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Emerging Trends in Oral Thin and Buccal Films

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Abstract: Oral film Phrasings have surfaced as an innovative and patient-friendly medicine delivery system designed to ameliorate remedial efficacity, convenience, and patient compliance. These flicks are thin, flexible lozenge forms that snappily disintegrate or dissolve when placed on the lingo or in the buccal depression, allowing the medicine to be absorbed either locally or systemically through the oral mucosa. This mode of delivery offers distinct advantages over conventional lozenge forms similar as tablets and capsules, including ease of administration without the need for water, rapid-fire onset of action, and enhanced bioavailability due to the avoidance of first- pass hepatic metabolism. Depending on their intended purpose and point of action, oral flicks are generally classified into three main orders presto- dissolving flicks, which disintegrate fleetly in the oral depression; buccal flicks, which cleave to the buccal mucosa for controlled medicine release; and mucoadhesive flicks, which insure prolonged contact with the mucosal face for sustained remedial goods. The expression of oral flicks requires careful selection of applicable film- forming polymers (similar as hydroxypropyl methylcellulose or pullulan), plasticizers, active pharmaceutical constituents, and other excipients to gain the asked mechanical strength, inflexibility, decomposition profile, and stability. Critical quality evaluation parameters include film consistence, folding abidance, tensile strength, face pH, decomposition time, and medicine content uniformity, which insure harmonious performance and patient safety. With growing interest in case- centric medicine delivery systems and nonstop advancements in polymer wisdom, nanotechnology, and manufacturing ways similar as solvent casting and 3D printing, oral film phrasings are gaining elevation as an effective,non-invasive, and protean platform for both systemic and original medicine delivery in different remedial operations.

Keywords: Oral film formulations, Fast-dissolving films, Buccal films, Drug delivery system, Patient compliance.

I. Introduction

The most popular and patient-friendly system of drug administration is through the oral route. nearly all cases, including those who are adult, pediatric, and senior cases, take the maturity of the specifics in the form of tablets and capsules. still, between 26 and 50 percent of individualities have trouble swallowing tablets and hard gelatin capsules [1]. A new medicine delivery system for oral the administration of medicines is an orally presto- dissolving film [2, 3]. Due to their simplicity, capability to help pain, rigidity (to fit a variety of medicine campaigners), and, utmost significantly, patient compliance, oral routes of medicine administration are extensively accepted, account for between 50- 60 of all lozenge forms. also, since they do not need to be manufactured under sterile conditions, solid oral administration bias is less precious [4]. The drug is either dissolved or swallowed, after which the asked effect is produced by the medicine's systemic rotation [5, 6]. A film or strip is a lozenge form that uses a water-answerable polymer to incontinently hydrate, cleave, and dissolve when placed on the lingo or in the oral depression to deliver medicines locally or systemically. Changing the rate at which the flicks dissolve allows for either a fast or slow but steady release of the medicine [7]. Oral Dissolving flicks are thin, fleetly dissolving flicks with a zone that measures

5 to 20 cm2 in size what's the solidified form of the medicine is a hydrophilic polymer matrix. The current constituents used in drug are generally combined to 15 mg with relation to colorful excipients like plasticizers, sweeteners, flavours, enhancers, colorings, etc. The mounding of tradition medicines in buccal tenacious flicks legitimately absorbed through a subcaste of buccal towel that passes it on to the abecedarian inflow to demonstrate its effect [8]. The Greek terms poly, which means" numerous," and meros, which means" pieces or units of large molecular mass," are combined to form the word" polymer." Each patch is made up of an enormous number of individual structural factors that are regularly connected to one another by covalent bonds. By joining together multitudinous small motes, known as monomers, polymers are the mammoth, largely molecularly weighted macromolecules. Polymerization is the process of combining monomers to produce polymer [9]. The polymers used in the oral film expression cannot be poisonous and irritant, free of leachable contaminations, tasteless, have good wetting and spread capability characteristics, capability to use peel, shear, and tensile strength, be fluently accessible, affordable, have an acceptable shelf life, and not contribute to the product of secondary infections in the oral mucosa or dental regions [8].

Overview of Oral Films/ Buccal Delivery System:

Anatomy & Drug Absorption in the Oral Cavity:

The oral mucosa includes buccal(impertinence), sublingual (under lingo), and gingival areas [11, 12]. Sublingual mucosa is thinner and further passable (rapid-fire systemic uptake); buccal mucosa is thicker but suitable for sustained trans mucosal delivery and mucoadhesive systems [11, 12]. Saturation occurs via transcellular and para cellular routes; enzymatic exertion and mucus development influence hearthstone time and medicine stability [12, 13].

