WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 12, Issue 20, 119-127. Review Article ISSN 2277–7105

# REVIEW ARTICLE: ORAL PESTRO DISSOLVING FLICKS

**Priya Gaikwad***

India.

Article Received on
25 September 2023,

Revised on 15 October 2023,
Accepted on 05 Nov. 2023

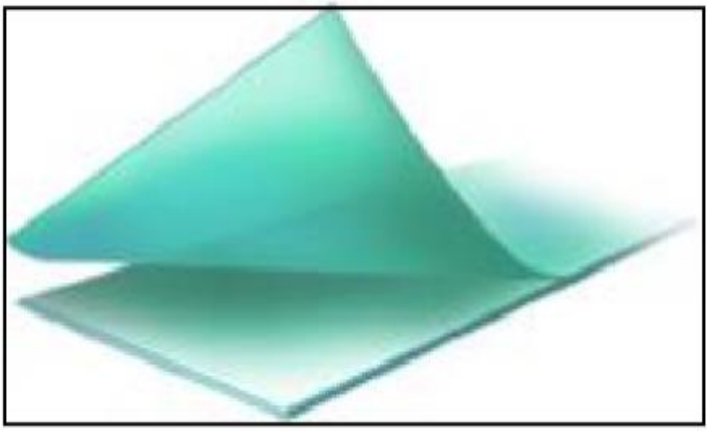
DOI: 10.20959/wjpr202320-30115

***Corresponding Author**
**Priya Gaikwad**
India.

## ABSRTACT

Orlly presto dissolving flicks is the type of medicine delivery system which when placed in the oral depression, disintegrate or dissolve within many seconds without the input of water. In the late 1970s rapid-fire disintegrating medicine delivery system was developed as an volition to capsules, tablets and bathos for senior and pediatric cases having problem in swallowing. To overcome to need, number of orally disintegrating tablets which disintegrate within one nanosecond in mouth without biting or drinking water where capitalized. also latterly oral medicine delivery technology had been bettered from conventional lozenge form and developed lately rapid-fire disintegrating flicks rather than oral disintegrating tablets. Orally presto dissolving flicks have been introduced in the request lately as the give convenience and ease of use over lozenge forms sweetmeat and oral care requests in the form of breath strip and come a novel and extensively accepted from by consumers, so orally fast dissolving flicks are gaining the interest of large number of medicinals diligence. Some companies introduced more robust form of fast dissolving medicine delivery the flicks is place on top or the bottom of the lingo. When put on the lingo, this film dissolve presently, releasing the medicine which dissolve the slaver. Some medicines are absorbed from the mouth, pharynx and esophagus as the slaver passes down into the stomach. In similar case is enhancing medicine bioavailability, no threat of checking, handed good mouth feel. The present review provides an account of colorful expression, consideration, system of medication and quality control of the orally fast dissolving flicks.

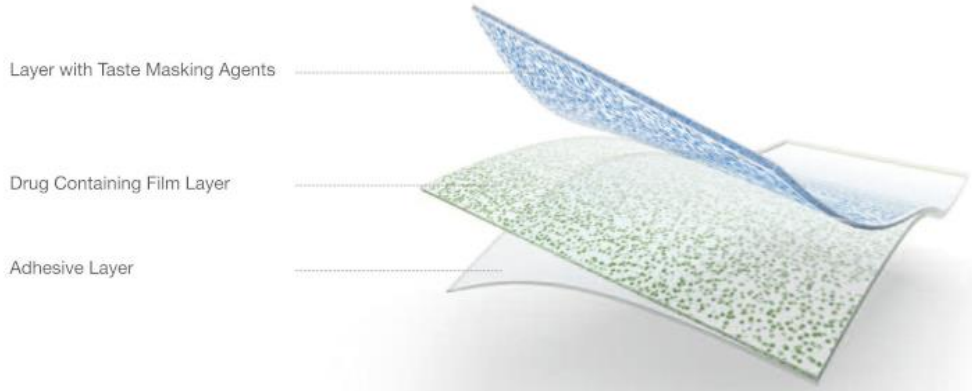
**KEYWORDS:** Oral Pestro Dissolving Flicks,Disentegrating tablet, Bioavailability.



