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Mucosal Drug Delivery System Current Trends and Future Direction

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Abstract: ***In recent years, mucosal drug delivery systems have drawn a lot of attention because of their potential to increase patient compliance and therapeutic efficacy. These systems provide a non-invasive substitute for traditional oral and parenteral techniques by administering medications through mucosal membranes, including the buccal, sublingual, nasal, pulmonary, vaginal, rectal, and ocular channels. The ability to avoid first-pass hepatic metabolism, which increases bioavailability and permits a quick commencement of action, is one of the main benefits. Mucoadhesive gels, nanoparticles, films, liposomes, and in situ gelling systems are some of the novel mucosal drug delivery platforms made possible by recent developments in polymer science, nanotechnology, and drug formulation techniques. These methods facilitate targeted therapy, regulate drug release, and improve mucosal retention. To further maximize drug absorption and reduce systemic side effects, intelligent delivery methods that react to physiological cues like pH, temperature, and enzymes are also developing. Despite their potential, mucosal drug delivery methods encounter a number of difficulties, such as restricted permeability for macromolecules, enzymatic degradation, and variations in mucosal physiology. Novel approaches include the use of Nano carriers, Bioadhesive polymers, and permeation enhancers are being used in ongoing research to solve these problems. Mucosal drug delivery has the potential to transform gene delivery, peptide and protein therapies, and chronic illness treatment approaches in the future. Future developments are anticipated to be fuelled by integration with 3D printing, AI, and personalised medicine, which will make these systems more effective and patient-focused.***

Keywords: Mucosal drug delivery, Mucoadhesive systems, Nanotechnology Buccal and nasal delivery, In situ gels ,Smart drug delivery ,Controlled release ,Non-invasive therapeutics.

I. INTRODUCTION

Due to its benefits over traditional techniques, drug delivery via mucosal channels has become extremely important in contemporary pharmaceutical research. The epithelial linings of internal organs, including the rectum, vagina, lungs, nasal passages, eyes, and oral cavity, are used in mucosal medication delivery. These pathways have special benefits, such as avoiding the gastrointestinal system, avoiding first-pass metabolism, and maybe having a quick start to action. Mucosal drug delivery systems are becoming the preferred option due to the rising emphasis on patient compliance and tailored therapy, particularly for medications that need localised effects or have limited oral bioavailability[1]. Because of their great permeability and vascularization, mucosal membranes are perfect for systemic medication absorption. Furthermore, these routes facilitate self-administration and convenient access, which improves patient adherence, particularly in older and paediatric populations. While the nasal and pulmonary routes are extensively studied for systemic and local drug administration, the buccal and sublingual routes offer a quick onset and are helpful in emergency situations. By providing localized treatment with little systemic exposure, vaginal and rectal methods lessen unwanted effects. This adaptability to different mucosal locations enables customized administration methods appropriate for particular patient populations and treatment requirements[2-3]. Novel mucosal drug delivery systems, such as mucoadhesive gels, patches, nanoparticles, liposomes, and in situ gelling formulations, have been developed as a result of advancements in pharmaceutical sciences. These developments ensure efficient and long-lasting drug release by improving penetration and lengthening the duration of drug retention at mucosal locations. In these formulations, bioadhesive polymers such hydroxypropyl methylcellulose (HPMC), carbopol, and chitosan are essential. By enhancing the solubility, stability, and targeting capacity of medications delivered through mucosal surfaces, these methods seek to get around the drawbacks of traditional dosage forms[4-5].

The hepatic first-pass effect, which frequently lowers the bioavailability of medications taken orally, is one of the main issues mucosal drug administration attempts to solve. The medication avoids hepatic metabolism by entering the systemic circulation directly through mucosal channels, particularly sublingual and nasal. This enhances absorption while enabling lower dosages and fewer adverse effects. Furthermore, the mucosal epithelium is better suited for the delivery of delicate substances like peptides, proteins, and vaccines since it has a lower enzymatic activity than the gastrointestinal system[6].

