FORMULATION AND EVALUATION OF FAST DISSOLVING ORAL FILM CONTAINING EXTRACTS OF *OCIMUM SANCTUM* AND *GLYCYRRHIZA GLABRA* TO TREAT MOUTH ULCER

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Abstract

This research focused on the formulation and evaluation of fast dissolving oral film containing extracts of ocimum sanctum and glycyrrhiza glabra to treat mouth ulcer. The extracts of ocimum sanctum and glycyrrhiza glabra was formulated as films by solvent casting method using various polymers viz. HPMC E5, HPMC E15, Sodium alginate and Polyvinyl alcohol. Propylene glycol was used to create the films as a plasticizer, sodium starch glycolate as a super disintegrate, and honey as a sweentner. Furthermore, the films are evaluated for thickness, weight variation, folding endurance, surface pH, percentage moisture uptake, percentage moisture loss, disintegration time, in vitro drug release study and stability study. The extracts of both ocimum sanctum and glycyrrhiza glabra was collected by maceration process. The phytoconstituents study of the extract revealed the presence of alkaloids, flavonoids, tannins, steroids and saponins. The extracts were formulated into films by solvent casting method with various polymers such as HPMC E5, HPMC E15, sodium alginate and polyvinyl alcohol. The idea of a quick-dissolving dose form has gained popularity as a new delivery method. By reducing dosing frequency, this approach will give better bioavailability and optimal stability. It will also avoid first pass metabolism of the medicines. From the above results it is evident that the developed formulation can be an innovative dosage form to improve the drug delivery, onset of action. Additionally, it will increase patient compliance.

Keywords: *Ocimum sanctum*, *Glycyrrhiza glabra*, Extracts, Oral films, Mouth ulcer, Solvent casting.

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1. Introduction

oral route of administration is regarded as the most prevalent route for pharmacological systemic activities because of its versatility, convenience of use, patient compliance, and painlessness[1]. The demand for patient comfort is constantly rising. Because of its low cost of treatment and ease of administration, the oral route is the most popular method for administering therapeutic drugs. This increases patient compliance[2]**.** Fast-dissolving films that, when applied to the tongue or oral mucosa of a patient, breakdown and disintegrate in a matter of seconds, releasing the medication for oromucosal or intragastric absorption. As a result, they provide a variety of benefits over conventional solid dose forms, such as tablets and capsules, by removing swallowing issues and preserving water, which increases patient compliance. The wide surface area of the film, which is exposed to the wet oral area and causes speedy disintegration and dissolution in the oral cavity in seconds, is what causes the rapid release of the medicine from the films[3]. A mouth ulcer is a break or rupture in the mucous membrane that lines the interior of the mouth. It is usually yellow or white in colour and resembles a depression in the mouth caused by the mucous membrane[4]. Ulcer refers to a rupture in the continuity of the epithelium caused by molecular necrosis. Ulcers most usually occur in the oral region, for which the patient seeks medical/dental attention. The most common symptoms are redness, a burning feeling, and/or pain. They can appear in any section of the oral cavity, but they become uncomfortable if they appear in the moveable area. Mouth ulcers are quite prevalent and usually result from trauma, such as ill-fitting dentures, shattered teeth, or fillings[5].

1.1Ocimum sanctum

Tulsi, or *Ocimum sanctum*, is a member of the Lamiaceae plant family. Because of its numerous medical characteristics, it has made significant contributions to science since ancient times as well as modern study. Because of its lipoxygenase inhibitory, histamine antagonistic, and antisecretory properties, the fixed oil demonstrated considerable antiulcer action. Ocimum sanctum has long been used in the Ayurvedic and Siddha Systems of Medicine for the prevention and treatment of numerous illnesses and common complaints, including the common cold, headache, cough, flu, earache, fever, sore throat, bronchitis, asthma, hepatic diseases, malaria fever, migraine headaches, fatigue, skin conditions, wounds, and insomnia.. The leaves are beneficial to nerves and memory. Tulsi leaves can be chewed to treat oral infections and ulcers[6]. Ayurvedic remedies for colds, headaches, stomach issues, inflammation, heart disease, various poisonings, and malaria include ocimum sanctum (OS) or tulsi extracts. Ocimum sanctum also has antiulcer efficacy when studied pharmacologically[7].

