NIOSOME-EMBEDDED BUCCAL FILMS: A TRANSFORMATIVE STRATEGY FOR CONTROLLED AND TARGETED MUCOSAL THERAPY

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ABSTRACT:

Buccal drug delivery is a promising alternative to traditional oral administration as it can be absorbed directly through the buccal mucosa and avoids hepatic first-pass metabolism leading to improved bioavailability. However, the buccal route has its disadvantages such as short residence time, low drug permeability and some drugs are unstable in oral cavity. In order to address these difficulties, niosomes are explored as significant carriers. Niosomes are vesicular nanocarriers composed of non-ionic surfactants and cholesterol. They have the ability to encapsulate hydrophilic and lipophilic drugs and to protect drugs from degradation while enabling controlled or sustained drug release. Niosomes are combined with mucoadhesive buccal films to obtain the merit of both systems. The use of buccal films increases their residence time in the oral cavity due to adhesion to the mucosal surface, along with better perception by patients than tablets and niosomes that not only increase drug stability but also permeation across the buccal membrane. Niosomes integrated into buccal films can increase drug delivery efficiency and therapeutic efficacy. This approach is especially beneficial for drugs with poor oral bioavailability or short half-life. Overall, niosomal buccal films represent a promising and advanced drug delivery system for oral mucosal administration.

KEYWORDS:

Niosomes, Buccal films, Vesicular drug delivery, Mucoadhesive systems, Oral mucosal delivery, Non-ionic surfactants, Cholesterol, Film-forming polymers, Hydroxypropyl methylcellulose, Controlled drug release, Enhanced bioavailability.

INTRODUCTION:

The oral route of drug administration remains the most widely utilized and accepted route owing to its simplicity, convenience, cost-effectiveness, and high patient compliance. Despite these advantages, conventional oral drug delivery systems often encounter significant challenges such as enzymatic degradation in the gastrointestinal tract, variable absorption, and extensive hepatic first-pass metabolism. These limitations can result in reduced bioavailability, delayed onset of action, and inconsistent therapeutic outcomes, particularly for drugs with poor solubility, short half-life, or narrow therapeutic index. Consequently, alternative drug delivery routes have gained increasing attention to overcome these drawbacks and enhance therapeutic efficacy.

Among the various non-invasive routes, buccal drug delivery has emerged as a promising approach for systemic and local drug administration. The buccal mucosa, lining the inner cheek, is relatively permeable, well vascularized, and capable of facilitating direct drug transport into the systemic circulation. This route bypasses gastrointestinal degradation and hepatic first-pass metabolism, leading to improved bioavailability and rapid onset of action. In addition, buccal administration offers ease of access, painless application, and suitability for patients who experience difficulty in swallowing conventional oral dosage forms.

Buccal films are thin, flexible, and polymeric dosage forms designed to adhere to the buccal mucosa and release the drug in a controlled manner. These films offer several advantages over traditional buccal tablets and patches, including better comfort, minimal interference with

speech, accurate dosing, and enhanced patient acceptability. Depending on the formulation, buccal films can provide immediate, sustained, or biphasic drug release profiles. However, conventional buccal films may still face limitations such as insufficient drug permeation through the mucosal barrier, poor stability of sensitive drugs, and limited drug loading capacity. These challenges necessitate the incorporation of advanced drug delivery technologies to improve the overall performance of buccal film systems.

Vesicular drug delivery systems have been extensively explored to enhance drug solubility, stability, and bioavailability. Among them, Niosomes have gained considerable interest due to their unique structural and functional properties. Niosomes are microscopic vesicles formed by the self-assembly of non-ionic surfactants in the presence of cholesterol, resulting in bilayered structures capable of entrapping both hydrophilic and lipophilic drugs. Compared to Liposomes, Niosomes offer advantages such as improved chemical stability, lower cost, ease of preparation, and reduced risk of oxidation and degradation.

