International Journal of Trend in Scientific Research and Development (IJTSRD)
Volume 8 Issue 6, Nov-Dec 2024 Available Online: www.ijtsrd.com e-ISSN: 2456 – 6470

A Review on Mouth Dissolving Films

Prof. Jayshree Patil, Tanvi Arun More, Manali Vishnu More

Matoshri College of Pharmacy, Eklahare, Nashik, Maharashtra, India

ABSTRACT

Mouth dissolving films, are now becoming more popular than fast-dissolving tablets. They are most advanced oral solid dosage form due to its flexibility and comfort in use. Mouth dissolving films are oral solid dosage form that disintegrate and dissolve within a minute when placed in mouth without taking water or chewing. Geriatric and pediatric patients are facing difficulty in swallowing of tablet and capsule, the oral film can bypass it, along with that it has other advantages like self-administrable, fast dissolving, rapid absorption that make it versatile dosage form. The aim of present study is to enlighten specifically different polymer along with their concentrations and applications The oral buccal mucosa being highly vascularized, drugs can absorbed directly and can enter the systemic circulation without undergoing first-pass hepatic metabolism. This advantage can be exploited in preparing products with improved oral bioavailability of molecules that undergo first pass effect. The sublingual and buccal delivery of a drug via thin film has the potential to improve the onset of action, lower the dosing and enhance the efficacy and safety profile of medicament. An ideal film should have the properties like pleasant taste, high stability and ease of handling. This study also focuses on use of plasticizer, polymer, sweetener, different methods which are used for the preparation of oral films and various evaluation parameter of the film. It is evaluated for its various parameters like thickness, physical property like folding endurance, disintegration and dissolution time. The polymer used in mouth dissolving films is crucial to their quick dissolution and disintegration. The polymer must be non-toxic, non-irritating, flavourless, and simple to use. Natural and synthetic polymers are the two types of polymers that are employed. Natural polymers used in formulation of film include chitosan, gaur gum, xanthan gum, soy polysaccharide, gellan gum, locust bean gum, maltodextrin, and rosin. Hydroxypropyl cellulose, polyvinyl pyrrolidone, Hydroxypropyl Methylcellulose, Polyethylene Oxide, and Polyvinyl Alcohol are synthetic polymers that are frequently used to make films.

How to cite this paper: Prof. Jayshree Patil | Tanvi Arun More | Manali Vishnu More "A Review on Mouth Dissolving Films" Published in International Journal of Trend in Scientific Research and Development (ijtsrd), ISSN: 2456-6470, Volume-8 | Issue-6, December 2024, pp.554-560, URL: www.ijtsrd.com/papers/ijtsrd72630.pdf

IJTSRD72630

KEYWORDS: *Introduction, Ideal Characteristics, Method of preparation, Evaluation parameter.*

INTRODUCTION:

Oral film technology was first invented in the late 1970s just to overcome swallowing difficulties related to tablets and capsules faced by geriatric and paediatric patients but now is trending in pharma industry due to less fragility than other oral dosage forms, dosage accuracy, rapid release, ease of administration.[7]

"These are drug delivery systems that they are quickly releasing the drug by dissolving or adhering in the mucosa with saliva within a few seconds due to it contains water-soluble polymers when it placed in the mouth cavity or on the tongue." [9,10]]

The oral route is one of the most preferred routes of drug administration as it is more convenient, cost effective, and ease of administration lead to high level of patient compliance. [7] Many drugs having amide, ester linkage (Peptide drugs) are prone to hydrolysis (breaking of ester & amide bonds) in the GIT by esterase, hydrolases, amidases and loss of therapeutic activity and being peptide drugs they have very high

