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Oral Medication Strips: The Present and Future Trends

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ABSTRACT: Oral Medication Strips (OMS), including dissolving films or Oro Dispersible Films (ODFs), offer a promising alternative to traditional solid and liquid oral dosage forms. These strips deliver drugs through oral absorption, ensuring immediate systemic circulation. If the drug crosses the membranes of the oral cavity, OMS bypass first-pass metabolism, making them ideal for emergency situations and for patients with cardiac issues, schizophrenia, or dysphagia. OMS provide rapid drug release without water, disintegrating within seconds. They are also suited for nutraceutical delivery, addressing emerging trends in this field. OMS can facilitate prolonged drug delivery using mechanisms such as muco-adhesion, and also better bioavailable with permeation and solubility enhancement, or the dose tailor made by modifying the strip size, rolling, folding, and layering. Solvent casting is the predominant method, employing film-forming polymers for quick disintegration, enhanced drug dispersion, and higher drug content. The composition, manufacturing processes, and evaluation methods vary based on the intended site of application and functionality, offering versatility in drug delivery systems. Overall, OMS present a unique and efficient strategy for delivering pharmaceuticals, future vaccines and nutraceuticals effectively and conveniently.

KEYWORDS: Oral medication strips, oro-dispersible films, drug and nutraceutical delivery, solvent casting, vaccine delivery.

I. INTRODUCTION

Oral Medication Strips (OMS) represent an innovative approach to enhance patient compliance in drug administration. Unlike traditional tablets, OMS dissolve rapidly in the oral cavity without the need for water, allowing for quicker therapeutic effects. According to the European Pharmacopoeia, ODFs are defined as thin, melting films composed of one or multiple layers, formulated with suitable materials, and designed to dissolve rapidly when placed in the mouth [1]. Oral Medication Strips also serves the same purpose and additionally, OMS can used for sustained release of medication in combination with mucoadhesive polymers and suitable modifications. This novel drug delivery system offers modified dosage forms, replacing conventional tablets and fast-disintegrating oral tablets due to their ease of handling, flexibility, longer storage capability and multipurpose applications. Because of the restricted area in the oral cavity, OMS up to $2 \times 2 \text{ cm}^2$ and $100 \mu\text{m}$ in thickness are deemed appropriate [2]. The present review explores benefits, various polymers, methods used in formulation and evaluation, and their applications in treating various diseases. Drugs with this innovative film technology have fewer adverse effects, minimize the frequency of doses, better absorption and, most importantly, have a higher bioavailability. OMS can offer optimal drug loading capacities, quick dissolving, and increased stability in therapeutic formulations [3].

Advantages of OMS

- No risk of choking.
- No water is required, dosage form disintegrates and dissolves rapidly
- Ease of administration for patients who are mentally ill, disabled & uncooperative.
- Used in the emergency situations such as motion sickness, bronchitis etc.
- Improve bioavailability for certain therapeutic ingredients.
- Minimize the frequency of doses.[4]

Disadvantages of OMS:

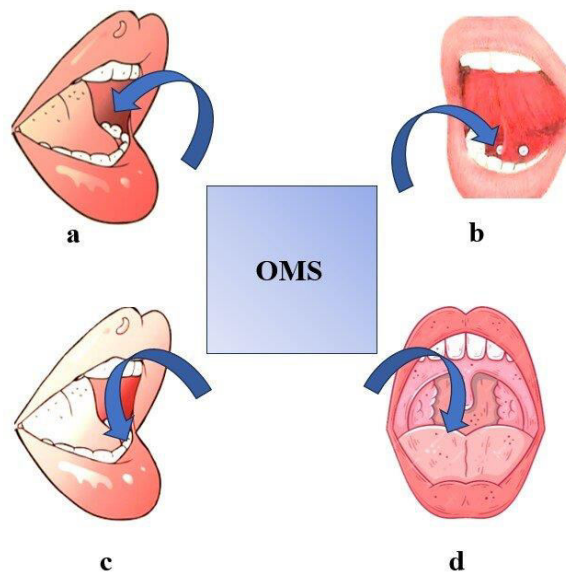
- Drugs that irritate the mucosa cannot be administered.
- Sometimes requires special packaging [5].

1.1 Sites of Administration

OMS can be placed in following sites depending on the functions and duration of stay. **Figure 1** represents locations of OMS to be placed in oral cavity for specific action.