The incorporation of Niosomes into buccal films represents a synergistic approach that combines the benefits of vesicular nanocarriers with the advantages of mucoadhesive buccal delivery systems. Niosomes can protect encapsulated drugs from enzymatic and chemical degradation, enhance permeation across the buccal mucosa, and provide sustained or controlled drug release. The vesicular structure of niosomes facilitates interaction with mucosal lipid layers, thereby improving drug diffusion and absorption. Furthermore, the presence of cholesterol within the Niosomal bilayer enhances vesicle rigidity and stability, contributing to prolonged drug retention and controlled release behavior.

Mucoadhesive polymers used in buccal films further complement the role of Niosomes by increasing residence time at the site of application and ensuring close contact with the mucosal surface. This prolonged contact allows sufficient time for drug release and absorption, leading

to improved therapeutic outcomes. The combination of niosomes with buccal films also enables dose reduction, minimizes dosing frequency, and enhances patient compliance.

In recent years, niosomal buccal films have been investigated for the delivery of a wide range of drugs, including antihypertensive agents, antimicrobials, peptides, and drugs with poor oral bioavailability. These systems have demonstrated improved drug permeation, enhanced bioavailability, and favorable release kinetics compared to conventional formulations. Therefore, Niosomal buccal films represent a novel and efficient platform that bridges vesicular nanocarriers with oral mucosal drug delivery, offering significant potential for the development of advanced pharmaceutical dosage forms.

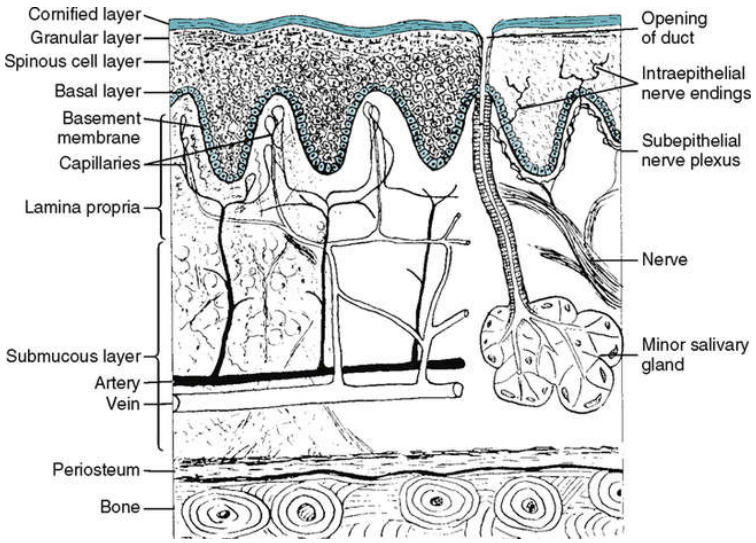

Fig 1: - Structure of Buccal Mucosa

Need For Niosomal Buccal Films:

Conventional drug delivery systems, particularly oral solid dosage forms, remain the most commonly employed route of administration due to their convenience and cost-effectiveness. However, many therapeutically important drugs exhibit poor oral bioavailability as a result of

extensive first-pass hepatic metabolism, enzymatic degradation in the gastrointestinal tract, variable gastric emptying, and limited permeability across biological membranes. These limitations often lead to sub-therapeutic plasma drug levels, frequent dosing, and poor patient compliance. In this context, buccal drug delivery has gained increasing attention as a promising alternative route for systemic drug administration.

The buccal mucosa is characterized by rich vascularization, relatively low enzymatic activity, and direct access to systemic circulation, thereby offering the advantage of bypassing hepatic first-pass metabolism. Despite these benefits, conventional buccal dosage forms such as tablets, gels, and simple polymeric films face several challenges, including limited residence time, insufficient mucosal penetration, and inadequate protection of drugs from degradation. These drawbacks necessitate the development of advanced delivery systems capable of enhancing drug stability, permeability, and therapeutic efficacy.

