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Review on Formulation Development of Buccal Tablet

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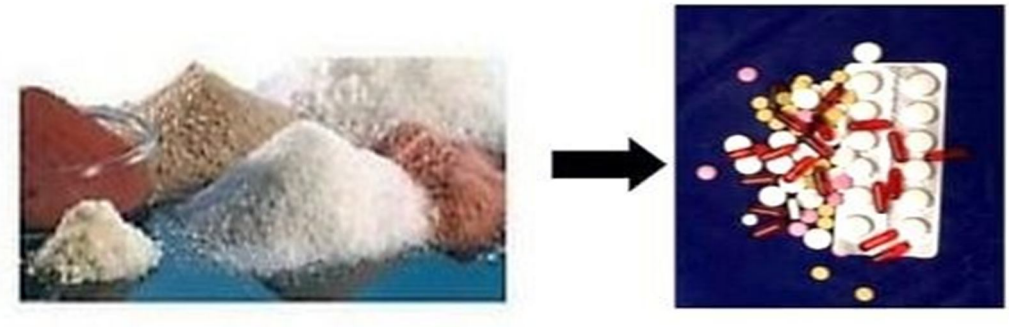
Abstract: ***By ensuring quality, safety, and effectiveness, formulation development is a crucial component of pharmaceutical development and is necessary for the product's therapeutic and commercial success.***
By bypassing the GIT and hepatic first pass impact, the buccal mode of administration offers numerous benefits, including increased patient compliance. Hardness, weight uniformity, thickness, friability, swelling index, mucoadhesive strength, surface pH, drug-excipient interaction studies, and drug content uniformity were among the metrics used to describe buccal tablets. For both systemic absorption and local administration in the oral cavity, the constant production of saliva and its subsequent swallowing might result in significant drug depletion from the dosage form and, consequently, limited bioavailability. In order to avoid the mentioned drawbacks of traditional oral dosage forms (i.e., tablets, capsules, syrups, etc.), new transmucosal routes such as nasal, rectal, vaginal, ocular, and oral mucosae are being explored as potential substitutes for current oral drug delivery methods. One of the target areas for administering medications in a wide range of dose forms is the buccal oral mucosa, especially for medications intended for systemic absorption and local distribution in the oral cavity.
Keyword-Formulation development, Buccal delivery system, Buccal tablet , Oral Mucosa, Drug absorption

I. INTRODUCTION OF FORMULATION DEVELOPMENT

1) One of the most important aspects of product development is formulation development, which can affect a pharmaceutical product's lifetime, patentability, and, eventually, success.[1]
2) The goal of formulation development is to identify the best possible dosage form, content, and manufacturing process for pharmaceuticals. In order to create a finished medical product with the desired dosage form, a chemical component, medication, and excipient are combined in this process [1].
3) By ensuring quality, safety, and efficacy, formulation development is a crucial component of pharmaceutical development and is necessary for the therapeutic commercial success of pharmacological products.[2]
4) The effective development of a drug product is linked to the discovery of a novel drug through the creation of pharmaceutical formulations. Based on patient needs, formulation development scientists must identify the best path to successful medication delivery. They must then optimize the formulation's characteristics using their understanding of the bioavailability of the therapeutic product and processing requirements. [2]

