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ORAL FILM IS AN EFFECTIVE DRUG DELIVERY ROUT.

ASHVIN DIPAK BHOGE*

DEPT. OF PHARMACEUTICAL QUALITY ASSURANCE

DR. D. Y. PATIL COLLEGE OF PHARMACY, AKURDI, PUNE

DR. D. Y. PATIL EDUCATIONAL COMPLEX, SEC. NO. 29, AKURDI, PUNE.

DR. DASWADKAR SHUBHANGI C.

ASSOCIATE PROFESSOR

DR. D. Y. PATIL COLLEGE OF PHARMACY, AKURDI, PUNE

DR. D. Y. PATIL EDUCATIONAL COMPLEX, SEC. NO. 29, AKURDI, PUNE.

Abstract

Fast dissolving drug-conveyance system were first developed during the 1970s as an option for the tablets, containers, and syrups for pediatric and geriatric patients who experience inconveniences consume solid dosage form. Fast dissolving films have become a novel way to deal with oral drug delivery conveyance system as it gives comfort and convenience oral dosage forms, for example, orally disintegrating tablets, buccal tablets, and sublingual tablets, so mouth dissolving films are picking up the interest of countless pharmaceuticals industries. Mouth dissolving films are thin solid dosage forms which, when place in the oral cavity, dissolve inside a couple of moments without biting and administration of water. The oral, buccal mucosa being profoundly vascularized, the drug can retain directly and can enter the systemic circulations without going through first-pass hepatic metabolism. This advantage can be used to improved oral bioavailability of molecules that go through first-pass impact. These oral film offer a helpful method of dosing drug pediatric, geriatric, and bedridden patients. The sublingual and buccal conveyance of a drug by means of fast dissolving film can possibly improve the onset of action, lower down the dosing, and inprove the efficacy and safety profile of medicament. An ideal film ought to have properties like pleasent taste, high stability, and simplicity of taking care of. The current review gives a record of different plan techniques and their assessment utilized in film details and uses of mouth dissolving films.

Keywords Oral film, Method of preparation, Disintegration, Dissolution

Introduction

The oral route remains the perfect route for the administration of therapeutic agents because the low cost of therapy and ease of administration lead to high levels of patient compliance. Oral dosage forms are more popular than other dosage forms because of the following reasons. Ease for administration**,** Accurate dosage**,** Self-medication patient.

Children, geriatric patients and many other person including disable patient often have trouble in swallowing tablet or capsule, furthermore, dossing is an issue as most medication are available in dosage that are significantly too large for the paediatric population and cannot easily and reproducibly be divided into smaller doses (e.g. enteric-coated tablet).

Oral fast dissolving films (FDF) are also known as mouth dissolving films (MDF), oral strips, orally dispersible films (ODF). On placing mouth dissolving film in the mouth, saliva serves to rapidly dissolve the dosage forms. The saliva containing dissolve or dispersed medication is then swallowed and the drug is absorbed in the normal way. Some drugs are absorbed from the mouth, pharynx and oesophagus as the saliva passes down into the stomach and it may produce rapid onset action. In such cases bioavailability of drugs is significantly greater than those observed from conventional tablet dosage form.

Advantages

- Administered without water, anywhere, any time.
- Oral fast dissolving strips (OFFDSs) (fast, accurate, safe and well-tolerated) are widely known and accepted by consumers.
- Suitability for geriatric or paediatric patient, who experience difficulties in swallowing and for other group that may experience problems using conventional oral dosage form, due to being mentally ill, the developmentally disable and the patient who uncooperative, or on reduces liquid intake plan or are nauseated.
- Advantageous in patient which is suffering from motion sickness, cold sudden episodes of allergic attach coughing, bronchitis or asthma where ultra-rapid onset of action is required.
- The development of thin-film prescription drugs are already in the early- to mid-development stages.
- An increase bioavailability, particularly in cases insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
- OFFDSs could potentially replace some orally dissolving tablet (ODTs) as competitively priced alternative.

Disadvantages

- Drug which is unstable at buckle pH cannot be administered.
- Drug which irritates the mucosa cannot be administered by this rout.
- Drug with small dose requirement can only be administered.
- Taste masking – Most drug have bitter taste, and need taste masking.
- Special packaging must be protected from water so it needs special packaging.

Formulation development

SR.NO	Category	Concentration (%)
1	Drug	1-25
2	Polymer	40-50
3	Plasticizer	25-35
4	Sweetener	2-10
5	Saliva stimulating agent	2-6
6	Flavour	2-5

Choice of drug candidate

Suitable drug candidate for Fast Dissolving Film posses

- ✓ No bitter taste
- ✓ Good stability in water and saliva
- ✓ Dose should be low as possible

Various categories of drugs such as antiemetic, neuroleptics, cardiovascular agents, analgesic, antiepileptic, anxiolytics, sedatives, hypnotics, diuretics, Antiparkinsonism agents, anti-bacterial agents, and drug use for erectile dysfunction, Anti-Alzheimer's, expectorant, antitussive.