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Advantages & Clinical Relevance:

Rapid onset (especially sublingual/ dissolving flicks) and implicit to bypass first- pass hepatic metabolism,

perfecting bioavailability [10, 11, 13].

Bettered compliance – no water needed, discreet use, cure delicacy vs. liquid dormancies or crushed tablets [10, 14].

Suitable for a broad range of actives small lipophilic medicines, some peptides proteins (with expression aids), vitamins, nutraceuticals, and original oral curatives [10, 14, 15].

Key Components & Formulation:

Film- forming polymers: Hydrophilic polymers similar as hydroxypropyl methylcellulose(HPMC), pullulan, polyvinyl alcohol(PVA), sodium alginate, chitosan(mucoadhesive), and cellulose derivations.

Plasticizers: Glycerol, propylene glycol, points – to give inflexibility and control fineness [11, 12, 13].

Taste masking agents/ flavours: essential for bitter APIs (e.g., ondansetron) [10, 13].

Saturation enhancers & enzyme impediments: To ameliorate transmucosal uptake (e.g., corrosiveness mariners, surfactants). Nanocarriers/ nanoparticles/ liposomes decreasingly used to ameliorate solubility, cover labile agents, and control release [13, 15].

Manufacturing / Preparation Methods:

Solvent-casting [most common]: polymer × API solution cast and dried – scalable but solvent removal and uniformity are considerations [11, 13].

Hot-melt extrusion [HME]: solvent-free; good for thermally stable APIs [11, 13].

Electrospinning: produces nano fibrous films, high surface area – useful for poorly soluble drugs and rapid dissolution [13, 15].

12D printing [additive manufacturing]: enables personalized dosing, layered designs, and complex release profiles; a growing area with recent demonstrations for buccal films [15, 16].

Coating/printing technologies: for multilayer films or spatially separated APIs [e.g., immediate + sustained release] [13, 15].

Characterization & Quality Control:

Typical tests you should cover in Methods/Materials section:

Thickness, uniformity, and weight variation [13, 14].

Tensile strength and percent elongation [mechanical properties] [13, 14].

Surface pH [mucosal compatibility] [14].

Folding endurance / brittleness [14].

Disintegration time / dissolution profile [in simulated saliva] [14].

Drug content uniformity and assay [HPLC] [13, 14].

Mucoadhesive strength [for buccal films] and residence time [in vitro/ex vivo] [11, 14].

Permeation studies using excised mucosa/Franz diffusion cells, and where applicable in vivo PK [11, 14].

Clinical & Regulatory Notes / Marketed Products:

The first FDA-approved prescription ODF containing illustrates clinical viability of the platform for antiemetics [10, 13].

Many other prescription and OTC ODFs exist or are in clinical trials [10, 13].

Regulatory focus is on drug content uniformity, stability [moisture sensitivity], packaging [laminate to protect films], and demonstrating bioequivalence or clinical benefit [10, 13, 14].

Recent Advances [2019–2025]:

Nanoparticle-loaded films [drug in NPs inside the film] to improve solubility and controlled release [13, 15].

12D printing & personalized films for dose titration and combined multi-drug films [15, 16].

Biologics & peptide delivery attempts: formulation strategies to protect labile molecules and enhance mucosal uptake [still challenging] [13, 15].

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Nutraceutical applications & functional foods – ODFs for vitamins, supplements, and cosmetic actives are emerging markets [14, 15].

Scale-up & industrial manufacturing studies: methods to ensure uniformity and packaging innovations to prevent moisture uptake [10, 13, 14].

Limitations & Challenges:

Loading capacity is limited [thin films carry only small to moderate doses] [13].

Taste masking and mouthfeel are crucial for acceptability [13, 14].

Stability – moisture sensitivity; requires protective packaging [10, 13].

For macromolecules [peptides, proteins], transmucosal permeability and enzymatic degradation remain major barriers [11, 13, 15].

Future Directions / Research Gaps:

Improved permeation enhancers and enzyme protective systems for biologics [13, 15].

Clinical trials comparing ODFs to conventional forms for PK, PD, and patient preference outcomes [10, 13, 15].

Standardized in vitro–in vivo correlation [IVIVC] models for ODFs/OTFs [10, 14].

Disposable/biodegradable packaging and greener manufacturing [13, 15].

Wider adoption of 12D printing for personalized ODFs in hospital pharmacies [15, 16].