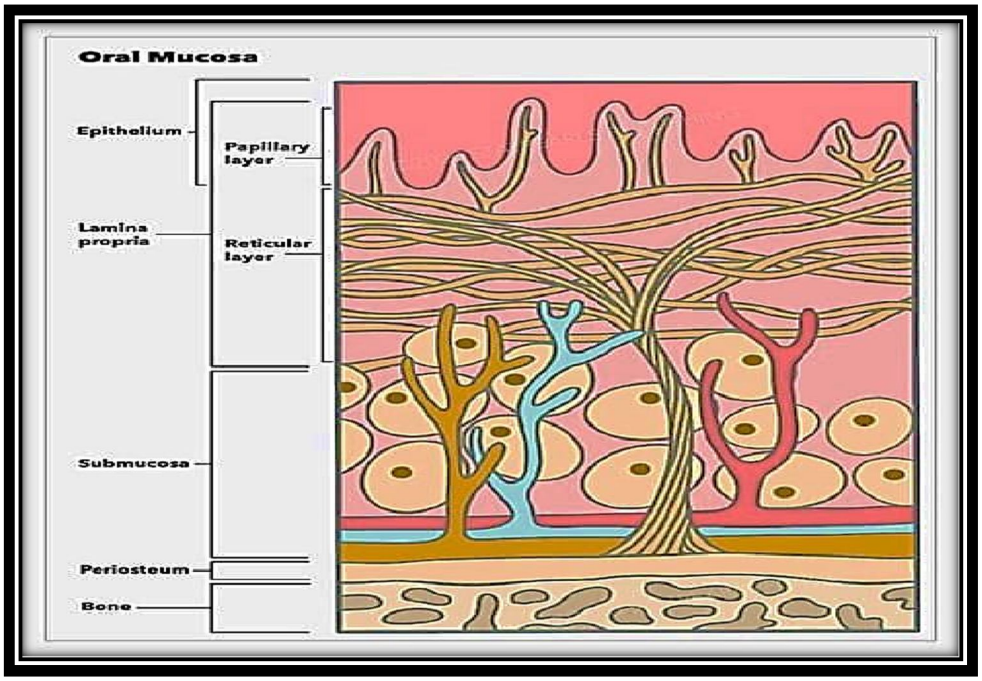


II. INTRODUCTION OF THE BUCCAL DRUG DELIVERY SYSTEM

1) Patients and medical professionals generally agree that the oral route is the most effective and most suitable way to provide drugs.[4]
2) The oral method of administration offers precise dose, medication stability, cost effectiveness, and convenience.[4]

3) However, it demonstrates hepatic first pass metabolism, which is the liver's removal of the medication prior to it entering the bloodstream and the breakdown of enzymes in the gastrointestinal tract (GIT).[4]
4) Because buccal administration has advantages over oral administration and overcomes its drawbacks, it is a good substitute for oral administration.[4]
5) It entails sandwiching the medication between the cheek and gums, where it dissolves and is taken into your bloodstream through a systematic circulation.[5]
6) One benefit of using the buccal route of administration is that it prevents drug degradation in the GIT environment and the hepatic first pass impact.[6] Because drugs are absorbed through the buccal mucosa this route is especially appealing.[7]
7) Compared to the nose, rectum, and vagina, the mouth has a comparatively big surface for drug application and adequate accessibility.[8] The medications enter the bloodstream through the jugular vein, which amply nourishes the salivary glands and their ducts into the systemic circulation. They do this by simply diffusing through the mucosal membrane. [5]

A. *Mucosa of the Mouth*



The mucosa of the mouth is the outermost layer of stratified squamous epithelium..The basement membrane, a lamina propria, and the submucosa, the innermost layer, are located beneath this.[9]

B. *Epithelium buccal [5,6,9]*

40 to 50 layers of non-keratinized stratified squamous cells make up the buccal epithelium.
It has different levels of maturity and ranges in thickness from 500 to 800 µm.The flattened, compact, differentiated cells that make up the topmost superficial layer of cells are around 150 µm thick.
Leaky epithelia that are in between intestinal and epidermal mucosae are known as oral mucosae.

C. *Propria Lamina [5,6]*

Collagen fibrils, blood arteries, smooth muscle, and a supportive layer of connective tissue make up the lamina propria.Drug penetration is not limited by the lamina propria's poor nature.