Niosomal buccal films have emerged as a novel drug delivery platform designed to address these limitations by integrating vesicular nanocarriers into mucoadhesive film matrices. Niosomes are non-ionic surfactant-based vesicles that possess a bilayer structure, enabling the encapsulation of both hydrophilic and lipophilic drug molecules. Incorporation of drugs into niosomes provides a protective microenvironment that shields the active pharmaceutical ingredient from chemical, enzymatic, and hydrolytic degradation. This protective effect is particularly beneficial for drugs that are unstable in saliva or susceptible to rapid degradation under physiological conditions.

One of the most significant advantages of Niosomal buccal films is their ability to enhance drug permeation across the buccal mucosa. The vesicular nature of Niosomes allows close interaction with mucosal lipid components, facilitating improved drug transport through the epithelial barrier. Additionally, non-ionic surfactants used in niosome formulation may act as

permeation enhancers, further improving transbuccal drug absorption. As a result, niosomal buccal films can achieve higher and more consistent systemic drug levels compared to conventional buccal films.

Another important rationale for the development of Niosomal buccal films is the potential to achieve sustained and controlled drug release. Drugs encapsulated within Niosomal vesicles are released gradually through diffusion from the bilayer structure, while the polymeric film matrix further modulates the release profile. This dual-controlled release mechanism helps maintain therapeutic drug concentrations over an extended period, reducing dosing frequency and minimizing fluctuations in plasma drug levels. Such controlled release behavior is particularly advantageous for drugs with short biological half-lives that require frequent administration when delivered through conventional dosage forms.

Niosomal buccal films also offer formulation flexibility, as they can accommodate drugs with diverse physicochemical properties. Hydrophilic drugs can be entrapped within the aqueous core of Niosomes, whereas lipophilic drugs are incorporated into the lipid bilayer. This versatility expands the range of drugs that can be effectively delivered via the buccal route, including poorly soluble molecules that pose formulation challenges in traditional systems.

From a patient-centric perspective, Niosomal buccal films provide significant benefits in terms of ease of administration and comfort. These films are thin, flexible, and non-invasive, eliminating the need for swallowing or injections. Their mucoadhesive nature ensures prolonged retention at the site of application, while their painless mode of administration enhances patient acceptability. Such features make Niosomal buccal films particularly suitable for pediatric, geriatric, and dysphagic patients who often experience difficulty with conventional oral dosage forms.

Overall, the development of Niosomal buccal films is driven by the need to overcome the pharmacokinetic and formulation limitations associated with conventional drug delivery systems. By combining the advantages of vesicular nanocarriers with the unique properties of buccal films, this delivery approach offers improved drug stability, enhanced permeation, controlled release, and better patient compliance. Niosomal buccal films are especially promising for drugs with low oral bioavailability, extensive hepatic metabolism, and short half-lives, making them a valuable platform for future pharmaceutical development.

Role of Niosomes in Enhancing Drug Stability:

Drug stability is a critical determinant of therapeutic efficacy, safety, and shelf life of pharmaceutical formulations. Many drug molecules, particularly peptides, proteins, and drugs with labile functional groups, are highly susceptible to degradation when exposed to physiological environments or during storage. Niosomes, vesicular systems composed of non-ionic surfactants and cholesterol, have emerged as effective nanocarriers capable of significantly enhancing drug stability through multiple protective mechanisms.

One of the major advantages of Niosomes is their ability to protect encapsulated drugs from enzymatic and hydrolytic degradation. In biological environments, drugs are often exposed to degrading enzymes such as esterases, proteases, and hydrolases, which can lead to premature drug inactivation. When a drug is entrapped within Niosomal vesicles, it is physically shielded by the surfactant bilayer, which acts as a barrier between the drug molecule and external degrading agents.

Hydrophilic drugs are retained within the aqueous core of Niosomes, while lipophilic drugs are incorporated into the hydrophobic bilayer. This compartmentalization reduces direct contact between the drug and aqueous surroundings, thereby minimizing hydrolytic reactions. Additionally, the non-ionic nature of surfactants used in Niosomes contributes to chemical

inertness, further limiting interactions that could trigger degradation. As a result, Niosomes enhance the stability of drugs during transit through biological membranes and within hostile physiological environments such as the oral or buccal cavity.