Notwithstanding these advantages, mucosal drug administration has a number of drawbacks, including as a small absorption area, enzymatic breakdown, quick evacuation brought on by mucociliary action, and fluctuations in physiological parameters like pH and mucosal thickness. The effectiveness of treatment and drug absorption may be impacted by these variables. Formulators are always trying to come up with delivery strategies that can get past these obstacles. Using permeation enhancers, enzyme inhibitors, and creating formulations with extended mucosal residence duration are some strategies. These methods aid in preserving steady medication levels and enhancing the predictability of treatment results[7].

The science of mucosal medication delivery has benefited greatly from nanotechnology in recent years. Solid lipid nanoparticles, nanoparticles, and nano emulsions are examples of Nano carriers that have been developed to increase medication solubility, improve mucosal penetration, and offer sustained release. By engineering these Nano systems to have mucoadhesive qualities, the duration of interaction with mucosal tissues can be extended. Furthermore, ligands can be added to their surface to enable targeted delivery and cellular uptake, particularly in cases where site-specific activity is essential, such as cancer, infections, and inflammatory illnesses[8].

The development of intelligent medication delivery systems has resulted from the integration of stimuli-responsive polymers into mucosal formulations. These systems deliver the medication in a regulated way in response to particular physiological cues like pH, temperature, or enzymatic activity. For example, when exposed to mucosal conditions, in situ gelling systems experience a sol-to-gel transition, guaranteeing localized and sustained drug activity. When treating chronic illnesses that call for regular drug levels and fewer doses, such sophisticated delivery systems are especially helpful[7].

The use of 3D printing technology to create customized mucosal drug delivery devices is another new trend. In order to administer patient-specific dosages and medicine combinations, 3D-printed buccal films, nasal inserts, and vaginal rings are being investigated. This degree of customization may be useful in managing polypharmacy in older people, treating unusual disorders, and creating formulations that are safe for young individuals. Additionally, 3D printing speeds up customization and prototype, cutting down on development timeframes and enhancing treatment compliance[9].

The potential of mucosal drug delivery systems has been recognized by regulatory bodies including the US FDA and EMA, which have also issued recommendations for their assessment and approval. However, issues with patient variability, repeatability, and product stability make the road to commercialization still difficult. To guarantee safety, efficacy, and consistency, thorough preclinical and clinical testing is necessary. Furthermore, the advancement of the area and regulatory approval depend heavily on the creation of predictive in vitro models and standardized testing procedures[10].

II. ANATOMY AND PHYSIOLOGY OF MUCOSAL TISSUES

The human body's numerous cavities and canals that are open to the outside world are lined with mucosal tissues. The mucosa of the mouth, nose, lungs, vagina, rectal cavity, and eyes are among them. Every mucosal surface has distinct structural and functional characteristics that are suited to its particular physiological function. An epithelial layer, a lamina propria, and a muscularis mucosae are the three main layers that make up mucosa. The lamina propria is home to immune cells, connective tissue, and blood vessels, whereas the epithelium acts as the frontline barrier and the site of medication absorption[11].

Because of its high vascularization and thin epithelium, the oral mucosa—especially the buccal and sublingual regions—is relatively permeable, allowing for quick medication absorption. Because turbinates are present, the nasal mucosa has a wide surface area and is highly vascularised. Enzymatic activity and mucociliary clearance, however, present formidable obstacles. Alveolar areas of the pulmonary mucosa are perfect for systemic administration because they have high permeability and little enzymatic activity[12].

Because they are less enzymatically active, the mucosae of the vagina and the rectal cavity provide ideal conditions for both local and systemic drug administration. However, the rectal mucosa has a small surface area and may experience irregular absorption, whereas the vaginal mucosa has a fluctuating pH and is affected by hormone fluctuations. Despite being accessible, the ocular mucosa is shielded by tear fluid and blink reflexes, which restricts the absorption and retention of drugs. All things considered, creating efficient mucosal drug delivery systems requires an awareness of the distinct physiological and anatomical characteristics of each mucosal tissue[11-13].

III. TYPES OF MUCOSAL DRUG DELIVERY SYSTEMS[14-15]

Mucosal drug delivery systems are classified based on their formulation design, mechanism of drug release, and site of application. These systems are designed to enhance drug bioavailability, prolong residence time at the mucosal site, and improve therapeutic efficacy.