## INTRODUCTION

preface Among the different routes, the oral routes is a most favored route of medicine administration for systemic effect due to ease of administration, non-invasiveness, rigidity case compliance and adequacy.[32,33] Orally presto- dissolving film is new medicine delivery system for the oral delivery of the medicines. nearly 90 of the medicines are administered to the body via oral route for the treatment of colorful diseases and conditions as it's regarded as the safest, most accessible and utmost provident system of medicine delivery and have the loftiest case compliance.[1-2] The medicine is either dissolved or swallowed, which also enters into the systemic rotation to produce the asked effect.[3- 4] Fast dissolving oral thin flicks is an ultrathin film that employs a hydrophilic polymer that fleetly hydrates or adheres when placed on the lingo or in the buccal depression.[7] These flicks disintegrate or dissolve within seconds to release the active agent without drinking and biting.[6-7] The instant bioavailability results from bypassing first pass metabolism. So they're generally designed for the medicines having high first pass metabolism for achieving better bioavailability.[8- 9] Tablet is the most favored lozenge form due to ease of manufacturing, transportation and further patient compliance.[34] Generally senior, paediatric, squeamish, bed ridden and noncompliance cases witness difficulties in swallowing the conventional oral lozenge form and don't take their drugs as specified. It's estimated that 50 of the population was affected by this problem, which eventually results in a advanced chance of resistance & ineffective remedy.[35] The senior constitute a major portion of moment's population substantially because of increased life expectation of individualities.[36] Dysphagia or difficulty in swallowing is common problem, this complaint is coupled with several medical conditions including stroke, AIDS, thyroidectomy, Parkinson's complaint, head and neck radiation remedy and other neurological diseases as well as encephalopathy.[37] The most common complaint with tablet

is size, fear of chocking. The problem of swallowing tablets is more apparent in senior and pediatric cases, as well as travelling cases who may not have ready access to water.[38] To overcome the Oral fast disintegrating medicine delivery systems were developed, these systems were originally developed within the late Seventies as an volition to tablets, capsules and bathos for pediatric & senior cases who witness difficulties in swallowing traditional oral solid lozenge forms. These lozenge forms either dissolve or disintegrate generally within a 3 nanosecond in mouth, without need of water. Oral fast Disintegrating lozenge form have started gaining fashionability & acceptance as new medicine delivery system due to better case compliance.[38] Oral flicks are newer technologies in the product of oral disintegrating lozenge forms. They're thin, elegant flicks composed of comestible, water-answerable polymers in different sizes and shapes similar as blocks, places, and discs. The stripes may be flexible or brittle, opaque, or transparent. They're intended to dissolve snappily on the lingo without the need for water. Fast dissolving flicks(FDFs) have a wide specific face area for decomposition. The flicks minimize the threat/ fear of choking, are easy to handle and administer, and give easy- to- manufacture packaging, prostrating the short fails of oral fast disintegrating tablets. The low medicine lading capacity and limited taste masking possibilities of these lozenge forms are significant downsides. A fast disintegrating film is a thin film with a consistence of 1- 10 mm and an area of 1- 20 cm2 of any figure. medicines should be incorporated up to a single lozenge of around 30 mg. The quick dissolving of slaver is due to a special matrix composed of water-answerable polymers; it has a low method for ease of running and operation. still, when wetting down the wet method and muco cohesion parcels of system are designed to secure the film to the operation point. The inflexibility and strength of the flicks were chosen to grease the product process as well as processes similar as rewinding, die slice, and packaging. A fast dissolving film is put on the case's lingo, which is mucosal towel that's incontinently bathe by slaver. The film hydrates snappily and adheres to the operation point. It also snappily disintegrates and dissolves, releasing the medicine for oral mucosal immersion or gastric immersion on swallowing.[51,52]




**THE BENEFITS OF FDOFS[46,47]**

* The large face area promotes fast decomposition and dissolution in the mouth depression.
* It's flexible and less fragile, it's easier to transport, store and handle by the consumer.
* Ease of administration of internal ill, impaired and unco- oprative cases.
* Delicacy in lozenge administration.
* Excellent mouth feel.
* Provides water free treatment.
* Increased Bioavailability, better immersion, and briskly action.
* Bettered cases compliance.
* Ameliorate the product's life cycle.
* Excellent stability.