Drug leakage during storage or upon administration is a common challenge associated with vesicular drug delivery systems. Niosomes address this issue through their structurally stable bilayer, particularly when cholesterol is incorporated into the formulation. Cholesterol plays a vital role in regulating membrane fluidity and permeability, thereby preventing the premature escape of the entrapped drug.

The presence of cholesterol reduces the mobility of surfactant molecules within the bilayer, resulting in a more rigid and compact membrane structure. This rigidity decreases vesicle permeability and significantly limits drug diffusion out of the vesicle. Furthermore, optimized surfactant selection and appropriate surfactant-to-cholesterol ratios enhance vesicle integrity, minimizing vesicle fusion, aggregation, and rupture. Consequently, Niosomes provide sustained retention of the drug within the vesicle, ensuring controlled release and consistent therapeutic performance.

Compared to other vesicular systems such as liposomes, Niosomes exhibit superior shelf stability due to their composition and physicochemical properties. The use of non-ionic surfactants imparts greater resistance to oxidative degradation, which is a common cause of instability in lipid-based carriers. Additionally, Niosomes demonstrate reduced sensitivity to temperature fluctuations and pH variations, making them more suitable for long-term storage.

Niosomal formulations are less prone to chemical degradation, vesicle fusion, and sedimentation, especially when stored under optimized conditions. The enhanced stability translates into prolonged shelf life without significant changes in vesicle size, entrapment

efficiency, or drug content. This makes Niosomes particularly attractive for commercial pharmaceutical development, where product stability and reproducibility are essential.

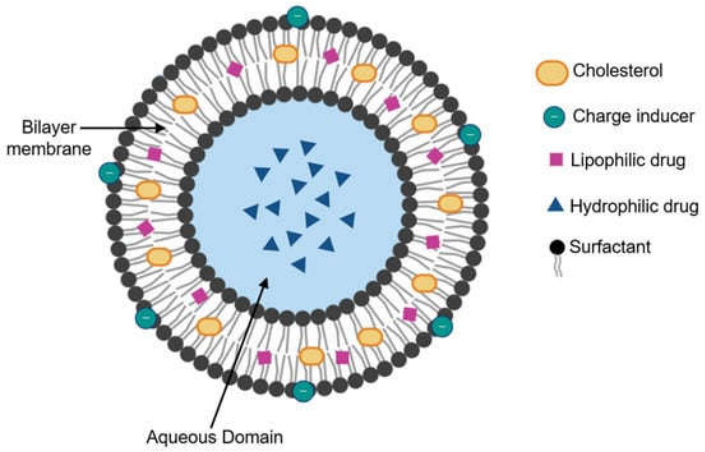

Fig 2: - Structure of Niosome

MATERIALS AND METHODS:

MATERIALS:

The formulation of Niosomal buccal films requires carefully selected excipients to ensure vesicle stability, film integrity, and effective drug delivery. A suitable therapeutic agent is chosen as the model drug based on its physicochemical properties and intended pharmacological action. Non-ionic surfactants such as Span 20, Span 60, Tween 60, and Tween 80 are employed for the preparation of Niosomes, as they facilitate the formation of stable bilayer vesicles capable of entrapping both hydrophilic and lipophilic drugs. Cholesterol is incorporated as a membrane stabilizer to enhance the rigidity and structural integrity of the vesicles, thereby minimizing drug leakage and improving storage stability.

For the fabrication of buccal films, film-forming polymers including Hydroxypropyl methylcellulose (HPMC), Polyvinyl alcohol (PVA), Carbopol, and Sodium alginate are utilized to provide adequate mechanical strength, flexibility, and mucoadhesive properties. Plasticizers such as glycerol and Polyethylene glycol 400 (PEG 400) are added to improve film

elasticity and prevent brittleness. Organic solvents like Chloroform and Ethanol are used for dissolving surfactants and Cholesterol during Niosome preparation, while distilled water serves as the hydration medium and solvent for polymeric dispersion. Where necessary, permeation enhancers may be incorporated to facilitate drug transport across the buccal mucosa and enhance overall absorption.