1.2Glycyrrhiza glabra

Leguminoceae member Glycyrrhiza glabra is well known for its expectorant and demulcent properties. Additionally useful for treating stomatitis-related mouth ulcer discomfort and inflammation is liquorice. To lessen the size of mouth ulcers caused by stomatitis and hasten healing, licorice root extract can be used. Clinical studies have shown that Glycyrrhiza possesses the following pharmaceutical properties, including anti-ulcer, anti-asthmatic, anti-diuretic, and anti-hepatotoxic properties[8]. Glycyrrhiza glabra has a plethora of potential advantages that can be turned into pharmaceutical usefulness. A variety of medicines and therapies remain in clinical trials to treat cancer, asthma, ulcers, diabetes, obesity, and other diseases. Glycyrrhiza glabra can assist us in all of them[9].

2. Material And Methods

2.1 Materials

The leaves of the plant Ocimum sanctum and the roots of Glycyrrhiza glabra were collected directly from the local market in Pandharpur, Maharastra. HPMC E5, HPMC E15, PVA, sodium alginate, propylene glycol, and sodium starch glycolate were procured from LOBA Chemie, Mumbai. Honey was purchased from the local market. All ingredients were pure and analytical-grade.

2.2 Methods

2.2.1 Extraction of Ocimum sanctum

The plants were obtained green and fresh of Ocimum sanctum. The leaves were cleansed with distilled water before being carefully separated from the branches. The separated leaves were weighed again and net weight was allowed for air drying under the room temperature to avoid destruction of active group in the leaves. The dried leaves were ground into very little pieces by hand. The crushed raw material was macerated with absolute ethanol in a round bottom flask, sealed with aluminium foil, and stored in the dark for seven days. The maceration extract residue and maceration filtrate were separated and retained inside the cabinet for further screening[10].

2.2.2 Extraction of Glycyrrhiza glabra

The dried roots of liquorice were collected and then dried powder of roots was used for extraction. In case of liquorice roots, the solvent used was ethanol and water (30:70 v/v) for liquorice root extract. For about 60 minutes, the root extract was immersed in this extraction solvent. The residue of maceration extract and filtrate of maceration were separated and being kept inside the cabinet for further screening[11].

2.2.3 Phytochemical screening of the extract

The extracts were tested for the presence of various active chemical constituents namely alkaloids, flavonoids, glycosides, tannins, saponins, steroids[12,13]. The results of the phytochemical study were given in table 2.

2.2.4 Preparation of Fast Dissolving Oral Films

Eight formulas with different composition as shown in Table.no 1. were formulated by using solvent casting method. Polymer soluton was prepared by using polymers such as HPMC E5, HPMC E15, PVA and Sodium Alginate with countinuous stirring using magnetic stirrer. Then after, resultant solution was kept for 3-6 hrs to expel the air bubbles within the solution. In separate beaker precisely weighed amount of herbal drugs (ocimum sanctum, glycyrrhiza glabra), plasticizer (propylene glycol) and other excipients (SSG,honey) were dissolved in distilled water. The drug-plasticizer and all excipient solutions were added and properly mixed after the polymer had been fully hydrated with water. The volume was then finished with distilled water up to 10 ml. The resultant solution was poured into petri dish with defined surafce area then left to dry using an oven supplying 40^0c. The film was carefully taken from the petri dish, checked for flaws, and trimmed to the desired size (2 x 2 cm^2) per strip. The resultant films were stored into aluminium foil[14].

