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REVIEW ARTICLE

A REVIEW ON BUCCAL FILMS

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ABSTRACT:

Today there is a demand for the design and development of new dosage forms to improve patient compliance, safety, and efficacy. Buccal Film is a new film technology that meets all these requirements. Buccal films are delivered via a buccal drug delivery system. Oral films are small, have small doses, are easy to administer, and are more palatable and dose-tolerant than other oral drug delivery systems such as wafers, troches, microparticles, gels, and tablets. Buccal film bypasses first-pass metabolism and is therefore an effective dosage form that improves bioavailability. It adheres well to the buccal layer of the oral cavity and is easier to use than other dosage forms. Cost-effective, biodegradable, fast-absorbing, elegant, easy-to-use, non-irritating, no need to swallow drugs. Therefore, it is an acceptable dosage form for geriatric and pediatric patients. This article provides a comprehensive overview of the benefits, limitations, manufacturing methods, evaluation parameters, and formulation of buccal films.

Keywords: *Buccal film, cost effective, buccadhesion, bioavailability.*

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INTRODUCTION:

Buccal films are a recently developed delivery form for buccal administration. They are gaining attention as new drug delivery systems that are cost-effective, effective with excellent patient compliance. Since oral films are intended to adhere to the buccal mucosa, they can be formulated to have both local and systemic effects. Buccal films may be preferred over buccal tablets because of their flexibility and comfort. The buccal film provides direct access to the systemic circulation via the internal jugular vein, bypassing the drug from hepatic first-pass metabolism and thus increasing bioavailability. Additionally, these dosage forms are self-administrable, pharmaco-economical, and have excellent patient compliance. Films can be defined as dosage forms that use water-soluble polymers that hydrate, adhere, and dissolve rapidly when the dosage form is placed on the tongue or buccal cavity, resulting in systemic drug delivery. The main property of the buccal film is that the large surface area of the film allows rapid wetting of the film and rapidly accelerates drug absorption compared to tablets. The oral mucosa has a rich blood supply and serves as a perfect and rapid site for drug absorption. A mucoadhesive buccal film is formulated to demonstrate topical efficacy for the treatment of oral fungal infections. The current focus is on buccal films. This dosage form is less fragile than most commercially available orally disintegrating tablets, which typically require special packaging. Mucoadhesive buccal foils have some of these advantages. Furthermore, since mucoadhesion means adhesion to the buccal mucosa, films can be formulated to have systemic or local

effects. Many mucoadhesive buccal films are formulated for topical drug delivery to treat oral fungal infections such as oral candidiasis. Bio adhesion is a term that broadly encompasses adhesive interactions with biological or biologically derived substances, mucoadhesion being used when bonds are formed with mucosal surfaces. However, buccal films present the greatest challenge of high-quality development, which is also required for the constant evaluation and understanding of performance.

IDEAL PROPERTIES OF BUCCAL FILMS:

1. Buccal films provide large surface area that leads to rapid disintegration and dissolution in the oral cavity due to which it promotes the systemic absorption of Active pharmaceutical ingredient.
2. No need of chewing and swallowing.
3. The film increases the systemic bioavailability of the drugs, as it bypasses the hepatic first pass metabolism.
4. Drug can be protected from degradation by GI enzymes and the acidic environment.
5. Rapid onset of action and minimum side effects.
6. Self-administration is possible.
7. Accurate dosing compared to liquid dosage forms.
8. Taste masking is possible.
9. Prolongs the residence time of the dosage form at the site of absorption, hence increases the bioavailability.
10. Ease of administration to pediatric, geriatric patients, and also to the patients who are mentally retarded, disabled or non-cooperative.
11. Good mouth feel and good stability

ADVANTAGES OF BUCCAL FILM:

1. No risk of chocking.
2. No need of chewing and swallowing.
3. Rapid onset of action and minimum side effects.
4. Accurate dosing compared to liquid dosage form.
5. Taste masking is possible.
6. Good mouth feels and good stability.
7. Requires less excipient.
8. Ease of transportation, storage, and consumer handling.
9. More Economical
10. Ease of administration to paediatric, geriatric patients. Also, to patients who are mentally retarded, disabled, or non-cooperative.
11. Prolongs residence time of dosage form at site of absorption. So improves bioavailability.
12. Drug can be protected from degradation in GI tract and acidic environment.
13. Buccal film has large surface area that leads rapid disintegration and dissolution in oral cavity.

DISADVANTAGES OF BUCCAL FILM:

Saliva is continuously secreted into the oral cavity diluting drugs at the site of absorption resulting in low drug concentrations at the surface of the absorbing membrane. Instinctively swallowing of saliva results in a maximum part of dissolved or suspended released drug being removed from the site of absorption. Moreover, there is risk that the delivery system itself would be swallowed.

Drug characteristics can make boundary for use of the oral cavity as a site for drug delivery. Taste, irritancy, allergy and adverse properties such as discoloration or erosion of the teeth can limit the drug candidate list for buccal route. Conventional type of buccal drug delivery systems did not allow the patient to concomitantly eat, drink or in some during talk.

