustained release without synthetic polymers
- Cost-effective and safe for topical applications
- Can be used in combination with synthetic or semi-synthetic polymers (e.g., PVA, HPMC) for improved mechanical strength

VIII. FORMULATOIN AND CONSIDERATIONS

1) Clean the cladodes of Opuntia ficus indica and cut them into small pieces.
2) Soak the small pieces of cladodes in distilled water (1:5 W/V) for 6 hours.
3) Boil the soaked material in a water bath for 5 hours.
4) Cool the mixture overnight at a temperature below 20°C.
5) Filter the mixture through a muslin cloth.
6) Grind the filtered material into powder using a mortar and pestle.
7) Store the mucilage powder in an airtight container.
8) Transdermal patches containing Diclofenac Sodium were prepared by the solvent casting method
9) First, take 7.5 ml of water in the glass beaker and keep it for boiling in a water bath for 5 min.
10) Weigh 1 gm of OFI mucilage powder and add it in the water with continuous stirring till the powder dissolves completely.
11) After that, weigh 0.75 gm xanthan gum and mix it in the OFI mucilage powder
12) Cool down the mixture under running water.
13) Once the mixture is cooled down, add 10 mg of drug (Diclofenac Sodium) into the above solution.
14) Lubricate the mixture by adding 1.5 ml of glycerine and mix it by continuous stirring.
15) Prepare the petri plate by washing and drying.
16) Pour the solution into the petri plate without disturbance; keep it for 24 hours for drying at room temperature.
17) After the complete drying, remove the patch from the petri plate by peeling and store it.

Batches	Drug	Xanthum Gum	Glycerine	Mucilage Powder	Dil. Water
F1	10 mg	0.75 g	1.5 ml	1.25 g	7.5 ml
F2	10 mg	0 g	1.5 ml	1.25 g	7.5 ml
F3	10 mg	0.75 g	1.5 ml	01 g	7.5 ml
F4	10 mg	0.75 g	1.5 ml	1.5 g	7.5 ml

IX. EVALUATION AND RESULTS

A. *Thickness of Patch*

The thickness of the drug prepared patch is measured by using vernier calliper at different point of patch and this determines the average thickness and standard deviation for the same to ensure the thickness of the prepared patch.

Typically, thickness is measured using instruments like a vernier calliper.

Recommended thickness range for transdermal patches is usually around 0.1 mm to 1.0 mm, depending on formulation requirements.

IP standard practice expects that the variation in thickness across the patch should be minimal - usually within ±5% deviation from the mean value.

- Average thickness of patch was found to be: 0.15 mm

B. *Weight uniformity*

The prepared patches are to be dried at 60°C for 4 h before testing. A specified area of patch is to be cut in different parts of the patch and weighed in digital balance. The average weight and standard deviation values are to be calculated from the individual weights.

- $$\textbf{\% Deviation} = \frac{\textbf{Individual weight – Average weight}}{\textbf{Average weight}} \textbf{ X 100}$$

Typically, not more than 2 out of 10 patches should deviate from the average weight by more than ±5%.

None should deviate by more than ±10%.

C. *Folding Endurance*

A specific area of strip is cut and repeatedly folded at the same place till it broke. The number of times the film could be folded without breaking gave the value of folding endurance. A folding endurance value of >300 is generally considered acceptable.

Higher values indicate better flexibility and durability, especially important for patches worn over joints or moving areas.

- Folding endurance value was found to be 325 folds

D. *Percentage Moisture Content*

The prepared patches are to be weighed individually and to be kept in a desiccator containing fused calcium chloride at room temperature. After 24 h, the films are to be reweighed and the percentage moisture content determined by below formula.

Percentage moisture content (%) = [Initial weight - Final weight/Final weight] ×100

- % moisture content was found to be 5 to 15 %

E. *Tack Property*

Tack is the ability of a polymer to adhere to substrate with little contact pressure. It is important in transdermal devices which are applied with finger pressure. Tack is dependent on the molecular weight and composition of polymer as well as use tackifying resins in the polymer.

