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An Overview on Oroflash Release Films

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ABSTRACT

Nowadays, a lot of research work has been carried out in pharmaceutical industries so as to come up with a better product. Of all the routes that are used to administer the drug, oral route is the widely accepted route as it is more patient compliant than the other routes. Oral delivery systems do not require sterile conditions and are less expensive to manufacture. Many attempts have been made to formulate a dosage form that eases the discomfort of the patients especially pediatrics and geriatrics who have difficulty in swallowing. Oro flash release films are one of such attempts which in addition to patient compliance it also facilitates rapid release of drug. Oro flash release films are prepared using hydrophilic polymers which when placed on tongue gets dissolved rapidly. This review emphasized on Oro-flash release film, polymers used for preparation, critical aspects of manufacturing, commercial technologies and marketed formulations of oral films.

INTRODUCTION

The epithelia of oral cavity are composed of an intracellular ground substance called mucus. It is composed of an intracellular ground substance called mucus. It is composed of proteins and carbohydrates. Mucus is used to maintain hydrated condition in oral cavity provides lubrication and reduces attachment of microbes. Saliva and salivary mucin acts as barriers of oral mucosa. Saliva is secreted by different glands located in tips, buccal mucosa and inlining of mouth and throat. The total turnover ratio of saliva under normal physiological conditions has a flow rate of 1-2 ml/min. Drug absorption through buccal cavity can be transcellular or paracellular.

Buccal mucosa is best suited for formulations that are intended for sustained release action as it is relatively immobile and readily accessible. The primary disadvantage of buccal delivery is low flux that in turn results in low drug bioavailability. Constant salivary secretion makes it difficult for dosage form to be retained for long time. Accidental swallowing of the dosage form is another limitation. Maximum duration of buccal delivery is 4 – 6 hrs.

In spite of these challenges, buccal route has been widely used for administering drugs that are prone to first pass metabolism. Different buccal delivery products have been marketed and are generally used for diseases viz. trigeminal neuralgia, menieris disease, diabetes, addiction etc. Buccal delivery is used as a platform for mucoadhesive systems and local delivery to oral cavity.

Tablets are widely accepted by elders and adolescents' but younger children tend to prefer liquid formulations that are easier to swallow. Apart from ease of administration, palatability also plays a major role in designing a dosage form for children which made it a challenging task. Keeping ease of administration and swallowing in mind, Oro dispersible tablets (ODT) are designed. ODT as per United States Food and Drug Administration "solid preparations disintegrate rapidly in oral cavity, with a disintegration time of approximately 30 sec or less as per USP.

Research in pharmaceutical industries with the view of improving the patient compliance has led to the transition of oral dosage forms from conventional tablets to ODT and to the latest Oro flash release films. Oro films are basically considered as ultra thin films of postage stamp size with an API and other excipients. Oro films have the advantages of convenience of

dosing and portability that led to wider acceptability of this dosage form (pediatric and geriatric equally).

The pharmaceutical firms apart from introducing ODT into the market get engaged in informing/educating the people about proper way of administering the product by giving instructions "do not swallow/ do not chew". As the strips (films) are already popular as breath-freshening strips, no further efforts are needed to re-instruct the people about the technique of administration of this dosage form.

Oro flash films are superior to other oral formulations in the following aspects:

- Larger surface area – rapid disintegration and dissolution in oral cavity[1]
- ODT- fragile and brittle –special packaging (storage and handling)
- Oro Flash Film (OFF)- flexible, not fragile – no special packing
- More precision in administered dose as compared to drops or syrups
- Ease of swallowing- no need of water
- Consumable at any place and anytime as per convenience
- No first pass effect
- Reduction in dose as first pass is circumvented.

A wide variety of drug moieties can be incorporated into this delivery system which includes cough/cold remedies (antitussives, expectorants) sore throat, erectile dysfunction, antihistaminics, antiasthmatics, GI disorders, nausea, pain and CNS (anti-Parkinson's disease). These are also used as snoring aid, sleeping aid and can also incorporate multivitamins and caffeine.

This article covers the general aspects of Oro-flash release films, polymers used for preparation, critical aspects of manufacturing, commercial technologies and future prospects of the area.

Formulation variables[2]:

Formulation of Oro flash release films involves excellent aesthetic and performance characteristics such as taste masking, fast dissolving, physical appearance, mouth feel etc. Excipients used in this formulation are given below.