molecular weight therefore impossible to be absorb by passive diffusion the most common route of absorption due to this they being taken in systemic circulation by active transport process. Active transport has its own disadvantage of being a saturable process. This Novel drug delivery system was introduced as substitute to Conventional dosage form for drugs having difficulty in formulation as conventional dosage form & for patient showing difficulty in swallowing medicine. This NDDS solve the problem of drug which having poor bioavailability due to either slow dissolution or low permeation.[5] Both problems are solved by this as drug is Fastly disintegrate into its original particles & going very Fastly into solution form & will Fastly absorbed from the buccal mucosa. Mouth dissolving films contain active pharmaceutical ingredient either in dissolved or dispersed form, the way to take this dosage form is placing the films on the tongue where it disintegrate & dissolved and gets absorbed. It is one of the best suitable dosage form to substitute the conventional oral dosage forms. They are similar in size, shape, and thickness to postage stamps (buccal). These drug delivery methods enable the medication to skip the first pass metabolism, increasing the bioavailability of the drug.[1,3]

SPECIAL FEATURES OF MOUTH DISSOLVING FILM [1]

- Thin elegant films
- Various sizes
- Unobstructive
- Mucoadhesion
- Quick dissolving
- Fast disintegrating

ADVANTAGE OF MOUTH DISSOLVING FILM[4,5]

- Can be used safely even when access to water is not possible (such as travel).
- No risk of suffocation.
- Improved stability.
- Easy to apply.
- Easy application to mental and incompatible patient.
- Low dosage and low side effects.
- It provides more accurate dosage when compared to liquid dosage forms.
- Provides rapid onset of effects in conditions requiring urgent intervention, for example, allergic attacks such as asthma and intraoral diseases.
- Improves the absorption rate and amount of drugs.
- No chocking hazard.
- Appropriate dosage form for all age group.

DISADVANTAGES OF MOUTH DISSOLVING FILM[4,5]

- Requires special equipment for packaging.
- Is not suitable for drugs that cause irritation in the oral pH and are not durable.
- Is hygroscopic by nature. For this reason, it causes difficulties for long-term protection.
- Preparation method is costly compared with oral dissolving tablets.
- Moisture/Temperature sensitive.

Mouth dissolving Film are classified in three ways,[26,27]

1. Flash release (quick release)
2. Mucoadhesive melt away wafers (mucoadhesive wafer)
3. Mucoadhesive sustained-release wafers (mucoadhesive extended-release wafer)

