RESEARCH ARTICLE

Development of *Zingiber officinale* in oral dissolving films: Effect of polymers on *in vitro*, *in vivo* parameters and clinical efficacy

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Oral dissolving drug delivery system offers a solution for those patients having difficulty in swallowing tablets/capsules, etc. *Zingiber officinale*, has been used for medicinal purpose since antiquity to treat motion sickness, pregnancy, and cancer-chemotherapy-induced vomiting, mild stomach upset, cough, chronic bronchial problems, and low-grade infections of all kinds and anorexia condition. This work investigates the possibility of developing *Zingiber officinale* oral dissolving films allowing fast, reproducible dissolution in oral cavity; thus bypassing first pass metabolism. The oral dissolving films were prepared by solvent-casting method. Prepared films were evaluated for film-forming properties, physico-mechanical properties, palatability, microbial limit test, accelerated stability studies, and clinical efficacy test. The different polymers such as hydroxypropyl methylcellulose 5cps, maltodextrin, pullulan, and polyvinyl alcohol were explored individually and in combination with each other for the formation of film. Among all polymers, maltodextrin and HPMC 5 cps alone and in combination showed excellent film-forming properties as well as very good physico-mechanical properties. The films resulted into excellent palatability along with least disintegrating time. But at accelerated stability studies, only HPMC 5 cps was found to be stable when compared with other formulations. So, it was concluded that HPMC 5 cps is the best film forming as well as stable polymer with respect to *Zingiber officinale* oral dissolving film.

Key words: *Film-forming polymers, oral thin films, solvent-casting method, Zingiber officinale*

INTRODUCTION

From past one decade, there has been an enhanced demand for more patient-friendly and compliant dosage forms. As a result, the demand for developing new technologies has been increased greatly. Oral-dissolving films (ODF) are the latest development in this field. ODFs are the ultrathin films of postage stamp size with an active agent or active pharmaceutical ingredient and other excipients.[1] These dosage forms can rapidly disintegrate and/or dissolve to release the medicament as soon as they come in contact with saliva thus obviating the need for water during administration, an attribute that makes them highly attractive for pediatric and geriatric patients.[2] ODFs provide accurate dosing in safe and efficacious format, without the need of measuring devices as is the case with liquid oral dosage forms.

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Ginger, rhizome of *Zingiber officinale*, has been used for medicinal purpose since antiquity. In particular, it has been an important plant for the traditional Chinese and Indian pharmacopoeia. Several components of ginger such as 6-gingerol, 6-shogaol and galanolactone have been reported to have anti-5HT$_3$ activity.[3,4] *Zingiber officinale* is used to treat various types of "stomach problems," including motion sickness, morning sickness, upset stomach, gas, and diarrhea. It is also used for treatment of nausea caused by cancer treatment, nausea, and vomiting after surgery, as well as loss of appetite.[5-7] It is also used as a digestive aid for mild stomach upset, cough, chronic bronchial problems, and low-grade infections of all kinds and anorexic conditions. Currently *Zingiber officinale* is marketed as extract (Zinaxin), tincture (Bioforce Jan De Vries), capsule and oil for the oral use. But out of these,

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liquid formulations have the problems such as inaccuracy in dosing, transportation, etc., while the capsules contain powders that contain powders which take time for wetting and, hence, dissolution is slower. Since the main use of ginger is in motion sickness and nausea and vomiting, so it is advisable to formulate it in oral thin films. This dosage form will allow convenient administration even for the patients who are traveling as water is not required for swallowing. During frequent vomiting, oral antiemetic agents are expelled out with the emesis, the sublingual absorption of the ginger through ODF will produce the action faster. There are no ODF of ginger in the market. Hence, there is a need to develop the same.

