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REVIEW ARTICLE

Fast Dissolving Films: A Technology for Rapid Release of Medicament

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ABSTRACT

In the recent years, several of the pharmaceutical groups are focused their research on rapid dissolving technology. Amongst the variety of approaches investigated for rapid medication release product, Fast Dissolving Films technology is getting great attention. Fast Dissolving Films originated over the past several years from the confection and oral care sectors in the shape of breath strips and became an innovative and well appreciated form by consumers for delivering vitamins and personal care goods. These are solid dose forms, which disintegrate or dissolve within 1 min when placed in the mouth without drinking water or chewing. This technology has been used for local action, rapid release products. Polymers, plasticiser, flavours, colours, and sweeteners are used in the creation of the oral films. This review speaks about the formulation approach, assessment factors and the future prospects of rapid dissolving films.

Keywords: *Fast Dissolving Films, Pharmaceutical Administration, Rapid Release*

INTRODUCTION:

Oral route of administration is the most convenient and favoured route administration among the different other delivery technique. Due to their adaptability (to accommodate different types of drug candidates) and ability to prevent pain, oral drug delivery systems account for more than 70% of all pharmaceuticals on the market [1].Dysphagia is widely encountered throughout all age groups. Due to this difficulty, roughly 50% of population, primarily paediatric and geriatric patients, tend to avoid taking oral solid dose formulations due to fear of choking. To tackle numerous challenges linked to swallowing, Fast dissolving Tablets (FDTs) were designed in early 19th century, which progressively led to their further advancement and thus Fast Dissolving Films (FDFs) were developed. Fast dissolving dosage form has become more significant due of their unique features. They swiftly disintegrate and dissolve, and can be delivered without water, making them particularly ideal for paediatrics and elderly patients. Fast dissolving films (FDFs), have gained popularity not only in breath strips but also in personal care, food and medicine delivery markets [2,3]. Pharmaceutical businesses and consumers alike have welcomed FDFs as a practical and accepted alternative to traditional OTC medicines, such as liquids, tablets and capsules, because of the multiple benefits of the films. FDFs enable quick, accurate dosage in a safe, efficacious formulation that is handy and portable, without needing the use of water or a spoon. A range of polymers are available for preparation of RDFs. The polymers can be employed alone or in combination to get the desired film characteristics. The films obtained should be robust enough so that they are not damaged when handling or during shipping. On the other hand, Mouth dissolving films should have the property to dissolve within seconds when inserted in mouth and deliver the medicine to the oral cavity immediately. The excipients employed in FDFs are preferably hydrophilic in nature whereas drug may be either hydrophilic or hydrophobic. At least 40–50% w/w of polymer and up to 20% (total weight of polymer) of plasticiser should typically be present based on the total weight of dry RDFs since the film-forming polymer, which serves as the platform for the RDFs, and plasticiser are the most important and significant components of the FDFs. According to Technology Catalysts, the market for pharmaceutical items in oral thin-film formulations was estimated to be worth $500 million in 2007 and might grow to $2 billion by 2012. The rapid dissolving dose industry has the potential to generate $13 billion in sales by 2015, based on the upward global growth trends of the last ten years [4]. The FDFs technology continues to be viewed as an alternative for FDT products that would give a superior barrier to generic entry

and product differentiation to over-the-counter brands. A patented ODF technique would be advantageous from a marketing standpoint. The provision of marketing exclusivity to the new dosage form would help to obtain more cash. The different synonyms used for FDFs include mouth dissolving films (MDFs), orally disintegrating films (ODFs), melt in-mouth films, oro-dispersible, quick dissolving and rapid disintegrating films.[4,5]

Active Pharmaceutical Ingredients

A variety of active pharmacological compounds can be supplied. High-dose drugs are tough to include in the movie due to a restriction on the size of the dosage form. Ideal dynamic voice for oral films pharmaceutical ingredients (APIs) should preferably be robust, highly lipophilic, and less bitter. About 5% w/w to 30% w/w of the dry film is made up of the medication, and up to 10% w/w of the dry film can be made up of multivitamins. Both children and many adults detest active pharmacological drugs that have a bitter taste and/or irritate the mouth and throat [6].

Film-forming polymer

The water-soluble polymers give the films fast disintegration, a pleasant mouth feel, and mechanical qualities[7]. Brand-new polymers utilised in drug delivery [8]. By increasing the molecular weight of the polymer film bases, the disintegration rate of the polymers is slowed down. HPMC E-3 and K-3, Methylcellulose A-3, A- 6 and A-15, Pullulan (The creation of pullulan was a logical extension of Hayashibara'soriginal 1883-founded firm, which was the manufacture of starch syrup. Hayashibara began marketing Pullulan films in 1982.) [9], Carboxymethyl Cellulose Cekol 30, Polyvinylpyrrolidone PVP K-90, Pectin, Gelatin, Sodium alginate, Hydroxypropyl cellulose, Polyvinyl alcohol, Maltodextrins, and Eudragit-RD10 are some of the water-soluble polymers used as film formers. POLYMERIC FILMS are being used in a greater variety of pharmaceutical research, development, and dosage form generation activities. There is currently no coating process that can compete with film coating in terms of production capacity or cost-effectiveness for coating tablets and other solid dosage forms [10].

Thin Film Delivery System

Drugs are delivered to the systemic circulation using thin films that disintegrate in a technique known as "thin film drug delivery." referred to as dissolving films or strips that, when placed in the mouth without any liquid or chewing, disintegrate in 1 min A user would normally place a dissolving film or strip on, under, or along the inside of the cheek while administering medication orally. The thin film offers an alternative for persons with swallowing difficulty and patients experiencing nausea, such as chemotherapy patients, because it dissolves swiftly without the need for water. The first fast-dissolving dosage form to be invented was a tablet, and the quick-dissolving features were achieved through alteration to the formulation or unique method [10]. Powerful medicines with short plasma half-lives have their effects for a longer duration while maintaining a steady plasma level of the substance [11]Fast-dissolving films are becoming more popular recently as an alternative to fast-dissolving medications for treating patients with blockages and reducing their fear of choking. Usually, films that dissolve quickly are composed of plasticised hydrocolloids. Foaming during film manufacturing brought on by material heating or solvent evaporation, flaking during slitting, and cracking during cutting are all problematic. The films must be flexible, show the proper tensile stress, be moisture-stable, facilitate handling, and not stick to fingers or packing materials. provide distinct advantages over other solid dose forms because of their compact size and thickness, which promote patient compliance [12].A perfect mucoadhesive system sticks to the attachment site for a few hours, releases the medication in a controlled way, helps with the rate and degree of drug absorption, doesn't irritate or hurt the patient, doesn't interfere with their ability to drink, talk, or carry out other everyday tasks, and provides unidirectional drug release toward the mucosa [13]. Applying, localising, and removing the drug is made easy by excellent accessibility [14]. The majority of commercially available formulations, such as Listerine PocketPaksTM,3, Ora-filmTM,1 (benzocaine), andTheraflu®,2(dextromethorphan/phenylephrine HCl, diphenhydramine HCl/phenylephrine HCl, or diphenhydramine HCl), are made to deliver locally acting drugs [15]. New administration routes for present pharmaceuticals are typically significantly less expensive to develop, resulting to greater efficacy and bioavailability as well as lower dose frequency to lessen unpleasant effects [16].To accomplish good drug therapy, it is required to overcome a variety of advantages and drawbacks, including the following [17]

Advantages of Fast Dissolving Films

No risk of choking and blockage.

