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# Preparation and Optimization of Fast Dissolving HPMC/PVA Blended films of Loperamide Hydrochloride

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## Abstract

Discovery of new chemical entities is a multifaceted, costly and time consuming process, so recent trends are shifting towards design and development of innovative drug delivery systems for already existing drugs. Recently fast dissolving oral films have been introduced in the market that gained the interest of large number of pharmaceutical companies due to their tremendous advantages such as easy administration, better patient compliance, rapid drug absorption and rapid onset of action with instant bioavailability, over other conventional oral dosage forms. Apart from these benefits, fast dissolving oral films can be used in pediatric, geriatric and bed ridden patients who find difficulty in swallowing a tablet or capsule. Initially fast dissolving oral films of breath strips, confectionery and oral care preparations were prepared but now it has become a novel and widely accepted technology for delivering OTC and prescription medication too.

Fast dissolving films are gaining interest as an alternative to fast dissolving tablets. The films are designed to dissolve upon contact with a wet surface, such as the tongue, within a few seconds, meaning the consumer can take the product without need for additional liquid. This convenience provides both a marketing advantage and increased patient compliance. As the drug is directly absorbed into systemic circulation, degradation in gastrointestinal tract and first pass effect can be avoided. The Loperamide hydrochloride mouth dissolving film is prepared by using solvent casting method. The ingredient used for formulation Loperamide hydrochloride as a Anti-Diarrheal, HPMC-E50, HPMC-E15-LV and PVA as film forming polymer, propylene glycol as a plasticizer, Sodium starch glycolate (2-8%) as super disintegrant, lemon oil (2-5%) as a flavoring agent, citric acid (2-6%) as a Saliva Stimulating Agent, methylparaben (0.015%) as a preservative.

Film former polymers were selected as independent variables & tensile strength, disintegration time & percentage drug dissolution was selected as a response variable. The formulations were evaluated based on uniformity of mass, thickness, percent drug content, folding endurance, surface pH, moisture uptake, percentage swelling, percentage elongation, tensile strength, in vitro disintegration time, in vitro percentage drug dissolution. The drug Loperamide found to be feasible to develop into Fast mouth dissolving films. The method solvent casting adopted for the formulation of Loperamide oral films is convenient and economical. The super disintegrants employed in this work found it appreciable. The drug-excipient compatibility by FT-IR studies revealed no physicochemical interaction. The oral films obtained found clear, enough physical strength and showed a reasonable degree of disintegration time. The in vitro dissolution studies of all the formulations in contrast to pure drugs showed a better release profile. From the observations of evaluation results, it was concluded that film formulation F7 containing blend of HPMC E15 and PVA film formers is found to be the best formulation among the all other formulations.

**Keywords:** Loperamide hydrochloride, HPMC (Hydroxy Propyl Methyl Cellulose) E5, HPMC E50, PVA (Polyvinyl alcohol), Solvent casting method, FDF (Fast Dissolving Film).

## Introduction

Many pharmaceutical dosage forms are administered in the form of granules, liquids, powders, pills. Pill design is for swallowing intact or chewing to deliver a precise dosage of medication to patients. The pills, which include tablets and capsules, however, some patient's particularly pediatric and geriatric patients have difficulty swallowing or chewing solid dosage forms. The fear of taking solid tablets and the risk of choking for some patient populations still exist despite their short disintegration time. Hence oral film drug delivery is a better alternative in such cases.[1]

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**Fig. 1: Mouth Dissolving Film**

Pharmaceutical scientists throughout the world are trying to explore thin film as a novel drug delivery tool. It has been identified as an alternative approach to the conventional dosage form. Mouth dissolving films/ Fast dissolving films are the most advanced solid dosage form due to its flexibility. It improves the efficiency of active pharmaceutical ingredients dissolving in short duration oral cavities after contact with saliva as compared to tablets.[2]

Recently fast-dissolving technology has emerged as a new drug delivery system. It provides a very convenient means of taking medications and supplements. These systems disintegrate in a minute. The delivery system consists of thin-film, Which is placed under the patient's tongue or mucosal tissue, instantly wet by saliva, the film is rapidly dissolved then releases the medication for oral mucosal absorption. They undergo disintegration in salivary fluids of oral cavities, where they release the active ingredient.[3]