Table 1. Formulation table of Fast Dissolving Oral Films

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8
Ocimum sanctum extract(mg)	10	10	10	10	10	10	10	10
Glycyrrhiza glabra extract(mg)	10	10	10	10	10	10	10	10
HPMC E5(mg)	20	40	----	----	----	----	----	----
HPMC E15(mg)	----	----	20	40	----	----	----	----
Sodium Alginate(mg	----	----	----	----	20	40	----	----
Polyvinyl Alcohol(ml)	----	----	----	----	----	----	2	4
Propylene Glycol(ml)	2	2	2	2	2	2	2	2
Sodium Starch Glycolate(mg)	3	3	3	3	3	3	3	3
Honey(ml)	2	2	2	2	2	2	2	2
Water(ml)	10	10	10	10	10	10	10	10

2.2.5 Evaluations tests-

2.2.5.1 Morphological properties

Visual observations were made of the morphological characteristics, such as the homogeneous nature of the films, colour, transparency, and surface texture. All the formulations were stored at room temperature 25±30 °C in air-tight containers.

2.2.5.2 Weight variation

Films can be weighed on an analytical balance to determine the average weight for each film. It is helpful in ensuring that a film includes the appropriate amount of excipients and medication.

2.2.5.3 Uniformity of film thickness

The thickness of the film was measured using a screw gauge with high accuracy. The measurements were taken from various strategic locations i.e. the center and four corners of the film[15].

2.2.5.4 Folding Endurance

The folding endurance of the film was evaluated by folding a tiny strip of film (2x2cm^2) repeatedly until it broke. The number of times that the film could be folded at the same place without breaking gives the value of folding endurance[16].

2.2.5.5 Percentage moisture loss

Percentage moisture loss test was carried to check the integrity of films in dry condition. Three films were weighed accurately and kept in desiccator containing fused anhydrous Calcium chloride. The films were removed and weighed 72 hours later. Percentage moisture loss was calculated using below mentioned formula[17].

Percentage moisture loss = ((intial weight – final weight) / intial weight) x 100

2.2.5.6 Percentage moisture uptake

The films were placed in the dessicator containing saturated solution of potassium chloride. After 3 days the films were taken and weighed the percentage moisture absorption of the films was

found. The percentage moisture uptake calculated by mentioned formula[18].
Percentage moisture uptake = ((intial weight – final weight) / intial weight) x 100

2.2.5.7 Surface pH
The film kept in a Petri dish was moistened with 5 ml of distilled water and kept for a few minutes. The pH was noted after bringing the electrode of the pH meter in contact with the surface of the formulation and allowing equilibration for 1 min[19].

2.2.5.8 Disintegration time
In vitro disintegration time was determined visually in a glass beaker. 25 ml distilled water maintained at 37°C is taken in the beaker and the OFDF strip was added. The time taken for the film to disintegrate is noted[20].

2.2.5.9 Content Uniformity
The films were tested for content uniformity. Films of 2 cm^2 was cut, placed in 100 ml volumetric flask and dissolved in methanol, volume was made up to 100 ml with water. Solution was filtered using wattman filter paper. The content uniformity standards are met if the amount of active component in each film is between 90 and 110%[21].

2.2.5.10 In Vitro Dissolution studies
The release rate of the fastdissolving films was determined by the help of USP Dissolution Test Apparatus-II. The release test was carried out in 900 ml of phosphate buffer, pH 6.8, at 37±5 °C and 50 rpm. Aliquot of the solution was collected and replaced with fresh medium at every 2 minutes to maintain the sink conditions. Solution was filtered using wattman filter paper. Absorbance of the filtrate was measured at 280nm (ocimum sanctum) and 282nm (glycyrrhiza glabra) respectively using double beam U.V. Spectrophotometer[22].

2.2.5.11 Stability studies
The accelerated stability was checked by keeping the film at room temperature up to 30 days. Samples were evaluated for assay and drug release[23].

3. Results and Discussion

3.1 Phytochemical constitutents data of herbal drugs

The results of the alkaloids, flavonoids, glycosides, tannins, saponins, steroids preliminary phytochemical screening revealed the presence of chemical constitutes present in herbal drugs. The data were given in table 2.