Development of herbal medicines in novel drug delivery systems is the need of hour. This approach is an interesting blend of therapeutic effectiveness of herbal medicines and advantages of novel drug delivery systems. This increases the patient compliance for the useful herbal drugs, which generally are free from side effects. At present, researchers are working toward developing novel drug delivery systems such as mouth-dissolving tablets, soft gelatin capsules, sustained and extended release formulations, mucoadhesive systems, transdermal dosage forms, microparticles, microcapsules, nanoparticles, implants, etc. of herbs, along with this, many oral retention formulations consisting of gels, pastes, and chewing gums have been developed from the last few years. But poor flowability, poor compressibility of plant extracts, requirement of more functional excipients, etc. poses formulation hurdles for the development of such novel formulations.[8] But as recent market studies indicate that among the different oral marketed dosage forms, ODFs are largely gaining acceptance as the delivery system of choice. Thus there is a great need to deliver this potentially useful herbal drug into the ODF.

The aim of present invention is to formulate and develop ODFs of hydro-alcoholic extract of *Zingiber officinale*. The ODFs were formulated using wide range of film-forming agents such as hydroxypropyl methylcellulose (HPMC), pullulan, maltodextrin, polyvinyl alcohol (PVA). The polymers were used alone and in combination to obtain the desired film properties which were later evaluated for film forming properties, physico-mechanical properties, palatability, microbial limit test, accelerated stability studies, and clinical efficacy test.

HPMC is known for its good film-forming properties and has excellent acceptability. Maltodextrin is classified as a complex carbohydrate, but acts such as a simple carbohydrate in the body. It acts as film-forming agent, solubilizer, and imparts sweetness to the formulation. Pullulan is natural water-soluble polysaccharide, produced from starch by fermentation. It is an excellent film-former. For the fabrication of films, polyethylene glycol (PEG) 4000 was used as a plasticizer along with preservative, sweetener, emulsifier, flavoring agent.

MATERIALS AND METHODS

Materials

Zingiber officinale extract was procured as a gift sample from Unijules Life Science Limited, Nagpur, India. Maltodextrin was received as generous gift from Gujrat Ambuja export Ltd., India. Pullulan was procured from Hayashibara International, Leatherhead, UK. HPMC 5 cps, tween 80, mentha oil and spearmint oil were procured from S. D. Fine Chemical Lab., A.B. Enterprises, Mumbai, India. All other chemicals and reagents were of analytical grades. Deionized double-distilled water was used throughout the study.

Preparation of *Zingiber officinale* ODFs

ODFs of *Zingiber officinale* extract were prepared using solvent casting method. The formulation codes and their respective compositions are given in Table 1. *Zingiber officinale* extract was mixed with measured amount of water using over headed stirrer for 5 min. The extract was then filtered through the muslin cloth. To this filtered extract of *Zingiber officinale,* successively measured amounts of polymer, tween 80, bronopol, sweetening and flavoring agents were added, and the solution was stirred for 30 min. The thick viscous solution was degassed to remove air entraps by ultrasonication.

Table 1: Composition of different formulation of ODFs of ginger

Ingredients	F1	F2	F3	F4	F5	F6	F7
Zingiber officinale extract	10	10	10	10	10	10	10
HPMC 5cps	30	-	-	-	15	15	15
Maltodextrin	-	30	-	-	15	-	-
Pullulan	-	-	30	-	-	15	-
PVA	-	-	-	30	-	-	15
Polyethylene glycol	10	10	10	10	10	10	10
Polysorbate 80	5	5	5	5	5	5	5
Bronopol	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Sucralose	3	3	3	3	3	3	3
Distilled water	Q. S.	Q. S.	Q. S.	Q. S.	Q. S.	Q. S.	Q. S.

Note: quantities given in mg/film, HPMC: Hydroxypropyl methylcellulose, PVA: Polyvinyl alcohol

Measured quantity of solution was casted on a 30 × 45 cm^2 glass plate and was kept in hot air oven at about 80°C for 15 min. The film was carefully removed from the glass plate, checked for any imperfections and cut to the required size to deliver the dose equivalent to 100 mg (2 × 3 cm^2) per film. The films were stored in airtight plastic containers for further studies. The film samples were also stored for accelerated stability studies as per International Conference on Harmonisation (ICH) guidelines.