Loperamide, sold under the brand name Imodium, among others, is a medication used to decrease the frequency of diarrhea. It is often used for this purpose in gastroenteritis, inflammatory bowel disease, and short bowel syndrome. It is not recommended for those with blood in the stool. The medication is taken by mouth. Common side effects include abdominal pain, constipation, sleepiness, vomiting, and a dry mouth. It may increase the risk of toxic megacolons. Loperamide's safety in pregnancy is unclear, but no evidence of harm has been found. It appears to be safe in breastfeeding. It is an opioid with no significant absorption from the gut and does not cross the blood-brain barrier when used at normal doses. It works by slowing the contractions of the intestines.

**Mechanism of Action of Loperamide**:

Loperamide is an opioid -receptor agonist and acts on the μ-opioid receptors in the myenteric plexus of the large intestine; by itself, it does not affect the central nervous system. It works similarly to morphine, by decreasing the activity of the myenteric plexus, which in turn decreases the tone of the longitudinal and circular smooth muscles of the intestinal wall. This increases the number of time substances stay in the intestine, allowing for more water to be absorbed out of the fecal matter. Loperamide also decreases colonic mass movements and suppresses the gastrocolic reflex.

**Ideal characteristics of suitable drug candidate**

- The drug should be stable and soluble in water as well as saliva.
- The drug should be of smaller or moderate molecular weight.
- The drug should have a pleasant taste.
- The dose of the drug should below up to 40 milligrams.
- The drug should have the ability to permeate in oral mucosal tissue.
- It should be partially unionized at the Ph of the oral cavity.
- It should be non-toxic, biodegradable.
- It should have sufficient drug loading capacity.
- It should exhibit low sensitivity to environmental conditions such as temperature and humidity

**Dose calculation of Loperamide Hydrochloride for mold**

- Area of mold: 12×2 cm
- Area of film is 4 cm2 : 2×2 cm
- Total number of the film in each mold: 24/4= 6
- One film contains 2 mg of the drug, so 6 films contain 12 mg of the drug.
- So one mold contains 12 mg of the drug.

## Material and Methods

**Solvent Casting Method**

Among several techniques of film manufacturing, solvent casting is feasible, preferable, and undoubtedly a widely used method mainly due to the straightforward manufacturing process and low cost of processing. The first solvent system selection is done. After the selection of the solvent system, polymeric solution or suspension is prepared. Then the casting of the polymeric solution is done. Casted solution or suspension is dried in a hot air oven at 40-50 °C. After the

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complete drying of the film, it is cut into suitable shapes and sizes depending upon the required dosage of the formed strip. In the majority of the cases, the strips are rolled and stored for a certain time before cutting, which is known as 'roll stock' in an industry. The prepared film is packed into a suitable container.[2]

**Table 1. Composition of fast mouth dissolving film formulation of Loperamide Hydrochloride.**

| S/No. | Ingredients | Formulation code | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
| 1 | Loperamide Hydrochloride(mg) | 12 | 12 | 12 | 12 | 12 | 12 | 12 | 12 | 12 |
| 2 | HPMC E 15(mg) | 100 | 200 | - | - | - | - | 50 | 100 | 50 |
| 3 | HPMC E 50(mg) | - | - | 100 | 200 | - | - | - | - | - |
| 4 | PVA(mg) | - | - | - | - | 100 | 200 | 50 | 50 | 100 |
| 5 | Sodium starch glycolate(mg) | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| 6 | Aspartame(mg) | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| 7 | Propylene glycol(ml) | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| 8 | Citric acid(mg) | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| 9 | Menthol(ml) | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 10 | Distilled water(ml) | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 |