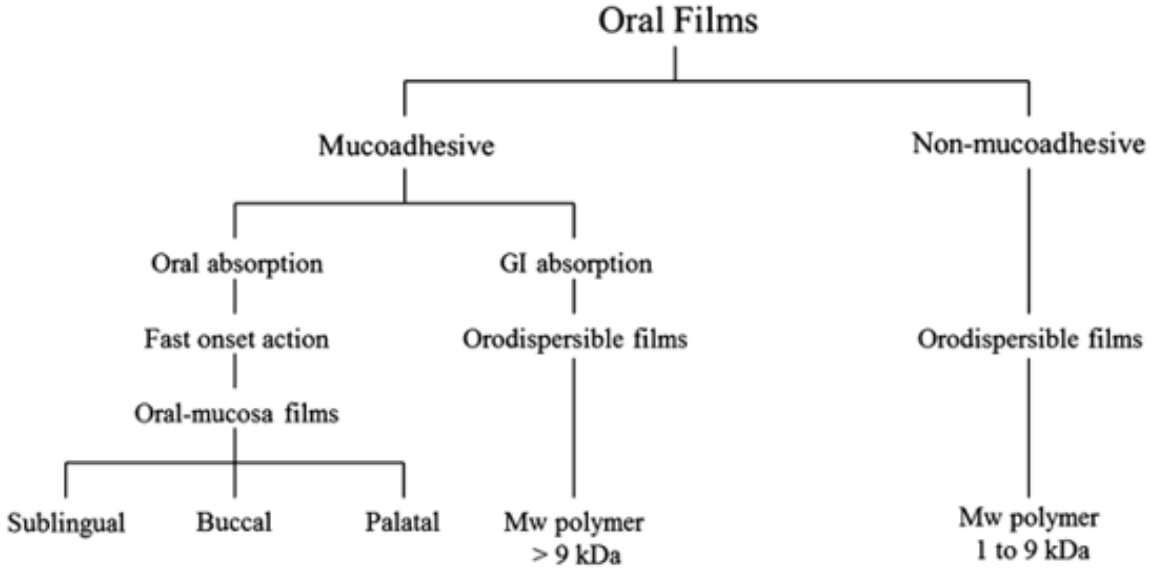

Fig: Classification on Films

IDEAL CHARACTERISTICS OF MDF :[13,14]

- It should taste good.
- Drugs should be very moisture resistant and soluble in the saliva.
- It should have appropriate tension resistance.
- It should be ionized in the oral cavity PH.
- It should be able to penetrate the oral mucosa.

APPLICATIONS:

1. Film forming systems used in field of surgery.
2. It can also be used as substrate for various barrier membranes that are used in Industries.
3. Film forming polymers are used to increase the integrity of soil and elevate the soil temperature which is useful in crop production.
4. Film formers used for non-medical uses such as, the delivery of active ingredients contained in beauty products like silicone film forming technologies used to prepare cosmetic creams and ointments.
5. Film forming systems were used for wound care. [29,30]
6. Orally dissolving films are used to treat localised discomfort, allergies, sleeping problems, and CNS issues.
7. Soluble films are appropriate for topical administration as analgesics or antibacterial agents in wound treatment.
8. Orally disintegrating films can be used to improve the bioavailability of medications that are poorly bioavailable.
9. Topical application of dissolvable films as analgesics or antibacterial agents for wound treatment is possible. [31]

METHOD OF PREPARATION:[6]

1.Solid dispersion extrusion 2.Hot melt extrusion 3.Solvent casting method 4.Semisolid casting 5.Rolling method

1. Solid Dispersion Extrusion:

Term solid dispersion refers to dispersion of active ingredients in an inert carrier in solid state in the presence of amorphous hydrophilic polymers. In starting, the drug is dissolved in suitable liquid solvent and later this solution is added in the melt of polyethylene glycol at below 70oC without removing the liquid solvent. And at last the solid dispersions are passed through dies to shape them in form of film. [21,22]

- **Precautions while preparing solid dispersions**

The selected solvent or dissolved drug may not be miscible with the melt of polyethylene glycol and polymeric form of drug precipitated in the solid dispersions may get affected by the liquid solvent used.

Advantages

- Low shear method.
- Uniform dispersion of fine particles.
- Less processing steps.

2. Hot melt Extrusion:

This method involves shaping polymer into film through heating process. Firstly, the drug - polymer mixture is filled in hopper and is conveyed, mixed and melted by the extruder. A die gives shape to the the drug polymer mixture. Organic solvents are not used in this method and it can operate continuously with minimum product wastage. Operating parameters can be controlled efficiently by this method. melt in required form. This method involves lower temperature and short residence time (< 2 min.) for the drug polymer mixture. Organic solvents are not used in this method and it can operate continuously with minimum product wastage. Operating parameters can be controlled efficiently by this method [25.26]