MANUFACTURING METHODS OF BUCCAL FILM:

Buccal film formulation is mainly prepared by following five methods.

1. Solvent Casting Method
2. Hot Melt Extrusion Method
3. Direct Milling Method
4. Solid dispersion extrusion
5. Rolling

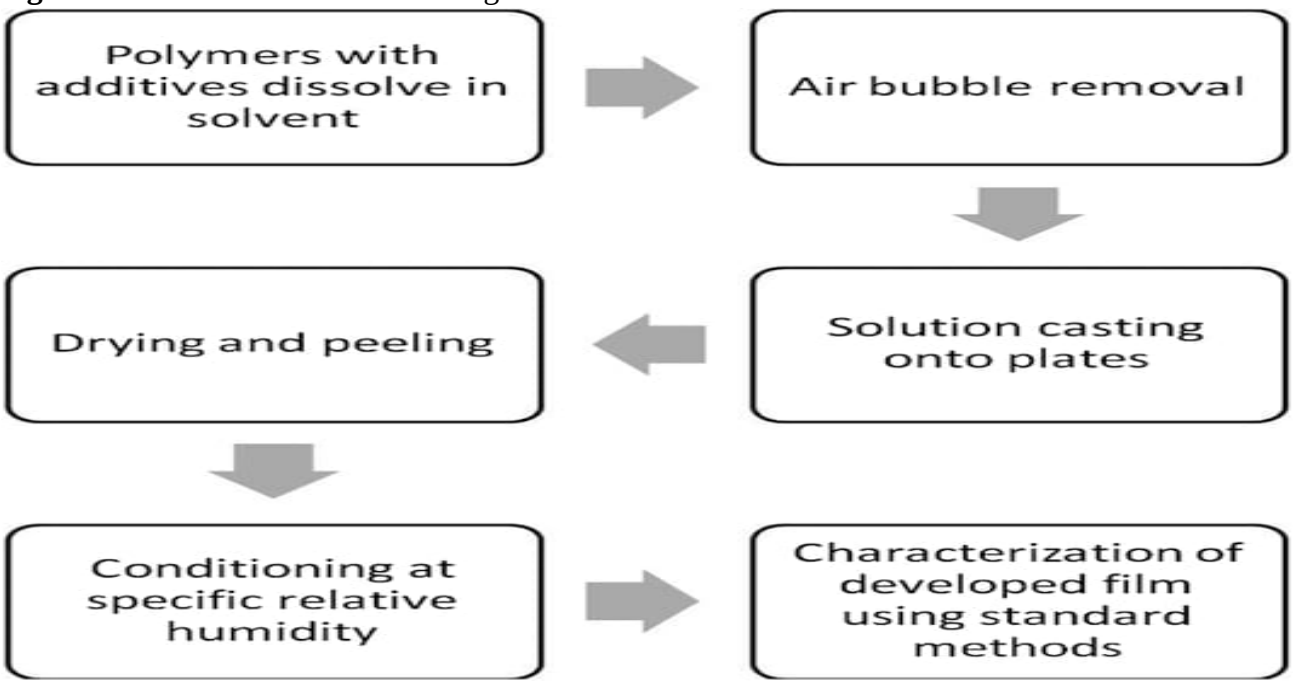
1. Solvent Casting Method:

In solvent casting method, required quantity of polymer is added and dissolved in distilled water. Active pharmaceutical ingredient in small quantity added in this solution. Plasticizer is added in solution and stirred well. Solution is then casted on petri dish and kept in hot air oven for drying at 400C. After drying removed it from petri plate by cutting with blade and allowed to keep in desiccator for 24hours. Henceforth cut in required size and shape.

Steps involved in Solvent Casting Method

Step 1: Preparation of casting solution.
Step 2: Deaeration of solution.
Step 3: Transfer of appropriate volume of solution into the mould.
Step 4: Drying the casting solution.
Step 5: Cutting the final dosage form to contain desired amount of drug.

Figure1: Flowchart of Solvent Casting Method



2. Hot Melt Extrusion Method:

In hot melt extrusion method mixture of drug and other excipients is molten. Then forced through orifice to yield a more homogenous material in different shapes like granules, tablets, or films. It is used for transdermal drug delivery System.

Steps involved in Hot Melt Extrusion Method

Step 1: The drug is mixed with carriers in solid form.
Step 2: Extruder having heaters melts the mixture.
Step 3: Finally, the melted mixture is shaped in films by the dies.

3. Direct Milling Method:

This method is solvent free method. In this method, drug and excipients are mixed without presence of liquid by direct milling or by kneading. Then resulting material is rolled on release liner til the required thickness is obtained. This method is usually preffered because of there is no possibility of residual solvent and no association of solvent related health issue.

4. Solid dispersion extrusion:

In this method immiscible components are extruded with drug and then solid dispersion are prepared. Finally, the solid dispersions are shaped into films by means of dies.

5. Rolling method:

In this technique, the film is produced by making a pre-mix, followed by the incorporation of an active ingredient and subsequently the formation of a film.