No need of water has led to higher acceptability amongst the dysphagic patients

• Improved oral bioavailability of medicines
• Taste masking
• Enhanced stability
• Improved patient compliance
• Oral films are flexible and they are not as fragile as most of the ODTs
• Reduction in first pass metabolism may lead to reduction in the dosage
• The oral or buccal mucosa is highly vascularised, so medicines can be absorbed immediately and can enter the systemic circulation without undergoing first-pass hepatic metabolism [18]

Ideal Properties of Fast Dissolving Films
It should have an acceptable taste.
The mouthfeel should be pleasant.
• It should be mechanically strong and less friable to endure handling after manufacture.
• In environmental circumstances, it ought to be steady.
• It should leave little to no residue in the mouth after oral intake.
• It should immediately dissolve to release medication instantaneously in mouth.
• It must work well with the other ingredients [19].

Drug Selection Criteria for Fast Dissolving Films
• The medicine should have good taste.
The medication to be added should have a modest dosage of no more than 40 mg.
• The medications with smaller and moderate molecular weight are recommended.
• Good solubility in water as well as in saliva and also good stability[20]

Classification of Oral Films
There are three different subtypes of oral films:
i. Flash release
ii. Mucoadhesive melt-away wafer
iii. Mucoadhesive sustained-release wafers Types of oral films and their properties [21]

Classification of Fast Dissolving Technology
For convenience of description, fast-dissolve technology can be split into three broad groups:
i. Lyophilised systems: A mould or blister pack is used to create tablet-shaped units from a medication suspension or solution with additional structural excipients [18]. The units or pills are then and lyophilised in the pack or mould. Because of their extremely high porosity, the resultant units can quickly absorb water or saliva and disintegrate. [22]

ii. Compressed tablet-based systems: These systems are made by directly compressing excipients using conventional tablet technology. The hardness and friability of tablet technology vary depending on the manufacturing process. The speed of disintegration for fast-dissolve tablets compared with a conventional tablet is achieved by formulating utilising either water soluble excipients, super-disintegrant or effervescent components, to allow rapid penetration of water into the core of the tablet. [23]

iii. Thin film strips: Oral films, also called oral wafers, evolved during the past few years from the confection and oral care sectors in the form of breath strips and became an innovative and widely recognised form by consumers for delivering vitamins and personal care goods. Today, FDFs are a proven and approved technology for the systemic administration of APIs for over-the-counter (OTC) pharmaceuticals and are in the early- to mid-development phases for prescription drugs. This has been ascribed to the success of the breath freshener goods by customers such as Listerine Pocket Paks in the US consumer market. Such systems use a range of hydrophilic polymers to form a 50-200 mm film. The film is made as a big sheet and then sliced into individual dose units for packaging in a range of pharmaceutically approved formats.[24]

Formulation Aspects for Fast Dissolving Films
1) Drug Category
2) Film Forming Polymers
3) Plasticizers
4) Sweetening Agents
5) Saliva Stimulating Agents
6) Cooling Agent
7) Flavoring Agent
8) Coloring Agent
9) Surfactants

i. Drug Category: This technique offers the potential for delivery of variety of APIs. However as the size of the dosage form has limitation, high dose medications are challenging to be included in films. Fast-dissolving films can be made from a number of medication families, such as NSAIDs, expectorants, antihistaminics, antitussives, antiulcer, and antiasthamatics.

ii. Film Forming Polymers: Water-soluble polymers are employed as film formers because they give the films quick disintegration, a pleasant mouthfeel, and mechanical strength. The robustness of the strip depends on the type of polymer and its amount in the formulations. Film made of water-soluble polymers sticks to the bucosal mucosa and quickly enters the bloodstream. A range of polymers are available for manufacture of films among which pullulan, gelatin and

hypromellose are most typically utilised. At least 45%w/w of polymer should normally be present depending on the total weight of dry film [26]. Examples of water-soluble polymers include: Pullulan, Gelatin, guargum, Xanthum gum, Hydroxyl propyl methyl cellulose, Modified starches, Hydroxyl ethyl cellulose etc.[27]

iii. Plasticisers: An essential component of oral films is plasticiser. The selection of plasticiser depends upon its compatibility with the polymer and also the type of solvent employed in the casting of film. It lessens the film's brittleness and increases its flexibility. Plasticiser greatly enhances the strip characteristics by decreasing the glass transition temperature of the polymer. Typically the plasticisers are employed in the concentration of 1 - 20%w/w of dry polymer weight. Examples include: Glycerol, Propylene glycol, Low molecular weight polyethylene glycols, Citrate derivatives like triacetin, acetylcitrate, Phthalate derivatives like dimethyl, diethyl, dibutyl derivatives, Castor oil etc.
iv. Sweeteners: Sweeteners are now a crucial component of both food and medicinal preparations that are meant to dissolve or disintegrate in the mouth. Thesweet taste in formulation is very crucial in case of paediatric population. Both artificial and natural sweeteners are employed to enhance the mouth-dissolving formulations' palatability. Suitable sweeteners include:
(a) Water soluble natural sweetener: xylose, ribose, glucose, sucrose, maltose, stevioside etc.
(b) Water soluble artificial sweetener: sodium or calcium saccharin salts, cyclamate salts, acesulfame-k etc.
(c) Aspartame, a dipeptide-based sweetener [28]

v. Saliva stimulating agent: The goal of using saliva stimulating agents is to increase the rate of production of saliva that would aid in the faster dissolution of the film formulations. Generally acids which are employed in the preparation of food can be utilised as salivary stimulants. Citric acid, malic acid, lactic acid, ascorbic acid and tartaric acid are the few instances of salivary stimulants, citric acid being the most liked amongst them.

vi. Cooling agents: Cooling agents like monomethyl succinate can be added to improve the flavour strength and to enhance the mouth-feel effect of the product. Other cooling agents like WS3, WS23 and Utracoll II can also be used in conjunction with flavours [29].