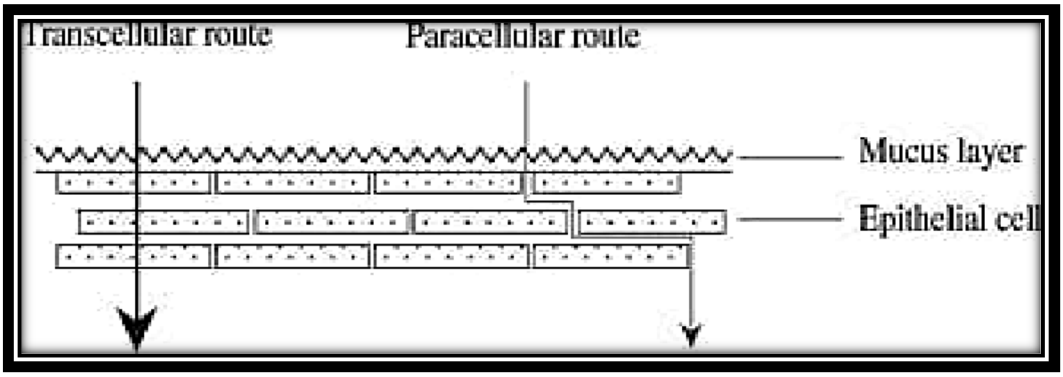
D. *Submucosa [5,6]*

A small number of accessory salivary glands, or mucus acinus, are found in the comparatively dense connective tissue known as the submucosa.Myoepithelial cells that surround mucus acini help with salivary secretion.

III. DRUG ABSORPTION VIA THE BUCCAL ROUTE [10,11,12]

For passive drug transport over the oral mucosa, there are two penetration pathways: transcellular and paracellular.

1) Transcellular permeation: Drugs pass through the basolateral membrane, the intracellular space, and the apical cell membrane in order to enter the epithelial cells.
2) Paracellular permeation: Transport across lipids or between epithelial cells is another way that drugs



IV. THE BUCCAL MEDICATION DELIVERY SYSTEM'S IDEAL FEATURE [3]

1) Good solubility, swelling, wetting, and spreadability; non-toxic and non-irritating
2) Adhesion must be strong enough mechanically and occur quickly.
3) Economical
4) The medication should be stable at buccal pH.
5) The drug should have an appropriate shelf life, be tiny enough to pass through the buccal mucosa, and have an ideal molecular weight (200–500).
6) The medication shouldn't encourage the growth of secondary infections, like dental infections

The buccal drug delivery system's advantages [4,5,6,11]

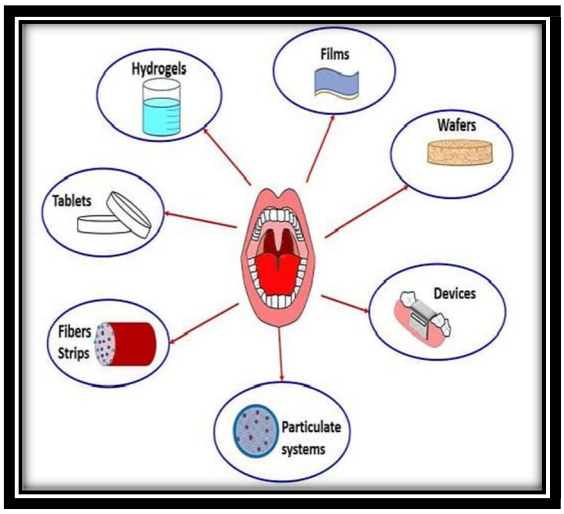
1) Steer clear of enzyme metabolism.
2) Easy administration
3) Direct medication absorption into the bloodstream
4) Outstanding accessibility
5) Enhanced bioavailability and favorable patient compliance
6) If the medicine becomes poisonous, it can be taken out.
7) Self-management is feasible.
8) Compared to other routes, this one has a substantially faster penetration rate. enter epithelial cells.

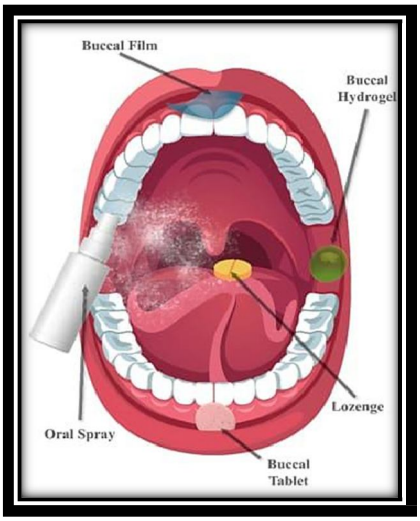
The buccal drug **delivery system's disadvantages** [4,6,7,11].