1. Produce a pre-mix comprising a film-forming polymer, polar solvent, and other additives with exception of a drug.
2. Incorporate premix to master batch feed tank.
3. Transfer it by a 1st metering pump and control valve to one or all the mixers.
4. Add the desired quantity of the drug to the desired mixer.
5. Mix the drug with master batch pre-mix to give a homogenous matrix.
6. Then, a fixed quantity of uniform matrix is then added to the pan utilizing the 2nd metering pump.
7. The film is ultimately produced on the base material and transported away utilizing a support roller.
8. The wet film is then dehydrated by supervised bottom drying.

PATENTED TECHNOLOGICAL PLATFORM OF ORODISPERSIBLE FILMS:

These are the technological platform that has been developed by various companies,

1. SmartFilm®

SmartFilm technology was developed by Seoul pharma, A south Korean pharmaceutical company, smartfilm have a high dose loading capacity about 140mg and are capable of incorporating both hydrophilic and hydrophobic drugs, bitter taste can be masked by taste masking agents. In 2012 the company launched Vultis(® containing 140.45 mg of sildenafil citrate , the sildenafil smartfilm is a fast dissolving film its bitter taste is masked by sodium hydroxide and magnesium oxide.[18-19]

2. Biodegradable transmucosal film

Auxilium pharmaceuticals have developed biodegradable transmucosal films that adhere to the upper gum, preferably above the back molar, where it dissolves completely. Biodegradable transmucosal films is the most effective way to deliver drug substance and to achieve the same therapeutic levels with lower doses due to high rate of drug absorption when compared with the other conventional dosage forms, where drug absorption is lowers due to shorter onset of action or reduction of first pass metabolism and probably less frequent dosing. The company is using this technique to incorporate drug for the treatment of overactive bladder, management of pain and androgen replacement therapy. In 2005 the company signed a licensing agreement with Pharmaform to receive exclusive worldwide rights to develop, manufacture and market analgesic compounds using Pharmaform transmucosal delivery system for the treatment of chronic and acute pain.[20-21].

3. Versafilm™

Versafilm patent technology was developed by IntelGenx technologies Corp. Versafilm TM is an edible film used for the instant delivery of savory flavors to food substrate. Versafilm is used as a system of choice requiring immediate onset of action. Maximum 40 mg of the drug can be incorporated in the versafilm TM and disintegration time can be brought from 30 sec to 10 min and it can be sublingual. The IntelGenx Corporation in association with RedHill Biopharma recently developed rizatriptan versafilm TM quick release film for the treatment of migraine.[22-24].

4. Rapidfilms®

Rapidfilms® is a patented technology developed and commercialized by Labtec GmBH. These are fast dissolving thin films made from water soluble polymers, non mucoadhesive, which can vary from single to multilayer design system. These films offer strong advantages to patients and combine the convenience of a liquid with the stability and dosing accuracy of a tablet. The film is based on a PVA-starch mixture which is plasticized by PEG. Up to 30 mg of the drug can be incorporate into Rapidfilms. Ondasetron Rapidfilms were the first oral films that have been approved worldwide, and there have been at least three more rapidfilms products in European markets.[25-28].

5. Quicksol®

SK Chemicals developed Quicksol technology, a wide variety of drug substances can be accommodated by using quicksol® techniques. But only two drug available in the market produced by quicksol techniques they are Montfree ODF (monteleukast) and Mvix-S ODF(mirodenafil). Mvix-S is a 50mg oral film which is thin and light. Mvix ODF absorption is 16.7% higher than Mvix tablet.[29,30]

6. Fast-Onset sublingual bilayer film

Cynapsus Company developed fast-onset sublingual bilayer film technique. Apomorphine was developed by this technique. The apomorphine in its neutral form is easily oxidized which makes it difficult to incorporate into film, therefore non-neural form of apomorphine is loaded in one film layer and a neutralizing agent is incorporated in other film layer, separated from each other. The neutralizing agent t dissolves rapidly when comes in contact with the saliva allowing drug substance to rapidly absorbed by sublingual membrane. Clinical trials of this film demonstrate that maximum blood levels were reach with in 20 min of administration. This sublingual bilayer film proved that it also works in most severe case of Parkinson's disease.[31,32]

7. Orally and Adhesive Disintegrating films

Japanese company Kyukyu pharmaceuticals has its own oral film technology these are orally disintegrating films which dissolves in 10 to 30 seconds, other is Adhesive and disintegrating film that adhere to the oral mucosa and disintegration time vary from 30 minutes to 8 hrs. Kyukyu pharmaceuticals in collaboration with Nippon Kayaku developed buccal films of fentanyl of which

phase II trial has been conducted. Recently company started to develop buccal films for the treatment of for the treatment of cancer related pain and nicotine dependence.[33-36]

8. XGelTM

XGEL film is introduced by Meldex international intellectual property, used in all film system. XGEL is a non-animal derived film which is suitable for vegetarians. These films can be taste masked,colured and layered and also have the capabilities to incorporate active pharmaceutical ingridients. The XGEL film is soluble in both hot and cold water.[37,38]