Table 2. Phytochemical constitutents data of herbal drugs

Sr.no	Phytochemical constituents	Ocimum sanctum	Glycyrrhiza glabra
1.	Alkaloids	+	+
2.	Flavonoids	+	+
3.	Glycosides	-	+
4.	Tannins	+	+
5.	Saponins	+	+
6.	Steroids	-	+

Where as (+) present, (-) absent

3.2 IR Spectra of herbal drugs

The compatibility of an extract with the polymers was studied by using IR spectroscopic methods. The spectra were shown in Fig.no 1 and 2. The spectra showed that formulations included peaks that were characteristic of pure extracts.

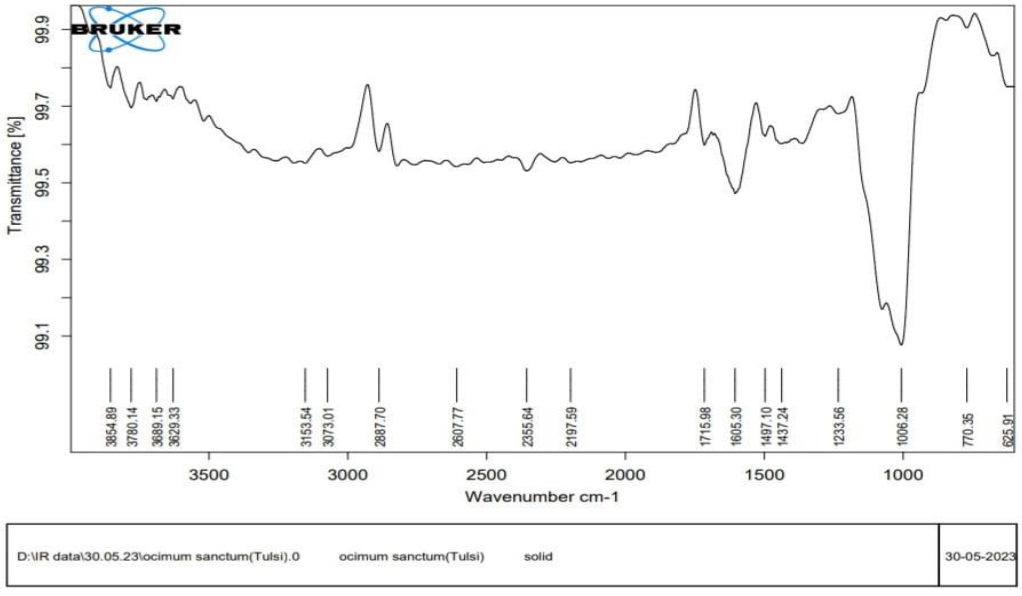

Figure 1. IR Spectra of Ocimum sanctum

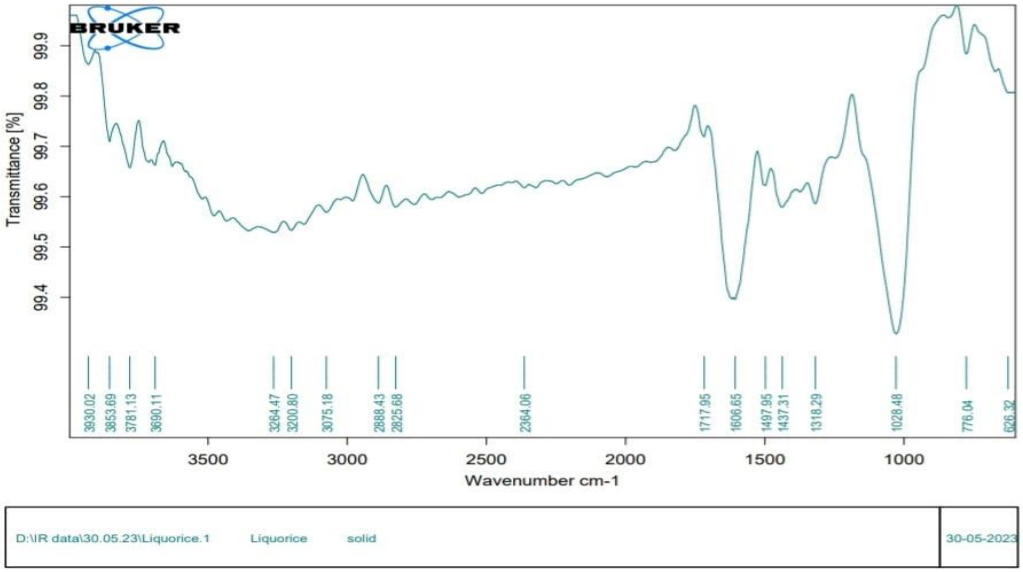

Figure 2. IR Spectra of Glycyrrhiza glabra

3.3 Morphological properties of Fast Dissolving Oral Films

The prepared films were then evaluated on the basis of certain morphological and physicochemical parameters. All formulated films should uniform thickness and were transparent in nature and had smooth surfaces. The visual appearance data of formulated films were given in Table.no 3.

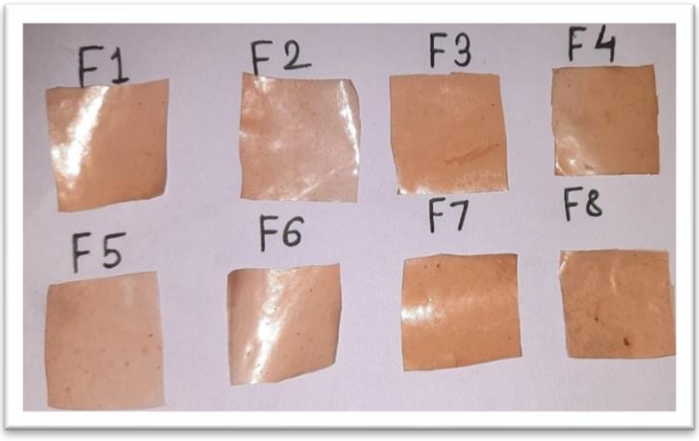

Figure 3. Formulated Fast Dissolving Oral Film

Table 3. Morphological properties of Fast Dissolving Oral Films

Formulation No.	Visual Appearance	Surface	Film forming capacity	Tackiness
F1	Transparrant, Brown	Smooth	Good	Non-tacky
F2	Transparrant, Brown	Smooth	Good	Non-tacky
F3	Transparrant, Brown	Smooth	Good	Non-tacky
F4	Transparrant, Brown	Smooth	Good	Non-tacky
F5	Transparrant, Brown	Smooth	Good	Non-tacky
F6	Transparrant, Brown	Smooth	Good	Non-tacky
F7	Transparrant, Brown	Smooth	Good	Non-tacky
F8	Transparrant, Brown	Smooth	Good	Non-tacky

3.4 Physico-mechanical properties of Fast Dissolving Oral Films