METHODS:

Method of preparation of Niosomes:

1. Thin Film Hydration Method
2. Ether Injection Method
3. Reverse Phase Evaporation Method
4. Microfluidization Method
5. Bubble Method
6. Bubble Method
7. Multiple Membrane Extrusion Method

1. Thin Film Hydration Method

The thin film hydration technique is one of the most widely used methods for preparing Niosomes. In this approach, non-ionic surfactants and cholesterol are dissolved in an organic solvent such as chloroform or a chloroform–methanol mixture. The solvent is evaporated under reduced pressure using a rotary evaporator, resulting in the formation of a thin lipid film on the inner wall of a round-bottom flask. The dried film is then hydrated with an aqueous solution containing the drug while gently agitating the system. Hydration causes swelling of the lipid film and leads to the formation of multilamellar niosomal vesicles. The vesicle size can be further reduced by sonication or extrusion to obtain a more uniform dispersion.

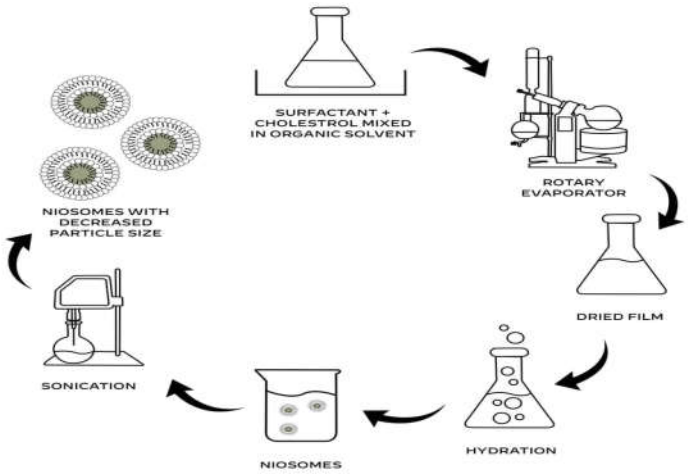

Fig 3: - Thin-film hydration method

2. **Ether Injection Method**

In the ether injection method, surfactant and cholesterol are dissolved in diethyl ether to form an organic phase. This solution is slowly injected through a fine needle into a warm aqueous phase containing the drug under continuous stirring. As the ether evaporates due to the high temperature of the aqueous phase, the surfactant molecules self-assemble to form single-layered vesicles. This method generally produces small unilamellar niosomes with relatively uniform size distribution.

3. **Reverse Phase Evaporation Method**

The reverse phase evaporation technique involves the formation of a water-in-oil emulsion. Surfactant and cholesterol are first dissolved in an organic solvent, and the aqueous drug solution is added to this mixture. The system is then sonicated to form a stable emulsion. Subsequent removal of the organic solvent under reduced pressure leads to the formation of vesicles. This method is known for producing niosomes with high drug entrapment efficiency due to the large internal aqueous volume of the vesicles.

4. **Microfluidization Method**

Microfluidization is a modern technique used to prepare uniform and stable niosomes. In this process, two fluid streams containing surfactant and aqueous drug solution are forced through microchannels at high pressure. The collision of the streams within the microfluidizer leads to the formation of vesicles with controlled size distribution. This method is particularly useful for large-scale production and ensures better reproducibility of the vesicles.

5. **Bubble Method**

The bubble method is a solvent-free technique used for preparing niosomes. In this method, surfactant and cholesterol are dispersed in an aqueous buffer solution and maintained at elevated temperature. Nitrogen gas is then bubbled through the mixture while continuously stirring. The mechanical agitation and temperature facilitate the formation of niosomal vesicles without the use of organic solvents.