- The buccal region:** For immediate or sustained release. Muco-adhesion is criteria to retain the oral cavity for sufficient time.
- Below the tongue:** Allowed to release immediately in saliva and get absorbed.
- The teeth or the tooth cavity:** For sensitized or decayed teeth with fluoride or antimicrobial agents, local anaesthetic, and analgesic.
- Between tongue and palate:** The film is allowed to be pressed and dissolved in saliva for immediate release. It may also be swallowed, but requires taste masking and organoleptic agents.

Figure 1. Represents locations of OMS to be placed: a). The Buccal region or on the cheek membrane b). Under the tongue c). On the teeth or the tooth cavity d) Between tongue and palate



1.2 Classification of OMS

OMS can be classified based on rate of release, laminar property, and source of materials.

The strips classified according to thickness and dissolution include three types[6];

Type 1: Fast OMS also called as Oro-dispersible films. These are strips that dissolve within thirty seconds have a thickness of around 50–150 μm (Ultra-thin)

Type 2: Moderate OMS that dissolve in thirty seconds to thirty minutes and have a variable thickness of 150 μm to 1000 μm (Thin)

Type 3: Slow OMS can take more than thirty minutes to dissolve may have thickness above 1 mm. (Thick).

OMS can be also classified into three, according to the number of layers they made of:

1. **Monolayer** consist of an API, a film-forming polymer, and excipients
2. **Bilayer** or double layer strips consist of one API layer and another taste-masking or permeation-enhancing layer
3. **Multilayer** strips sandwich the API between two layers for sustained release and/or muco-adhesion, with or without taste masking.

II. FORMULATION COMPONENTS

2.1 Active Pharmaceutical Ingredient (API)

Normally 5–30% (w/w) of drug can be used to formulate the buccal films. APIs in OMS vary depending on the intended therapeutic purpose, and the selection depends on the drug's solubility, stability, and desired pharmacokinetic profile. The most important quality of a drug candidate for use in an ODF is that it belongs to BCS class 1, having high permeability and solubility, as well as a low molecular weight with administrability at a low dose. Drugs with low aqueous solubility and slow dissolution rate can be loaded, with techniques to enhance the solubility of poorly water-soluble medicines.

2.2 Plasticizers

Plasticizers are low-molecular-weight additions used in polymer solutions to increase plasticity and flexibility. Plasticizers reduce the glass transition temperature of polymers, converting them from a hard, glassy material to a soft, rubbery material. The addition of plasticizers at a concentration ranging from 0–20% by weight of the dry polymer is employed to prevent undesirable physico-mechanical and thermal properties of the polymeric films. Some most used plasticizers are mentioned below. Their selection is based on polymer characteristics.

- Glycerine is commonly used as a plasticizer with polyvinyl alcohol (PVA) due to its low molecular weight and compatibility with the polymer. Glycerine can also be considered an effective plasticizer, as seen with starch, methylcellulose, highly carboxymethylated starch, and hydroxypropyl methyl cellulose (HPMC) films [6].
- Hydrophilic compounds, such as polyols (sorbitol), are commonly used in starch films.

2.3 Sweetening agents

Sweeteners are generally added to mask the unpleasant taste and odours of APIs or excipients, improving palatability and patient acceptability. These methods include the utilization of sweetening agents, ion exchange resins, microparticles, inclusion complexes, and nanocarriers. It is common to add flavours at a concentration of up to 10% w/w [7]. Sweeteners used in ODFs can be mainly classified into two types:

1. Natural sweeteners: Glycyrrhizin acid, Rebiana, Mannitol,
2. Artificial sweeteners: Aspartame

2.4 Polymers

Oral films are typically made up of a polymer matrix that provides film-forming characteristics while also maintaining structural integrity. The film-forming polymer, which serves as the major component which may constitute up to 65% of the weight based on the total dry weight of the film. A mixture of polymers can be used to improve hydrophilicity, flexibility, mouth feel, and solubility.

The polymers should be

- non-toxic, non-irritating,
- free from leachable impurities,
- possess excellent wetting and spreadability,
- have a good shelf life, and
- have adequate peel and tensile strength

To strike a balance between mechanical properties and disintegration time, proper selection of polymer type and concentration, and their combinations is an important issue[8].