vii. Flavouring agents: Perception for the flavour fluctuates from individual to individual based on the ethinicity and liking. It was noticed that age plays a considerable effect in the taste fondness. Synthetic flavour oils, oleo resins, and extracts from different plant parts, such as leaves, fruits, and flowers, can all be used as flavouring agents. Peppermint oil, cinnamon oil, oil of nutmeg are examples of flavour oils while vanilla, cocoa, coffee, chocolate and citrus are fruityflavors. Apple, raspberry, cherry, pineapple are few examples of fruit essence kind. The amount of flavour needed to cover the taste varies on the flavour type and its strength.

viii. Colouring agents: Pigments such as titanium dioxide or FD&C approved colouring agents are introduced (not exceeding concentration levels of 1%w/w) in OS when some of the formulation ingredients or medications are present in insoluble or suspension form.

ix. Surfactants: Surfactants are utilised as solubilising or wetting or dispersing agents so that the film gets dissolved within seconds and release active agent quickly. Surfactants also improve the solubility of poorly soluble medicines in fast dissolving buccal films. Some of the regularly utilised are polaxamer 407, sodium lauryl sulphate, benzalkonium chloride, benzthonium chloride, tweens and spans etc [30].

x. Stabilising and thickening agents: Before casting, the viscosity and consistency of the dispersion or solution of the strip preparation solution or suspension are improved by using stabilising and thickening agents. Natural gums including xanthan gum, locust bean gum,carragenan and cellulosic derivatives can be employed in the concentration up to 5%w/w as thickening agents and stabilising agent

Methods of Manufacturing Fast Dissolving Films
Following are the methods of manufacturing for fast dissolving films. One or combination of the following process can be used to manufacture the fast dissolving films –
i. Solvent casting method
ii. Semisolid casting method
iii. Hot melt extrusion
iv. Solid dispersion extrusion
v. Rolling method
Generally the solvent casting method is employed for manufacture of strips [31].

1) Solvent Casting Technique
Fast dissolving films are preferably formulated using the solvent casting method, whereby the water soluble ingredients are dissolved to form a clear viscous solution and the drug along with other excipients is dissolved in suitable solvent then

both the solutions are mixed and finally casted in to the Petri plate and dried, which is then cut into pieces of the desired size. When choosing an appropriate solvent, the characteristics of the API are crucial. Water-soluble hydrocolloids used to produce RDFs include: Pullulan, sodium alginate, pectin, carboxy methyl cellulose (CMC), polyvinyl alcohol (PVA), hydroxyl propyl methyl cellulose (HPMC), and hydroxyl propyl cellulose (HPC). Solvents utilised for the manufacture of solution or suspension should ideally be picked from ICH Class 3 solvent list. Pouring the solution on an inert base requires specialised equipment, such as rollers.[32]The necessary film thickness is determined by the distance between the roller and the substrate. The final stage, drying the film, eliminates the solvent and helps to obtain the finalised product. Usually, glass, plastic, or teflon plates are utilised as an inert base for film casting. When the manufacturing technique is translated from laboratory scale to production scale, numerous challenges can be encountered. These challenges can include the casting of the film, establishing equal thickness of the film, and correct drying of the sample. The selection of the correct type of drier is important in the last step of drying. Once the films are cured, cutting, stripping, and packaging is done. Suitable size and forms of films can be cut.

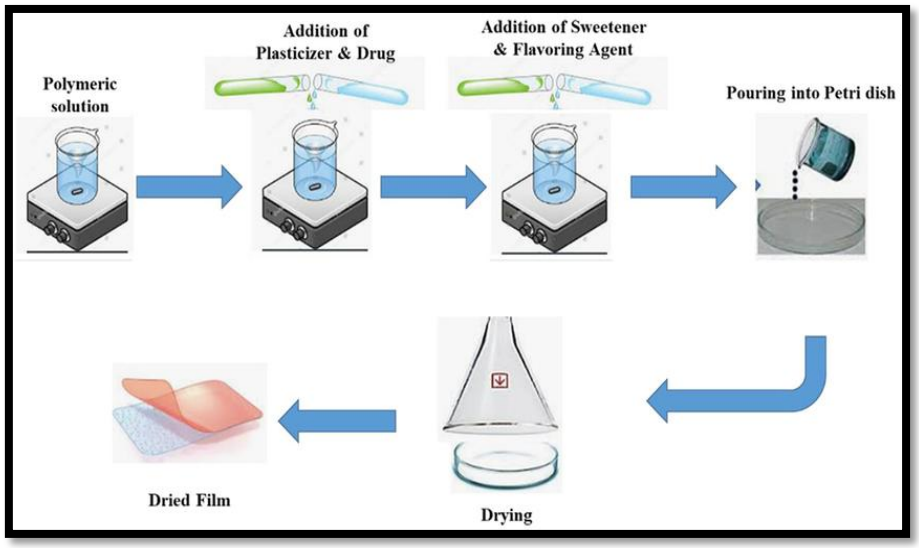

Fig no 1: Method of preparation of fast dissolving film with solvent casting technique

2) Semisolid casting

The first step in the semisolid casting process is to generate a water-soluble film-forming polymer solution. The resultant solution is mixed with an acid-insoluble polymer solution (such as cellulose acetate phthalate or cellulose acetate butyrate), which can be made in sodium hydroxide or ammonium. After that, the right amount of plasticiser is applied to create a gel mass. Lastly, heat-controlled drums are used to cast the gel mass into the films or ribbons. The film is between 0.015 and 0.05 inches thick. The ratio of the acid insoluble polymer to film forming polymer should be 1:4[32]

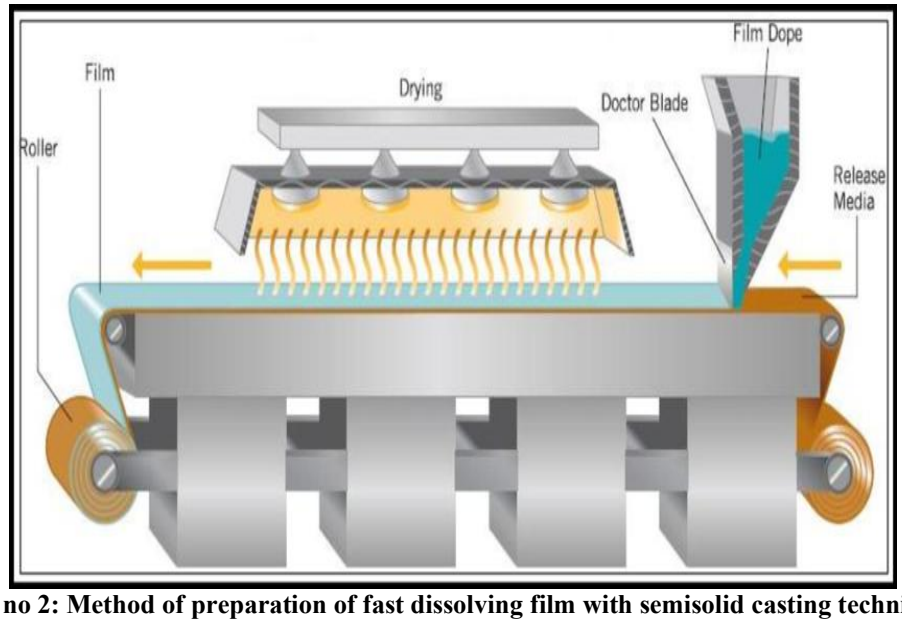

Fig no 2: Method of preparation of fast dissolving film with semisolid casting technique