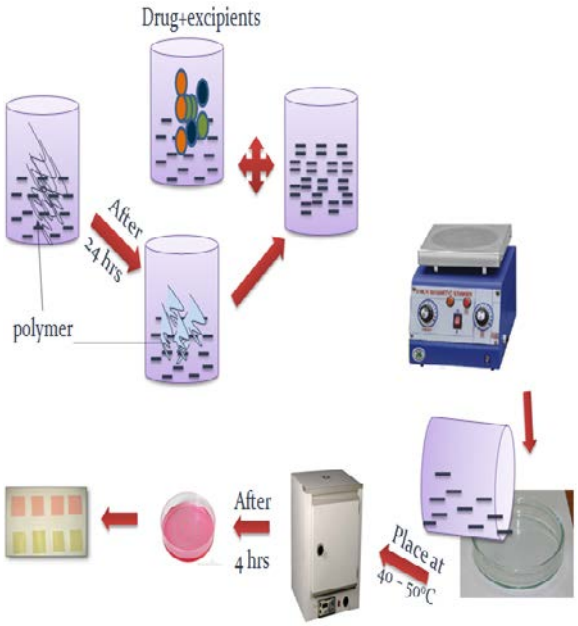


**Fig. 2: Preparation of film**

**FTIR Analysis:** FTIR analysis is done to study the incompatibility of drugs. FTIR spectrum of Loperamide hydrochloride, HPMC-E5-LV, physical mixture of Loperamide hydrochloride with HPMC-E5-LV was recorded by using FTIR spectrophotometer.[3]

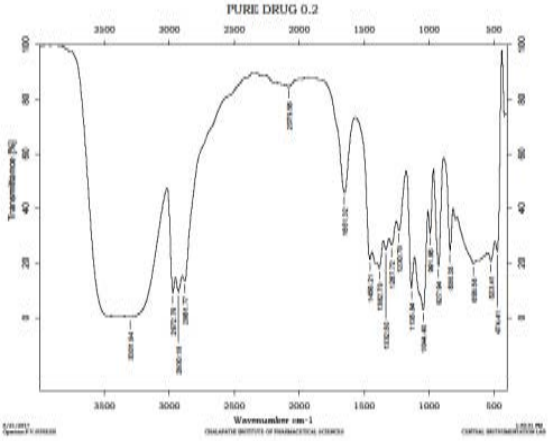


**Fig. 3: FT-IR of Loperamide Hydrochloride**

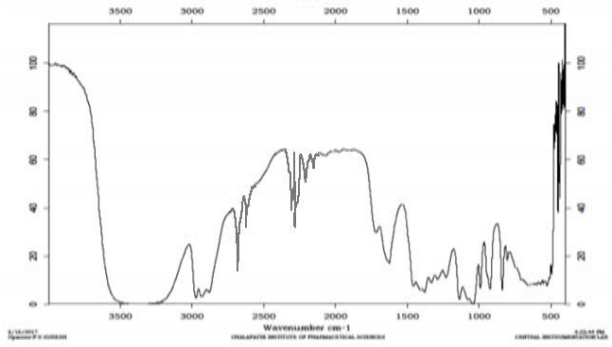

**Fig. 4: FT-IR spectrum of F7 Loperamide Hydrochloride film containing HPMC-E5 and PVA polymers**

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**UV Spectral Analysis**

In this study, the polymers used were blended with the drug. The blend was dissolved in phosphate buffer pH 6.8, filtered, and analyzed using a UV spectrophotometer. The UV spectrum obtained was compared with the UV spectrum of the pure drug.[4]

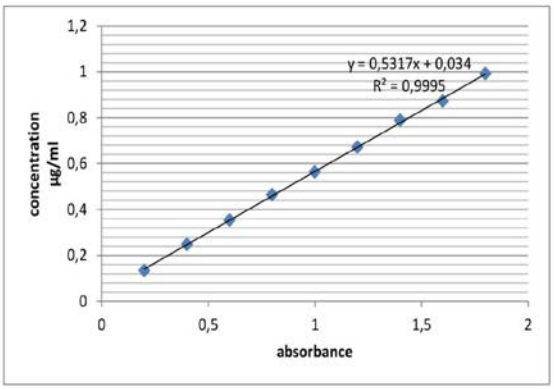


**Fig. 5: Standard calibration curve of Loperamide Hydrochloride in 0.01 N HCL at 214nm.**

**Weight variation test**

A random study of films is performed, from each formulation batch. The mean weight of films as well as the mean deviation of films is calculated and recorded [1].