Mucoadhesive systems are widely used due to their ability to adhere to the mucosal surface and resist clearance mechanisms. Polymers like chitosan, carbopol, and HPMC are employed to improve drug retention. These systems include buccal tablets, films, and patches. In situ gelling systems transform from liquid to gel upon exposure to physiological conditions such as temperature, pH, or ionic strength. These are particularly useful in nasal, ocular, and vaginal drug delivery as they enhance retention and controlled release. Micro particles and nanoparticles provide controlled release and targeted delivery. These particulate systems improve drug solubility and stability, and their small size allows better mucosal penetration. Nano-formulations can be further surface-modified to enhance mucoadhesion or targeting ability. Liposomes and Niosomes are vesicular systems that encapsulate drugs, protecting them from degradation and enhancing permeability. They are especially useful for peptide and protein delivery.

Sprays and aerosols are suitable for nasal and pulmonary routes. They allow rapid absorption and are often used for emergency or systemic delivery. Hydrogels are crosslinked polymeric networks that swell in the presence of water, forming a gel-like structure. These are employed in vaginal and ocular delivery for sustained drug release. Films and patches offer ease of application and prolonged release, particularly for buccal and sublingual routes. They can be tailored in terms of drug loading, release rate, and mucoadhesion. These various delivery systems allow customization based on the drug's physicochemical properties and the target mucosal site.

IV. CURRENT TRENDS AND TECHNOLOGIES

Enhancing bioavailability, targeted accuracy, and patient compliance have been the main goals of recent developments in mucosal medication administration. The incorporation of nanotechnology is among the most notable developments. It has been shown that dendrimers, nanoparticles, and Nano emulsions can improve mucosal penetration and shield delicate medications like peptides and nucleic acids from deterioration[16]. The development of stimuli-responsive or smart delivery systems, which release medications in reaction to environmental cues like pH, temperature, or enzyme activity, is another new trend. These devices work especially well for medication delivery in the gastrointestinal tract and vagina, where the local environment can change greatly. Significant advancements have also been made in bioadhesive polymers. Novel polymers with enhanced mucoadhesive strength, biocompatibility, and drug release profiles have been developed as a result of advances in materials science. These consist of lectin-conjugated carriers and thiolated polymers[17]. Personalised mucosal drug delivery systems, such as vaginal rings and buccal films, are being investigated using 3D printing technology. This method has the potential to completely transform the way medicines are tailored by enabling patient-specific doses, forms, and release profiles[18].

V. MARKETED PRODUCTS AND CASE STUDIE[19-20]

Table.1: Marketed products

Product Name	Drug Name	Route of Delivery	Indication	Manufacturer	Key Feature
Oravig®	Miconazole	Buccal	Oropharyngeal candidiasis	Strativa Pharma	Mucoadhesive buccal tablet
Striant®	Testosterone	Buccal	Testosterone deficiency	Columbia Labs	Sustained release over 12 hours
Abstral®	Fentanyl	Sublingual	Breakthrough cancer pain	ProStrakan	Rapid onset via sublingual route
Onsolis®	Fentanyl	Buccal	Cancer pain	BioDelivery Sciences	Bioerodible mucoadhesive film
Zelrix®	Sumatriptan	Transdermal Patch	Migraine	NuPathe Inc.	Iontophoretic patch system
Rybelsus®	Semaglutide	Oral	Type 2 Diabetes	Novo Nordisk	First oral GLP-1 agonist
Sinuva®	Mometasone furoate	Nasal implant	Nasal polyps	Intersect ENT	Bioabsorbable corticosteroid implant
Nascobal®	Cyanocobalamin	Nasal	Vitamin B12 deficiency	Par Pharmaceutical	Nasal spray with systemic absorption
Exparel®	Bupivacaine	Buccal	Post-surgical pain	Pacira BioSciences	Liposomal extended-release injection
Instanyl®	Fentanyl	Nasal	Breakthrough pain in cancer	Takeda	Fast systemic uptake via nasal route

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VI. REGULATORY ASPECTS

Mucosal drug delivery systems, like all pharmaceutical products, are subject to stringent regulatory oversight to ensure safety, efficacy, and quality. Regulatory bodies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have issued specific guidelines for evaluating novel drug delivery systems[21].