Selection of Polymers

For the preparation of FDF the various polymers can be used in the film up to 40% w/w of the film content. The polymers are responsible for the strength of the film. The film should be tough to prevent damage during handling and transportation. The polymer can be used as single and in combination as per requirement

Plasticizer

The role of plasticizer is beneficial for preparation of FDF. Plasticizer helps to improve the flexibility of the film and reduce the brittleness of the film. The plasticizer should be compatible whit polymer and solvent. The flow of polymer will get better with the use of plasticizer and enhances the strength of the polymer.

Flavouring agent

Flavourings include: both natural and artificial flavour such as artificial vanilla, cinnamon, and various fruit flavours; either individual or mixed Mints such as peppermint, menthol, Essential oils such as thyme, eucalyptol and methyl salicylate.

Sweeteners

Sweeteners include both natural and artificial sweeteners as: Natural sweeteners include monosaccharides, disaccharides and polysaccharides such as xylose, ribose, glucose, lactose, fructose, dextrose, sucrose, maltose, partially hydrolysed starch, or com syrup solids and sugar alcohols such as sorbitol, xylitol, and mannitol. Water- soluble artificial sweeteners such as the soluble saccharin salts, cyclamate salts, acesulfam-K and the hike and free acid form of saccharin and dipeptide based sweeteners. Aspartame, Neotame is successfully used for taste masking.

Saliva stimulating agent

The purpose of using saliva stimulating agents is to increase the rate of production of saliva that would aid in the faster disintegration of the FDF. Generally acids are used as salivary stimulants. Citric acid, malic acid, lactic acid, ascorbic acid and tartaric acid are the few examples of salivary stimulants, citric acid being the most preferred amongst them. These agents are used alone or in combination between 2 to 6%.

Method of Preparation

Solvent Casting Method

The oral fast dissolving films are prepared by dissolving strip forming agents, plasticizer and saliva stimulating agent in the distilled water, then solution is continuous stirred up to 4 hrs. On magnetic stirrer and kept for I hour to remove all the air bubbles entrapped. Meanwhile, in the separate container remaining water soluble excipients i.e. sweetening agent, disintegrating agent, saliva stimulating agent, flavour and drug ace dissolved with constant stirring for 45 min. When the stirring is over both the solutions are mixed together with stemming for another I h on magnetic stirrer. Then keep the solution stationary for I Hour to let the foams settle down. The resulting formulation is casted on a suitable platform and is dried to form a film. The film is preferably air-dried or dried under oven then the film is carefully removed.

Hot-Melt Extrusion Method

Drug and polymers are blended into a sigma blade mixer for 10 min, and then plasticizer is slowly added. The mixture is granulated in the presence of an anti- sticking agent. Granules are stored overnight at room temperature and then sieved through a 250 um sieve in order to remove the excess of powder and standardize the particle size. The dried granular material is fed into the extruder. The screw speed is set at 15 rpm in order to process the granule's inside the barrel of the extruder for approximately 3-4 min. The processing temperatures are set at 80 C (zone I), 115C (none 2), 100 C (zone 3) and 65 C (zone 4). The extrudate (T- 65 C) is then pressed into a cylindrical calendar in order to obtain a film with a thickness of about 200 um. At the end of the preparation processes, the films are cut according to the sue required for testing, individually sealed in airtight packets and stored at 25°C until use.

Semisolid Casting

In semisolid casting method, firstly a solution of water soluble film forming polymer is prepared. The resulting solution is added to a solution of acid insoluble polymer (e.g. cellulose acetate phthalate, cellulose acetate butyrate), which was prepared in ammonium or sodium hydroxide. Then appropriate amount of plasticizer is added so that a gel mass is obtained. Finally the gel mass is casted in to the films or ribbons wing heat controlled drums. The thickness of the film is about 0.015-0.05 inches.

Rolling Method

In rolling method, a solution or suspension containing drug is rolled on a carrier. The solvent is mainly water and mixture of water and alcohol. The film is dried on the rollers and cut in to desired shapes and sizes.

Evaluation parameters

Organoleptic properties

In the organoleptic properties of oral film was determine by observing the colour, odour, teats of the oral film

Thickness of films

The thickness is measured using vernier callipers at three different places. The thickness measure was turned and the film was embedded subsequent to making the pointer was set to zero.

In-vitro Disintegration study

There are a number of authentic techniques accessible for disintegration tests. The necessary size of film (2cm Diameter) was placed in a container containing 10ml distilled water. The disintegration time was noted which was the point at which the film began to break or crumble.

pH Value

The pH value was decided by dissolving film in 10ml distilled water. All assurance was acted in triplicate. It is important that films have almost uniform pH value.