9. SoluleavesTM

Bioprogress Company introduces SoluleavesTM, these are designed to dissolve rapidly when comes in contact with saliva and quickly release the active ingredients and flavors. This makes films excellent for delivering large range of products that require fast release in the mouth. SoluleavesTM films are designed to adhere to the mucous membrane and release the active ingredients slowly over 15 minutes. This can be used for flavor release products.[38]

10. BEMA®

BEMA drug delivery technology consists of a small, bioerodible polymer film which quickly adhere to the oral mucosa less than 5 sec with a backing layer that assures the unidirectional flow of the drug. BEMA stands for bio-erodible mucoadhesive drug delivery system. BEMA films were designed to rapidly deliver either local or systemic level of drug across mucosal membranes for time sensitive conditions or to facilitate administration of drug with poor oral absorption. The multilayer buccal film can rapidly deliver dose of a drug to oral mucosa and dissolved completely within 15-30 min. This technology is developed to deliver several drug substances especially if quick onset of the action is required or oral dosing is not optimal or intravenous injections are unable. The first product developed and marketed using BEMA technology was onsolis (fenatyl buccal soluble film) in 2009 for the management of cancer pain in opioid tolerant adults.[39]

Table 1: The buccal film technological platform, company name, marketed products and salient features.

Sr. No.	Name of patent technology	Owner/ Distributor	Salient features	Marketed products
1	BEMA® (Bio-erodible mucoadhesive)	BioDelivery science international (BDSI)/ KunWha Pharmaceutical Co Ltd; Meda AB; TTY Biopharm Co Ltd	Bio-erodible mucoadhesive films that adhere quickly to oral mucosa.	• Onsolis. • BEMA® Granisetron BEMA®Buprenorphine • BEMA®Triptan • BEMA®Zolpidem BUNAVIL
2	SmartFilm®	Seoul Pharma Co Ltd/ Pfizer Inc	These Oral films have high dose loading capacity.	• Vultis®
3	Biodegradable transmucosal films	Auxilium Pharmaceuticals	These films adhere to the upper gum preferably above the back molar.	• Rotavax™ • Fentanyl • Oxybutynin

4	Pharmafilm®	MonoSol Rx LLC/ C.B. Fleet Company/ Reckitt Benckiser Pharmaceuticals/ Prestige Brands	Films can be used for both fast dissolving and buccal delivery and maximum 80mg of the drug can be loaded.	• Pedia Lax® Quick Dissolve Strips. • Suboxone® Sublingual Film. • Chloraseptic® • Zuplenz®
5	Versafilm™	Intelgenx Technology Corp	Disintegration time of this film can be brought from 30 sec to 10 film, maximum 40mg drug can be loaded and film can also be sublingually administered.	–
6	Rapidfilms®	Labtec GmBH / APR Applied Pharma Research/ Norgine / SciClone Pharmaceuticals, Inc / Takeda Canada	Fat dissolving rapid films based on water soluble polymers, non mucoadhesive film and can be vary from single to multilayer design, these films can accommodate upto 30 mg of drug	• Setofilm® Ondansetron • Rapidfilm® *Ondissolve*™ • Zolmitriptan ODF • RapidFilm® Aripiprazole ODF • Olanzapine ODF • Donepezil ODF
7	Quicksol®	SK Chemicals Co Ltd	Wide variety of drug substance can be accommodated	–
8	Soluleaves™	Bioprogress	these films designed to dissolve rapidly when comes in contact with saliva and quickly release the active ingredients and flavors in mouth.	• Nicotine
9	Fast-Onset sublingual bilayer film	Cynapsus Therapeutics	These films permit fast mucosal absorption of the drug in mucosa.	• Apomorphine
10	Orally and Adhesive Disintegrating films	Kyukyu Pharma Co Ltd/ mochida pharma/Teva Pharma Japan Inc/Kyukyu Pharma Co Ltd; Nippon Kayaku Co Ltd	Orally disintegrating films which dissolves in 10 to 30 seconds, other is Adhesive and disintegrating film that adhere to the oral mucosa and disintegration time vary from 30 minutes to 8 hrs.	• Amlodipine OD Film • Voglibose OD Film • Olopatadine • Hydrochloride OD Film • Zolpidem Tartrate OD Film • Loratadine OD Film • Waplon

EVALUATION OF BUCCAL FILMS[40-54]:

The buccal films are evaluated by

1. **Weight and thickness of the film:**

For evaluation of film weight, three films of every formulation are taken and weighed individually on a digital balance. The average weights are calculated. Similarly, three films of each formulation were taken and the film thickness is to be measured using micrometer screw gauge at three different places, and the mean value is to be calculated.

2. Surface pH of films:

For determination of surface pH, three films of each formulation are allowed to swell for 2 h on the surface of an agar plate. The surface pH is to be measured by using a pH paper placed on the surface of the swollen patch. A mean of three readings is to be recorded.