One key regulatory concern is bioavailability and bioequivalence. Since mucosal routes bypass first-pass metabolism, establishing consistent and predictable systemic exposure is crucial. Regulatory submissions must include robust pharmacokinetic and pharmacodynamic data.

Excipients used in mucosal formulations must be proven safe for their intended route. For instance, nasal and pulmonary products require excipients that do not irritate or damage mucosal linings. Toxicological assessments**,** including local irritation and histopathological studies, are often mandatory[22].

Manufacturing practices must adhere to Good Manufacturing Practices (GMP) and include controls for dose uniformity, sterility (especially for nasal and ocular products), and stability. In situ forming systems and nano carriers introduce complexities in manufacturing and require validated analytical methods.

Device-drug combinations, such as nasal sprays and vaginal rings, fall under combination product regulations. These require coordinated reviews by different regulatory departments and rigorous validation of both the drug and the delivery device.

Clinical trials must demonstrate not only efficacy but also patient acceptability, especially for routes like rectal and vaginal. Endpoints may include local tissue response, ease of use, and retention time.

Post-marketing surveillance is essential to monitor adverse events, especially for products intended for long-term use. Regulatory agencies may require Risk Evaluation and Mitigation Strategies (REMS) for drugs with serious safety concerns.

Overall, regulatory pathways for mucosal drug delivery demand comprehensive documentation and cross-disciplinary expertise[23-25].

VII. FUTURE DIRECTIONS OF STUDY

The future of mucosal drug delivery lies in the convergence of biotechnology, nanotechnology, and precision medicine. One of the most promising directions is the development of oral and nasal vaccines for widespread diseases. These vaccines could revolutionize public health by eliminating the need for injections and enabling mass immunization during pandemics.

Another frontier is the delivery of biologics such as peptides, proteins, and monoclonal antibodies via mucosal routes. Overcoming challenges related to enzymatic degradation and permeability could allow non-invasive delivery of drugs previously limited to injections. Gene therapy and RNA-based therapeutics**,** including siRNA and mRNA, are being investigated for mucosal administration, particularly in nasal and pulmonary routes. These approaches could treat genetic disorders, cancers, and respiratory infections more effectively.

Artificial intelligence (AI) and machine learning are expected to aid in optimizing formulation design, predicting drug absorption, and personalizing therapy. AI-driven platforms could streamline development timelines and enhance success rates.

Wearable and implantable mucosal systems are also under exploration. These devices can offer feedback-controlled release, improving chronic disease management through real-time monitoring and dose adjustment.

Sustainable and biodegradable materials are being researched for environmentally friendly and safer mucosal drug delivery platforms. These materials reduce the burden of medical waste and enhance patient safety.

Furthermore, 3D printing and microfabrication will continue to evolve, allowing on-demand production of patient-specific drug delivery devices with complex release profiles.

In conclusion, future research will focus on enhancing bioavailability, ensuring long-term safety, and developing patient-centric delivery platforms that align with modern therapeutic needs[26-30].

VIII. CONCLUSION

Mucosal drug delivery systems, which provide non-invasive, patient-friendly substitutes for conventional drug administration routes, constitute a revolutionary approach in contemporary pharmaceutics. These methods take advantage of the distinct physiological and anatomical properties of mucosal tissues to offer targeted therapy, enhanced bioavailability, and a quick onset of action. Thanks to developments in biotechnology, nanotechnology, and materials science, mucosal delivery has developed into an advanced platform that can handle a range of therapeutic issues. Mucoadhesive systems, in situ gels, and nanoparticulate carriers are examples of innovations that have greatly improved therapeutic efficacy, permeability, and retention. Successful case studies and commercially available medicines in the oral, nasal, vaginal, and ocular routes show how adaptable and useful these systems are in therapeutic settings.