6. **Sonication Method**

In the sonication method, surfactant, cholesterol, and the aqueous drug solution are mixed and subjected to ultrasonic energy using a probe or bath sonicator. The ultrasonic waves break down larger vesicles into smaller ones, producing nanosized niosomes with relatively uniform size. This technique is often used as a post-preparation step to reduce vesicle size and improve dispersion stability.

7. **Multiple Membrane Extrusion Method**

The multiple membrane extrusion method is a technique used to obtain niosomes with a uniform and controlled vesicle size. In this method, a previously prepared niosomal suspension—usually obtained by the thin film hydration method—is passed repeatedly through polycarbonate membranes with defined pore sizes. The extrusion is carried out using an extrusion device where the vesicle dispersion is forced through the membranes

under controlled pressure. By passing the suspension several times through membranes of decreasing pore diameter, larger vesicles are broken down into smaller and more uniform ones. This process helps produce niosomes with narrow size distribution and improved stability. The technique is particularly useful for preparing nanosized vesicles suitable for drug delivery applications where particle size plays an important role in permeability and drug release behavior.

Method of preparation of Buccal Films:

1. **Solvent Casting Method**

The solvent casting technique is the most commonly used method for preparing buccal films because it produces uniform and flexible films. In this method, film-forming polymers are dissolved in a suitable solvent such as distilled water or a water–ethanol mixture to obtain a clear polymeric solution. Plasticizers and other excipients are then added under continuous stirring. The drug or drug-loaded carrier system is incorporated into the polymer solution and mixed thoroughly to ensure uniform distribution. The resulting solution is poured onto a leveled casting surface such as a glass plate or petri dish and allowed to dry at controlled temperature conditions. After solvent evaporation, a thin film is formed which is carefully peeled off and cut into pieces of required dimensions.

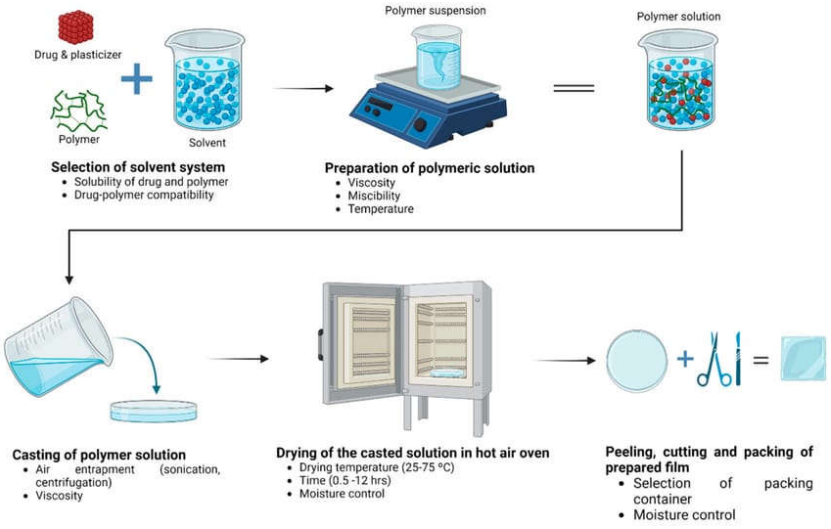

Fig 4: - Solvent casting method

2. Semisolid Casting Method

In the semisolid casting method, a water-soluble polymer is dissolved in water to form a viscous solution. A second polymer that is insoluble in water may be dissolved in an appropriate solvent and mixed with the aqueous polymer solution to form a homogeneous semisolid mass. Plasticizers are incorporated to enhance film flexibility. The prepared semisolid mixture is cast onto a flat surface and allowed to dry to form a thin film. This technique is useful for producing films with improved mechanical strength and controlled drug release properties.