Film forming polymers:

A wide variety of polymers are used for Oro flash films. Polymers are used alone or in combination so as to obtain the desired film properties. The film obtained should resist the wear and tear during transportation and storage. The robustness of the film depends on the type of polymer and the amount of polymer. It should disintegrate in seconds when placed on tongue. The general concentration of the polymer that can be used is 45%w/w of total weight of the dry film. Of all the polymers available pullulan, gelatin and hypromellose are most commonly used.

Modified starches are also used for the preparation of Oro flash films. Typically 60-65% w/w of hydrophilic polymer is preferred for the preparation of OFF with desired properties. Many a time, mixture of polymers are used to improve hydrophilicity, flexibility, mouth feels and solubility characteristics of OFF.

The polymer employed should be non-toxic, non-irritant and devoid of leachable impurities. It should have good wetting and spreading property. The polymer should exhibit sufficient feel, shear and tensile strengths. The polymer should be readily available and should be cheap. Different polymers are used to modulate the disintegration time of film as in the case of bioadhesive films. Polymers used to have good shelf life and should not aid in causing secondart infections in oral mucosa or dental regions. It would be beneficial to have a polymer that would have local enzyme inhibition action along with penetration enhancing property.

Plasticizers:

It is a vital ingredient in OFF formulation. It helps in improving flexibility of films and reduces the brittleness of the film. Plasticizers improve the film properties by reducing the glass transition temperature of polymer. Selection of polymer depends on the compatibility with polymer and solvent used. Used plasticizer will enhance the flow and strength of polymer.

e.g. Glycerol, propylene glycol, low molecular weight PEG, Phthalate deviation like dimethyl, diethyl and dibutyl phthalate, citrate derivatives (tributyl, triethyl, acetyl citrate, triacetin and Castrol oil).

The concentration generally used is 0-20w/w of drug polymer weight. Inappropriate use of plasticizer leads to cracking, splitting and peeling of film.

Plasticizer employed should impart permanent flexibility to strip and should be compatible with drug as well as other excipients used for preparation of film. Plasticizer is by internal plasticization and external plasticization. Later is preferred as there is no chemical interaction and no alteration in drug release characteristics.

Active Pharmaceutical Ingredient:

Wide variety of drugs can be incorporated into films. Since the size of dosage form has limitation, high doses are difficult to incorporate. Generally, 5%w/w to 30%w/w can be incorporated. Multi-vitamins up to 10%w/w of dry film can be incorporated into film.

Water soluble APIs are present in dissolved state or on solid solution forms whereas water insoluble drugs are dispersed uniformly in strip. APIs can be milled so as to have an aesthetic appearance and also for better dissolution. Since most of the APIs are better and hence taste has to be masked so as to increase the palatability of the dosage form. In order to increase the palatability various techniques are used; of which the simplest method involves mixing and co-processing of bitter tasting API with excipients with pleasurable taste (obscuration technique).

The OFF offers special advantages for certain drugs in some situations. For drugs projected as local anesthetic or painkiller, OFF has showed improved clinical benefits.

Sweetening agents:

Sweeteners have become an important part of food products as well as pharmaceuticals intended to be disintegrated/dissolved in the oral cavity. Natural sweeteners, as well as artificial sweeteners, are used to improve the palatability of mouth dissolving formulations. Most widely found source is sucrose. Sweeteners of fructose are perceived rapidly as compared to sucrose and dextrose. Fructose is sweeter than sorbitol and mannitol. Polyhydric alcohols (sorbitol, mannitol, isomalt and maltitol) used in combination as they provide good

mouth feel and cooling sensation. Use of natural sugars is to be restricted in case of diabetic patients. Due to this reason, artificial sweeteners are used i.e saccharin, cyclamate and aspartame (I gen)- II gen–acesulfame–K, sucralose, alitame and neotame. Disadvantage of artificial sweeteners is the after test effect. Hence a combination of natural and artificial sweetening agents is to be used.

Saliva stimulating agents:

The purpose of using saliva stimulating agents is to increase the rate of production of saliva, that aids in faster disintegration of Oro flash release film formulations. Citric acid, malic acid, lactic acid, ascorbic acid and tartaric acid are commonly used while citric acid is the most preferred amongst them. These are used alone or in combination between 2-6%w/w of weight of film. Some sweeteners themselves act as saliva stimulating agent e.g. glucose, fructose, xylose etc. Stimulation of saliva can be measured by comparing the amount of resting flow and stimulated at equal time under same conditions.