3. Swelling index:

After determination of the original film weight and diameter, the samples are allowed to swell on the surface of agar plate kept in an incubator maintained at 37 ± 0.2ºC. Weight of the films (n=3) is determined at different time intervals (1-5 h). The percent swelling, % S is to be calculated using the following equation:

Percent swelling [% S]=[Xt –Xo /Xo]×100,

Where, Xt =The weight of the swollen film after time t,

x Xo =The initial film weight at zero time.

4. Folding endurance:

Three films of each formulation of required size are cut by using sharp blade. Folding endurance is to be determined by repeatedly folding the film at the same place, till it is broken. The number of times, the film could be folded at the same place without breaking gives the value of folding endurance. Moisture content The prepared films are to be weighed individually and kept in a desiccators containing calcium chloride at room temperature for 24 h. The films are to be weighed again after a specified interval, until they show a constant weight. The percent moisture content is to be calculated by using following formula.

% Moisture content=[Initial weight–Final weight/Final weight]×100

5. Moisture uptake:

Weighed films are kept in desiccators at room temperature for 24 h. These are then taken out and exposed to 84% relative humidity using saturated solution of potassium chloride in desiccators, until a constant weight is achieved. % moisture uptake is calculated as given below.

% Moisture uptake=[Final weight–Initial weight/Initial weight]×100

6. In-vitro residence time:

The in vitro residence time is determined using IP disintegration apparatus using 900 mL of the disintegration medium maintaining at 37 ± 2°C. The segments of rat intestinal mucosa, each of 3 cm length, are to be glued to the surface of a glass slab, which is then vertically attached to the apparatus. Three mucoadhesive films of each formulation are hydrated on one surface and the hydrated surface is brought into contact with the mucosal membrane. The glass slab is vertically fixed to the apparatus and allowed to move up and down. The film is completely immersed in the buffer solution at the lowest

point and is out at the highest point. The time required for complete erosion or detachment of the film from the mucosal surface is to be recorded.

7. Drug content uniformity:

Three film units (each of 20 mm diameter) of each formulation has to be taken in separate 100 mL volumetric flasks, 100 mL of solvent has to be added and continuously stirred for 24 h. The solutions have to be filtered, diluted suitably and analyzed at specified nm in UV spectrophotometer. The average of drug contents of three films has to be taken as final reading.

8. Surface characterization studies:

The scanning electron photomicrograph of the film is taken at 6000 X magnification. The prepared film containing drug is examined for clear and colorless surface. The photomicrographs of the film with the drug and the blank film are compared and are examined whether the drug is distributed uniformly throughout the film in an amorphous form.

9. In-vitro dissolution studies:

Dissolution studies are carried out for all the formulations, employing USP dissolution apparatus at 37 ± 0.5ºC, rotated at constant speed of 50 rpm using 900 mL of dissolution medium. A sample of drug film is used in each test. An aliquot of the sample is periodically withdrawn at suitable time interval and the volume is replaced with fresh dissolution medium. The sample is analyzed spectrophotometrically at specified nm.

10. Organoleptic evaluation:

The prepared buccal film should possess the desired features of sweetness and flavor, which is acceptable to a large mass of population. Controlled human taste panels are used for psychophysical evaluation of the product. In-vitro methods of utilizing taste sensors, specially designed electronic tongue measurement devices can be used for this purpose.

Packaging:

Many options are available for buccal films packing, such as single pouch, blister card with multiple units, multiple-unit dispenser and continuous roller dispenser. Single packaging is mandatory for films. An aluminium pouch is the most commonly used packaging system. There are some patented packaging systems for oral films. Labtec company has patented packaging technology called Rapid card and Amcor Flexibilities Company has patented Core-peel technology.

Table 2: Marketed preparation of buccal film:

Brand name	Active ingrediant	Category	Indication	Mfg. by
Suboxone	Buprenorphine/nalaxone hydrochloride	Analgesic	Psycological support and patient counseling	Reckitt Benckiser
Zuplenz	Ondansetron	Anti emetic	Prevention of nausea and vomiting before and after of cancer chemotherapy	PharmFilm technology