EVALUATION METHODS

Preliminary characteristics

Film forming capacity: It is the ability of a polymer to form films that can be separated from the surface on which they are casted. The films were characterized as very poor, poor, average, good, better, best depending upon their ability to form films.[9]

Appearance of films

Appearance of film was evaluated by visual observation. The films were characterized as transparent or translucent.[9-11]

Tackiness

Upon stacking the films should not stick to each other. This is a criterion which a film should possess for better dispensing of dosage form.

Thickness

All the formulations were evaluated for uniformity in thickness by using calibrated digital vernier caliper. Ten films (pieces) from each formulation were taken randomly from different places of the plate. Thickness was measured and mean value was calculated. The uniformity in thickness is directly related to the accuracy of dose in the film.[9,10]

Folding endurance

The folding endurance was measured manually for the prepared films. A film was cut and firmly folded through the middle. The number of folds on the same crease, required to produce crack in the film was noted as the value of folding endurance.[12,13]

Surface pH study

The surface pH of fast dissolving strip was determined in order to investigate the possibility of any side effects *in vivo*. As an acidic or alkaline pH may cause irritation to the oral mucosa, it was determined to keep the surface pH to neutral as close as possible. A combined pH electrode was used for this purpose. Oral strip was slightly wet with the help of water. The pH was measured by bringing the electrode in contact with the surface of the oral film. The experiments were performed in triplicate, and average values were reported.

Disintegration test

Disintegration test was performed in the USP disintegration apparatus. Simulated salivary fluid (PH 6.8) was used as the medium. The films were placed in the tubes of the container and the discs were placed over it. The average disintegration time of six films from each formulation was noted.

Table 2: Key for evaluation of organoleptic study

Parameters	Taste	After taste	Physical appearance
0	Not good	Not bitter	Not good
+	Good	Slightly bitter	Good
++	Very good	Bitter	Very good
+++	Excellent	Very bitter	Excellent

Organoleptic evaluation

Since the ODFs are intended to disintegrate rapidly in oral cavity, the product needs to have accepted organoleptic palatable characteristics. Organoleptic evaluation of prepared ODFs was carried out on panel of healthy volunteers with sound organoleptic senses, with their prior consents. The ODFs were rated on the basis of taste, mouth feel (grittiness or smoothness) and physical appearance. Table 2 gives the key for the organoleptic evaluation of ODFs.

Stability studies

For stability testing the ODFs were stored under controlled conditions of 40°C±2°C/75%±5% RH, 30°C±2°C/75%±5% RH over a period of 3 months according to the ICH guidelines. During storage the ODFs were checked for their physical appearance, tackiness, disintegration time, active content (6-gingerol) identification.

Analysis of stable formulation (by HPTLC)

The formulation performing best in all the above characterization tests was analyzed to estimate the stability of active constituents of ginger extract upon storage. Films containing ginger extract equivalent to 5 g of raw herb from each formulation were picked randomly and weighed individually. Films were agitated in methanol for 45 min and then it was cooled, filtered, and dried on water bath. The dried residue was diluted with 5 ml methanol in volumetric flask. The reference standard was prepared with 10 mg reference standard of 6-Gingerol.

Chromatographic condition

Stationary phase	HPTLC precoated, silica gel 60, F_{254} (Merck)
Thickness	0.2 mm
Mobile phase	Toluene: ethyl acetate:methanol:formic acid (5:4:1:1)
Scanning wavelength	500 nm
Visualization aid	Through UV-cabinet under 254 nm and 366 nm and under day light also.
Spray reagent	Anisaldehyde, sulphuric acid reagent

Microbiological limit test

The most stable formulation was subjected to microbiological examination as the herbal products are most susceptible for microbial contamination. This test was designed to determine total aerobic microbial, yeast and mould count including *Staphylococcus aureus, Escherichia coli*, *and Pseudomonas aeruginosa, Salmonella, C. albicans*, *and A. niger*. For ODFs of *Zingiber officinale* microbiological limit test was performed for the development of safe and effective consumer product. The microbiological limit test was performed according to Indian pharmacopoeia specification.