2.5 Saliva-stimulating agents

They are referred as sialagogues. They stimulate saliva production in the mouth. They can be useful for people who suffer from dry mouth (xerostomia) or who struggle to produce enough saliva. The addition of these substances can speed up the disintegration process, resulting in rapid dissolution within a short period of time. Citric acid, malic acid, lactic acid, ascorbic acid, and tartaric acid are common ingredients used to stimulate salivation in rapidly dissolving strip formulations. These compounds are frequently used alone or in combination, with concentrations ranging from 3 to 5% by weight relative to the film [9].

2.6 Stabilizing agents

These agents are critical components for maintaining structural integrity, preventing degradation, and ensuring the desirable qualities of the film. These substances can aid to maintain the film's smoothness, elasticity, and capacity to disintegrate quickly. Several stabilizing agents are routinely utilized, including Hydroxy propyl cellulose (HPC), Polyvinyl pyrrolidone (PVP), xanthan gum, sodium alginate, locust bean gum, carrageenan, gelatin, sorbitol, and surfactants.

III. PREPARATION METHODS

The strips or films with varied thickness and drug loading are made by various methods. But the most popular methods are mentioned below.

3.1 Solvent casting method

One of the most prominent methods for producing oral films involves dissolving water-soluble polymers and other necessary excipients. Both the active pharmaceutical ingredient (API) and other excipients are dissolved in a suitable solvent, and the solutions are then mixed through agitation. Any entrapped air is removed by vacuum, and the final solution is cast and left to dry overnight. Once dried, the film is cut into the desired shape and size.

The solvent casting approach is ideal for manufacturing heat- and light-sensitive active components because to its lower temperature requirements and ability to remove solvent from films. However, there are several drawbacks with this strategy. Casting the solution onto plates mechanically can lead to the formation of brittle films due to uneven distribution of the solution, resulting in varying thicknesses. Prolonged drying times may cause shrinkage and rippling of the film, further contributing to non-uniformity [10].

3.2 Hot- melt extrusion method

This method involves melting and mechanically processing polymeric materials above their glass transition temperature to achieve molecular mixing of polymers, drug substances, and other agents. HME is efficient, cost-effective, and capable of improving the solubility and bioavailability of poorly soluble crystalline drug substances by converting them into amorphous solid dispersions or liquid solutions.

However, HME also has limitations. Common challenges include die swell phenomenon, fish eye effect during blending, bubbles in the extrudate, and bambooning effect. Another drawback is the high process temperatures, which may directly impact the polymers and drugs used in the formulation. In the HME process, the active pharmaceutical ingredient (API) and other formulation ingredients are combined in a dry state and heated until the mixture melts. The molten mixture is then extruded using a film extrusion system equipped with twin screws, ensuring uniform mixing of materials and the creation of thin films. The resulting films are further cooled and sized as required [4].

3.3 Printing techniques

Another method utilized for creating ODFs involves printing technologies, including two-dimensional (2D) ink-jet printing, three-dimensional (3D) additive printing, and flexographic printing. The process commences with the preparation of an ink formulation intended for printing onto an edible substrate. Depending on the type of printer head used, the ink is expelled onto the surface of the substrate. Subsequently, the printed orodispersible films (POFs) undergo drying and are then cut into the desired shape and size before being packaged and stored for use by patients [4]. However, printing technologies do have their limitations, including the potential for smearing, nozzle clogging, buckling effects, and satellite effects. This additive manufacturing approach involves depositing successive layers of ingredients. Extrusion technologies, particularly those utilizing fused deposition, are commonly employed in 3D printing drug delivery systems. For instance, aripiprazole ODFs have been fabricated using a 3D printing method. Initially, aripiprazole filaments are prepared through hot-melt extrusion, then mixed with polyvinyl alcohol (PVA) and moistened with ethanol before drying. These film filaments are subsequently processed using an extruder, where the blended powder is fed and extruded through a die at a constant speed. The resulting film filament is collected and utilized to fabricate 3D-modeled ODFs with desired dimensions [11]. Different drugs and excipients, used to treat various diseases were casted as films using suitable manufacturing methods [11-27] are mentioned **Table 1**.

Table 1. API, excipients, manufacturing methods to prepare films for treating various diseases.