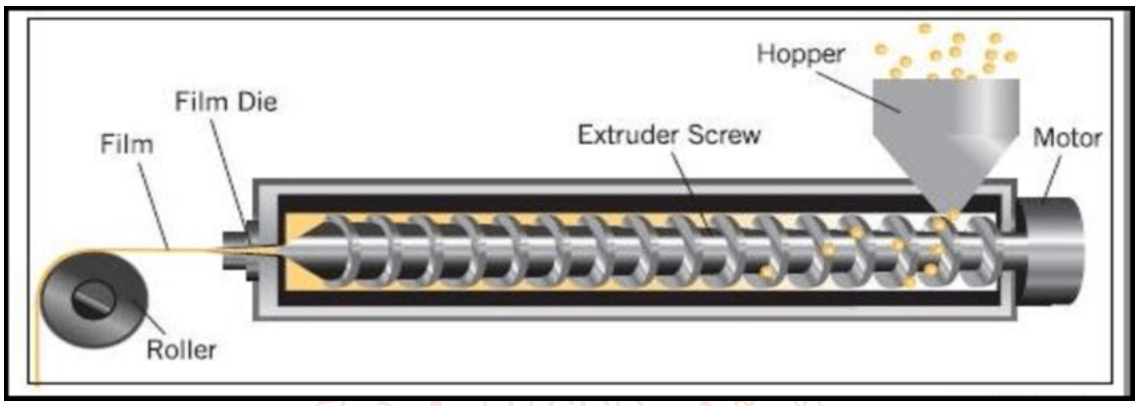

Figure: Hot Melt Extrusion Method.

- **Advantages :**

- Less processing steps.
- No need of solvent or water.
- Less energy is required compared to high shear methods.
- Uniform dispersion of fine particles due to intense mixing and agitation.
- No importance of drug compressibility properties**.**

- **Disadvantages:**

- Number of polymers is limited.
- Polymer flow properties are essential to processing.
- Drug/polymer stability problem as it is a thermal process.

3. Solvent Casting Method:

It is very old film making method. In this method the drug is either dissolved or suspended in a solution containing polymers, plasticizers and other excipients which are dissolved in a volatile solvent, like ethanol or water. It is referred as film dope , it is then casted in petri plate and passed through drying equipment like oven to remove all the volatile solvents. Then the dried film is die cut into strips and packed in sealed atmospherically resistant pouches. This method is suitable for films containing heat sensitive drug/API as the temperature needed to remove the volatile solvents is comparatively low than hot melt extrusion method.[21]

- **Advantages :**

- Better film clarity and thickness uniformity than extrusion method.
- Fine gloss on film and lack of die lines.
- Films with more flexible and better physical properties are produced by this method.

- **Disadvantages :**

- Polymers to be used should be soluble in volatile solvents.
- Formation of a stable solution with considerable minimum solid content and viscosity is required, which is difficult to attain.
- Homogenous film preparation with proper drug release from casting support must be attained**.**

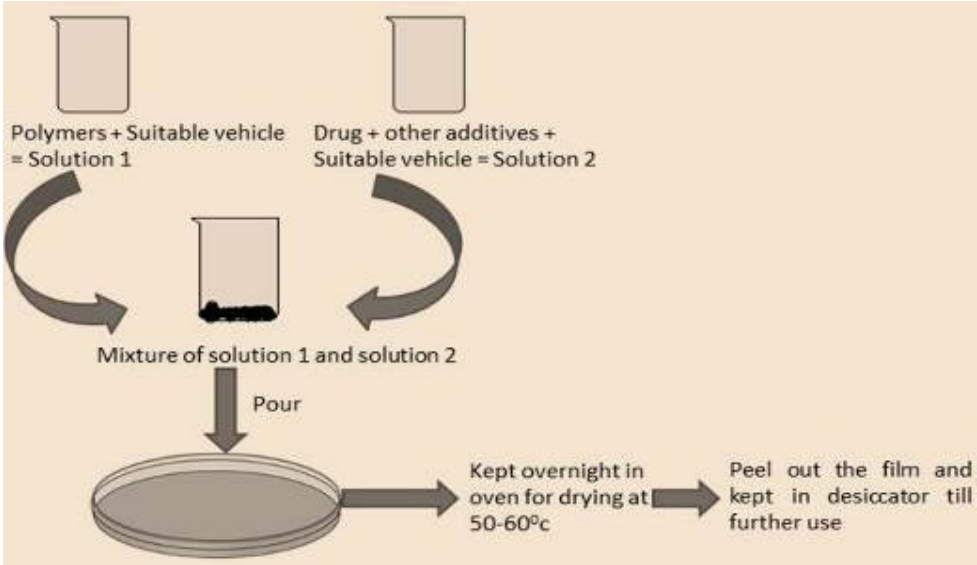

Figure : Solvent Casting Method.