## ORAL FLICKS SPECIAL FEATURES OF ORAL FLICKS

* Thin, seductive flicks
* Available in a variety of shapes.
* Excellent mucoadhesion.
* Fast decomposition and release.

## ADVANTAGES

1. Easy transportation[10,11]
2. Ease of swallowing for senior and paediatric cases.
3. Accessible and accurate dosing.
4. There's no need for water for administration.
5. There's no threat of choking
6. Rapid onset of action with bettered bioavailability as a result of avoiding the hepatic first pass effect and stability.
7. Ease of administration of film to the cases suffering from dysphagia, repeated emesis, stir sickness, and internal diseases.[48]

## DISADVANTAGES

1. Film packing requires the use of specialise outfit.[12]
2. delicate to pack.
3. A high cure can not be incorporated.
4. Oral flicks that are humidity sensitive.
5. Medicine which are unstable at buccal pH can not be administered.
6. Medicine which irritate the mucosa can not be administered by this rout.[50]
7. As it's fragile and must be defended from water, it requires special packaging.
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**Table 1: Comparison between fast dissolving oral flicks and tablets.[40,41]**

| Sr.No. | Oral disintegrating tablet | Orally dissolving films |
|---|---|---|
| 1. | It is a tablet. | It is a film. |
| 2. | lower dissolution due to lower face area. | Greater dissolution due to large face area. |
| 3. | lower durable as compared with oral flicks. | More durable than oral disintegrating tablet. |
| 4. | lower case compliance than flicks. | further patient compliance. |
| 5. | Low cure can only be incorporated. | High cure can be incorporated. |
| 6. | It has a fear of chocking. | No threat of chocking. |

**Bracket OF ORAL flicks.**[37]

There are three different subtypes of oral flicks.

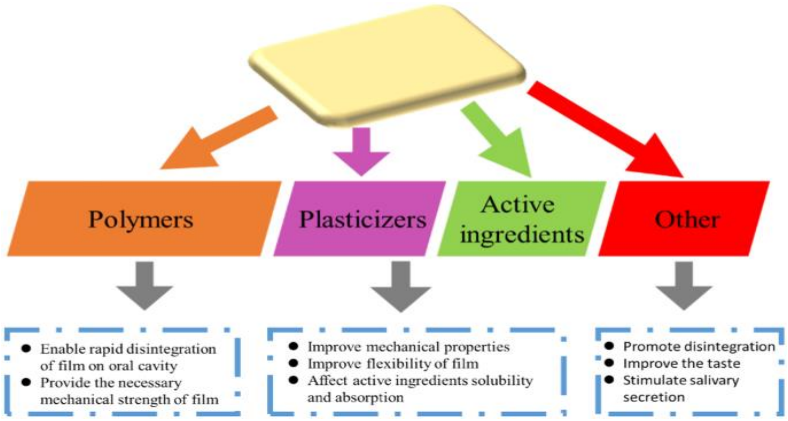
1. Flash release.
2. Mucoadhesive melt- down wafer.
3. Mucoadhesive sustained release wafer.