3) **Hot melt extrusion**

Granules, sustained-release pills, and transdermal and transmucosal drug delivery systems are frequently made via hot melt extrusion. The medicine and carriers are initially combined in solid form using the hot melt extrusion process. The mixture is then melted by the extruder's heaters. Ultimately, the dies shape the melt into films. Usually, while constructing RDFs, polymers with low molecular weight or viscosity, such as HPMC E5 or pullulan PI.20, are preferred. A combination of multiple grades of polymers may also be utilised to produce desired physical qualities. [31]Mixing polymers of high and low viscosity provides a film with good mechanical strength and high drug solubility in the film. There are several processes in the pharmaceutical industry's wafer manufacturing process.Generally, the mass is prepared initially under the control of temperature and steering speed. Afterwards, the wafers are coated and dried in a drying tunnel, and again the temperature, air circulation and line speed are controlled. Then follows a slitting and in the last stage the wafers are punched, pouched and sealed.

• Fewer operation units
• Better content uniformity
• An anhydrous process [32]

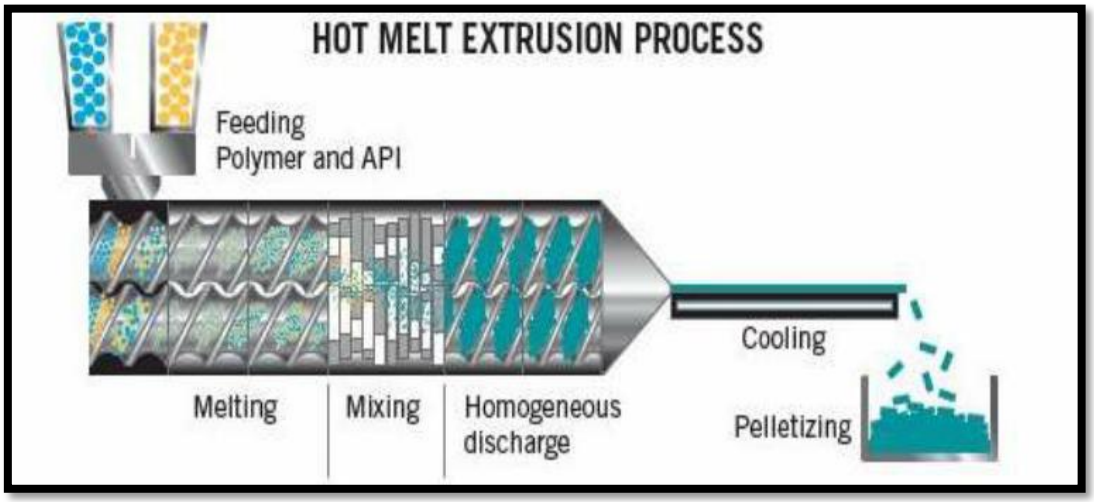

Fig no 3: Method of preparation of fast dissolving film with hot metl extrusion technique

Disadvantages:

• Thermal process thus drug/polymer stability problem
• Flow characteristics of the polymer are critical to processing
• There aren't many polymers available.

5) Solid dispersion extrusion

The phrase solid dispersion refers to the dispersion of one or more APIs in an inert carrier in a solid state in the presence of amorphous hydrophilic polymers utilising methods such as HME. This process creates solid dispersions by extruding immiscible components with the medication. Finally the solid dispersions develop in to films by means of dies.[33]

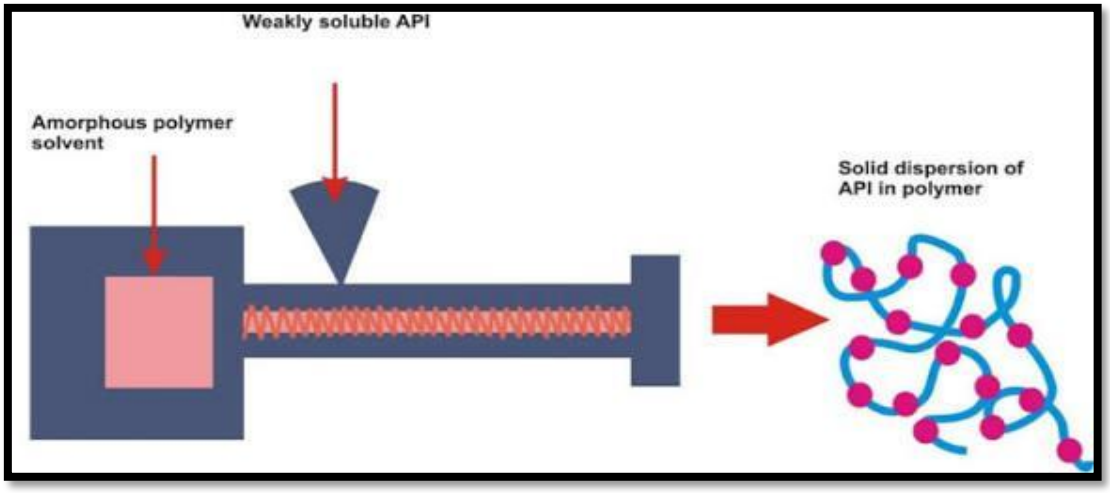

Fig no 4: Method of preparation of fast dissolving film with solid dispersion extrusion

6) **Rolling Method**
In rolling method a solution or suspension containing drug is rolled on a carrier. The solvent is mainly water or a mixture of water and alcohol. The film is dried on the rollers and cutted into desired shapes and sizes.[32]