3. Hot Melt Extrusion Method

Hot melt extrusion involves the mixing of drug and polymer under controlled temperature and pressure conditions without the use of organic solvents. In this process, the drug, polymer, and plasticizer are blended together and fed into an extruder. The mixture is heated and forced through a die to form a uniform film. After extrusion, the film is cooled and cut into suitable sizes. This method offers advantages such as reduced processing time, uniform drug dispersion, and elimination of solvent-related issues.

4. **Solid Dispersion Extrusion Method**

   In this technique, the drug is first dispersed within a suitable polymer matrix to form a solid dispersion. The dispersion is then combined with film-forming polymers and plasticizers and processed through an extruder. The extruded mass is flattened into thin films and subsequently cooled. This approach is particularly useful for improving the solubility of poorly water-soluble drugs while simultaneously producing buccal films.

EVALUATION OF NIOSOMES:

Comprehensive characterization of Niosomes is essential to ensure vesicle stability, drug encapsulation efficiency, and suitability for buccal delivery.

Vesicle Size and Size Distribution:

A diluted sample of the Niosomal suspension is analyzed using a dynamic light scattering (DLS) instrument at room temperature. The instrument measures fluctuations in light scattering caused by particle movement and calculates the average vesicle size and polydispersity index (PDI), indicating uniformity of distribution.

Zeta Potential:

The surface charge of Niosomes is determined using a zeta potential analyzer based on electrophoretic mobility. The diluted formulation is placed in a specialized cell, and an electric field is applied to measure particle movement, which is then converted into zeta potential values.

Scanning electron microscopy:

Scanning electron microscopy was employed to examine the surface characteristics and morphological features of the prepared films, particularly to observe the distribution of the drug within the polymeric matrix and its interaction with excipients. A small section of the film was

carefully mounted on an appropriate sample stub and, if required, coated to enhance conductivity. The specimen was then analyzed under the scanning electron microscope at a magnification of approximately ×1000 using a tungsten filament as the electron source. Representative micrographs were captured to assess surface texture, uniformity, and the presence of pores or irregularities.

Entrapment Efficiency:

The Niosomal suspension is centrifuged at high speed to separate free drug from vesicle-entrapped drug. The amount of unentrapped drug in the supernatant is quantified spectrophotometrically, and entrapment efficiency is calculated using a standard formula.

In Vitro Drug Release:

The Niosomal formulation is placed inside a dialysis membrane, which is immersed in a dissolution medium maintained at 37°C with continuous stirring. Samples are withdrawn at predetermined intervals and analyzed to determine the cumulative amount of drug released over time.

Stability Studies:

The formulation is stored in sealed containers under different temperature conditions (e.g., refrigerated and room temperature) for a specified duration. Periodically, samples are evaluated for changes in vesicle size, drug content, and physical appearance to assess stability.

EVALUATION OF NIOSOMAL BUCCAL FILMS:

After incorporation of Niosomes into films, additional parameters specific to buccal dosage forms are assessed.

Physical Appearance:

The prepared films are examined visually against a light background for color, uniformity, transparency, surface smoothness, and the presence of imperfections such as cracks or air bubbles. Flexibility is assessed manually by gently bending the film to ensure it does not break or show surface defects.

Thickness and Weight Uniformity:

Film thickness is measured at three to five different locations using a calibrated micrometer screw gauge, and the mean value is calculated. For weight variation, individual film units of equal size are weighed separately, and the average weight is determined to confirm uniformity across samples.

Folding Endurance:

Folding endurance was evaluated to assess the mechanical strength and flexibility of the prepared films. A small film strip of approximately 2 × 2 cm^2 was repeatedly folded at the same location until visible cracking or breakage occurred. The total number of folds the film withstood without breaking was recorded as the folding endurance value. The test was performed in triplicate for each formulation, and the mean value along with the standard deviation was calculated to ensure reproducibility and consistency.

Surface pH:

For the determination of surface pH, each film was carefully placed in a Petri dish and moistened with a small quantity of distilled water to allow hydration of the surface. After permitting sufficient time for equilibration, the pH of the film surface was measured using a calibrated pH meter by gently bringing the electrode into contact with the moistened film. The

procedure was carried out for at least six films from each formulation, and the average pH value was calculated and reported.