**Their parcels are described in Table 2.**

| Sr. No. | Property/Sub / Type | Flash release water. | Mucoadhesive Melt-Down water. | Wafer. Mucoadhesive Sustained release wafer. |
|---|---|---|---|---|
| 1. | Area $(cm)^2$ | 2-8 | 2-7 | 2-4 |
| 2. | Consistence(µm) | 20-70 | 50-500 | 50-250 |
| 3. | Structure | Film: Single subcaste | Single or multilayer System | Multilayer System |
| 4. | Excipients | Answerable largely hydrophilic polymers. | Soluble, hydrophilic polymer. | Low/Non answerable polymer |
| 5. | Medicine phase | Solid result | Solid result or Suspended medicine. | suspense and/or Solid result. |
| 6. | Operation | lingo (upper palate) | Gingival or buccal Region | Gingival, (other region in the oral depression). |
| 7. | Dissolution | Maximum 60 sec | Decomposition in a manymin. forming gel | Maximum 8- 10 hur. expression |

**CONSIDERATION**

- Active Pharmaceutical component.
- Film Forming Polymer.
- Plasticizer.
- Enhancing Agent.
- Slaver Stimulating Agent.
- Flavouring Agent.
- Colouring Agent.




**Active Pharmaceutical Ingredient**

A typical conformation of the film contains 1- 25 w/ w of the medicine. Variety of active pharmaceutical constituents can be delivered through fast dissolving flicks. Small cure motes are the stylish campaigners to be incorporated in oral fast dissolving flicks. Multivitamins up to 10 w/ w of dry film weight was absorb in the flicks with dissolution time of lower than 60 seconds. It's always useful to have micronized active pharmaceutical constituents which will ameliorate the texture of the film and also for better dissolution and uniformity in the oral fast dissolving flicks. numerous active pharmaceutical constituents, which are implicit campaigners for oral fast dissolving flicks technology, have bitter taste. This makes the expression nonedible especially for pediatric medications. therefore before incorporating the active pharmaceutical constituents in the oral fast dissolving flicks, the taste needs to be masked. colorful styles can be used to ameliorate the comestible of the expression. Among the ways employed, the simplest system involves the mixing andco-processing of bitter tasting active pharmaceutical constituents with excipients with enjoyable taste. This is frequently nominated as obscuration fashion.[13-14]

**Film Forming Polymers**

Polymers are the most important component of the fast dissolving oral film. Robustness of the film depends on the volume of polymer added in the oral strip. Generally, 45 w/ w of polymer is used which is grounded on total weight of dry film. The selection of polymer is one of the most important and critical parameters for the successful development of oral flicks because of their tensile strength which depends upon the type and volume of polymer used.15 substantially hydrophilic polymers are used in the oral strip as they fleetly disintegrate in the oral depression as they come in contact with slaver.16 presently, both natural & synthetic polymers are used for the medication of fast dissolving film.

**Plasticizers**[15- 18]

It's an main component of oral thin flicks. The plasticizers help to better the mechanical parcels of film similar as tensile strength and extension to the film. It also minimizes the fineness of the film. It may more the inflow and enhances the strength of polymer. The proper selection of the plasticizers is veritably main. It should be compatible with the medicine, polymers as well as with the other excipients. The irregular selection may beget cracking, unyoking and shelling of the film. The generally used plasticizers are glycerol, propylene glycol, polyethylene glycol, dimethyl, dibutyl, diethyl phthalate, n- tributyl, triethyl, actyl citrate, triacetin and castor oil painting.

**Surfactants**[19- 20]

Surfactants are used as a wetting or solubilizing or dispersing agent so that the film is getting dissolved within seconds and release active agent incontinently. Generally employed are poloxamer 407, benzethonium chloride, sodium lauryl sulfate, tweens, benzalkonium chloride, etc. Out of these most generally used surfactants is poloxamer 407.

**Sweetening Agents**[21]

Sucrose is the most generally used sweeteners in fast dissolving oral flicks. Sucrose is veritably answerable in water and being colourless doesn't conduct any undesirable colour to the final expression. Some of the generally employed sweeteners are dextrose, sucrose, fructose, glucose, isomaltose, polyhydric alcohols (sorbitol, mannitol) etc. Atificial sweeteners like soupy, cyclamate, aspartame (first generation) sucralose, alitame, and neotame (alternate generation) can also be use.