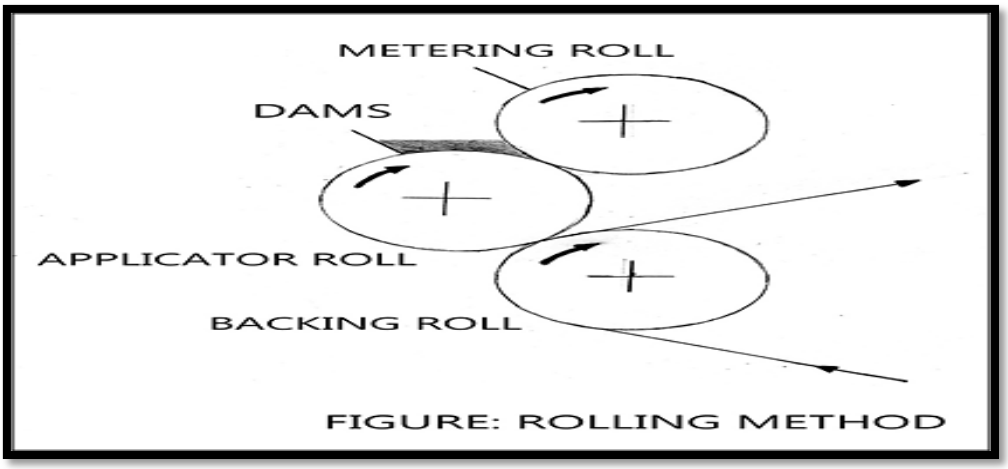

Fig no 5 : Method of preparation of fast dissolving film with rolling technique

Physical Parameters
• **Thickness:** Uniform thickness is critical for dosage accuracy and reproducibility. It is measured using a digital micrometre at several locations in the film. The USP establishes limits for thickness variation [33].
• **Weight homogeneity:** The weight of individual film units is verified to guarantee content homogeneity, an essential quality attribute for dosing precision. The allowed variation is normally within ±5-10% [34].
Morphological Characteristics
• **Scanning Electron Microscopy (SEM):** SEM offers high-resolution images of the surface morphology and cross-section of the film. It is used to check for homogeneity, smoothness, and the dispersion of the API inside the polymer matrix [35].
• **Atomic Force Microscopy (AFM):** AFM offers 3D topographic information on the film surface at a nanoscale level, important for measuring surface roughness[36]

Other Tests
• **Folding Endurance:** Determined by repeatedly folding a film at the same location until it breaks. It gives an indication of the film's brittleness and capacity to sustain mechanical stress during packaging and shipping.[37]
• **Moisture Content:** Measured with a Karl Fischer titrator or by loss on drying. Low moisture level (<5%) is desirable to ensure physical stability and inhibit microbiological growth.
• **Palatability and Sensory Evaluation:** Organoleptic testing, generally via human taste panels, is conducted to examine taste masking, mouthfeel, and overall acceptability.[38]

Objective of Formulation of Fdfs
In order to accomplish the following goals, the current research project aims to develop and characterise mouth-dissolving oral films of a suitable pharmacological candidate:
i. To improve patient compliance.
ii. To offer a quick start to action.
iii. To limit the extent of hepatic first pass metabolism.
iv. To lower the dosage given and, consequently, the adverse effects.
v. To improve the oral bioavailability of compounds.[39]

Patented Technologies
1) XGel: All of Meldex International's film systems and ingestible delivery technologies rely on XGel as its core intellectual property. XGel film Technology created by BioProgress is delivering a revolution in the product offerings and manufacturing methods now available to the pharmaceutical industry. X Gel film could improve the stability of the product. It has also been developed for non-ingestible applications such as cosmetic, ostomy pouches, sanitary and healthcare devices. The creation and fabrication of XGel films involves a process called “solution casting”[39]

2) Soluleaves: In this technique, the film is manufactured in order to release the active chemicals on coming in contact with saliva. This is applied to flavour-release items such as mouth fresheners, confectionary and vitamin products. SOLULEAVES technology can be utilised to deliver active chemicals to oral cavity efficiently and in a pleasant and easily portable form. The delivery system can be employed for the cough/cold, gastrointestinal and pain therapeutic areas as well

as nutritional items. SOLULEAVES films can also be developed to attach to mucous membranes and to release the active ingredients slowly over 15 minutes. [37]

3) Wafertab: Ingestible films containing pharmaceutical active ingredients are part of the WAFERTAB drug delivery system. This proprietary delivery technique creates drug-loaded thin films that can be applied topically or orally using a special method. After casting, active chemicals are added to the movie. WAFERTAB technology gives itself to various options for creative drug design, permitting many films with different actives to be connected together.

4) Foamburst: FOAMBURST is a patent granted in September 2004 which is for capsules composed of foamed film. Gas is blown into the film during production, resulting in a film with a honeycombed structure. The gaps in the film may be gas-filled, unfilled or filled with other materials to induce certain taste-burst characteristics or to deliver active medications. The light honeycombed structure results in capsules that dissolve swiftly, causing a melt-in-the mouth experience. FOAMBURST has garnered attention and confectionary makers as a mean of carrying and releasing tastes.

5) Micap: Micap inked an option agreement in 2004 to combine its expertise in microencapsulation technology with the Bio Progress water-soluble films. The advances targeted at offering novel delivery systems for the $1.4bn global market for smoking cessation products (SCPs)[40].

Pharmacopoeial Status of Oral Films

Monographs of common dose forms are provided by the pharmacopoeias (e.g. Ph. Eur., USP). Even if dosage forms for application in the oral cavity such as Medicated chewing gums, Oromucosal preparations, Orodispersible tablets or oral Lyophilisates are covered, monographs and standards for oral films with diverse dissolving kinetics has not yet been created. There are inadequate pharmaceutical technical processes for analysis in creation and quality control of oral films as well. For instance, disintegration and dissolution testing protocols may be provided, however the recommended circumstances such as quantities of medium do not match the natural conditions in the oral cavity. [41]

Evaluation of Fast Dissolving Films

1) Organoleptic evaluation
2) Mechanical properties
a) Thickness
b) Dry test/tack test
c) Tensile Strength
d) Percent Elongation
e) Tear Resistance
f) Young's modulus
g) Folding endurance
3) Swelling properties
4) Transperency
5) Contact angle
6) Assay/Content uniformity
7) Disintegration time
8) In-vitro Dissolution test [39]

Organoleptic assessment

For evaluation of the product, highly controlled human tasting panels are used. *In-vitro* methods of using taste sensors, are being used for this purpose. These *in-vitro* taste assessment apparatus and procedures are well suited for high-throughput taste screening of oral films.(40)

Mechanical properties:

The thickness of strip can be determined by micrometre screw gauge at numerous crucial spots. This is crucial to determine homogeneity in the thickness of the film as this is directly related to the accuracy of dose in the strip [42].

Dryness test/tack test

Tack is the degree to which the strip sticks to a piece of paper or other accessory that has been rubbed against it.