Zelapar	Selegilin hydrochloride	Antiparkinsonism	Parkinsons disease	Valent pharmaceuticals international Inc.
Eclipsed flash strips	mint	Antibacterial	Mouth freshener	Wringleys
Health Strips	Soluble vitamins	Soluble Vitamins	As A Supplement	Mattle/ Momentus solution , LLC
Benadryl	Diphenhydramine hydrochloride	Antihistamin, allergy, sinus	Treatment of cough	Pfizer
Tetraflu thin strips	Dextromethophan	Antitusive	Cough	Novartis
Oral films	Benzocain	Local Anesthetic	Sore Throat	Apothecus Pharmaceutica Corporation
Sudafed PE	Phenylephrine	Decongestant	Nasal and sinus congestion	Pfizer
Orajel	Menthol/pectin	Local Anesthetic	Canker sores,fever blisters	Del
Zentrip	Medizine Hydrochloride	Antihistamic	Nausea, vomiting with motion sickness	Sato
Melatonin PM	Melatonin	Sedative, hypnotics	Insomnia	AdvaCare
Bioevelop	Nicotin			Paladine Labs Inc.
Listerin Pocketpaks	Mint	Antibacterial	Mouth freshener	Pfizer inc
Azatidine Maleate	Azatidine	Antihistaminic	Perennial and allergic rhinitis	Fulford (India) Ltd
Habitrol	Nicotine	Smoking cessation	To reduce smoking habit	Dr.Reddy’s laboratories
Loperamide	Loparamide Hydrochloride	Anti- diarrheal	Diarrhea	Ralington Pharma LLP(India)
Zofran ODT	ondansetron	Anti emetic	Prevent nausea and vomiting	Dr.Reddy’s Laboratories
Covan	Triplodine hydrochloride	Antihistaminic	Relieve sneezing & runny nose	Shanghai coven chemical co.Ltd
Zomig	Zolmitriptan	Anti migrain	Headache	AstraZeneca
Coralan	ivabradine	Hyperpolarisation channel blocker	Angina and chronic heart failure	Serdia pharmaceuticals india pvt.ltd
Ivabratco	Ivabradine	Hyperpolarisation channel blocker	Angina and chronic heart failure	Natco phama ltd

Belbuca	Buprenorphine	Narcotic analgesic	Treat opioid use disorders	Collegiums pharmaceutical,Inc
Setofilm	Ondansetron ODF	Antiemetics	Nausea	Bioavailance pharma
Onsolis	Fentanyl	Opoid analgesic	Cancer	Biodelivery science international
Rapid film	Ondansetron and donepezil ODF	Antiemetic	Nausea, psychosis	Labtech GmbH
Triaminic thin strips	Phenylephrine and diphenhydramine	Nasal decongestant	Cough and cold	Novartis
Pedia lax	Sennosides ODF	Hyperosmotic laxative	Constipation	C.B. fleet company. Inc.
Sudafed PE	Phenylephrine ODF	Nasal decongestant	Cough and cold	Pfizer
Triaminic thin strips	Phenylephrine	Nasal decongestant	Cough	Novartis consumer health
Ondissolve	Ondansetron	Antiemetic	Nausea, vomiting	Labtech pharma
Zuplenz	Ondansetron	Antiemetic	Nausea and vomiting	Monosol Rx

APPLICATIONS OF BUCCAL FILMS:

1. It is feasible to make multilayer drug films, also known as an emerging field possessing immediate applications. Two or more medications might be integrated in one structure, and the layers could be designed to dissolve at the same rate or at different speeds.

2. The dissolving rates of the medications might range from minutes to hours depending on how the films are made.

3. Films can be employed as gastro retentive dosage forms, with dissolution initiated by the pH or enzyme secretions of the gastrointestinal tract and could be utilized to treat gastrointestinal illnesses.

BUCCAL FILM: FUTURE ASPECTS:

1. Potent drugs that meet the parameters for buccal film as a drug delivery technology can be included into mucoadhesive buccal films.[59]
2. For drug release profile investigations, we can assess the dissolution of buccal film.
3. In-vivo research can be enhanced for the preparation of buccal film.
4. For buccal film, we can do a stability study.

CONCLUSION:

The present review concluded that buccal film is most acceptable, palatable dosage form. It is bypasses first pass metabolism and enhance bioavailability of active molecule due to its specific characteristic features than other novel buccal drug delivery system. Buccal film is an innovative dosage because of its wide range of advantages to geriatric, paediatric as well as patients having swallowing issues. Buccal film is novel approach for replacement of conventional dosage form as buccal film is available in low cost and no irritancy in oral cavity. Buccal film is promising area for continued research with

the aim of systematic delivery of orally inefficient drugs. It is feasible and alternative source for non-invasive delivery of potent peptide and protein drug molecules. As buccal films have good buccoadhesive property, it gives rapid onset of action. Buccal film is buccoadhesive drug delivery system which enhances safety, efficacy and stability of active pharmaceutical ingredient. Buccal film is novel technology due to its better option to optimize therapeutic efficacy.

REFERANCES:

[1] Shinde P, Salunkhe V, Magdum C.Buccal film:an innovative dosage form designed to improve patient compliance. Int. J of Pharmaceutical and Chemical science, 2012; 1(4):1262-1278

[2] Nair AB, Kumaria R, Harsha S. In vitro techniques to evaluate buccal films. J of Controlled Release. 2013;166:10-21

[3] Lee JW, Park JH, Robinson JR (2000) Bioadhesive-based dosage forms: the next generation. J Pharm Sci 89: 850-866.

[4] Veuillez F, Kalia YN, Jacques J, Deshusses, Buri P (2001) Factors and strategies for improving buccal absorption of peptides. Eur J Pharm Biopharm 51: 93-109.

[5] Sudhakar Y, Kuotsu K, Bandyopadhyay AK (2006) Buccalbioadhesive drug delivery- a promising option for orally less effective drug. J Control Release 114: 15-40.