Drug Content Uniformity:

The uniformity of drug content in the prepared films was evaluated by dissolving an individual film sample in 100 mL of phosphate buffer (pH 6.6) taken in a 250 mL beaker. The beaker was placed on a temperature-regulated magnetic stirrer maintained at 37°C, and the solution was continuously stirred at 300 rpm using a Teflon-coated magnetic bar for 3 hours to ensure complete drug extraction. Afterward, the solution was filtered through a 0.45 μm membrane filter to remove any undissolved particles. The filtered sample was then analyzed using a UV–visible spectrophotometer to determine the drug concentration.

Tensile Strength and Percentage Elongation:

Film strips of defined dimensions are fixed between two clamps of a tensile testing apparatus. Force is gradually applied until the film breaks, and tensile strength is calculated from the applied force, while percentage elongation is determined from the increase in length before breaking.

Swelling Index:

Pre-weighed film samples are placed in simulated saliva or phosphate buffer solution. At predetermined intervals, films are removed, lightly blotted to remove excess surface fluid, reweighed, and the swelling index is calculated based on weight gain.

Swelling index (SI) was calculated by using the following formula.

$$\text{Swelling index (SI)} = \frac{W - Wo}{Wo} \times 100$$

Where;

SI = Swelling index

W = Final weight of buccal film

Wo = Initial weight of buccal film.

In Vitro Drug Release:

Drug release studies are performed using a dissolution apparatus or Franz diffusion cell containing simulated saliva or phosphate buffer maintained at 37°C. Samples are withdrawn at regular intervals and analyzed spectrophotometrically to determine cumulative drug release.

Ex Vivo Permeation Studies:

Drug permeation was evaluated using a modified Franz diffusion cell with porcine buccal mucosa. The mucosal tissue was carefully mounted between the donor and receptor compartments. The receptor chamber was filled with isotonic phosphate buffer (pH 6.8) and maintained at 37 ± 0.5 °C, while the donor compartment contained 1 mL of simulated saliva (pH 6.8). Continuous stirring at 50 rpm was provided using a magnetic stirrer to maintain uniform conditions. At predetermined intervals, samples were withdrawn from the receptor compartment and replaced with fresh buffer. The amount of drug permeated was quantified by measuring absorbance spectrophotometrically.

Stability Studies:

Films are stored under specified temperature and humidity conditions, such as room temperature and accelerated conditions. Samples are periodically evaluated for changes in appearance, drug content, mechanical properties, and release profile.

Percentage Moisture Loss:

For determination of percentage moisture loss, each film sample was first weighed accurately and its initial weight was recorded. The weighed film was then placed inside a desiccator containing fused anhydrous calcium chloride as a drying agent and kept undisturbed for a period of three days. After the specified duration, the film was removed and reweighed to determine the reduction in weight, which was used to calculate the percentage moisture loss. Percentage moisture loss was calculated by the following formula

$$Moisture\ Content(\%) = \frac{Initial\ Weight - Final\ Weight}{Initial\ Weight} \times 100$$

CONCLUSION:

Niosomal buccal films offer a strategically advanced platform for drug delivery by integrating vesicular nanocarriers within a mucoadhesive polymeric matrix. This combined system addresses many of the limitations associated with conventional oral and buccal dosage forms, including poor bioavailability, rapid drug degradation, and limited mucosal permeation. Encapsulation within Niosomes enhances drug protection and modulates release behavior, while the buccal film ensures prolonged residence time and improved patient convenience. The dual advantages of controlled release and bypass of hepatic first-pass metabolism make this delivery approach particularly beneficial for drugs with low oral bioavailability or short biological half-life. Although promising preclinical findings support its therapeutic potential, further optimization, scale-up studies, and clinical validation are necessary to translate this technology into commercially viable pharmaceutical products. Overall, Niosomal buccal films represent a forward-looking and versatile system with significant scope in both local and systemic drug therapy.

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