**Slaver Stimulating Agent**

slaver stimulating agents are used to increase the rate of timber of slaver that would help in the briskly decomposition of the quick dissolving strip phrasings. illustration of salivary instigations are citric acids, malic acid, lactic acid, ascorbic acid and tartaric acid.

**Flavouring Agents**[21]

Flavours used in the expression must benon-toxic, answerable, stable and compatible with excipients. The volume of flavouring agent needed to mask the taste depends on the flavour type and its strength.

**Colouring agents**[22]

Generally incorporated colouring agents have FD&C approved colours, natural colours, colors similar as titanium dioxide etc. The colouring agents shouldn't exceed attention situations of 1w/w.

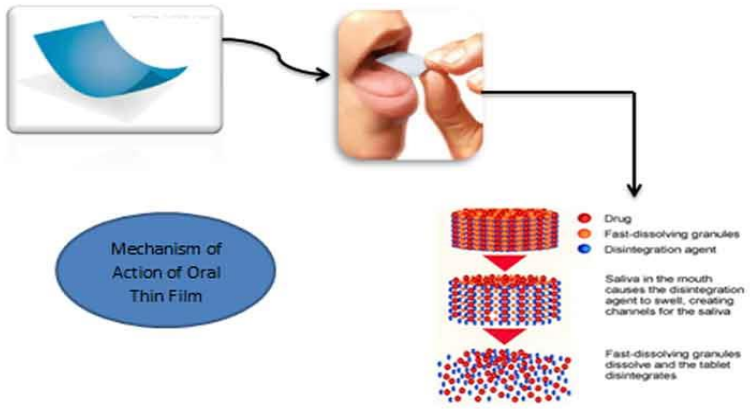



**Table 2: Expression of film.**

| SR. No. | Composition of Film | Quntity |
|---|---|---|
| 1 | Active pharmaceutical ingredient | 5-30% |
| 2 | Film forming polymer | 40-50% |
| 3 | Plasticizers | 0-20% |
| 4 | Slaver stimulating agent | 2-6% |
| 5 | Sweetening agent | 3-6% |
| 6 | Surfactants, Flavour, Colouring agents. | Q.S |

**Table 3: Shows: Types of agents used for preparation of oral dissolving films.**

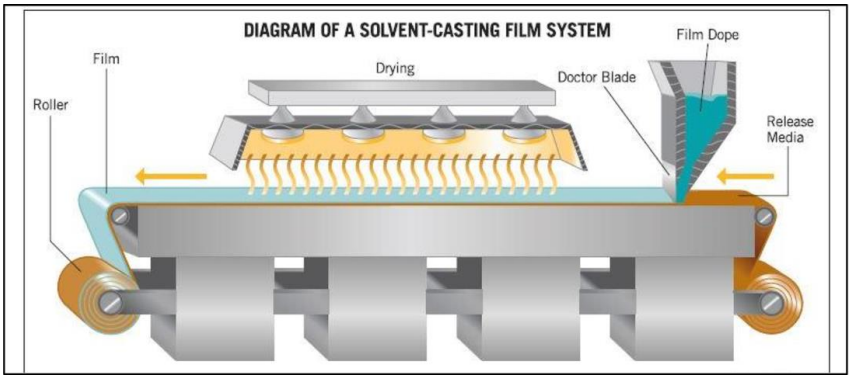
| Plasticizers | Sweetening agents | Flavouring agents | Colouring agents | Saliva stimulating agents | Surfactants |
|---|---|---|---|---|---|
| Acetyl triethyl citrate | Mannitol; Sorbitol | Lemon | Natural colouring agent | Citric acid | Polaxamer 407 |
| PEG | Xylitol; Polyols | Peppermint | Titanium oxide | Lactic acid | Benzalkonism chloride |
| Propylene glycol | Aspartame | Cinnamon | Silicon dioxide | Malic acid | Benthonium chloride |
| Sorbitol | Glycyrrhizin | Vanillin | Zinc oxide | Ascorbic acid | Tweens |
| Glycerin | Saccharin; Cyclamate | Menthol | | Tartaric acid | Spans |
| Citrate ester | Manitol; Isomalt malitol | Winter green | | Sodium lauryl sulphate | |
| Triacetin | Acesulfame potassium | Orange | | | |
| Triethyl citrate | Dextrose; Fructose | Clove | | | |