Tensile Strength

Tensile strength is the highest 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 the strip as stated in the equation below:[41]

$$\text{Tensile strength} = \frac{\text{load at failure} \times 100}{\text{Strip thickness} \times \text{Strip width}}$$

Elongation Percentage
Strain is the term used to describe the stretching of a strip sample under stress. In essence, strain is the strip's deformation divided by the sample's initial dimensions. Generally elongation of strip rises as the plasticiser content increases.[41]

$$\% \text{ Elongation} = \frac{\text{Increase in length of strip} \times 100}{\text{Initial length of strip}}$$

Resistance to Tear
Tear resistance of plastic film or sheeting is a complex function of its ultimate resistance to rupture. Basically very low rate of loading 51 mm (2 in)/min is applied to measure the force to induce ripping. The tear resistance value in Newtons (or pounds-force) is the maximal stress or force (often found close to the commencement of ripping) needed to tear the specimen.[41]

Young's Modulus
Young's modulus, often known as elastic modulus, is a gauge of a strip's stiffness. It is described as the ratio of applied stress over strain in the region of elastic deformation as follows:

$$\text{Young's modulus} = \frac{\text{Slope} \times 100}{\text{Strip thickness} \times \text{speed of cross-head}}$$

Folding Endurance
Folding endurance is determined by repeated folding of the strip at the same point till the strip breaks. The folding endurance value is calculated as the number of times the film can be folded without breaking. [41,42]

3) Swelling property: Film swelling study is conducted using simulated saliva solution. Each film sample is weighed and placed in a preweighed stainless steel wire mesh. In a plastic container, the mesh containing the film sample is immersed in 15 ml of media. Increase in the weight of the film is determined at preset time interval until a steady weight is recorded. The degree of swelling is computed using formula-[42] $\alpha = (wt - wo)/wo$ wt is weight of film at time t, and wo is weight of film at time zero.

4) Transparency: A basic UV spectrophotometer can be used to assess the films' transparency. The film samples should be cut into rectangles and put on the spectrophotometer cell's inside. Determine the transmittance of films at 600 nm. The transparency of the films can be estimated as follows:
Where T600 is the transmittance at 600 nm, b is the film thickness (mm), and c is concentration, transparency is equal to $(\log T600)/b = - €c$ [43].

5) Contact Angle: A goniometry is used to measure contact angles at room temperature. A drop of double distilled water was placed on the surface of the dry film. Digital cameras were used to capture photographs of the water droplet, and image 1.28v software was used to analyse the digital images and determine the angle.

6) Assay/ Content uniformity: This is determined by any standard assay method defined for the particular API in any of the standard pharmacopoeia. Content homogeneity is determined by predicting the API content in individual strip. Limit of content homogeneity is 85–115 percent. [43]

7) Disintegration Time: Fast dissolving oral strips can be subject to the CDER guidance's disintegration time limit of 30 seconds or less for oral disintegrating tablets [26]. Oral fast-disintegrating films and strips may be used as a qualitative guideline for quality control testing or during the development stage, despite the lack of established guidelines. Pharmacopoeial disintegrating test device may be employed for this study. Typical disintegration time for strips is 5–30 s.[43,44]

8) In-vitro Dissolution Test: Any pharmacopoeia's standard basket or paddle apparatus can be used to conduct dissolution testing. The dissolution medium will essentially be selected as per the sink conditions and maximal dose of the API. Because of the strips' propensity to float on the dissolution medium when a paddle system is employed, dissolution tests can frequently be challenging.[44]
Storage and Packaging of Films A range of storage and packaging options are available for rapid dissolving films. Drug manufacturers have product flexibility throughout the packaging step. Films are pharmaceutical goods that must be packaged in a single container; the most popular type of packaging is an aluminium pouch. APR-Labtec has developed the Rapid card, a proprietary and patented packaging method, which is exclusively built for the Rapid films. The fast card is same size as a credit card and holds three raid videos on each side. Each dose may be removed separately. [42]

FTIR
IR grade KBr was separately combined with pure drug and drug coupled with polymers to investigate compatibility using FT-IR spectroscopy. The mixture was subsequently converted into KBr pellets using a hydraulic press and scanned over a

range of 4000–400 cm-1 [43]. XRD To ascertain the crystallinity of raw pharmaceuticals and drugs incorporated in films, X-ray diffraction was used. For the objective of analysing the amorphous/crystalline behaviour of treated medications, diffraction patterns were collected. Research on DSC, or differential scanning calorimetry, to identify potential interactions between the drug and excipients, DSC experiments were carried out using a Perkin-Elmer DSC-4 system, calibrated using an indium standard [44]. Film-forming abilityThe ability of a polymer to form the required strip is known as film-forming capability. It is split into groups based on its capacity to form strips, such as very poor, poor, average, good, better, and best. The way films look Using visual signals such as transparency and semitransparency, the strip's appearance was rated [40].Drug release kinetics The release data were fitted to the following kinetic models to explore the mechanism of drug release. Kinetics of zero order Qt = Q0 + k0tWhere Q0 is the starting dose of the medication in the pharmaceutical dosage form, Qt is the dose at time t, and k0 is a zero-orderrate constant.First-order kinetics: Qt = Q0 e-k1t or ln Qt = lnQ0 + k1twhere k1 is the first-order release constant, Qt is the amount of drug released at time t, and Q0 is the drug's initial concentration in the solution. Dissolution efficiency (DE) was proposed by Khan as a useful statistic for the assessment of in vitro dissolution data [45].

Application of Mouth-Dissolving Film

Vaccines Fast-dissolving buccal films can provide vaccines that are stable at room temperature and easily dissolve in saliva and the mouth. The American-made rotavirus vaccine is a buccal film that dissolves quickly and is stable at room temperature, making vaccinations almost as easy as using mouthwash. Improved patient compliance, enhanced bioavailability, and a decrease in the expenses of handling, administration, and storage are just a few of the benefits that this delivery system offers. Controlled and sustained release film Chitin and chitosan derivatives, among other polymers, are utilised as excipients in hospital preparations for the sustained-release buccal film.

Taste Masking

Fast-dissolving pills must have flavour masking to be successful commercially. The active ingredients that come into contact with the patient's taste buds are released when fast-dissolving buccal films breakdown or decompose in their mouth. For the patient to comply, this characteristic is consequently essential. Drugs with an unpleasant bitter taste can be microencapsulated into pH-sensitive acrylic polymers utilising solvent evaporation and solvent extraction techniques. These polymer microspheres displayed speedy and complete disintegration as well as effective taste masking. Orally disintegrating film Fast-dissolving buccal films are based on a water-soluble polymer that dissolves when eaten. The film's ability to dissolve rapidly without the need for water provides an alternative for patients who have difficulty swallowing or who are suffering nausea, such as those undergoing chemotherapy [46].