4. Semisolid Casting Method:

Semisolid casting method is generally used when acid insoluble polymers are used. In this method a solution of water-soluble film forming polymer is made then this solution is poured in the solution of acid insoluble polymer, which is prepared in sodium or ammonium hydroxide. After this plasticizer is added to form the gel mass. Amount of plasticizer added affect the property of gel mass formed. The gel mass formed is then casted into film or ribbons using heat-controlled rollers/drums. The ratio of acid insoluble polymer and film forming polymer should be 1:4. The films thickness formed by this method is about 0.0150.05 inches. [21,22]

5. Rolling Method:

In rolling method, a pre-mix is prepared for preparation of film, later active drug is added and film is prepared. Pre-mix batch include film forming polymer, polar solvent, plasticizer and other excipients except the drug, which is added in to the master batch. Master batch and premix of required quantity are pumped into separated containers and later drug is blended with master pre-mix for specific time to provide uniformity. The mixture so formed is then fed to the roller; metering roller controls the thickness and applies the mixture to the roller. The film is formed and it is carried away by the support roller. A specific amount of matrix is fed into pan through second metering pump. The metering roller determined thickness of film. The film is finally formed on substrate and carrier away by the support roller As the film formed is wet so it is then dried using controlled bottom drying, it is desirable to avoid presence of external air while drying. After drying, film is cut into different sizes and shapes according to need. [22]

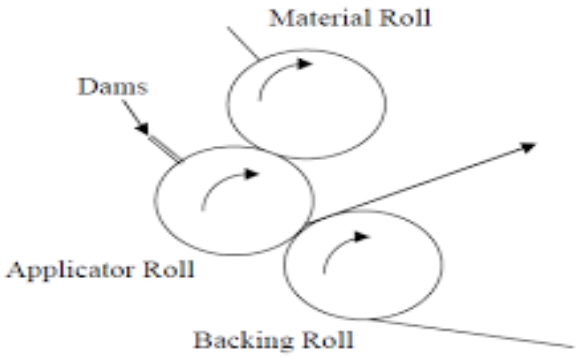

Figure : Rolling Method

➢ **EVALUATION PARAMETER:**

- Thickness
- Organoleptic tests
- Surface pH test
- Folding endurance
- Transparency
- Disintegration test

1. Thickness :

Because the thickness of the film is directly related to drug content uniformity, it is vital to ensure uniformity in the thickness of the film. At various important places, it can be measured with a micrometre screw gauge or calibrated digital Vernier Callipers.[16]

2. Organoleptic tests:

Special controlled human taste panels are employed for psychophysical evaluation of the product. For this goal, in-vitro approaches utilising taste sensors, specially developed apparatus, and drug release via modified pharmacopoeia procedures are being used. These in-vitro taste assessment apparatus approaches are ideal for high-throughput taste testing of oral medicinal formulations. [18,24]

3. Surface pH test:

The surface pH of a fast dissolving film was evaluated to investigate the likelihood of any in vivo adverse effects. Because an acidic or alkaline pH might irritate the oral mucosa, the surface pH was set to be as close to neutral as possible. For this, a mixed pH electrode was employed. The pH was determined by putting the electrode into contact with the surface of the oral film, which had been previously soaked with water.. [15]

4. Folding endurance:

Folding endurance is measured by repeatedly folding the strip at the same location until the strip breaks. The folding endurance value is calculated by counting the number of times the film can be folded without breaking.[17]

5. Transparency:

A basic UV spectrophotometer can be used to determine the transparency of the films. Cut the film samples into rectangles and lay them on the spectrophotometer cell's interior side. The transmittance of films at 600 nm is determined. The films' transparency was determined as follows:

Transparency=(logT600)/b= - €c

Where, T600 is the transmittance at 600 nm, b is the film thickness in millimetres, and c is the concentration.[19]

6. Disintegration test;

Orally fast dissolving films must be disintegrated using US disintegration equipment. Fast dissolving oral strips are subject to the same disintegration time limit of 30 seconds or less for orally disintegrating tablets as indicated in Centre for Drug Evaluation and Research (CDER) guidance. Depending on the formulation, disintegration times can vary, although they commonly range from 5 to 30 seconds. However, there is no formal advice for oral fast dissolving film strips. [19,20]

- **COMPARISON BETWEEN ORALLY FAST DISSOLVING FILMS AND ORAL DISINTEGRATING TABLET: [7]**

Orally Fast Dissolving Films	Orally Disintegrating Tablet
1.Larger Surface area gives greater dissolution.	1.Less surface area gives less dissolution than OFDF
2.These are flexible and durable.	2.These are brittle and less durable than ODF.
3.Only low dose can be incorporate**.**	3. High dose can be incorporated.
4. ODF thickness are 50 to 500 um	4. ODT thickness as like convention tablet.
5. Patient compliance is more than ODT	5. Patient compliance is less than ODF
6.No risk of chocking.	6.It has a fear of chocking.

REFERANCE :

[1] Ghodake, P.P.; Karande, K.M.; Osmani, R.A.; Bhosale, R.R.; Harkare, B.R.; - Mouth Dissolving Films: Innovative Vehicle for Oral Drug Delivery‖, International journal of pharma research and review, 2013; 02(10): 41-47.

[2] Halnor, P.K.; Gondkar, S.B.; Saudagar. R.B.; - A short review: An innovative drug delivery system of fast dissolving oral films‖, International journal of institutional pharmacy and life sciences, 2015; 05(03): 381-393.

[3] Aggarwal, J.; Singh, G.; Saini, S.; Rana, A.C.; - Fast dissolving films: A novel approach to oral drug delivery‖. International research journal of pharmacy, 2011; 02(12): 69-74.

[4] Sharma D, Kaur D, Verma S, Singh D, Singh M, Singh G, Garg R. Fast dissolving oral films technology: A recent trend for an innovative oral drug delivery system. Int. J. Drug Deliv. 2015;7:60–75

[5] Kathpalia H, Gupte A. An Introduction to Fast Dissolving Oral Thin Film Drug Delivery

Systems: A Review. Current Drug Delivery. 2013;10:667–684

[6] Kulkarni AS, Deokule HA, Mane MS, Ghadge DM. Exploration of different polymers for use in the formulation of oral fast dissolving strips. J Curr Pharm Res. 2010;2(1):33–38.

[7] Mandeep K, Rana AC, Nimrata S. Fast dissolving films: an innovative drug delivery system. Int J Pharm Res Allid Sci., 2013; 2: 14-24.

[8] Aggarwal J, Singh G, Saini S, Rana AC. Fast dissolving films: a novel approach to oral drug delivery. Int Res J Pharm, 2011; 2: 69-71.

[9] Hussain MW, Kushwaha P, Rahman MA, Akhtar J. Development and Evaluation of Fast Dissolving Film for Oro-Buccal Drug Delivery of Chlorpromazine. Indian Journal of Pharmaceutical Education and Research. 2017;51:S539–S547.

[10] Mahboob MBH, Riaz T, Jamshaid M, Bashir I, Zulfiqar S. Oral Films: A Comprehensive Review. International Current Pharmaceutical Journal. 2016;5:111–117.

[11] Khatoon N, Rao NR, Reddy BM. Overview on fast dissolving oral films. Int J Chem Pharm Sci., 2013; 1: 63-75.

[12] Gavaskar, B., Vijayakumar, S. and Sharan, G., "Overview on fast dissolving films." Int. J. pharm. Pharma. Sci. 2010, 2(3), 29-33.