1) Eating and drinking are restricted; just a little amount may be administered.
2) The administration of medications that are unstable at buccal pH, have an unpleasant taste, or are inadvertently swallowed cannot be done this way.
3) Constant salivation causes medication dilution
4) Limited absorption area

V. BUCCAL FORMULATION TYPE [7]

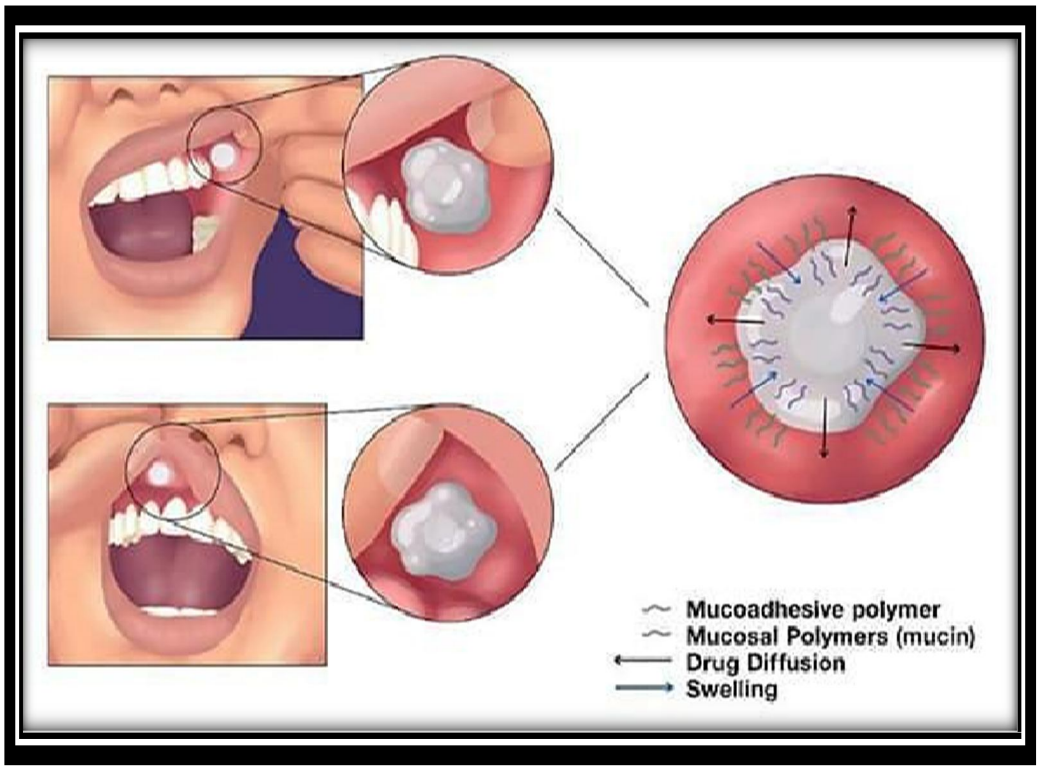
1) Buccal pill
2) Buccal patches
3) Buccal movie
4) Hydrogel that adheres to buccal mucosa
5) Buccal spray
6) Buccal wafers





VI. BUCCAL TABLET

1) The most used dosage form for oral drug delivery is the buccal tablet.[6]
2) Buccal tablets are tiny, flat tablets that are meant to be retained in the mouth between the cheek and gums or in a cheek pouch where the medication is absorbed straight via the oral mucosa.[12]
3) The buccal tablet can be made to release the medicine slowly for a longer duration of action, which improves bioavailability, or it can release the drug quickly.[8]
4) Buccal tablets softly stick to the mucosa and stay there till the disintegration process is finished. [12]
5) These tablets can be applied to the palate, the mucosa lining the face, the lip, and the gums, among other areas of the oral cavity.[8]