## MANUFACTURING METHODS

1. Solvent Casting
2. Circumfluous casting
3. Hot melt extrusion
4. Solid dispersion extrusion
5. Rolling

### Solvent casting[42]

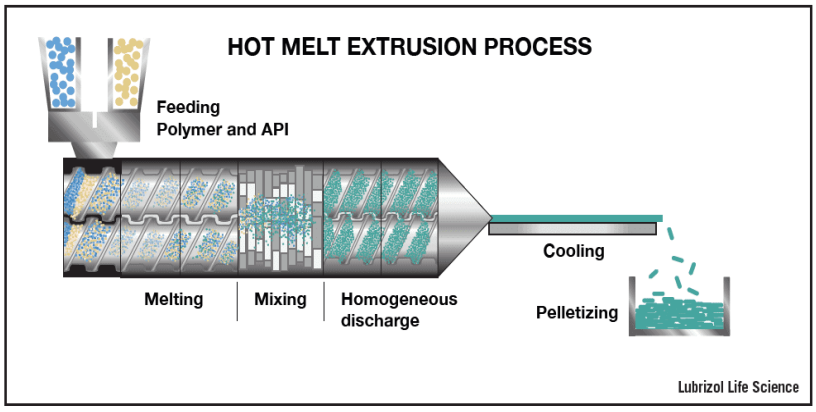
Fast dissolving buccal flicks are rather formulated using the solvent casting system, whereby the water answerable constituents are dissolved to form a clear thick result and the medicine along with other excipients is dissolved in suitable detergent also both the results are mixed and stirred and eventually casted in to the Petri plate and dried.




### Hot melt extrusion[43]

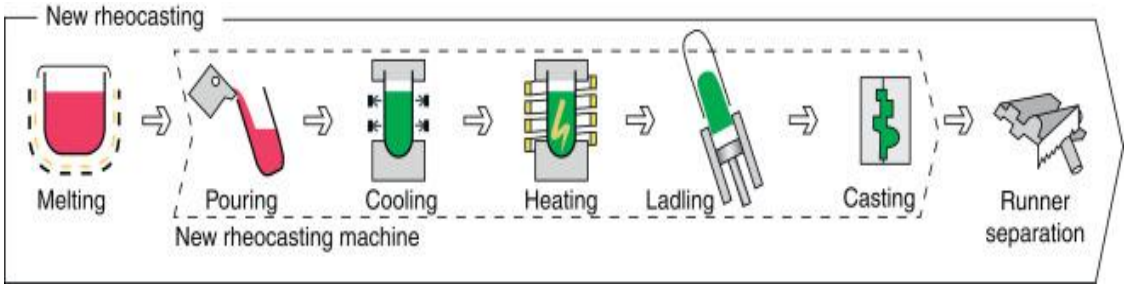
Hot essence extrusion is generally used to prepare grains, sustained release tablets, transdermal and trans mucosal medicine delivery systems. Melt extrusion was used as a manufacturing tool in the pharmaceutical assiduity as early as 1971.

Figure 1



**Circumfluous Casting**[44]

Result of water answerable film forming polymer is prepared. Performing result is added to a result of acid undoable polymer(e.g. cellulose acetate phthalate, cellulose acetate butyrate). Applicable quantum of plasticizer is added so that gels mass is attained. Eventually the gel mass is casted in to the flicks or lists using heat controlled cans. The consistence of the film should be about0.015-0.05 elevation. The rate of the acid undoable polymer to retake forming polymer should be 1:4.