[13] Hoffmann EM, Breitenbach A, Breitkreutz J. Advances in orodispersible films for drug delivery. Expert Opin Drug Deliv 2011;8:299-316.

[14] Shinde RB, Phoke SV, Sarda RR, Chaudhari PM, Kasture PV. Fast dissolving film: Current status and approaches. Invent Impact: NDDS 2013; 3:3-11

[15] Dinge, A. and Nagarsenke,r M., "Formulation and evaluation of fast dissolving films for delivery of triclosan to the oral cavity", AAPS Pharm. Sci. Tech. 2008, 9(2), 349-356.

[16] Bhyan B, Jangra S, Kaur M and Singh H, Orally fast dissolving films: innovations in formulation and technology. International Journal of Pharmaceutical Sciences Review and Research 2011; 9(2): 50-57.

[17] Nishimura, M., Matsur, K., Tsukioka, T. and Yamashita, H., characteristics "In-vitro of and prochlorperazine In-vivo oral disintegrating film." Int. J. Pharma. 2009, 368, 98-102.

[18] Carpenter G, Maheshwari RK, Formulation and development of fast dissolving oral film of a poorly soluble drug. Journal of Drug Delivery and Therapeutics. 2018; 8(6):132-141.

[19] Smriti T, "Mouth dissolving films: A review", Int J Pharm Bio Sci, 2013, Pageno.899-908.

[20] Narayana PR, Kumar MS, Reddy M, Ravishankar K. Formulation and Evaluation of Fast Dissolving Films of Loratidine by Solvent Casting method. Pharm Innova J. 2013; 2(2): 31-35.

[21] Pravin S. Formulation and Evaluation of Mouth Dissolving Films of Amlodipine Besylate by using Natural and Synthetic Polymers. Research Journal of Pharmacy and Technology. 2022;15(11):51545161.

[22] Desu, P.K., Brahmaiah, B., Nagalakshmi, A., Neelima, K., Nama, S., Baburao, C., 2013. An overview on rapid dissolving films. Asian J. Pharm. Res. 3, 15–23.

[23] Dinge, A., Nagarsenker, M., 2008. Formulation and evaluation of fast dissolving films for delivery of triclosan to the oral cavity. AAPS Pharm. Sci. Tech. 9, 349–356.

[24] Bhupinder B Sarita J Formulation and evaluation of fast dissolving sublingual films of Rizatriptan Benzoate, International Journal of drug development and research 20:01

[25] Fast Dissolving Oral Films Technology: A Recent Trend For An Innovative Oral Drug Delivery system Deepak Sharma, Daljit Kaur, Shivani Verma, Davinder Singh, Mandeep Singh, Gurmeet Singh, Rajeev Garg, International Journal of Drug Delivery, 2015; 7:6075.

[26] Fast dissolving drug delivery system: a review, Arunachalam, A., M. Karthikeyan, S. Ashutosh kumar and K. Kishore,. Journal of Global Trends in Pharmaceutical Sciences, 2010; 1(1): 92-110.

[27] Kulkarni AS, Deokule HA, Mane MS, Ghadge DM. Exploration of different polymers for use in the formulation of oral fast dissolving strips. J Curr Pharm Res. 2010;2(1):33–38.

[28] Hoffmann EM, Breitenbach A, Breitkreutz J. 2011.

[29] Vondrak B , Barnhart S "Dissolvable films. Dissolvable films for flex product format in drug delivery", Supplementto Pharmaceutical technology 2008, 1-5.

[30] Kaur M Rana AC and Seth N. "Fast Dissolving Films An Innovative Drug Delivery System", International Journal of pharmaceutical Research and allied science 2013, 2(1): 14-24.

[31] Zajicek A. Fossler MJ. Barrett JS, Worthington JH. Termik R Charkoftaki G. et al. 2013