[6] Joseph RR, Vincent K L (1987) Lee controlled drug delivery. (2ndEdn), Marcel Dekkerinc, New York, USA 42-43.

[7] Pfister WR, Ghosh TK (2005) Drug delivery to the oral cavitymolecules to market. Marcel Dekker, New York, USA.

[8] Bhura N, Sanghvi K, Patel U, Parmar B, Patel D (2012) A review on fast dissolving film. IJPRBS 1: 66-89.

[9] Ratha Adhikari SN, Nayak BS, Nayak AK, Mohanty B (2010) Formulation and evaluation of buccal patches for delivery of atenolol. AAPS Pharm Sci Tech 11:1038-1044.

[10] Donnelly R, McCarron P, Tunney M, Woolfson A (2007) Potential of photodynamic therapy in treatment of fungal infections of the mouth. Design and characterisation of a mucoadhesive patch containing toluidine blue O. J Photochem Photobiol B 86: 59-69.

[11] Khanna R, Agarwal SP, Ahuja A (1997) Preparation and evaluation of mucoadhesivebuccal films of clotrimazole for oral Candida infections. Indian J Pharm Sci 59: 299-305.

[12] Repka M, Prodduturi S, Stodghill S (2003) Production and characterization of hot melt extruded films containing clotrimazole. Drug Dev Ind Pharm 29: 757-765.

[13] Radha MB, Murthy VS. Buccal film drug delivery system-an innovative and emerging Technology. Molecular Pharmaceutics and Organic Process Research. 2013; 1(3):1-6

[14] Mishra S, Kumar G,Kothiyal P. A review article: Recent advances in buccal patches.2012;1(7):78 86.

[15] Parmar HG, Jain JJ, Patel TK. Buccal patch: a technical note. Int. J of Pharmaceutical Sciences review and research.2010; 4(3):178-182

[16] Neelagiri R, Reddy MS, Rao NG. Buccal Patch as Drug delivery system: an overview. International Journal of Current Pharmaceutical Research.2013;5(2):42-47

[17] Arya A, Chandra A, Sharma V, Pathak K. Fast dissolving oral film: an innovative drug delivery and dosage form.Int J of Chemtech Research.2010;2(1):576-583

[18] Cortellis TR, LG Life Sciences, Zemiglo granted the Korea New Drug Award, Pharma Koreana. 23, April, 2013 (01) 25, Source ID: 1447789 in: Development Profile, 2013.

[19] Cortellis TR, High-dose unit film formulations expected to heat the erectile dysfunction drug market, Pharma Koreana, 2013 23 (January 01), Source ID: 1357733 in: Development Profile, 2013.

[20] Auxilium Pharmaceuticals, Auxilium Pharmaceuticals Announces Top-Line Results for Phase II Androgen Replacement Transmucosal Film Proof of Concept Study in, http://www.sec.gov/Archives/edgar/data/1182129/000119312505 153257/dex991.htm, 2005.

[21] Auxilium Pharmaceuticals, Auxilium Pharmaceuticals Announces Licensing Agreement with PharmaForm for Transmucosal Film Technology, in, http://ir.auxilium.com/phoenix.zhtml?c=142125&p=irolnewsArticle 2&ID=671741&highlight.

[22] Intel Genx, RedHill Biopharma. (2014, 02-2014). IntelGenx and RedHill Biopharma Receive Complete Response Letter From FDA for VersaFilm(TM) Oral Film Product for Acute Migraines fro http://ir.redhillbio.com/releasedetail.cfm?ReleaseID=823064.

[23] Intel GenX Corp, (2006), Pipeline, Retrieved 02-2014, from http://www.intelgenx.com/pipeline/Ishise: Nishikawa AH Intra orally dissolving film preparation, WO2013121663 A1, 2013.

[24] Paiement N, Angusti A, Zerbe H, Long C, Solid oral film dosage forms and methods for making same, US20110136815 A1, 2011

[25] Leichs, C, Breitenbach A, Lehrke I, Galfetti P, Non-mucoadhesive film dosage forms, WO2008040534 A2, 2008.

[26] Reiner GN, Giarratana V, Reiner U, Becker A, Breitenbach, P, Klaffenbach, Ph regulating antibacterial films for the oral or vaginal cavity, in, Google Patents, 2010.

[27] Press Release, (2009), APR and Labtec's Ondansetron Rapidfilm® licensed to SciClone Pharmaceuticals for Chinese Market. Retrieved 09-2015, from http://www.tesalabtec. com/eng/company/press/apr-and-labtecs-ondansetron-rapidfilmlicensed-to-sciclonepharmaceuticals-for-chinesemarket,3701696,1.html

[28] Press Release, (2013), Launch of Setofilm® byNorgine in several European countries. Retrieved 02-2014, from http://www.tesalabtec.com/eng/company/press/tesa-labtec-tesa-labtec-

andaprapplied-pharma-research-apr-announce-the-launch-of setofilmondansetron-oral-dispersible-filmin-several-european-countries bynorgine, 5163100, 1.html

[29] Choi WJ, Gyo OJ, Jun LY, Yong LB, Choi NY, Film for oral administration containing mirodenafil or pharmaceutically acceptable salt thereof, WO2013085276 A1, 2013.