VII. WORKING OF BUCCAL TABLET [5]

Buccal tablet

⬇

Drug dissolved in saliva, or buccal fluid

⬇

Drug dissolution in the buccal membrane

⬇

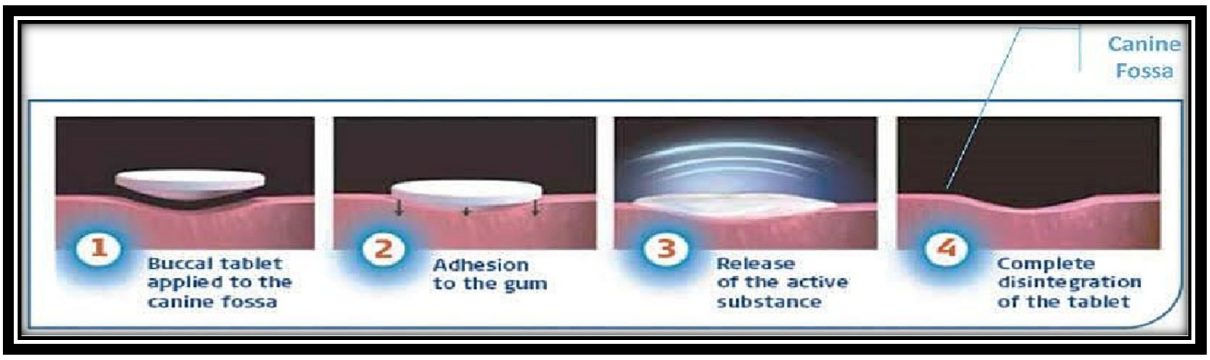
The medication enters the bloodstream and is distributed.

⬇

Reaches the intended tissue

⬇

Demonstrate a therapeutic impact



VIII. FORMULATION OF A BUCCAL TABLET

A. Drug Selection

1) Water soluble drugs: These are the best options because they dissolve readily in saliva
2) Low molecular weight: These help the drug be absorbed quickly through the buccal mucosa
3) Low firstpass metabolism: Reduces drug degradation before it reaches the systemic circulation 2.Exipient
4) Fillers: These include lactose, croscarmellose sodium, sodium starch glycolate, and HPMC
5) Disintegrants: Encourage tablet disintegration in saliva
6) Lubricants: These include magnesium stearate and stearic acid
7) Flavouring agents: Improve taste and patient compliance
8) Sweeteners: Improve palatability.

IX. METHODS FOR FORMULATION OF BUCCAL TABLETS

Typically, two main techniques are used to prepare buccal tablets:

A. Direct Compression[13]

The most popular technique for making buccal tablets is this one. Using a tablet press, a powder blend is directly compressed into tablets.

Steps Used:

1) Powder Blending: It is created by precisely weighing and carefully mixing all of the ingredients, including the medication, flavoring agents, excipients (such as binders, fillers, disintegrants, and lubricants), and excipients.
2) Sieving: To guarantee a consistent particle size distribution, which is essential for effective tablet compression, the powder blend is run through a sieve.
3) Compression: A tablet press receives the sieved powder mixture and compresses it into the appropriate size and shape of tablets.
4) Tablet Coating: To enhance the tablets' appearance, flavor, or release profile, a thin subcaste may sometimes be applied.

B. Wet Granulation(13)

Although this fashion is less constantly employed for buccal tablets, it can be used for phrasings that call for controlled release or bettered inflow characteristics.

Steps Used :

1) Granulation: For producing a wet mass, the drug and excipients are combined with a liquid binder, similar as water or alcohol. A granulator is used to produce slightly sized grains from the wet bulk.
2) Drying: To exclude the humidity, the wet grains are dried in a fluid bed tippler or roaster.
3) Sieving: To insure harmonious partical size, the dried grains are settled.
4) Lubrication: To enhance the granules' flow characteristics, a lubricant, such as magnesium stearate, is added.
5) Compression: A tablet press is used to compress the lubricated granules into tablets.

X. EVALUATION TEST OF BUCCAL TABLET

A. Dimensions and thickness [12]

1) To test tablet thickness, a micrometer or screw gauge with a minimum count of 0.01mm is used.
2) By sandwiching the tablets between two tiny slides at five distinct locations, the thickness may be determined.
3) The film's thickness at various locations was determined by subtracting the thickness of the two glass slides from the thickness of the samples assembled using a screw gauge or micrometer.
4) Although 1 to 3 cm is typically a comfortable size range, the maximum likely size for buccal tablets is 15 mm.
5) Tablet thickness should not exceed a few millimeters. Patients find that circular shapes are the most pleasant to utilize.

B. Weight Variation[12]

1) Each film's weight must be deducted from the average weight of 20 buccal tablets.
2) If there are significant discrepancies, the preparation process used was inadequate. Significant weight change is clinically inappropriate since it results in variations in medicine dosage.

C. Friability

By following the steps, the friability was ascertained using a Roche friabilator.

Using a Roche friabilator device that rotates at 100 rpm for four minutes, ten pre-weighed tablets from each batch were dropped six inches apart with each revolution.