Flavoring agent:

Perception of flavor changes from individual to individual says geriatric population like mint/ orange whereas younger generation like flavors like fruit punch/raspberry. Selection of flavors depends on the type of drug to be incorporated.

e. g. Mint flavor- for products related to gastric ailments.

The amount of flavor needed to mask the taste depends on flavor type and its strength used preferably up to 10%w/w of film.

The acceptance of oral disintegrating /dissolving formulation by an individual depends on the initial flavor quality which is observed in first few seconds after the product has been consumed and aftertaste of formulation which lasts for at least 10 min. Flavoring agents are used alone or in combination. Cooling agents are also used in conjunction with flavorants.

e. g. Peppermint oil, cinnamon oil, spearmint oil, oil of nutmeg flavor oils, vanilla, cocoa, coffee, chocolate and citrus- fruity flavors.

Coloring agents:

If the drug is insoluble or in suspension form, colorants which are approved by FD and C are used in order to improve the aesthetic sense of the formulation (film).

Advantages: These rapid dissolving films offer several advantages like,

- Convenient dosing
- Fast disintegration or dissolution followed by quick effect which is desirable in some cases such as pain.
- No water needed.
- No risk of choking.
- Enhanced stability
- Improved patient compliance
- Life cycle management.
- Difficulties caused from swallowing tablets are circumvented, that is especially advantageous for pediatric and geriatric patients are in diseases with nausea or vomiting.

Disadvantages: The disadvantage of OTF is that high dose cannot be incorporated into the strip and expensive packaging of oral film.

Mechanism of action: The delivery system is simply placed on the patient's tongue or any oro-mucosal tissue. Instantly wet by saliva due to the presence of hydrophilic polymer and other excipients the film rapidly hydrates and dissolves to release the medication for oro-mucosal absorption.

Composition of mouth dissolving film:

A typical mouth dissolving film contains the following polymers:

Composition	Concentration
Drug	1-25%
Water soluble polymer (film forming agent)	40-50%
Plasticizers	0-20%
Fillers, colors, flavors	0-40%

Methods of manufacturing oral films:

The oral film manufacturing methods include:

- Solvent casting method
- Hot-melt extrusion
- Solid dispersion extrusion
- Rolling method
- Semi solid casting method

Marketed products of oral strips[3]:

Product category	Ingredient/s	Indication/ applications
Appetite suppressant	Focus vesiculosus and guarana extract, garcinia cambogia	These are top selling natural ingredients associated with weight loss. cambogia helps to reduce the food intake by suppressing appetite.
Vitamins and food supplements	Various vitamins, minerals and supplements	It is useful for the people who do not like to pop up the tablets or soluble supplements

Breath freshener strip, (Antibacterial strip)	Contains mint flavor and antibacterial agent, cetyl pyridinium chloride	It is used as mouth freshener and to stop bad breath.
Saliva promoting strips	Fruit acid extracts, range of flavors	It is used in the dry mouth as a side effect of the other medications
Labtec GmbH Ondansetron Rapidfilm®	Ondansetron 4 mg and 8 mg.	It is used in the prevention of chemotherapy and radiation-induced nausea and vomiting and prevention of postoperative nausea and vomiting
Donepezil Rapidfilm®	Donepezil Hydrochloride 5 mg and 10 mg	Treatment of mild to moderately severe dementia of the Alzheimer's type
Minerals	Chromium	Mineral supplements
Natural products	Ginseng, Guarana	Aphrodisiac, Appetite reducer
InnozenInc Chloraseptic® Relief StripsTM	Benzocaine 3 mg, BHT, corn starch, erythritol, FD&C Red 40, hydroxypropyl methylcellulose, malic acid, menthol, mono ammonium glycyrrhizinate, cherry flavors, polyethylene oxide, sucralose	Occasional minor irritation, pain, sore throat and sore mouth
Loratidine	10 mg-20 mg	It is a nonsedative antihistaminic agent used to treat the allergy

EVALUATION PARAMETERS[4]:

Thickness

The thickness of film is measured by micrometer screw gauge or calibrated digital Vernier Calipers. The thickness of film should be in range of 5-200µm. The thickness should be evaluated at five different locations (four corners and one at center) and it is essential to ascertain uniformity in the thickness of film as this is directly related to accuracy of dose distribution in the film.