[30] Giovino C, Ayensu I, Tetteh J, Boateng JS, Development and characterization of chitosan films impregnated with insulin loaded PEG-b-PLA nanoparticles (NPs): A potential approach for buccal delivery of macromolecules, International Journal of Pharmaceutics, 428, 2012, 143-151.

[31] Cynapsus, APL-130277 Overview, in: APL-130277 Product, http://www.cynapsus.ca/general.php?pid=7,2014.

[32] Awamura T, Nishikawa H, Inagi T, Film preparation containing loperamide hydrochloride, 2010.

[33] Awamura T, Nishikawa H, Kokaji K, Ishise A, Ara T,Film preparation containing medicament with unpleasant taste, 2011.

[34] PMB Intelligence, Nippon Kayaku Cancer Pain Relief Drug To Enter Phase II Development, in: Pharm Asia News, Elsevier Business Intelligence, http://www.elsevierbi.com/publications/pharmasianews/2009/7/1 5/nippon-kayaku-cancer-pain-relief-drug-to-enter-phase-iidevelopment, 2009.

[35] Zbygniew N, John S, Water-soluble films comprising nicotine, WO2006114604 A3, 2006.

[36] Kushwaha V, Akhtar J, Usmani S and Prakash SS, A review on fast dissolving formulation technologies, World journal of pharmacy and pharmaceutical sciences. 4(7), 2015, 574-585.

[37] Richard HWO, Adhesive bioerodible transmucosal drug delivery system, WO2005016321 A1, 2005

[38] Anders R, Merkle H (1989) Evaluation of laminated muco-adhesive patches for buccal drug delivery. Int J Pharmaceut 49: 231-240.

[39] Chun M, Kwak B, Choi H (2003) Preparation of buccal patch composed of carbopol, poloxamer and hydroxypropyl methylcellulose. Arch Pharm Res 26:973-978.

[40] Repka MA, Gutta K, Prodduturi S, Munjal M, Stodghill SP (2005) Characterization of cellulosic hot-melt extruded films containing lidocaine. Eur J Pharm Biopharm 59: 189-196.

[41] Cilurzo F, Cupone IE, Minghetti P, Selmin F, Montanari L (2008) Fast dissolving films made of maltodextrins. Eur J Pharm Biopharm 70: 895-900.

[42] Shidhaye SS, Saindane NS, Sutar S, Kadam V (2008) Mucoadhesivebilayered patches for administration of sumatriptan succinate. AAPS Pharm Sci Tech 9: 909-916.

[43] Perioli L, Ambrogi V, Angelici F, Ricci M, GiovagnoliSet al. (2004) Development of mucoadhesive patches for buccal administration of ibuprofen. J Control Release 99: 73-82.

[44] Patel VM, Prajapati BG, Patel MM (2007) Effect of hydrophilic polymers on buccoadhesive Eudragit patches of propranolol hydrochloride using factorial design. AAPS Pharm Sci Tech 8.

[45] Satishbabu BK, Srinivasan BP (2008) Preparation and evaluation of buccoadhesive films of atenolol. Ind J Pharm Sci 70: 175-179.

[46] Khanna R, Agarwal SP, Ahuja Alka (1996) Preparation and evaluation of bioerodiblebuccal tablets containing clotrimazole. J Pharm Pharmaceutics 138: 67-73.

[47] Morales Javier O, McConville Jason T (2011) Manufacture and characterization of muco adhesive buccal films. Eur J Pharm Biopharm 77: 187-199.

[48] Dixit RP, Puthli SP (2009) Oral strip technology: Overview and future potential. J Control Release 139: 94-107.

[49] Ratha Adhikari Surya N, Nayak Bhabani S, Nayak Amit K, Mohanty Biswaranjan (2010) Formulation and evaluation of buccal patches for delivery of atenolol. AAPS Pharm Sci Tech 11: 1038-1044.

[50] Anders R, Merkle H (1989) Evaluation of laminated muco-adhesive patches for buccal drug delivery. Int J Pharmaceut 49: 231-240.

[51] AnandV, Kataria M, Kukkar V, Saharan V, Choudhury PK (2007) The latest trends in the taste assessment of pharmaceuticals. Drug Discov Today 12: 257-265.

[52] Murray OJ, Dang W, Bergstrom D (2004) Using an electronic tongue to optimize taste masking in a lyophilized orally disintegrating tablet formulation. Pharm Technol.

[53] Mahajan A, Chhabra N, Aggarwal G. Formulation and characterization of fast dissolving buccal film. Scholars Research Library.2011;3(1):152-165

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[55] Medically reviewed by Philip Thornton, DipPharm. Last updated on Aug 1, 2022.

[56] Neelagiri R, Reddy MS, Rao NG. Buccal Patch as Drug delivery system: An overview. International Journal of Current Pharmaceutical Research 2013; 5(2):42-47.