**Thickness**

Methods like dial gauge or vernier calipers or screw gauge or microscope were used to measure the thickness. Thickness at different points is measured to find out the average thickness of the film. By using a micrometer screw gauge the thickness was measured as after making sure that pointer was set to zero, then the film was held on the anvil and the reading on the dial was noted in triplicate and average was recorded. [1, 2].

**Folding endurance**

The number of folds required to form visible cracks is expressed as folding endurance. The folding is performed at the same place for a number of times that is 300 in some cases, the number of folds required to form cracks gives the value of folding endurance.[1]

**Drug uniformity**

This test is performed to find out whether there is a drug uniformity in all the films that are produced; it is determined by any selected assay method described for that particular API in any of the standard pharmacopeias. Content uniformity is determined by estimating the API content in individual strips. The limit of content uniformity is 85-115%. In the case of Loperamide, each film is dissolved in 50 ml of the volumetric flask containing methanol. Which is later filtered through what Mann filter paper No.41.Aliquot of 1ml of filter solution taken into 25ml of volumetric flask made up to 25 ml with 6.Phosphate buffer. The solution is analyzed in the U.V spectrophotometer at 223nm against the phosphate buffer pH 6.8 solution as blank. [5,1]

**Surface PH**

Surface pH of the film was determined to investigate side effects. The acidic or alkaline pH causes irritation to oral mucosa hence it is necessary that the film has the surface pH close to neutral. The film allowed for swelling in the petri dish at room temperature for a few seconds, In that 1ml of the solution was placed under the digital pH meter to find out the surface pH of the film. [1.]

**Tensile strength**

The stress required to break the film is considered as tensile strength.It is calculated by the load at rupture divided by the cross-sectional area of the film as given below.[22]

$$\text{Tensile strength} = \frac{\text{Load at failure}}{\text{Film thickness} \times \text{Film width}} \times 100$$

A film which is free from any physical imperfections is to be selected to get proper results. The film is placed between two clamps at a distance of 10mm, The film was pulled at the rate of 5mm to 10mm/min. The whole experiment is repeated three times. [3]

**In-vitro disintegration test**

Disintegration time was measured by inserting the film strip ($2\times2cm^2$) in a Petri dish of 6cm in diameter containing 6ml of phosphate buffer of pH 6.8. Time was recorded required to complete disintegration of the film. In triplicate, the evaluations were carried out and an average of it was reported.[27, 28]

**In-vitro dissolution study**

In-vitro dissolution studies were performed in a beaker containing 30ml phosphate buffer (pH 6.8) with 1% w/v SLS at 37 ± 0.50°C. Beaker placed on a magnetic stirrer with incorporating magnetic bead inside, for continuous stirring purpose. 1ml sample aliquot was withdrawn at different time intervals and replaced with the same fresh media. Samples were filtered and diluted with phosphate

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buff er (pH 6.8) and analyzed by using a UV spectrophotometer. The in-vitro release data obtained were subjected to a zero-order and first order kinetics to understand the release profile and release mechanism [29, 30].

**Swelling test**

Take a Petri dish containing 40 ml of 6.8 phosphate buffer, then submerge the wire mesh into it. Then the increase in weight of film was determined at regular time intervals till the constant weight is obtained. The hydration ratio of the film was calculated by using the following formula:

$$\text{Swelling index (SI)} = \frac{(Wt - Wo)}{Wo}$$

Where,

Wt=weight of film at 't' time.

Wo=weight of film at '0' time.