Dryness/tack test

In all, there have been eight stages identified for film drying and these are set-to-touch, dust-free, tack-free (surface dry), dry-to-touch, dry-hard, dry-through (dry-to-handle), dry-to-recoat, and dry print-free. Tack is the tenacity with which the strip adheres to an accessory (a piece of paper) that has been pressed into contact with strip. Instruments are also available for this study.

Tensile strength

Tensile strength is the maximum stress applied to a point at which the strip specimen breaks. It is calculated by the applied load at rupture divided by the cross-sectional area of strip as given in the equation below:

Tensile strength = Load at failure × 100/Strip thickness × Strip width

Percent elongation

When stress is applied on a film (2 × 2 cm^2) sample it gets stretched, this is referred to strain. Strain is basically the deformation of strip before it gets broken due to stress. It is measured by using houns field universal testing machine. Generally, elongation of strip increases as the plasticizer content increases. It is calculated by the formula:

% Elongation = Increase in length of strip × 100/Initial length of strip

Tear resistance

Tear resistance is the resistance which a film offers when some load or force is applied on the film specimen. The load mainly applied is very low rate 51 mm/min. The unit of tear

resistance is Newton or pounds-force. In other words, it is the maximum force required to tear the specimen.

Young's modulus

Young's modulus or elastic modulus is the measure of stiffness of strip. It is represented as the ratio of applied stress over strain in the region of elastic deformation as follows:

Young's modulus = Slope × 100/Strip thickness × Cross head speed

Hard and brittle strips demonstrate a high tensile strength and Young's modulus with small elongation.

Folding endurance

Folding endurance gives the brittleness of a film. The method followed to determine endurance value is that the film specimen (2×2 cm^2) are repeatedly folded at the same place until it breaks or a visible crack is observed. The number of times the film is folded without breaking or without any visible crack is the calculated folding endurance value.

***In vitro* disintegration test**

Disintegration time is the time when an oral film starts breaking when brought in contact with water or saliva. For a fast dissolving film, the time of disintegration should be in range of 5-30s. United State Pharmacopoeia (USP) disintegration apparatus can be used to study disintegration time. In another method, the disintegration time can be visually determined by dipping the film in 25 ml water in a beaker. The beaker should be shaken gently and the time was noted when the film starts to breaks or disintegrates.

***In vitro* dissolution studies**

Dissolution is defined as the amount of drug substance that goes into the solution per unit time under standardized conditions of liquid/solid interface, temperature, and solvent concentration. The standard basket or paddle apparatus described in any of the pharmacopeia can be used for dissolution testing. The selection of dissolution medium will essentially depend as per the sink conditions and highest dose of API. The temperature of dissolution medium should be maintained at 37 ± 0.5°C and at 50 rpm speed. When the paddle apparatus

is employed, it has a disadvantage that oral films have a tendency to float over the dissolution medium.

Drug content uniformity

This is determined by any standard assay method described for the particular API in any of the Pharmacopeia. Content uniformity is determined by estimating the API content in individual strip. Limit of content uniformity should be as per pharmacopeial specifications.

Organoleptic test

The desired organoleptic properties a fast dissolving formulation should have are color, flavor, and taste. As the formulation will disintegrate in the oral cavity so it should provide acceptable organoleptic palatable characteristics. Color makes a formulation acceptable among the patients and moreover, oral films should have attractive color as they are administered to children. Hence, color of formulation should be uniform and attractive. Color can be evaluated by visual inspection. The other organoleptic property is the odor. The flavor used in the formulation should provide good odor to the formulation. The odor of the polymer, drug and any other excipient should be masked with use of flavoring agent. Taste is also an important factor which has to be evaluated. To evaluate the taste, special human taste panels are used. Experiments using electronic tongue measurements have also been reported to distinguish between sweetness levels in taste masking formulation. Electronic tongue technique works on the principle of potentiometric titration method. In this liquid samples can be analyzed directly, whereas solid samples need to be dissolved in a suitable solvent before analyzing. In this method, reference electrode and sensors are dipped in a beaker containing a test solution for 120 s and a potentiometric difference between each sensor and a reference electrode is measured and recorded by the E-tongue software.