The thickness of the oral fast dissolving films was measured by using a screw gauge and was varied from 0.29 to 0.43 mm. The weight variations of films was observed between 40.02 to 49.34 mg. %. Folding endurance is an indication of brittleness of the film. The folding endurance values of films were between 190-285, it shows that films were non brittle. The surface pH of all the formulations

was in the range of 5.13 ± 0.13 to 6.78 ± 0.10, these values were nearer to pH of the saliva. It suggested that the films were not irritating the mouth mucosa. The result was showed in Table.no 4.

Table 4. Physico-mechanical properties of Fast Dissolving Oral Films

Formulation No.	Weight Variation (mg)	Thickness (mm)	Folding Endurance	Surface pH
F1	40.02	0.32	200	6.24 ± 0.15
F2	42.34	0.37	190	6.50 ± 0.11
F3	41.59	0.41	253	5.13 ± 0.13
F4	44.12	0.39	264	6.58 ± 0.15
F5	42.14	0.37	273	6.70 ± 0.11
F6	42.02	0.29	267	5.44 ± 0.17
F7	46.05	0.38	279	5.32 ± 0.11
F8	49.34	0.43	285	6.78 ± 0.10

3.5 Physico-chemical properties of Fast Dissolving Oral Films

Percentage moisture uptake by the films gives information about the stability of the films. The all formulations shows moisture uptake of all formulations was observed less than 5.18%. Percentage moisture loss study shows moisture present in films after drying. The all formulation shows percentage moisture loss was found to be less than 5.65%. The data revealed that all films disintegrated in the range of 3.8-7.3 min. As the polymer concentration increases the thickness, folding endurance and disintegration time of the film also increases. The result was showed in Table. no 5.