**Percent elongation:**

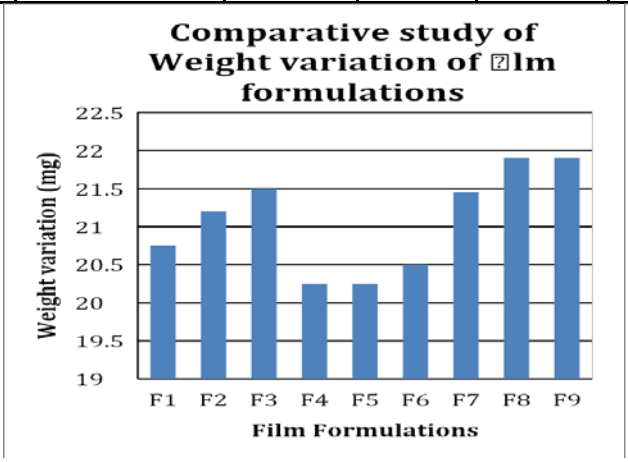
After exerting stress on the film, the film stretches which is referred to as a strain. The strain is defined as change in length of film divided by its original/initial length of the film which is used. Percent elongation is related quantitatively to the amount of plasticizer used while formulating the film. More amount of plasticizer in the preparation results in the film which has more elongation properties. It is determined by the following Formula:

$$\text{Percentage elongation} = \frac{\text{change in length}}{\text{Initial length}} \times 100$$

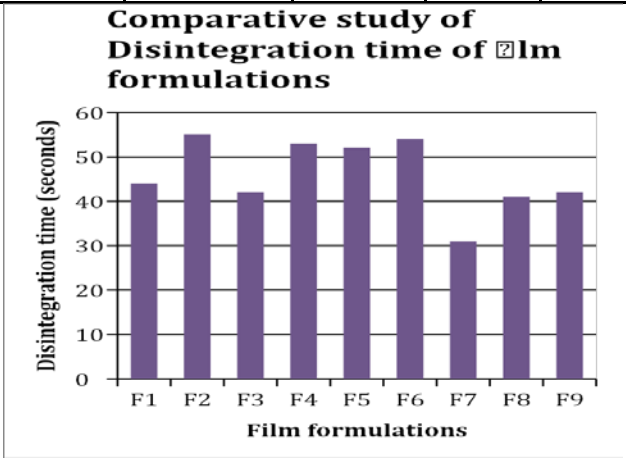
## Results and Discussion

**Table 2: Evaluation of Mouth Dissolving Film**

| S/No | Test | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Weight variation (mg) | 20.75±0.20 | 21.20± 0.85 | 21.50± 0.58 | 21.70± 0.50 | 20.25± 0.75 | 20.50± 0.50 | 21.45± 0.50 | 21.9± 0.55 | 21.9± 0.35 |
| 2 | Thickness | 0.040±0.010 | 0.043± 0.015 | 0.044±0.018 | 0.047± 0.008 | 0.040± 0.007 | 0.042± 0.025 | 0.044± 0.010 | 0.043± 0.020 | 0.042± 0.015 |
| 3 | Folding endurance | 185 | 215 | 230 | 240 | 210 | 220 | 227 | 232 | 222 |
| 4 | Tensile strength | 1.2± 7.5 | 1.35± 5.0 | 1.5± 4.5 | 1.6± 4.0 | 1.55± 3.75 | 1.6± 2.5 | 1.7± 3.5 | 1.6± 2.6 | 1.4± 4.5 |
| 5 | Disintegration time (Seconds) | 44 ±1.12 | 55± 0.63 | 42± 1.25 | 53± 2.5 | 52± 7.5 | 54± 7.5 | 31± 1.8 | 41±0.5 | 42 ± 2.2 |
| 6 | Surface PH | 6.65± 0.48 | 6.78± 0.54 | 6.90± 0.56 | 6.78±0.52 | 6.70± 0.50 | 6.75± 0.52 | 6.68± 0.48 | 7.20±0.50 | 6.60± 0.52 |
| 7 | Drug content (%) | 97.9± 1.1 | 98.9± 2.2 | 98.7± 1.4 | 99.2±2.1 | 98.5± 1.3 | 99.4± 2.1 | 99.8± 1.4 | 97.6±1.6 | 98.6±. 6 |




(A)




(B)