Manufacturing method	API	Disease	Film forming polymers	References
3D Printing	Aripiprazole	Schizophrenia	Polyethylene oxide	11
	Benzydamine hydrochloride	Antiseptic	Maltodextrin	12
Electrospinning	Acetylsalicylic acid	Antipyretic	Pullulan, chitosan	13
	Carvedilol 61	Hypertension	PVPK30, hydroxypropyl- β -cyclodextrin	14
	Isoniazid 74	Tuberculosis	HPMC/ Pullulan	15
	Risperidone	Antipsychotic	Polyethylene oxide	16
Hotmelt Extrusion	Loratadine	Antihistamine	Polyvinylcaprolactum-polyvinylacetate- polyethylene glycol	17
Inkjet Printing	Hydrocortisone	Cortisone deficiency	Polyvinylcaprolactum-polyvinyl acetate- polyethylene glycol	18
	Metoprolol	Heart diseases	HPMC	19
Solvent Casting	Amphotericin B	Oropharyngeal candidiasis	Dextrose derived polymers/ HPMC	20
	Breviscapine	Cardiovascular Diseases	HPMC/ HPC	21
	Donepezil hydrochloride	Alzheimer's disease	HPMC, hydroxypropyl- β -cyclodextrin	22
	Eletriptan hydrobromide	Migraine	PVA	23
	Entecavir	Antiviral	PVA/PEG Copolymer	24
	Frovatriptan	Migraine	HPMC E15, Chitosan	25
	Ibuprofen	Painkiller, anti-inflammatory	HPC	26
	Rasagiline Mesylate	Parkinson	Polyethylene oxide	27

IV. CHARACTERIZATION

4.1 Organoleptic evaluation

Organoleptic evaluation serves as a crucial method for assessing taste, both in vivo and in vitro, employing specialized human taste panels for controlled evaluations. Electronic tongues offer a novel approach to assess films loaded with drugs that possess undesirable tastes, thus aiding in taste-masking formulations.

4.2 Surface morphology

Analysis of films provides valuable insights into their transparency, homogeneity, and colour. This assessment is typically conducted using light microscopy and scanning electron microscopy (SEM). SEM offers enhanced performance, allowing for detailed examination of surface characteristics, such as uniformity and absence of pores, which indicates high-quality films/strips.

4.3 Weight variation

This assessment involves weighing minimum six films from each formulation individually using a digital balance. The average weight is calculated, and the standard deviation from the average weight is determined [2].

4.4 Disintegration time

Pharmacopoeia lists several disintegration apparatuses for determining film disintegration times (DTs). Two common methods for determining disintegration times of ODF formulations are the slide frame method and the petri dish method.

In the slide frame method, films are clamped onto a glass slide frame or a petri dish, and drops of pure distilled water are added onto the film. The time taken for complete dissolution is noted.

In the petri dish method, distilled water is poured into a petri dish, and 2*2 cm sized films are placed into it. The dish is then gently shaken, and the time taken for the film to disintegrate is recorded [1].

4.5 In Vitro dissolution test

In vitro dissolution testing of oral films typically involves the use of two official apparatuses: the paddle and basket apparatuses. A common issue encountered during dissolution testing is film flotation, particularly with the paddle apparatus. Consequently, the basket apparatus method is often preferred.

In a typical study, simulated saliva fluid (SSF) is taken as media. Sampling is conducted at regular intervals, with six aliquots of 5 mL drawn after every minute and then at specific time points such as 6, 8, 10, 12, 16, 20, and 30 minutes. These samples are then analyzed using a suitable analytical method.

4.6 Drug content uniformity

The film of specific dimensions is immersed in phosphate buffer solution or suitable solvent. After being sonicated for 15 minutes, the solution is filtered through Whatman filter paper. The absorbance of the filtrate is then measured using a UV spectrophotometer to determine the concentration of the drug in each strip. The average and percent deviation are then calculated.

4.7 Mechanical Properties

The mechanical properties of ODFs were evaluated based on various parameters including surface thickness and folding endurance.

4.7.1 Thickness

Film thickness is determined to ensure uniformity of drug content and is measured using a micrometre. Consistency in film thickness is crucial for ensuring accurate drug dosing. Measurements are taken from the four corners and centres of the films, with mean values recorded and then standard deviation is calculated.

4.7.2 Folding Endurance

Folding endurance assesses the mechanical properties of films by measuring their flexibility. Films are folded repeatedly at 180° angles until cracks appear. The higher FE values indicating greater mechanical strength [2].