F. *Cell Diffusion Test*

The test substance is applied to a skin sample placed between donor and receptor compartments of a diffusion cell—either static (manually sampled) or flow-through (uses a pump). Skin can be oriented horizontally (common for absorption studies) or vertically

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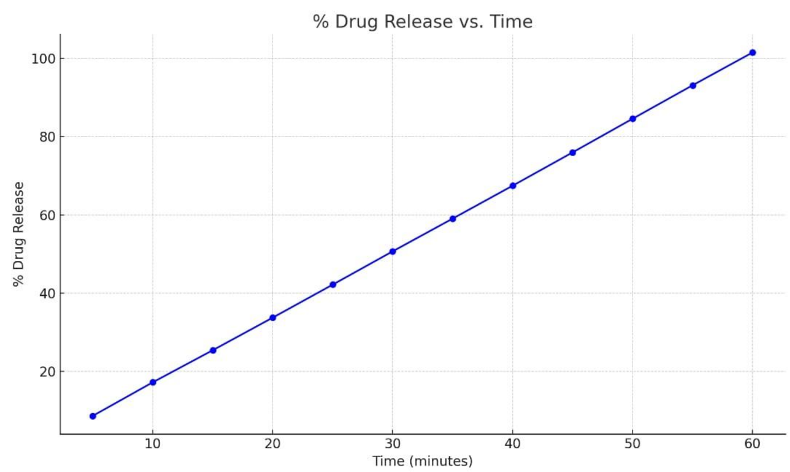
(used for drug delivery techniques like iontophoresis). Vertical setups may overhydrate the skin. Cells are made from inert materials, with receptor volumes of 0.5–10 mL and membrane areas of 0.2–2 cm². At least six skin samples are required. The method measures drug release and cumulative permeation.

Drug Release and Cumulative Frequency Data

Time (min)	Abs	Conc.	Conc. (After Dilution)	Diluted Conc.	Cumulative Conc.	Cumulative Conc. (mg)	% Drug Release
5	1.27012	25.4024	12.7012	11400.50	11400.50	11.40050	8.62%
10	1.26140	25.2280	12.6140	11327.42	22727.92	22.72792	17.20%
15	1.20621	24.1242	12.0621	10834.91	33562.83	33.56283	25.40%
20	1.22359	24.4718	12.2359	11000.24	44563.07	44.56307	33.73%
25	1.24024	24.8048	12.4024	11148.97	55712.04	55.71204	42.17%
30	1.25123	25.0246	12.5123	11249.63	66961.67	66.96167	50.68%
35	1.23112	24.6224	12.3112	11075.10	78036.77	78.03677	59.05%
40	1.23762	24.7524	12.3762	11129.49	89166.26	89.16626	67.46%
45	1.25192	25.0384	12.5192	11254.23	100420.5	100.4205	75.98%
50	1.27010	25.4020	12.7010	11400.28	111820.8	111.8208	84.58%
55	1.25587	25.1174	12.5587	11274.69	123095.5	123.0955	93.13%
60	1.22485	24.4970	12.2485	11014.27	134109.8	134.1098	101.12%



X. CONCLUSION

This study demonstrated that *Opuntia ficus indica* mucilage powder is a promising natural excipient for transdermal patches. Its hydrophilic and film-forming properties enhanced patch strength, flexibility, and controlled drug release. The patches showed good physical characteristics (0.15 mm thickness, uniform weight, 325-fold endurance, 5–15% moisture) and achieved over 101% Diclofenac Sodium release in 60 minutes. The mucilage is biodegradable, biocompatible, and eco-friendly, making it suitable for topical drug delivery. Further in vivo and stability studies are needed for clinical and commercial validation.

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[7] "Natural Polymers in Drug Delivery: A Review" - This review covers various natural polymers used in drug delivery systems, including mucilaginous substances, and discusses their advantages in terms of biocompatibility and sustainability.