Packaging of Mouth-Dissolving Film

Packing issues play a major role in the dosage form's stability, storage, and protection. Barrier films, single pouches, aluminium pouches, blister packaging with multiple units, and foil paper or plastic pouches are among the packaging choices for oral thin films. For drugs that are extremely moisture-sensitive, barrier films are most usually employed. There is adequate opportunity for logos, codes, directions, or other information on primary packaging composed of a sealing pouch owing to Labtech GmbH's fast film technology. The films are made by a laminating technique, and the cost of packaging is equivalent to that of tablets [47].MDFs in biopharmaceutical consideration. Before creating a new dosage form, it is important to take biopharmaceutical considerations into account. Fast-dissolving oral films dissolve instantly, making it easier for the medicine to be absorbed through the oral mucosa from the mouth, throat, and esophagus. Age, the makeup of the mouth cavity, and blood flow there should all be taken into account. Drug distribution is influenced by factors such as tissue permeability, perfusion rate, medication binding to tissue, and drug interactions. The amount of time it takes for the drug to leave your body or reach its target depends on how quickly it leaves. Different characteristics, such as the patient's age, sex, and health, have an impact on the dose form's pharmacodynamics performance [48]. Throughout the trial, adverse occurrences were gathered [49]. Such a decline in food quality might be prevented by edible films and coatings [50].

The panel of human taste

The study was carried out in accordance with the ethical principles derived from the Declaration of Helsinki and followed the ICH-GCP guidelines of January 17, 1997, and was in compliance with local regulatory requirements. It was approved by the Ethical Committee of the University deli Study di Milano. All participants were fully apprised of the necessary information and the study's objectives. Each subject received a written consent form, read it, understood it, and signed it before tasting test samples. Ten healthy subjects each tasted a 0.50 mL aliquot at random. All samples were held in the mouth for 15 s before being removed, the individuals gargled thoroughly, and at least an hour passed before tasting the next one [51]. Bitterness were measured by the consensus of a trained taste panel, with 20 mg of each sample held in the mouth for 5–10 s, then spat out; the bitterness level was then recorded [52].

CONCLUSION

Fast Dissolving Films have various advantages over the standard dosage forms. They are recognised as a most essential medication delivery technology today because of their quick breakdown, enhanced dissolving. They combine the increased

stability of a solid dosage form and good application of the liquid and thereby bridge the gap between the two notions, merging positive characteristics from both solid and liquid dosage forms into an elegant, stable and successful delivery vehicle. Therefore, they are crucial in emergency situations like allergic responses and asthma attacks when prompt action is required. The majority of pharmaceutical businesses are finding it difficult to manufacture oral films for a variety of active pharmaceutical ingredients due to the rapid growth of this technology.Both mucoadhesive and Oro dispersible films have been successfully used as effective drug delivery platforms, particularly for proteins and peptides, thanks to the prominent characteristics of oral films, including fast drug absorption, high bioavailability, easy-to-use nature, and avoidance of the first pass effect both in GI tract and in the liver. The evolution of fabrication processes, as well as formulation strategies employing both natural and synthetic polymers, has progressed oral films greatly for their practical uses. In addition, actives could be enclosed in nanoparticles or inclusion complexes, which are uniformly or unevenly distributed into the oral films produced, not only to nicely enhance the bio adhesion to the targeted oral mucosa but also to sufficiently improve both the solubility and permeability of the corresponding drugs, ultimately resulting in a fully promoted drug absorption and highly enhanced bioavailability. Despite the aforementioned developments, there are still various difficulties that prohibit such appealing oral videos from being widely industrialised and commercialised. On the one hand, future research has to focus on developing novel formulations that boost drug loading rates while also considering biocompatibility and biodegradability. However, in order to produce these newly created oral films with shorter processing times and higher output, current production methods must be modified

REFERENCES

1. Dixit, RP, Puthli, SP., Oral strip technology: overview and future potential, J Control Release 2009, 139, 94-107
2. Patel, R, Prajapati, S, Raval, A., Fast dissolving films (FDFs) as a newer venture in fast dissolving dosage forms, Int J Drug Dev& Res 2010, 2(2), 232-236.
3. Rathi, V, Senthil, V, Kammili, L, Hans, R., a brief review on oral film technology, Int J Res Ayurvedic & Pharmacy 2011, 2(4), 1138-1147.
4. Jeong, S.H., Y. Takaishi, Y., Fu and K. Park, 2008, Material properties for making fast dissolving tablets by a compression method, Journal of Materials Chemistry, 18, 3527-3535.
5. Banker, G.S, Film coating theory and practice, J. Pharm. Sci,. 1966 ; 55: 81- 89.
6. Mennella JA, Beauchamp GK. Optimizing oral medications for children. Clin Ther 2008;30:2120-32. DOI: 10.1016/j.clinthera.2008.11.018
7. Tiwari RR, Umashankar MS, Damodaran N. Recent update on oral films: A bench to market potential. Int J Appl Pharm 2018;10:27-33. DOI: 10.22159/IJAP.2018V10I6.28725
8. Boateng JS, Matthews KH, Stevens HN, Eccleston GM. Wound healing dressings and drug delivery systems: A review. J Pharm Sci 2008;97:2892-923.
9. Leathers TD. Biotechnological production and applications of pullulan. Appl Microbiol Biotechnol 2003;62:468-73. DOI: 10.1007/s00253-003-1386-4
10. Banker GS. Film coating theory and practice. J Pharm Sci 1966;45:81-9.
11. Bala R, Pawar P, Khanna S, Arora S. Orally dissolving strips: A new approach to oral drug delivery system. Int J Pharm Investig 2013;3:67-76. DOI: 10.4103/2230-973X.114897
12. Shojaei AH. Buccal mucosa as a route for systemic drug delivery: A review. J Pharm Pharm Sci 1998;1:15-30.
13. LV QY, Li XY, Shen BD, Dai L, Xu H, Shen CY, et al. A solid phospholipid-bile salts-mixed micelles based on the fast dissolving oral films to improve the oral bioavailability of poorly water-soluble drugs. J Nanopart Res 2014;16:2455.
14. Dixit RP, Puthli SP. Oral strip technology: Overview and future potential. J Control Release J 2009;139:94-107. DOI: 10.1016/j.jconrel.2009.06.014
15. Rathbone MJ, Hadgraft J. Absorption of drugs from the human oral cavity. Int J Pharm 1991;74:9-24.
16. Gaisford S, Verma A, Saunders M, Royall PG. Monitoring crystallisation of drugs from fast-dissolving oral films with isothermal calorimetry. Int J Pharm 2009;380:105-11. DOI: 10.1016/j.ijpharm.2009.07.00
17. Sastry SV, Nyshadham JR, Fix JA. Recent technological advances in oral drug delivery-a review. Pharm Sci Technol Today 2000;3:138-45.
18. Aggarwal, J, Singh, Gurpreet, Saini, Seema, Rana, A.C., Int Res J Pharmacy 2011, 2(12), 69-74.
19. Bhyan B, Jangra, S, Kaur M, Singh H., Orally fast dissolving films: innovations in formulations and technolog, Int J Pharm sci Rev &Res 2011, 9(2), 50-57.
20. Arya, A, Chandra, A, Sharma, V, Pathak, K., Fast dissolving films: an innovative drug delivery system and dosage form, Int J ChemTech 2010, 576-83.
21. Frey, P., Film strips and pharmaceuticals, pharma. mfg. & package, Sourcer, winter, 2006, 92-93.
22. Gavaskar, B, Kumar, SV, Sharan, G, Rao, Y.M, .overview on fast dissolving films, Int J Pharmacy &Pharm Sci, 2010, 2(3), 29-33.
23. Zhang, H, Zhang, J, Streisand, JB., Oral mucosal drug delivery: clinical pharmacokinetics and therapeutic applications, ClinPharmacokinet, 2002, 41(9), 661-80.
24. Choudhary, D., Patel, V., Patel, H., Kundawala. A., Film former properties of film former used in the formulation of Rapid dissolving films, Int J ChemTech Res, 2011, 3(2), 531-533.