Table 5. Physico-chemical properties of Fast Dissolving Oral Films

Formulation No.	% Moisture uptake	% Moisture loss	Disintegration time (min)	Drug content
F1	0.19 ± 0.04	2.09 ± 0.05	4.6	85.24%
F2	0.25 ± 0.01	5.24 ± 0.04	5.1	87.42%
F3	0.072 ± 0.01	5.65 ± 0.07	4.4	83.54%
F4	2.03 ± 0.02	3.51 ± 0.05	6.1	92.05%
F5	0.071 ± 0.01	0.09 ± 0.01	3.8	94.58%
F6	0.42 ± 0.04	4.16 ± 0.03	5.7	90.67%
F7	5.18 ± 0.07	1.43 ± 0.09	6.9	89.34%
F8	0.58 ± 0.05	3.93 ± 0.05	7.3	90.47%

3.6 In Vitro Drug Dissolution Profile of Fast Dissolving Oral Film

The dissolution studies of the formulations from F1 - F8 were carried out to know the in-vitro drug release. The drug release at different time intervals was determined and calculated to know the release at variable concentration of polymer used. The results were converted in form of % drug release. For formulation F7 the dissolution time was 12 min in which 89.97% drug was release. The result was showed in Table.no 6.

Table 6. In Vitro Drug Dissolution Profile of Fast Dissolving Oral Film(F1-F8)

Time (min)	Cumulative percentage drug dissolved (%)							
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**
0	0	0	0	0	0	0	0	0
2	12.34	10.14	28.63	31.43	36.62	42.26	42.30	43.77
4	25.45	29.56	40.17	41.19	51.52	42.87	52.64	53.76
6	45.78	41.89	56.29	51.34	63.49	61.49	67.46	70.49
8	59.54	62.52	67.45	64.29	68.20	69.87	72.06	76.06
10	63.90	71.87	74.19	73.76	71.86	78.30	81.37	83.47
12	75.14	77.29	79.20	81.79	82.72	82.59	89.97	87.23

3.7 Stability studies of Fast Dissolving Oral Films

The formulations were subjected to stablity studies by storing them at room temperature for period of 30 days. The formulations were tested for various parameters after test period. The data revealed that formulations F7 and F8 was stable throughout the period. The stability data were given in table 7.

Table 7. Stability studies of Fast Dissolving Oral Films

Formulations No.	Physical appearance	Tackiness	Film separation	Disintegration time(min)
F7	Good	Non tacky	Separates	6.9
F8	Good	Non tacky	Separates	7.3

The dissolution profile of all the formulations was depicted in Fig.no 4. Among the all formulations F7 batch achieved maximum percentage drug release at the end of 12 minutes. Therefore formulation F7 was the best formulation for Fast dissolving oral film of herbal extracts containing *Ocimum sanctum* and *Glycyrrhiza glabra*. The drug release for the batch F7 was 89.97 % at the end of 12 minutes.