Surface pH test

The surface pH of fast dissolving strip can cause side effects to the oral mucosa, so it is necessary to evaluate the surface pH of film. The surface pH of film should be 7 or close to neutral. For this purpose, a combined pH electrode can be used. With the help of water, OS was made slightly wet and the pH was measured by bringing electrode in contact with surface of oral film. This study should be done on at least six films of each formulation and their mean ± SD can be calculated. In another method to determine the surface pH, the films are

placed on the 1.5%w/v agar gel and then the pH paper are placed on the film, change in color of pH paper gives surface pH of the film.

Contact angle

Contact angle measurement predicts the wetting behavior, disintegration time, and dissolution of oral film. These measurements are performed with help of goniometer (AB Lorentzen and Wettre, Germany) and the measurements should be done at room temperature. The water used to determine contact angle should be double distilled water. A drop of double distilled water is placed on the surface of dry film. Images of water droplet are recorded within 10 s of deposition by means of digital camera. Digital pictures can be analyzed by image J 1.28v software (NIH, USA) for angle determination.

Transparency

To determine transparency of oral film, a simple ultraviolet (UV) spectrophotometer can be used. The film specimen is placed on the internal side of spectrophotometer cell. The transparency of films is calculated as follows:

Transparency = (log T600)/b = −€c

Where T600 is the transmittance at 600 nm and b is the film thickness (mm) and c is concentration.

Scanning electron microscopy

To study the surface morphology of film between different excipients and drug scanning, electron microscopy can be used. The film sample should be placed in sample holder and at ×1000 magnification; various photomicrographs can be taken using tungsten filament as an electron source.

Permeation studies

Even though permeability of oral mucosa is 4-1000 times greater than that of skin, permeation studies should be carried out. To study the permeability, modified Franz diffusion cell can be used along with porcine buccal mucosa. The Franz diffusion cell consists of a donor and a receptor compartment. In between the two compartments, mucosa is mounted and the size of the mucosa should be of the same size as that of the head of receptor

compartment. The receptor compartment is filled with buffer and maintained at 37 ± 0.2°C and to maintain thermodynamics a magnetic bead stirring at a speed of 50 rpm is used. A film specimen moistened with a few drops of simulated saliva should be kept in contact with mucosal surface. The donor compartment should consist of 1 ml simulated saliva fluid of pH 6.8. At particular interval, samples are withdrawn and replaced by same amount of fresh medium. By suitable analytical method, percentage of drug permeated can be determined.

Percentage moisture loss

To determine percentage moisture loss films of area 2 × 2 cm^2 are cut and weighed accurately on an electronic balance. After weighing, the films were kept in desiccators containing fused anhydrous calcium chloride. The films should be kept for 72 h in the desiccator. After 72 h, they are taken out and again weighed and the percentage moisture loss of films was measured by using the formula:

Percent moisture loss = (Initial weight − Final weight)/Initial weight × 100

The percentage moisture loss studies are done to determine physical stability and integrity of the film.

Determination of % yield of buccal patches

Percentage yield of buccal patches can be calculated by the following formula:

% yield = Mass of the buccal patches obtained/Total weight of drug and polymer × 100

Stability study

Stability study should be carried out according to the International Conference on Harmonization (ICH) guidelines. The prepared formulation is wrapped in a special way. Firstly, it is wrapped in a butter paper then above it an aluminum foil is wrapped and the packing should be placed in an aluminum pouch and make it heat sealed. The storage conditions at which formulations are kept should be 30°C/60% relative humidity (RH) and 40°C/75% RH. After 3 months, the films is evaluated for drug content, disintegration time, and physical appearance observation.

Storage and packaging of OS

Fast dissolving strips can be packed using single pouches, blister card with multiple units, multiple-unit dispenser, and continuous roll dispenser. There are certain patented packaging systems for fast dissolving films such as Rapid card by Labtec and Core-peel by Amcor flexible. The rapid card is of same size as a credit card and holds three films on each side. Every dose can be taken out individually.