**Solid Dispersion Extrusion**

The term solid dissipations relate to the dissipation of one or further active constituents in an inert carrier in a solid state in the presence of unformed hydrophilic polymers. medicine is dissolved in a suitable liquid detergent. also result is incorporated into the melt of polyethylene glycol, accessible below 70 ◦ C Eventually the solid dissipations are shaped into the flicks by means of dies.

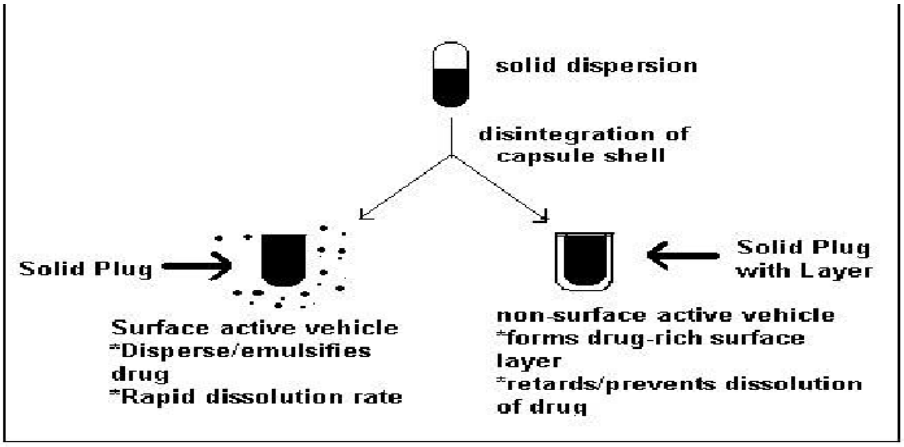



Figure 4 Solid dispersion extrusion method

**Rolling Method**[45]

In this system the film is prepared by medication of apre-mix, addition of an active and posterior conformation of a film. Preparepre-mix with film forming polymer, polar detergent

and other complements except a medicine Add pre mix to master batch feed tank. Fed it via a 1st metering pump and control stopcock to either or both of the 1st and 2nd mixer. Add needed quantum of medicine to the asked mixer. Blend the medicine with master batch pre mix to give a invariant matrix. also a specific quantum of invariant matrix is also fed to the visage through 2nd metering pumps. The film is eventually formed on the substrate and carried down via the support comber. The wet film is also dried using controlled nethermost drying.

**EVALUATION PARAMETERS**[25-26]

1. **Mechanical properties**

1. **Density test**

Density specifies the cure perfection of medicine in the film. It's measured by a micrometer screw hand or calibrated digital Vernier calipers at five unlike strategic locales and the mean value is calculated which indicates the final density of the film. The range of the film should be in the range of 5- 200 µm.

*** Emptiness test**

About eight stages of the film drying process have been linked and they're set - to - touch, dust - free, system - free (face alkie), Dry - to touch, dry - hard, dry - through (dry - to - handle), dry - to - recoat and dry print - free. Although these tests are basically used for makeup flicks utmost of the studies can be change intricately to estimate pharmaceutical OFDF. The details of estimation of these parameters can be checked down and are beyond

the compass of this review. system is the determination with which the strip adheres to an accessory (a piece of paper) that has been pressed into contact with the strip. Instruments are also available for this study.

*** Tensile strength**

Tensile strength is the topmost stress applied to a point at which the strip case breaks. It's calculated by the applied weight at break divided by the cross sectional area of the strip as Given in the equation below Tensile Strength = weight of breakage/ strip density × strip range.

*** Present extension**

When stress is appeal, a strip sample stretches and this is citation to as strain. Strain is principally the distortion of strip decisiveness by original dimension of the sample. Generally extension of strip increases as the plasticizer content increases30. extension = Increase in length × 100/ original length.

*** Young's modulus**

It's the estimate of film stiffness. It's set up as balance of applied stress to the strain in the elastic distortion region. It's determined by the following formula

Young's modulus = (pitch/ strip density * cross head speed)/ 100

It can also be written as Young's modulus = force at corresponding strain/ cross sectional area * corresponding strain Hardness and fineness are attributing of the flicks which are related with Young's modulus and tensile strength. A hard and brittle film represents advanced value of tensile strength and Young's modulus with small extension.