Clinical efficacy test

Evaluation of clinical effectiveness is a measure of the extent to which a particular formulation works. The most stable formulation was selected for clinical efficacy studies of *Zingiber officinale* ODFs in given dose of 100 mg of raw herb. These trials were conducted at Clinics of Ayurvedic Physicians with proper ethical consideration for the period of two weeks. All the subjects were completely informed concerning the pertinent details and the purpose of the study. A written consent form was supplied, understood, and signed by each subject prior to dispensing the ODFs of *Zingiber officinale*. The studies were related to six different clinical conditions nausea, cough, anorexia, motion sickness, pregnancy-induced vomiting and travel sickness. The studied were conducted on five volunteers from each clinical condition. The effectiveness of *Zingiber officinale* ODFs, for all the conditions was rated as below:

0% – 25%	Clinically ineffective
25% – 50%	Comparatively effective
50% – 75%	Clinically effective
75% – 100%	Most clinically effective

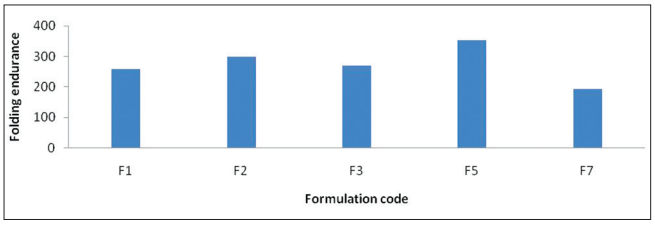

Figure 1: Comparative study of folding endurance of ODFs of *Zingiber officinale*

Table 3: Evaluation of Film forming properties of different polymers with *Zingiber officinale*

Formulation code	Film forming capacity	Appearance of films	Tackiness
F1	Very good	Transparent	Non tacky
F2	Very good	Transparent	Non tacky
F3	Poor	Transparent	Slightly tacky
F4	Average	Transparent	Non tacky
F5	Very good	Transparent	Non tacky
F6	Poor	Translucent	Non tacky
F7	Very good	Transparent	Non tacky

RESULTS AND DISCUSSION

Preliminary Characteristics

Determination of film forming capacity, visual appearance and tackiness for all the formulations are shown in Table 3. Pullulan alone and in combination with HPMC exhibited poor film forming capacity. Pullulan otherwise is good film forming agent but film forming ability of formulation F3 was found to be poor. The reason may be the presence of *Zingiber officinale* extract that interferes in the linking of pullulan molecules and hence structure flexibility of the films is not achieved. The higher temperatures involved in drying may also cause changes in the mechanical properties of the films, making them brittle and less flexible films. Similarly F6 also did not result in good films. This indicated that in this ratio of HPMC and pullulan the films could not be formed. The reason can be incompatibility between two polymers or the interference of drug extract with the films. Rest of the formulations showed good film forming abilities. F4 also yielded films with average quality. It explained the nature of PVA when used alone as film forming agent. Visual appearance of all films was found to be transparent and free of air bubbles, which is necessary for aesthetic appeal.

All the formulations were found to be non tacky at ambient conditions except ODFs containing pullulan. This might be because of slightly hygroscopic nature of pullulan. So the formulations F3, F4, and F6 were not studied further as they failed at the first stage only.

Thickness

The thickness of all films was found to be in the range of 0.05-0.07 mm [Table 4]. The difference in the thickness of these formulations might be due to the different viscosities of the polymers which were used to formulate the films. The low standard deviation values for the thickness of these formulations were confirming efficiency of the method that was employed for formulation of films.

Table 4: Evaluation of physical properties of *Zingiber officinale*

Formulation code	Film thickness (mm)	Disintegration (s)	Surface pH	Folding endurance
F1	0.07±0.24	24±0.25	6.91±0.85	258±0.56
F2	0.05±0.28	8±0.47	7±0.25	298±0.25
F5	0.06±0.54	17±0.74	7.1±0.32	351±0.46
F7	0.07±0.42	62±0.37	6.83±0.64	193±0.84

Folding endurance

All the polymers were able to give the acceptable folding endurance values. Figure 1 shows the results for all the formulations, the observed folding endurance was in the order F5 > F6 > F2 > F1. Folding endurance was found to be highest for formulation F5 (351±0.46). Combination of maltodextrin and HPMC 5 cps was found to perform better the folding endurance was increased.[10]

Surface pH study

The surface pH values of the formulations are given in Table 4. All the polymers resulted in the formulations that have neutral surface pH. The surface pH of the strips was ranging from 7.1±0.32 to 6.83±0.64. The neutral values of surface pH of films assured that there will not be any kind of irritation to the mucosal lining of the oral cavity.