List of oral films developed with different drugs

Ref	AUTHOR	DRUG	POLYMERS	SOLVENTS
5.	M. Srikanth et al.	Amlodipine	HPMC E5	Alcohol
6.	M. Swapna Sai et al.	Glibenclamide	HPMC E15	Alcohol
7.	NGN. Swamy et al.	Palonosetron hydrochloride	HPMC, NaCMC, PVP, Pullalangum-xanthangum-HPG(1:1:1)	Water
8.	S. Gousiaanzum et al.	Flunarizine dihydrochloride	HPMC E50 LV, CMC	Ethanol
9.	Mamata Thirunagari et al.	Atomoxetine	HPMC grades namely methocel E5 &E15	Ethanol
10.	Manjunath B. Mendon et al.	Amlodipin	HPMC K15, Pullulan, PEG4000	Water
11.	A. Deepthi et al.	Zolmitriptan	Guar gum, xanthan gum, PEG400, Alovera, sodium starch glycolate (SSG), sodium alginate	Water
12.	Nitesh S. Chauhan et al.	Dicyclomine HCL	HPMC, PVA,HPMC-15, HPMC-50, EutragitRL-100, PEG400,	Water, methanol, ethanol
13.	Farhana sultana et al.	Caffeine	HPMC, Kollicoat, sodium alginate	Water:ethanol96%(1:1)
14.	J. guljanpatel et al.	Levocetirizine	HPMC E15, PVA	Water
15.	Aggarwal Jyothi et al.	Granisetron hydrochloride	Pullulan, HPMC E5, HPMC E15	Water
16.	Udhan Ravindra Radhakisan et al.	Rofecoxib, Cetirizine	HPMC E5, HPMC E15, HPMC E50, MCC, gelatinPVA, gelatin, eudragit,	Water

		hydrochloride, etophylline, montelukast sodium, meclizine hydrochloride, fentanyl, metoclopramide, ambroxol hydrochloride	maltodextrin,pullulans	
17.	Mitra Jelvehgari et al.	Ergotamine tartrate, caffeine anhydrous	ET:HPMC E15 (1:10,1:20,1:30) CA:HPMC E15(1:2, 1:4, 1:6)	Polymer dissolved in dichloromethane. drug of different ratios dissolved in ethanol are added to the polymeric solution
18.	Pallavi Patil et al.	Salbutamol sulfate, omeprazole, expectorants, NSAIDs	HPMC E3, PVA, PVP K90, HEC, pullulan, carrageenan, PEG, gelatin, carboxymethyl cellulose cekol 30, and K-3, methyl cellulose A-3, A-6 and A-15, pectin, sodium alginate hydroxypropyl cellulose.	Water
19.	Vijayakuchana et al.	Buclizine	PVA	Water
20.	Prasanna P. Ghodake et al.	API (5-30%)	Methylcelulose A3 A6 A15' HPMC E3 K3, PVP K90,PVA, pectin,pullalans, eudragit RD10, pectin gelatin, maltodexrin, CMC,	Water
21.	Kapoor D. et al.	Montelukast sodium	HPMC, PEG400, PVP	Water, ethanol

22.	Arunarya et al.	Omeprazole, salbutamol sulphate, paracetamol, meloxicam, valdecoxib.	HPMC E3 K3, MC A3 A6 A15, Pullulan, CMC celkol 30, PVP K90, Pectin, gelatin, sodium gelatinate, HPC, maltodextrins, polymerized rosin	Water.
23.	Prasanna Kumar Desu et al.	API of OTC Medications	Pullulan, gelatin, hypromellose, combination of MCC and maltodextrins	Water
24.	Balvinderdhillon et al.	Glibenclamide	HPMC	Methanol
25.	Mudgal Shribhan Singh et al.	Glibenclamide	PEG 4000	Ethanol
26.	V. Manimaran et al.	Glibenclamide	PEG 4000, PVP	Chloroform mixture
27.	Tejas Patel, et al.	Glibenclamide	Poloxamer 407	All solvents of HPLC grade
28.	Prashanth Upadhay et al.	Glibenclamide	PEG 4000, PEG 6000, PVP K-30, Gelucire 50/13	Methanol
29.	S.S Smudgal et al.	Glibenclamide	PEG 6000, PVP K-30	Ethanol
30.	Anjum Pathan et al.	Promethazine HCL	HPMCE15	Water

CONCLUSION

Oro flash release films proved to be an excellent alternate for ODT with respect to patient compliance. As compared to ODT, Oro films are robust. Manufacturer of Oro films is cost effective with affordable end products. From clinical perspective, the improved bioavailability is advantageous in reducing the dose of formulation and thereby minimum side effects. The disadvantage of Oro films is that high dose cannot be incorporated. However, research has proven that concentration level of API can be improved by 50% per dose weight. (Novartis –gas X-62.5 mg of simethicone strip)

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