Composition of Oral Films:

The formulation of oral films involves the careful selection of various excipients that ensure desirable mechanical and physicochemical properties. [17,19]

Active Pharmaceutical Ingredient [API]:

- Can be incorporated in small doses [generally <50 mg]. [17]
- Should have good solubility and permeability. [17]
- Examples: Ondansetron, Loratadine, Clobazam, Rizatriptan. [19]

Film Forming Polymers:

These are the backbone of oral films and provide structural integrity. [17,18]

Examples: Hydroxypropyl methylcellulose [HPMC], Pullulan, Polyvinyl alcohol [PVA], Sodium alginate, Maltodextrin, Gelatin. [17,18]

Ideal properties: Non-toxic, tasteless, flexible, and fast-dissolving. [17]

Plasticizers:

Enhance flexibility and reduce brittleness of the film. [18]

Examples: Glycerol, Propylene glycol, Polyethylene glycol, Triethyl citrate. [19]

Saliva Stimulating Agents:

Facilitate rapid disintegration.

Examples: Citric acid, Malic acid, Tartaric acid. [19]

Sweeteners and Flavouring Agents:

Mask bitterness and improve patient acceptability.

Examples: Sucralose, Aspartame, Xylitol, Peppermint oil, Menthol. [17, 19]

Surfactants:

Enhance solubility and drug dispersion.

Examples: Polysorbate 80, Sodium lauryl sulfate. [17]

Colouring Agents and Stabilizers:

Provide aesthetic appeal and formulation stability. [18]

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II. Methods of Formulation

Solvent Casting Method:

Most commonly used technique.

Steps include: dissolving polymer in water, adding API and excipients, casting on a flat surface, drying, and cutting into desired sizes. [18,19]

Hot-Melt Extrusion:

No solvent required; polymer and drug are melted, extruded, and cooled.

Suitable for heat-stable drugs. [19]

Semisolid Casting Method:

Used for water-insoluble polymers; film is formed from a semisolid mass. [18]

Rolling Method / 19D Printing:

Modern techniques allowing precision control over dose and uniformity. [19]

Mechanism of Drug Release:

The drug release from oral films involves a series of physicochemical and physiological steps. [19,20]

Wetting and Hydration of the Film:

When placed on the tongue or buccal mucosa, saliva penetrates the film. The hydrophilic polymer matrix absorbs saliva and swells, forming a gel-like layer. [19,20]

Disintegration or Dissolution:

Depending on the film type:

Fast-dissolving films disintegrate within seconds, releasing the drug into saliva. Mucoadhesive buccal films remain attached to the mucosa for sustained release. The rate depends on polymer type, plasticizer, thickness, and drug solubility. [19, 20]

Drug Diffusion:

The drug diffuses through the hydrated polymer matrix into the surrounding saliva or mucosal tissue. [20]

Saliva-Mediated Transport:

In fast-dissolving films, dissolved drug mixes with saliva and is swallowed, entering the gastrointestinal tract for absorption. In buccal/sublingual films, drug diffusion occurs directly through the oral mucosa. [20]

Mechanism of Drug Absorption

A. Buccal or Sublingual Absorption

The oral mucosa is highly vascularized, allowing direct absorption into systemic circulation.

This route bypasses first-pass hepatic metabolism, leading to rapid onset and higher bioavailability. [17, 20]

Mechanisms involved:

- Passive diffusion: for lipophilic and low-molecular-weight drugs.
- Facilitated diffusion or active transport: for certain hydrophilic drugs.
- Paracellular transport: through tight junctions between epithelial cells.

Applications, Challenges, And Limitations of Buccal Drug Delivery:

1. Applications of Buccal Drug Delivery:

The applications of buccal drug delivery systems can be broadly divided into systemic and local therapeutic uses.

Systemic Applications:

The buccal mucosa provides an excellent route for systemic drug administration because of its rich vascularization and ability to bypass hepatic first-pass metabolism. This leads to improved bioavailability, rapid onset of action, and reduced gastrointestinal degradation of drugs. Shojaei (1998) emphasized that the buccal route is suitable for drugs undergoing extensive hepatic metabolism or those unstable in the gastrointestinal tract. Bertoni et al. (2023) demonstrated that buccal absorption enhances

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systemic availability of BCS Class III drugs. Experimental studies, such as those by Kaur et al. (2020), confirmed improved solubility and bioavailability of drugs like piroxicam through co-crystal-based buccal films [21, 22, 23].