In vitro disintegration time

All the films were found to be rapidly disintegrating except F7 [Table 4, Figure 2]. The observed disintegration time was in the order F2 > F5 > F1 > F7 as show in Figure 2. PVA was found to increase the disintegration time of HPMC films. It must be because of the slow solubility of PVA in water that delayed solubility of HPMC. Quickly disintegrating character of maltodextrin was retained even in the presence of other ingredients of film thus allowing F2 to disintegrate rapidly (disintegration time 8±0.47 s). Presence of maltodextrin reduced the disintegration time of HPMC from 24 to 17 s.

Organoleptic evaluation

The results of the organoleptic characterization are shown in Table 5 [key in Table 2]. All the formulations scored well in physical appearance but formulations F2 and F5 were found to be excellent in palatibity test. This suggested that maltodextrin acts both as film-forming agent and sweetener thus enhances palatability of formulation F2 and F5 [Table 5]. All the formulations also showed no bitter after taste, except F7. It suggested that appropriate amounts of flavors and sweeteners have already been incorporated in the films. The failure of F7 in after taste parameter might be due to the higher disintegration times required which ultimately reduces the palatability of prepared films. Formulation F7 was discarded at this stage and was not studied further.

Accelerated stability studies

The results of accelerated stability studies are given in Table 6. When selected *Zingiber officinale* ODFs formulations were stored at 40±2°C and 75%±5% RH, 30±2°C and 75%±5% RH changes were observed in formulation F2 and F5 in physical appearance, tackiness, separation of the films. The formulation F1 was found to be stable and subjected to the disintegration test, active content identification and for preservative efficacy test. The formulations F2 and F5 were found to be tacky and difficult to separate at accelerated stability conditions because of very hygroscopic nature of maltodextrin at relative humidities greater than 50%. Thus further studies were carried out only on F1.

Analysis of F1 (by HPTLC)

The active constituent of *Zingiber officinale*, i.e., 6-gingerol was assessed by comparing the spectra at peak start, peak apex, and peak end positions of the spot. The spectrum of

Table 5: Organoleptic characterization of selected formulations

Formulation code	Taste	Bitter aftertaste	Physical appearance
F1	++	0	+++
F2	+++	0	+++
F5	+++	0	+++
F7	0	+	+++

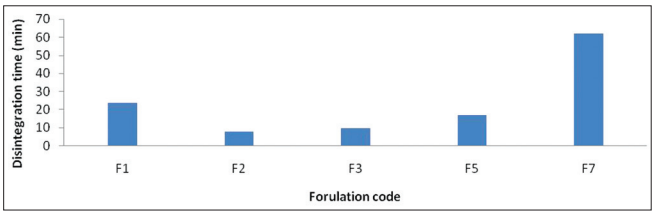

Figure 2: Comparative study of disintegration time of ODFs of *Zingiber officinale*

Table 6: Stability studies of selected formulations

Formulation code	Physical appearance	Tackiness	Film separation	Disintegration time (s)		Active content identification		Preservative efficacy test
				40±2°C, 75%±5% RH	30±2°C, 75%±5% RH	40±2°C, 75%±5% RH	30±2°C, 75%±5% RH	
F1	Very good	Non tacky	Separates	25±0.35	24±0.96	Present of 6-Gingerol	Present of 6-Gingerol	Pass as per IP
F2	Good	Tacky	Difficult to separate	NA	NA	NA	NA	NA
F5	Good	Tacky	Difficult to separate	NA	NA	NA	NA	NA

F1 could be completely overlaid on the spectrum of *Zingiber officinale* extract [Figure 3]. According to the method when TLC plate was scanned at day light and 366 nm, six spots (Rf values 0.06, 0.66, 0.69, 0.72, 0.81, 0.87) [Table 7] and five spots (Rf value 0.06, 0.66, 0.70, 0.83, 0.86) [Table 8] were observed respectively. The spots obtained in the F1 were compared with those obtained in standard *Zingiber officinale* extract.