Although there are still issues with guaranteeing patient acceptability, safety, and consistency, regulatory bodies have started to promote the creation and approval of such innovative formulations through organised guidelines. In the future, mucosal drug delivery is expected to be essential for the delivery of vaccines, gene treatments, and biologics, especially in personalised and preventive medicine. These technologies will be even more efficient and customisable when integrated with 3D printing, artificial intelligence, and smart materials. Mucosal drug delivery has the potential to be a key component of next-generation pharmaceutical care as research and technology develop, offering safer, more convenient, and more effective treatment choices for a variety of illnesses.

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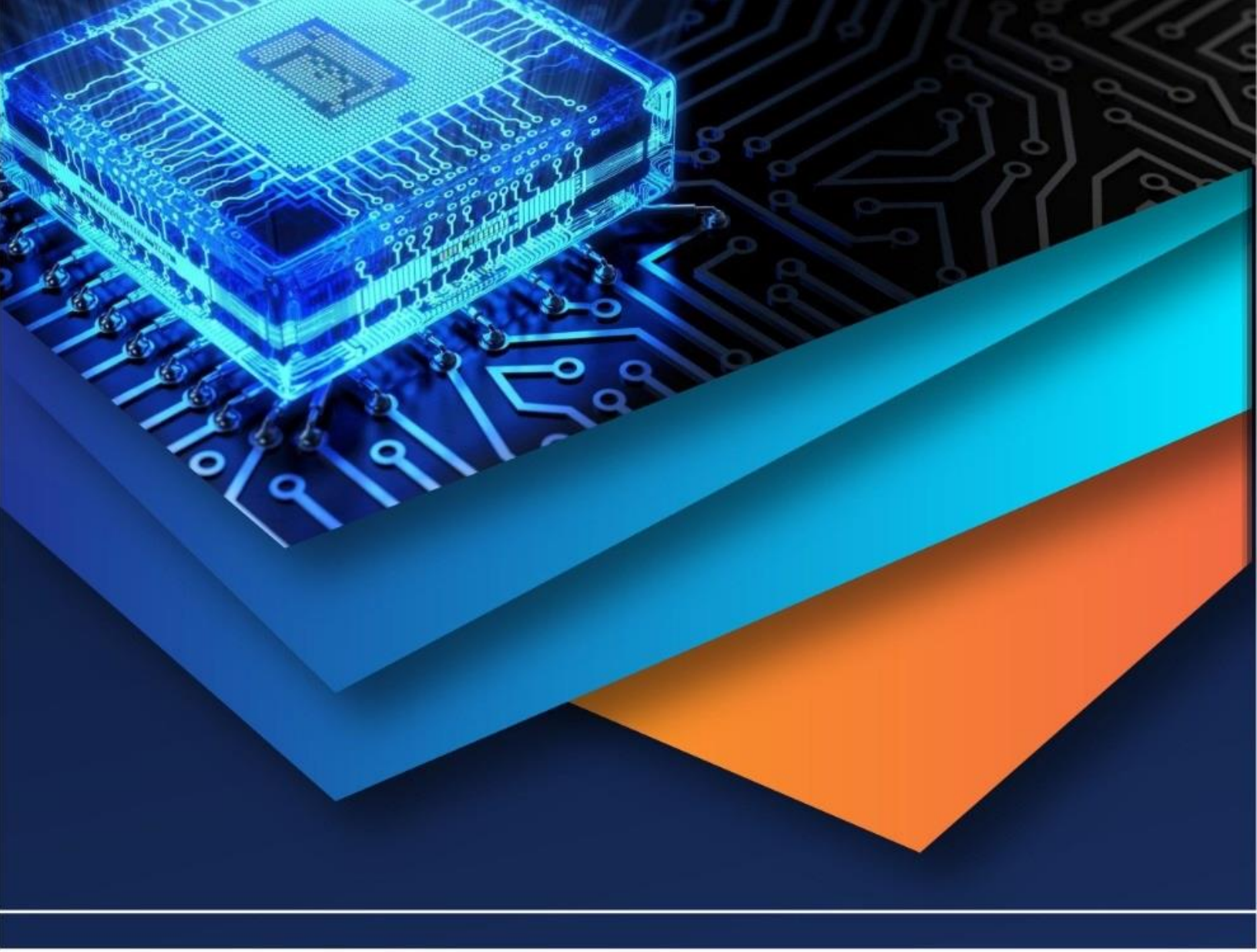

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