1) The percentage loss was calculated by reweighing the pills at the conclusion of the test.

D. Hardness [12]

1) The tablet's hardness determines how resistant it is to chipping, abrasion, or breaking during handling, storage, and transit prior to use.
2) Ten buccal table774ts were selected at random from each batch, and their hardness was measured using a Monsanto Hardness tester. The results were expressed in kilograms per centimeter. .The standard deviation and mean values were calculated and displayed.

E. Test of Disintegration: [2,11]

1) Make use of a modified basket in a typical disintegration test setup.In order to replicate the buccal tablet's position between the cheek and gum, the basket should be made to hold it in place.

2) Medium: Make use of simulated saliva, a 6.8 pH buffered solution
3) Process: Put the buccal tablet into the basket that has been altered. Submerge the basket at 37°C in the artificial saliva.Note how long it takes for the tablet to utterly break up into pieces that can be seen through the basket's screen.

F. Dissolution Test

The USP Apparatus 2 (paddle method) or a specific buccal dissolution apparatus are examples of dissolution test equipment that can be used.

1) Media: As the dissolving media, use artificial saliva.

The process involves setting the buccal tablet in the 37°C dissolution vessel with the artificial saliva.Use the proper technique (such as rotating the paddle) to agitate the medium.At pre-arranged intervals, remove samples of the dissolving media. To ascertain the quantity of drug discharged, analyze the samples.

XI. PACKAGING AND LABELING

The dosage form's presentation, protection, identity, and information can all be provided by packaging and labeling.[14]

A. Packaging Type

1) Primary packaging: the substance that initially encases and retains the product. This is often the smallest distribution unit. The component that makes immediate touch with the product [14] Vials, blister packs, strip packing, and ex-bottles, among others.
2) Secondary packing: It protects the primary packing by being outside of it. Ex: cartons and boxes.[14]
3) Tertiary Packaging: This method is utilized for transporting and managing large quantities. It offers protection while being transported.[14]

For example, barrels, containers, etc.

B. Packaging materials for Buccal Tablet

1) Blister packs: These are heat-sealed plastic or aluminum foil bags that act as a barrier against light and moisture. They are frequently utilized for buccal tablet dosages.[15]
2) Bottles: Buccal pills can be packaged in amber, opaque plastic, or glass bottles. To absorb moisture and keep the tablets from degrading, they frequently include a desiccant.
3) Aluminum foil: This substance is frequently used for individual doses of buccal tablets and offers good protection against light and moisture.
4) Plastic Pouch: Multiple dosages of buccal tablets can be packaged in pouches composed of plastic or aluminum foil. In order to create a barrier against light and moisture, they are frequently heat-sealed.

C. Buccal tablet labeling [2]

With certain special considerations for their particular route of administration, the labeling requirements for buccal tablets are comparable to those for other oral solid dosage forms.[2]

1) Product Name: Clearly visible and conspicuous.
2) Active Ingredient: The active ingredient's name and amount.
3) Dosage Strength: Each tablet's potency. The total amount of the goods within the container is known as the "net quantity of contents."
4) Administration Route: Make sure to prominently display "Buccal Use Only."
5) Detailed directions on how to take the tablet, such as "Place one tablet between the cheek and gum and allow it to dissolve slowly," are provided in the dosage instructions.
6) Storage Conditions: Advice on how to store items properly, including "Store in a cool, dry spot."
7) Expiration Date: The cutoff date for using the product.
8) Manufacturer's Name and Address: Details about the business that produced the item.
9) Warnings & Precautions: Any particular cautions or warnings related to the medication, like possible adverse effects or interactions.
10) Adverse Reactions: A list of possible negative outcomes.

XII. CONCLUSION

1) Buccal administration is a topical method of drug delivery that allows medications to diffuse through the oral mucosa, or the tissues lining the mouth, and enter the circulation straight.
2) Generally speaking, buccal administration increases a drug's bioavailability and speeds up its beginning of effect.
3) Buccal drug delivery offers several advantages, such as ease of administration, accessibility and withdrawal, retentivity, high patient compliance, low enzymatic activity, and the ability to prevent first-pass metabolism in the liver and pre-systemically occurring clearance in the GIT.
4) It can also be used to prevent first-pass metabolism in the liver and pre-systemically occurring clearance in the GIT.
5) With the right dosage form designs and formulations, permeability in the locally appearing environment of the mucosal layer can be controlled and modified to accommodate drug absorption.
6) Because of its effectiveness, advantages, and ease of access for drug administration through oral mucosal tissue, the buccal route offers a variety of formulation techniques and favorable potential.