Local Applications:

Buccal drug delivery is also useful for localized therapy within the oral cavity. It offers site-specific action, fewer systemic side effects, and prolonged mucosal contact time. Mohan and Ross (2010) highlighted the role of mucoadhesive buccal films and tablets in treating oral conditions such as ulcers, fungal infections, and periodontal diseases [24]. González-Rodríguez et al. (2023) discussed buccal films for local and transmucosal therapy, emphasizing sustained release and better patient compliance [25].

2. Challenges Related to Applications:

Despite their advantages, buccal systems face formulation and physiological challenges.

The limited surface area, saliva-induced wash-off, and mucosal permeability barriers affect drug absorption and residence time.

Mohan and Ross (2010) and Bertoni et al. (2023) suggested using permeation enhancers, mucoadhesive polymers, and controlled-release systems to overcome these limitations [22, 24].

Challenges and Limitations of Buccal Drug Delivery:

Although buccal delivery offers many therapeutic advantages, several physiological, formulation, and patient-related factors limit its effectiveness.

Physiological Barriers:

The buccal mucosa poses biological barriers that restrict drug diffusion and absorption. Factors like epithelial thickness, keratinization, and mucus layer significantly influence drug permeability. Shojaei (1998) and Sattar et al. (2014) reported that buccal epithelium is less permeable than sublingual mucosa.

Continuous salivary flow also reduces drug concentration and residence time at the absorption site [21, 26].

Formulation-Related Challenges:

Developing buccal systems requires balancing mucoadhesion, drug release, and film stability. Mohan and Ross (2010) stated that ensuring strong adhesion without irritation is difficult [24].

Issues such as taste masking, moisture sensitivity, and film brittleness affect product acceptability and shelf-life [23].

Bertoni et al. (2023) emphasized optimizing permeation enhancers and plasticizers to enhance systemic absorption while maintaining mucosal safety [22].

3. Limitation:

Only low-dose and highly potent drugs can be delivered effectively through the buccal route. González-Rodríguez et al. (2023) noted that limited surface area and restricted drug loading hinder achieving therapeutic plasma concentrations for high-dose drugs [25].

Patient-Related Factors:

Individual variations in saliva flow, mucosal health, and mouth movement can affect adhesion and performance.

Patel et al. (2011) mentioned that irritation or discomfort from prolonged contact may lead to poor patient compliance, especially for chronic use [27].

Stability and Storage Issues:

Buccal films often contain hydrophilic polymers sensitive to humidity and temperature, influencing film flexibility and drug release. Kaur et al. (2020) highlighted that maintaining mechanical integrity and drug stability during storage requires optimized polymer composition and protective packaging [23].

Regulatory and Manufacturing Challenges:

Standardized evaluation parameters for mucoadhesion, permeability, and in vitro–in vivo correlation (IVIVC) are still under development. Bertoni et al. (2023) also discussed challenges in scale-up, manufacturing reproducibility, and ensuring uniform drug distribution in films [22]

Future Prospectives And Innovations:

The development of ondansetron oral films represents a significant advancement in drug delivery systems, offering convenience, rapid onset of action, and improved patient compliance—especially for pediatric and geriatric populations [28, 29].

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Future innovations may focus on:

Nanotechnology Integration: Incorporation of nanoparticles or nanofibers to enhance solubility, stability, and bioavailability [32].

3D Printing Technology: Personalized oral film formulations can be fabricated using 30D printing for individualized dosing and drug combinations [31].

Smart Films: Development of stimuli-responsive films that release ondansetron in response to specific physiological conditions, such as pH or temperature [32].

Taste Masking and Polymer Innovation: Advanced polymer blends and sweetening agents can further improve palatability and mechanical strength [30, 31].

Combination Therapy Films: Formulations that combine ondansetron with other antiemetic or analgesic drugs for synergistic effects [29, 32].

Sustainable Manufacturing: Eco-friendly solvent systems and biodegradable polymers can make production more sustainable [31].

These innovations will likely make ondansetron oral films more effective, patient-friendly, and commercially viable in the future [28, 32].

III. Conclusion:

Ondansetron oral films are an emerging, patient-centric dosage form designed to overcome the limitations of conventional tablets and injections. They provide rapid drug absorption through the oral mucosa, bypassing first-pass metabolism and ensuring quick relief from nausea and vomiting associated with chemotherapy, radiation therapy, and surgery [28, 29]. With continued research in formulation science, nanotechnology, and polymer engineering, ondansetron oral films hold great potential to become a leading choice for antiemetic therapy, offering both efficacy and convenience [28, 29, 30, 31, 32].

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