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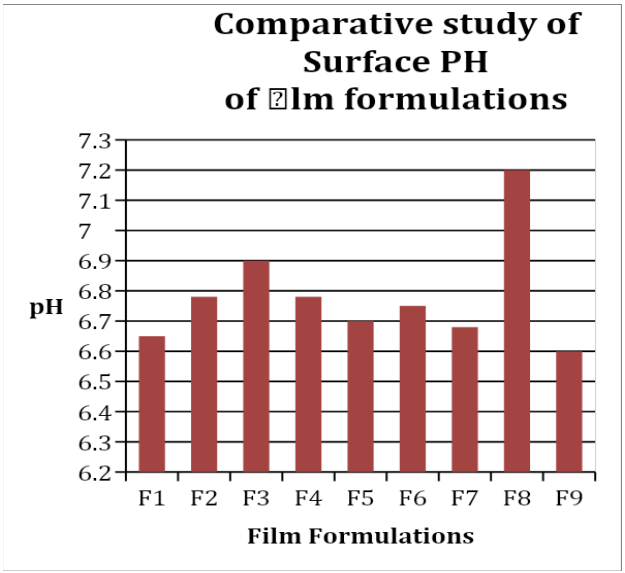


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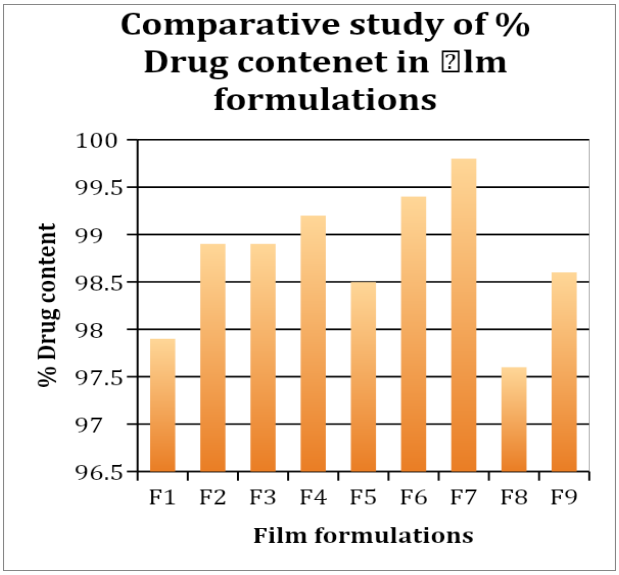


(D)

**Fig. 6: Graphical representation of comparative study of mouth dissolving Loperamide Hydrochloride film formulations of (A) Weight variation (B) Disintegration time (C) Surface pH (D) Percent Drug content**

**Table 3: *In-vitro* Dissolution Profile for F1-F9 Fast Mouth Dissolving Film of Loperamide Hydrochloride**

| Sr. No. | | % Drug Release | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Time (Sec) | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 5 | 5.5 | 2.1 | 6.7 | 3.2 | 5.6 | 2.2 | 7.1 | 6.9 | 6.6 |
| 3 | 10 | 11.2 | 5.2 | 14.9 | 6.6 | 11.4 | 4.9 | 19.2 | 12.8 | 12.2 |
| 4 | 15 | 22.9 | 11.6 | 21.4 | 14.1 | 15.7 | 10.1 | 32.1 | 22.4 | 16.9 |
| 5 | 20 | 39.7 | 18.3 | 39.1 | 21.3 | 20.9 | 17.9 | 50.8 | 33.2 | 22.2 |
| 6 | 25 | 49.2 | 25.3 | 46.2 | 35.3 | 25.8 | 27.4 | 71.1 | 47.8 | 30.4 |
| 7 | 30 | 62.2 | 38.7 | 67.5 | 48.7 | 43.1 | 34.9 | 89.4 | 69.6 | 44.8 |
| 8 | 35 | 78.8 | 48.2 | 81.9 | 58.2 | 64.1 | 46.8 | 94.2 | 80.7 | 67 |
| 9 | 40 | 88.2 | 66.3 | 89.9 | 74.4 | 82.8 | 69.8 | 96.3 | 88.3 | 81.5 |
| 10 | 45 | 96.4 | 78 | 94.2 | 83.4 | 87.4 | 76.3 | 98.7 | 93.8 | 85.3 |
| 11 | 50 | 99.2 | 84 | 97.6 | 91.2 | 93.3 | 88.8 | 99.6 | 96.6 | 89.5 |
| 12 | 55 | 99.6 | 93.6 | 98.8 | 93.3 | 96.4 | 97.2 | 99.8 | 98.2 | 94.7 |
| 13 | 60 | 99.8 | 95.5 | 99.6 | 97.6 | 99.6 | 99.4 | 99.8 | 99.2 | 97.2 |