Folding Endurance

Folding endurance of the film is fundamental to consider the flexibility of the film during capacity and handling. The folding endurance of the film was observed by the number of time films could be folded at the same place without breaking cracking given the value of folding endurance.

Percent elongation

At the moment that pressure is applied to the film one end and stretches out and then measures the stretch film. Rate stretching of the film was controlled by the following equation.

$$Percent\ elongation = \frac{Increase\ in\ length\ of\ film \times 100}{Initial\ length\ of\ film}$$

Drug Content uniformity

Drug content was determined by dissolving the film in 100 ml water to get 20 µg/ml solutions. An aliquot of 2 ml sample was withdrawal and diluted to 10 ml with water. At that point the solution was filtered through whatman filter paper and examined by UV-Spectrophotometer.

In-Vitro Dissolution Studies:

Mouth dissolving films drug release was dictated by Franz Diffusion Cell Apparatus having outside measurement is 3 cm, inside distance across is 2.8 cm, tallness of dissemination cell mechanical assembly is 8cm and volume is 30 ml. The receptor compartment kept up at 370C was consistently stirrer at 100 rpm. The oral film was placed over the cellophane membrane for the 30min. 1 ml sample were taken out after a 5 min and immediately replace with same quantity using phosphate buffer pH 6.8 and sample were analysed for drug content using UV-Spectrophotometer.

Conclusion

Fast dissolving oral films have several advantages over conventional dosage forms. So, they are of great importance during emergency cases such as allergic reactions and asthmatic attacks whenever immediate onset of action is desired.

References

1. Ali MS, Vijendar C, Sudheer Kumar D and Krishavevi J; Formulation and evaluation of fast dissolving oral film of diazepam, Journal of pharmacovigilance, Volume 4, (2016). Page no 1-5.
2. Alfard C. Liand and Li-an H Chen; fast dissolving intraoral drug delivery system, Ashey publication (2001). Page no 981-986.
3. Lily P.H, Yang and Grey L. Plosker; Palperidone extend release, Adis drug profile (2007). Page no 417-424.
4. Arun Arya, Amrish Chnadra, Vijay Sharma and Kamala Pathak; an innovative drug delivery system and dosage form, International journal of chemtech research, Volume 2 (2010). Page no 576-583.
5. Shawn A. Mitchell, Thomas D. Reynolds, Tina P ;A compaction process to enhance dissolution of poorly water soluble drug using hydroxypropyl methylcellulose, International journal of pharmaceutics (20030. Page no 3-11.
6. Rob Devidson and Jessica Rousset ; Oral film a multi fascinated drug delivery system and dosage form, Cure pharmaceutical (2018).
7. Ramesh Y, Gundala Praveena, Gobinath M ; Medicated wafer as novel carrier as drug delivery system, Internationaljournal of pharmaceutical science and analysis, Volume 4 (2016). Page no 90-97.
8. Totsuya Ishikawa, Yoshitera Watanabe, Kazau Takayama, HIsashi Endo and Mitsoumoto ; effect of hydroxymythylcellulose (HPMC) on the release profile and bioavaibility of poorly water soluble drug from tablet prepared using macrogol and HPMC, International journal of pharmaceutics (2000). Page no 173-178.
9. Prabhakarab Prabhu, Ravi Malli, Marina koland, K Vijaynarayana; Formulation and evaluation of fast dissolving film of livocetrizine dy-hydrochloride, International journal of pharmaceutical investigation, volume 1, (2011). Page no 99-104.
10. Kulkarni A. S, Deokale H.A, Mane M.S and Ghade D.M; Exploration of different polymer use in the formulation of fast dissolving film , Journal of current pharmaceutical research (2010).Page no 33-35.
11. Mussaki sugimoto, Takayu Okayaki, Shinji Narisawa, Yoshiyaki Koida and Kingo Nakajima ; Improvement dissolution characteristics and bioavailability of poorly soluble drug by novel co-grinding method using water soluble polymer, International journal of pharmaceutics (1998). Page no 11-19.
12. Kulkarni P.K, Disit Mundit, Gunashekara K and Kulkarni Ajay; Formulation and evaluation of mouth dissolving film containing rofecoxib. International research journal of pharmacy, volume 2 (2011). Page no 273-278.
13. S kunte, P tandale; Fast dissolving strips a novel approach for the delivery of verapamil, Journal of pharmacy and bio-allide science, Volume 2 (2010). Page no 325-328.
14. R.C. Mashru, V.B. Sutariya, M. G. Sankalia and P.P.Parikh; Development and evaluation of fast dissolving film of salbutamol sulphate, Drug development and industrial pharmacy (2005). Page no 25-34.
15. K.M.Maheshwari, P.K.Devineni, Sarsvati Deekandu, Salma Shaik and Buchi N Nalluri; Development and evaluation of mouth dissolving film of amlodipine besylate for enhance therapeutic efficacy, Journal of pharmaceutics (2014). Page no 170.