25. United States Pharmacopeia and National Formulary (USP 43–NF 38). (2020). Chapter <905> Uniformity of Dosage Units. United States Pharmacopeial Convention
26. Arya, A., Chandra, A., Sharma, V., & Pathak, K. (2010). Fast dissolving oral films: an innovative drug delivery system and dosage form. International Journal of ChemTech Research, 2(1), 576-583.
27. Kulkarni, P. K., Dixit, M., & Singh, U. B. (2011). Preparation and evaluation of mouth dissolving film of ropinirole hydrochloride by using Pullulan polymers. International Journal of Pharma and Bio Sciences, 2(1), 318-329.
28. Garsuch, V., & Breitkreutz, J. (2009). Novel analytical methods for the characterization of oral wafers. European Journal of Pharmaceutics and Biopharmaceutics, 73(1), 195-201.
29. Morales, J. O., & McConville, J. T. (2011). Manufacture and characterization of mucoadhesive buccal films. European Journal of Pharmaceutics and Biopharmaceutics, 77(2), 187-199.
30. Vondrak, B, Barnhart, Scott., Dissolvable films: Dissolvable films for flex product format in drug delivery, Pharm technol, 2008, 1-5.
31. Siddiqui, Nehal, M.D., Garg, G., Sharma, K.., A short review on: Noval Approach in Oral Fast Dissolving Drug Delivery system and their Patents, 2011, 5(6), 291-303.
32. Mishra, R, Amin, A., Quick API delivery, Pharm Technol Europe, 1-5.
33. Sau-hung, S, Robert, S, Lori D., "Fast dissolving orally consumable films", U.S. Patent, July 22, 2003, 6, 298-596.
34. Israel, K, Leo, M. "Salivary stimulant", U.S. Patent 4820506, April 11, 1989.
35. Kennedy, SW, Triethyl citrate, in, Rowe, RC, Sheskey, PJ, Owen, SC (Eds.)., Handbook of pharmaceutical excipients. Pharmaceutical press, London, 2006, 796–97.
36. Brown, D., Orally disintegrating tablets – taste over speed.,Drug Del Technol, 2003, 3(6).
37. Kennedy, SW, Dibutylsebacate, in:Rowe RC, Sheskey, PJ, Owen, SC(Eds.)., Handbook
38. of pharmaceutical excipients, Pharmaceutical press: London, 2006, 236–37.
39. International Conference on Harmonization, ICH topic Q3C(R3) Impurities, residual solvents. Note for guidance on Impurities, residual solvents. (CPMP/ICH/283/95),
40. Felton, L, Donnell, PO', McGinity, J., Mechanical properties of polymeric films prepared from aqueous dispersions, in: Aqueous polymeric coatings for pharmaceutical dosage forms, 3rd edition, McGinity, J, Felton, L(Eds)., Drug Pharm Sci vol.176, 108.
41. Fulzele, SV, Sattuwar, SV, Dorle, AK., Polymerized rosin: novel film forming polymer for drug delivery, Int J Pharm 2002, 249, 175–84.
42. American standard of testing and materials, ASTM D1004 – 08 Standard test method for tear resistance (Graves Tear) of plastic film and sheeting.
43. Shinde, AJ, Garala, KC, More, HN., Development and characterization of transdermal therapeutics system of tramadol hydrochloride, Asian J Pharm 2008, 2(4), 265–69.
44. Wale, A, Weller, PJ., Handbook of pharmaceutical excipients, 1994, 24,27,352,448.
45. Dinge A, Nagarsenker M. Formulation and evaluation of fast dissolving films for delivery of triclosan to the oral cavity. AAPS PharmSciTech 2008;9:349-56. DOI: 10.1208/s12249-008-9047-7
46. Prasanthi NL, Krishna CS, Gupta ME, Manikiran SS, Rao NR. Design and development of sublingual fast dissolving films for an antiasthmatic drug. Sch Res Libr 2011;3:382-95.
47. Vasisht N, Gever LN, Tagarro I, Finn AL. Evaluation of the single-and multiple-dose pharmacokinetics of fentanyl buccal soluble film in normal healthy volunteers. J Clin Pharmacol 2010;50:785-91. DOI: 10.1177/0091270010361354
48. Wu Y, Weller CL, Hamouz F, Cuppett SL, Schnepf M. Development and application of multicomponent edible coatings and films: A review. Adv Food Nutr Res 2002;44:347-94.
49. Mankar J, Biyani D, Umekar M. Oral thin film: Advanced oral dosage form. Glob J Pharm Allied Sci 2020;1:1-7. DOI: 10.47583/GJFPAS.2020.V01I05.001
50. Agarwal R, Mittal R, Singh A. Studies of ion-exchange resin complex of chloroquine phosphate. Drug Dev Ind Pharm 2000;26:773-6.
51. Agresti C, Tu Z, Ng C, Yang Y, Liang JF. Specific interactions between diphenhydramine and alpha-helical poly (glutamic acid)--a new ion-pairing complex for taste masking and pH-controlled diphenhydramine release. Eur J Pharm Biopharm 2008;70:226-33. DOI: 10.1016/j.ejpb.2008.04.004
52. Speer I, Preis M, Breitkreutz J. Novel dissolution method for oral film preparations with modified release properties. AAPS PharmSciTech 2019;20:7. DOI: 10.1208/s12249-018-1255-1
53. Nagaraju T, Gowthami R, Rajashekar M, Sandeep S, Mallesham M, Sathish D, et al. Comprehensive review on oral disintegrating films. Curr Drug Deliv 2013;10:96-108.