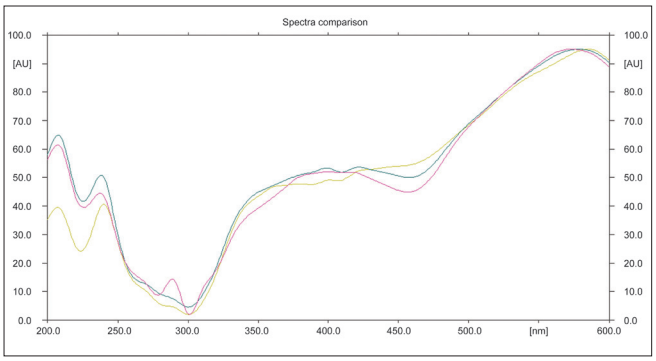

Figure 3: Overlay spectral display of ODFs (green and yellow color) along with the reference standard (pink color) of *Zingiber officinale* after scanning under 200 nm-700 nm

Table 7: Identification of bands of ginger raw herb and F1 under daylight

Identification of band	Rf	F1	Ginger extract
Green spot	0.06	+	+
Yellow spot	0.66	+	-
6-Gingerols	0.69	+	+
Violet spot	0.72	+	+
Violet spot	0.81	+	+
Violet spot	0.87	+	+

Table 8: Identification of bands of ginger raw herb and F1 at 366 nm

Color	Rf	F1	Ginger extract
Brown spot	0.06	+	+
Light orange spot	0.66	+	+
Dark orange spot	0.70	+	+
Orange Spot	0.82	+	+
Orange spot	0.86	+	+

Microbiological limit test

Microbial limit test was performed on the most stable formulation F1. The results of microbial limit test are given in Table 9. From the results obtained, it was concluded that formulation F1 was free from microbial contamination.

Clinical efficacy studies

The studies were related to six different clinical conditions that are nausea, pregnancy-induced vomiting, travel sickness, motion sickness, cough, anorexia. The studies were conducted on the five human volunteers from each clinical condition. The results obtained are given in Table 10. From the clinical efficacy studies, it was found that ODFs of *Zingiber officinale* are the most promising herbal remedy for these clinical conditions.

CONCLUSION

Among the prepared formulations, formulation F1 was found to have transparent visual appearance, best film-forming capacity, least disintegration time and also found to be stable at accelerated stability studies. *In vitro* and *in vivo* evaluation of the films confirmed their potential as an innovative dosage form to deliver *Zingiber officinale*. Thus, *Zingiber officinale* ODFs are found to be suitable especially for geriatric, bedridden, and non-cooperative patients due to its ease of administration as well as patient friendly dosage form.

Table 9: Results of microbiological limit tests

Test	Limits	Results		
		1 month	2 months	3 months
Total microbial plate count	NMT 10^5 cfu/g of sample	185 cfu/g	186 cfu/g	185 cfu/g
Total yeast and mould	NMT 10^3 cfu/g of sample	19 cfu/g	23 cfu/g	20 cfu/g
Specified Micro-organism				
Escherichia coli	Absent	Absent	Absent	Absent
Salmonella	Absent	Absent	Absent	Absent
Pseudomonas aeruginosa	Absent	Absent	Absent	Absent
Staphylococcus aureus	Absent	Absent	Absent	Absent

Note: cfu/g (colony forming unit/gram), NMT: not more than

Table 10: Clinical efficacy studies *Zingiber officinale* ODFs

Formulation F1	Nausea	Pregnancy-induced vomiting	Travel sickness	Motion sickness	Cough	Anorexia
Average clinical efficacy	84.2±2.5	85.8±7.2	88.4±3.3	87.6±5.8	87.8±9.6	74.8±10.3
Dosage form acceptability	Yes	Yes	Yes	Yes	Yes	Yes

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