*** Tear resistance**

Tear resistance of plastic film is a complex function of its ideal resistance to rupture. principally truly short rate of lading 51 mm(2 in)/ min is employed and is designed to measure the force to begin tearing. The maximum force demanded to gash the case is recorded as the gash resistance value in Newton.

*** Folding abidance**

Folding abidance is set by repeated folding of the strip at the same place till the strip breaks. The number of times the film is folded without breaking is assessing as the folding abidance value.

**2. Limpidity**[27- 28]

The limpidity of the flicks can be decide using a simple UV spectrophotometer. Cut the film samples into blocks and placed on the inner side of the spectrophotometer cell. The direct transmittance of flicks at 600 nm. The limpidity of the flicks was calculated as follows

limpidity = (logT600)/ b = -€ c

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

**3. Contact Angle**[25- 26]

It allows the information about wetting down down down geste corruption time and dissolution of oral film. This can be executing with the help of goniometer at room temperature. For this cause, double distilled water should be used. A dry film is taken and a drop of double distilled water is sticking on face of the dry film. Images of water drop are taken by a convey of digital camera within 10 s of deposit. Digital filmland should be analysed by image J1.28 v software for angle determination.

**4. Scanning Electron Microscopy**[28-29]

Scanning electron microscopy is an high system to study the face morphology of the film between different excipients and medicine. A film sample is taken and placed in sample holder and at × 1000 exaggeration and colorful photomicrographs were taken using the tungsten hair as source of electron.

**5. In vitro disintegrating test**[28-29]

The time at which the film disintegrates when conduct in contact with water. This test is carried out by position the film in the phosphate buffer. United State Pharmacopoeia corruption outfit can be also used to study the corruption time. The corruption time should be in the range of 5- 30sec.

**6. In- Vitro Dissolution test**[28-29]

Quantum of medicine substance that proceeds into the result per unit time under standard conditionsof temp, cleaner attention and liquid/ solid interface is called dissolution. A standard paddle outfit described in any of the pharmacopoeia can be used for dissolution testing. When paddle type dissolution outfit is used, it's delicate to perform dissolution study of oral film as they can float above the dissolution medium. Selection of the dissolution media depends on the Gomorrah conditions and the topmost cure of medicine. During

dissolution study, the temperature of the medium should be maintained at 37 ±0.50 C and rpm at 50.

### 7. Stability Studies[30- 31]

Stability testing of the set expression is substantially ready to check whether it's a stable product or not. It's also used for the determination of effect of temperature and moisture on the stability of the medicine for the factual storehouse, originally the expression is wrapped in a adulation paper followed by aluminium counter wrapping over it, also this is weight in an aluminium poke and toast sealed. expression should be stored at 45oC/ 75 RH for 3 months. Through the time of stability studies, trio samples are taken at three slice intervals i.e. 0, 1 and 3 month and flicks should be estimated for physical changes and medicine content.

## CONCLUSION

CONCLUSION lately FDF has gained fashionability as lozenge form and is most respectable and accurate oral lozenge form which bypass the hepatic system and show further remedial response. The pharmaceutical companies prefer this lozenge form due to both patient compliance (especially pediatric and senior) as well as artificial adequacy. They combine the lesser stability of a solid lozenge form and the good connection of a liquid. Oral flicks can replace theover-the counter medicine, general and brand name from request due to lower cost and consumer preference. This technology is a good tool for product life cycle operation for adding the patent life of being products. OFDFs are also having great eventuality of delivering the medicinal agent systemically as well locally and have several advantages over numerous lozenge forms indeed over the fast disintegrating tablets. This explains the expansive exploration laboriously going on this technology. So this technology is growing in fast pace challenging utmost of the pharmaceutical companies to develop oral flicks for a wide range of active pharmaceutical constituents.

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