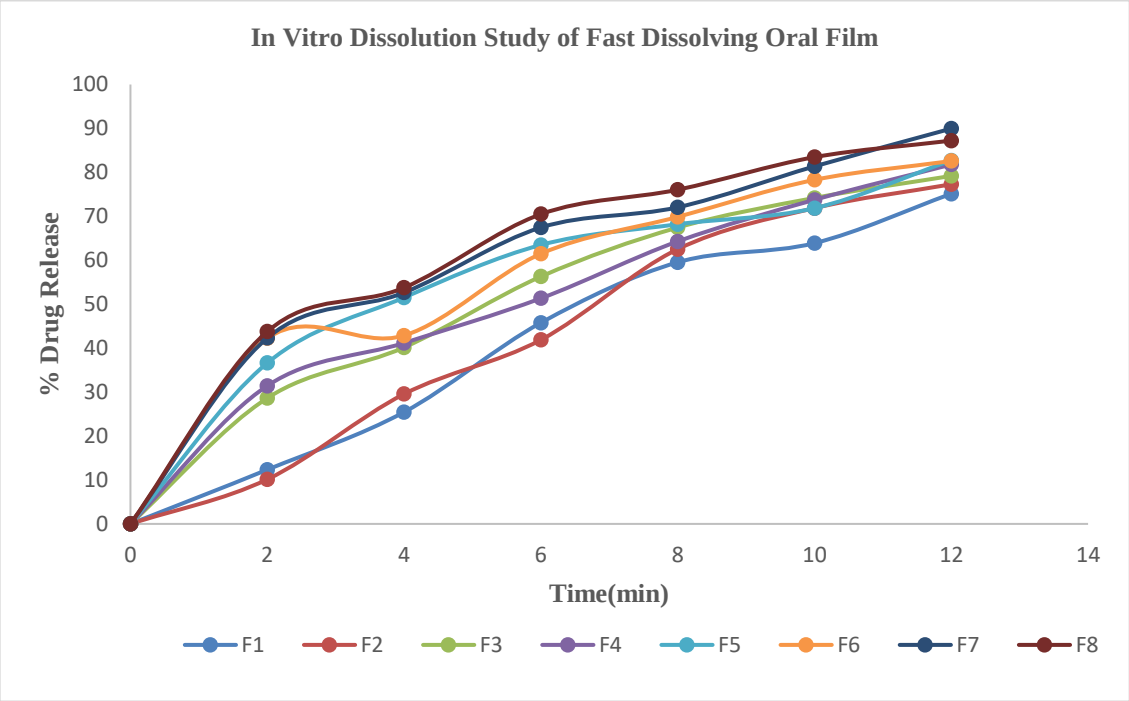

Figure 4. In Vitro Drug Dissolution Profile of Fast Dissolving Oral Film(F1-F8)

4. Summary

Fast-dissolving films that, when applied to the tongue or oral mucosa of a patient, breakdown and disintegrate in a matter of seconds, releasing the medication for oromucosal or intragastric absorption. In this present study herbal fast dissolving oral films prepared for treatment of mouth ulcer. Use of herbal drugs minimizes the side effects which is caused due to synthetic drugs as they absorb from oral mucosa and directly enter in blood circulation. The formulated herbal fast dissolving oral film contain herbal plants extracts of Ocimum sanctum(Tulsi), Glycyrrhiza glabra(Liquorice). These plants posses antiulcer, antimicrobial, anti-inflammatory activity. The herbal films were created using a solvent casting method with a polymer blend of HPMC E5, HPMC E15, Sodium alginate, and PVA. The films were subjected to physical investigatons such as uniformity of weight, thickness measurement, folding endurance, surface pH. Also films were evaluated by using parameters such as % moisture loss, % moisture uptake, disintegration time. These films are economic, convenient and do not show any side effects.

5. Conclusion

The objective of the present study was to formulation and evaluation of fast dissolving oral film containing extracts of *Ocimum sanctum* and *Glycyrrhiza glabra* to treat mouth ulcer. The extracts of both Ocimum sanctum and Glycyrrhiza glabra was collected by maceration process. The phytoconstituents study of the extract revealed the presence of flavonoids, tannins and saponins which have anti-ulcer activity. The extracts were formulated into films by solvent casting method with various polymers such as HPMC E5, HPMC E15, sodium alginate and PVA. The formulated films were subjected to physicochemical evaluation such as thickness, folding endurance, moisture uptake, moisture loss, surface pH and

drug release. All the formulations were good in appearance with smooth texture. The study revealed that out of the ten formulations F7 formulation showed good drug release, good appearance and stability. Based on the study results it can be concluded that *Ocimum sanctum* and *Glycyrrhiza glabra* extracts can be effectively formulated in the form of oral fast films with expected patient compliance.

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