4.8 Stability studies

The stability study of the formulated films is carried out under different environmental conditions. The formulations packed in aluminum foil is subjected to accelerated stability testing for 3 months at a temperature $40 \pm 2^\circ\text{C}$ and relative humidity $75 \pm 5\%$. Samples are taken at regular time intervals of 1 month for over a period of 3 months and analyzed for the change in physical appearance and for other parameters by using procedures stated earlier [5].

V. THE PRESENT AND FUTURE APPLICATIONS

5.1 Vaccine delivery

Oral delivery of vaccination remains a difficult challenge due to its low inherent stability, degradation, and metabolism, resulting in poor bioavailability. Protein in the trehalose and pullulan-based ODFs were used for protein delivery in oral

cavity [28], which allows ODFs a kind of potential alternative carrier for vaccine, especially during the outbreak of epidemic and pandemic. **Table 2** depicts some studies on vaccines that are incorporated into ODFs.

Table 2. List of Vaccines incorporated into the ODFs.

Vaccine	Type of ODF	Organization/Individual	References
Rotavirus vaccine	Monolayered or bi layered ODFs	The Johns Hopkins University	29
Cancer vaccine	Monolayer ODFs	Nitto Denko Corporation	30
Gonorrhoea	Bilayer ODFs	Nasir Uddin from Larkin University	31

5.2 Probiotics

Probiotics have shown great potential in the treatment of oral diseases and improving oral health, including caries and caries-associated microbes, periodontal diseases, oral candida, and halitosis. Probiotics are living bacteria that can rapidly lose their viability in tough gastrointestinal conditions. As a result, alternate delivery routes, such as delivering to the oral cavity, are preferable, as they can swiftly dissolve and release integrated probiotics in the mouth, bypassing the acidic conditions of the gastrointestinal tract [32].

5.3 Nutraceuticals

Nutraceuticals encompass natural bioactive compounds, including herbal extracts, vitamins, minerals, and antioxidants. These compounds not only offer nutritional benefits but also possess health-enhancing, disease-preventing, and therapeutic properties. Serving as dietary supplements, nutraceuticals are utilized to improve health, combat aging, ward off diseases, and maintain optimal bodily functions [33]. Oral medicated strips (OMS) represent a rapidly dissolving dosage form, ensuring swift onset of action due to their quick disintegration in the oral cavity.

5.4 Cardiovascular Diseases

Extensive medications were utilized to treat cardiovascular disorders. However, some medicines, such as propranolol, may have high first-pass metabolism following oral administration, resulting in limited bioavailability. Moreover, fixed-dose cardiovascular drugs in form of tablets or capsules are not suitable for paediatric use. Therefore, many research works have been done to incorporate cardiovascular drugs, for example, propranolol, enalapril maleate, metoprolol tartrate in ODFs [34].

5.5 Erectile dysfunction

Sildenafil citrate is the most used drug for the treatment of male erectile dysfunction. The commercial dosage form of sildenafil citrate for clinical use is a tablet, which causes inconvenience during administration. Sildenafil citrate has low oral bioavailability due to its substantial first-pass metabolism and poor water solubility. This can be delivered tailor made according to dose requirement in OMS platform.

5.6 Pulmonary Diseases

Frequent drug administration, less patient compliance, higher doses, and frequent dosage intervals increase the development of drug resistance. To address this issue, numerous novel distribution mechanisms, including ODFs, have been created. In addition to tuberculosis, researchers have expressed interest in using ODFs as carriers to treat several chronic obstructive pulmonary diseases. Khan et al. developed ODFs using cyclodextrins as polymer for improved water solubility of the cefixime trihydrate for treating bacterial infections in the respiratory tract [35].

VI. CONCLUSION

Taking a closer look, it can be concluded that the ODF products have popularity among oral medication strips. The ability to tailor the therapeutic dose to a specific patient, the range of APIs employed, and the diversity of production methods (not only on an industrial scale but also in community and hospital pharmacies) all contribute to OMS's

endless potential for future growth. The limitations if any can be tackled easily with advent of novel technologies, 3D printing and specialty packaging which not only contribute to the improvement of the quality and durability of the manufactured preparations. In conclusion OMS are yet an untapped potential among dosage forms for tailor made patient specific unit dose delivery.

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