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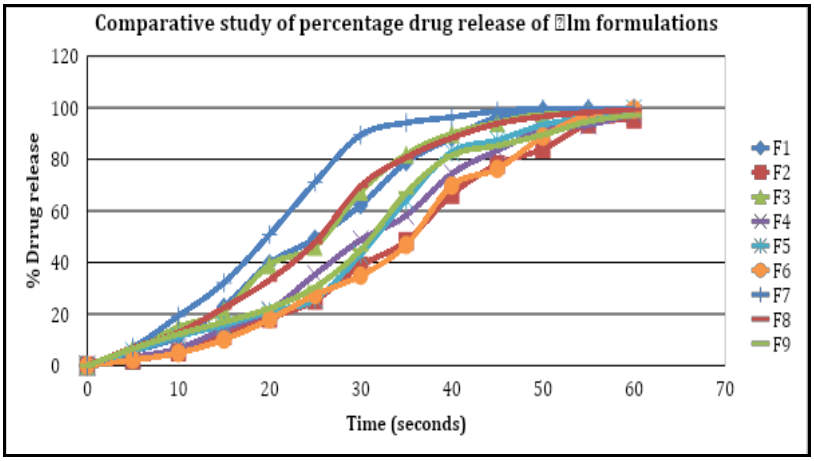


**Fig. 7: Graphical representation of comparative study of percent drug release of mouth dissolving Loperamide Hydrochloride film formulations**

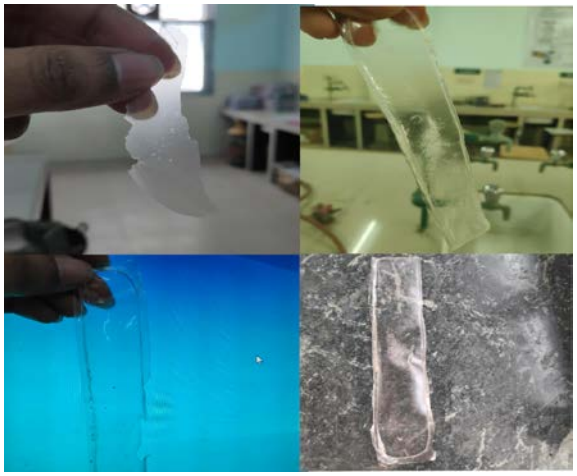

**Fig. 8: Mouth Dissolving Film**

In the preliminary phase, attention was given to select a proper concentration of film-forming agent and plasticizers to develop a successful FDF. These selections were used to impart suitable ductility, mechanical strength, and flexibility to the films under different types of mechanical stress. The combination of HPMC-E15 and Polyvinyl Alcohol was observed as a film-forming agent due to its excellent film-forming properties. Propylene Glycol was selected as a plasticizer for HPMC and PVA blended FDF as it developed clear homogenous preparation. The FDF prepared by using a combination of HPMC-E15 and Polyvinyl Alcohol found to be flexible with good mechanical strength and high disintegration property leads to Fast bioavailability of Loperamide.

Preliminary trials indicated 50% w/v levels of HPMC-E15 and PVA in the film casting solution showed fast drying and uniform texture without air globules. Levels of other excipients were fixed for all formulations. The surface pH results indicated that the film was acceptable, compatible and non irritating. Folding endurance gives an indication of the brittleness of the film. In-vitro disintegration study represents an indication of onset of action of the drug.

## Conclusion

The aim of the present research work was to formulate FDF and evaluate different formulations of fast dissolving films of anti-amoebic drug to achieve faster drug release to control diarrhea. The fast-dissolving films of anti-amoebic drugs were found to be a better option in control of diarrhea by way of fast onset of action for patient convenience and compliance.

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