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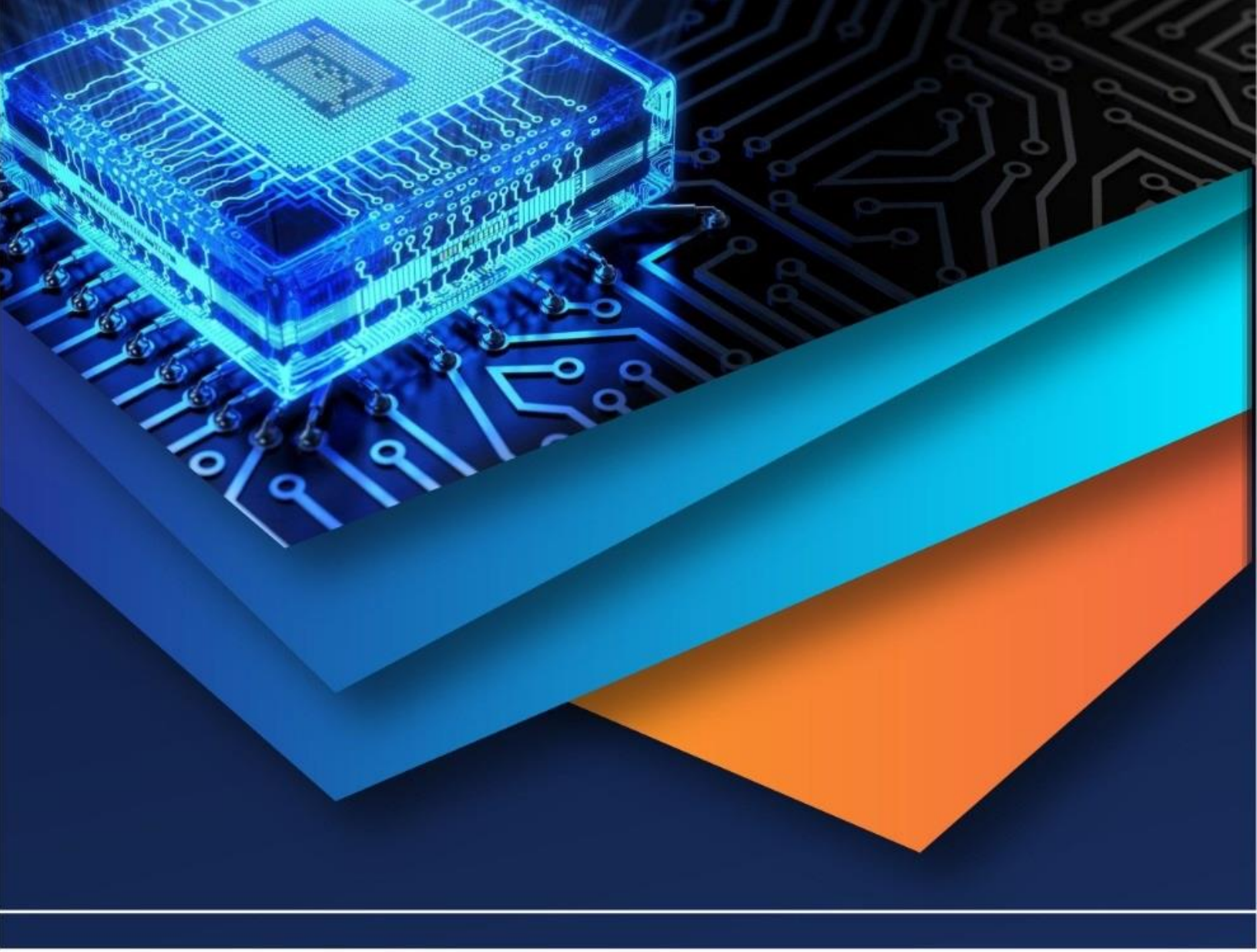

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