[8] "Mucilage from Opuntia Ficus Indica: Extraction and Characterization" - This paper focuses specifically on the extraction methods and properties of mucilage from Opuntia Ficus Indica, discussing its potential applications in pharmaceutical formulations.

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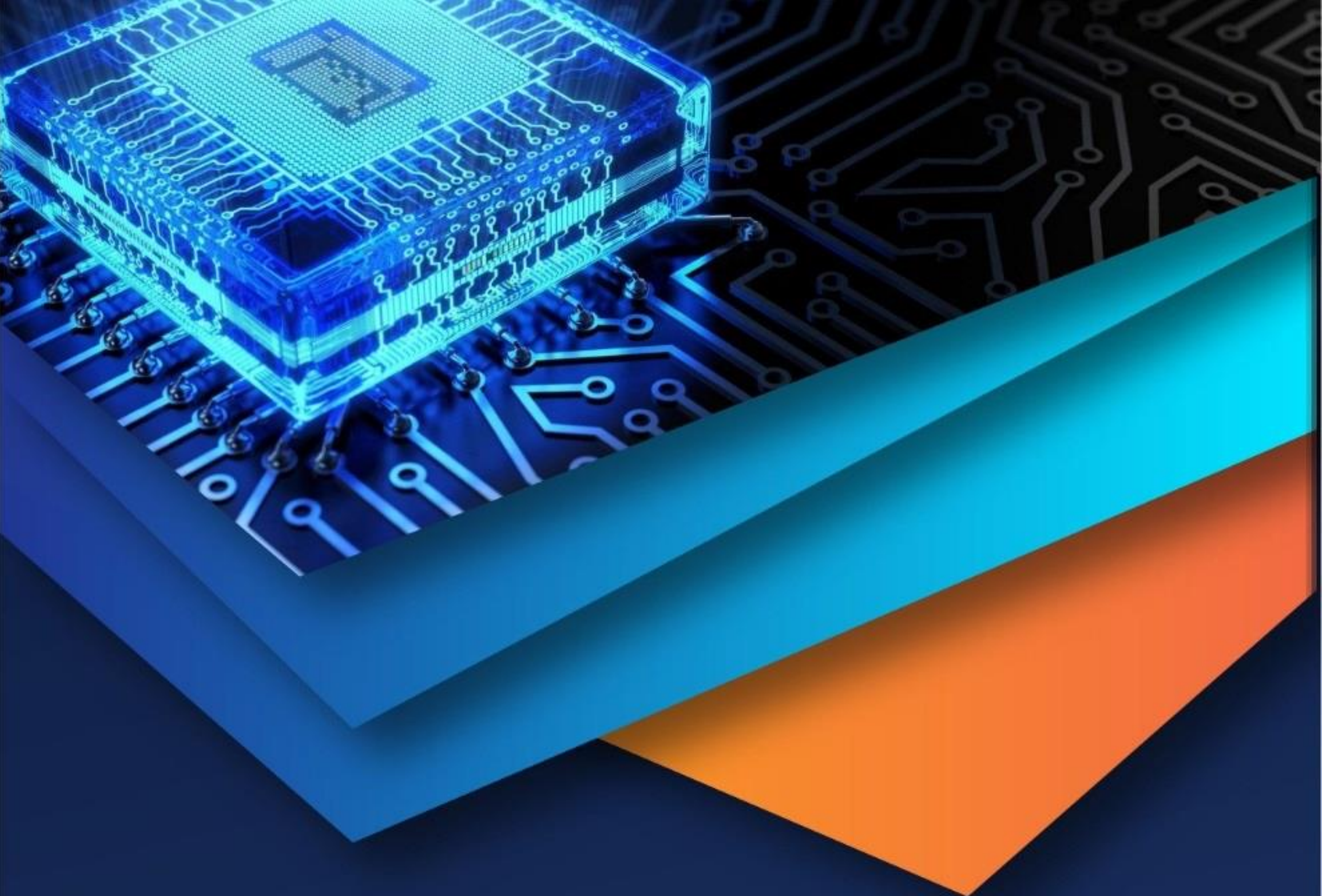

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