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Formulation And Evaluation of Dispersible Tablets From Zingiber officinale

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ABSTRACT

Patients who have trouble swallowing can benefit from an oral dissolving medicine delivery system. Since ancient times, Zingiber officinale has been used medicinally to treat a variety of conditions, including motion sickness, nausea brought on by chemotherapy for cancer, moderate stomach distress, coughing, persistent bronchial issues, low-grade infections of all types, and anorexia. In this research paper, Zingiber officinale acts for antimicrobial activity such as reducing respiratory infection, coughing, sore throat, cold, and bronchial conditions. In order to avoid first-pass metabolism, this study explores the feasibility of creating Zingiber officinale disintegrating tablets that dissolve quickly. The Direct Compression method was used to make the disintegrating tablets. Pre- and post- compressional parameters were assessed for the prepared tablets, such as flow characteristics, hardness, friability, disintegration and dissolution experiments, and accelerated stability studies. To create tablets, the various ingredients—including Lactose Monohydrate, MCC PH-102, Croscarmellose Sodium, Sodium Starch Glycolate, Sodium Saccharin, Magnesium Stearate, Glyceryl Behanate, and Propyl Paraben — were investigated alone and in combination. The formulation with croscarmellose sodium as the super disintegrant (F6) has the shortest wetting and disintegration times of all the formulations. It was discovered that the optimized formulations (F6) had a faster rate of dissolving than the other formulations. F6 was determined to be the most promising DT formulation out of all of them.

Keywords: *Direct compression method, disintegrating tablets (DTs), oral dissolving drug delivery devices, and Zingiber officinale, Antimicrobial Activity.*

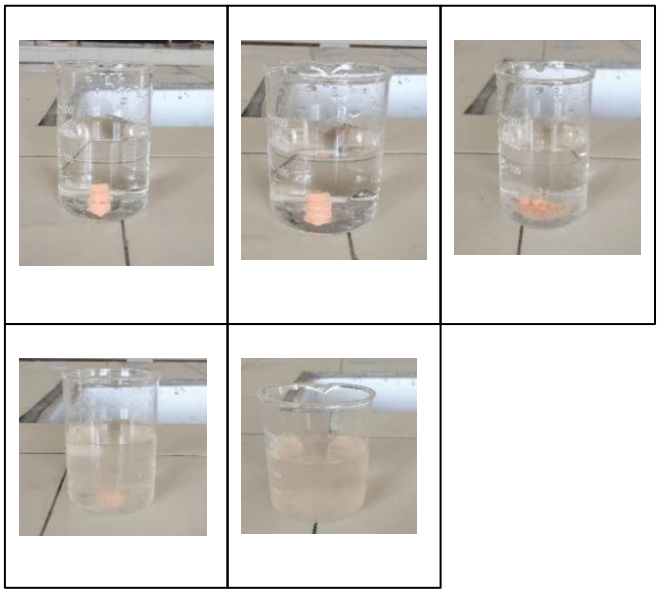
1. INTRODUCTION

Disintegrating Tablets

The need to give patients more traditional ways to take their medications gave rise to the idea of the Fast Dissolving Drug Delivery System [1-2]. Many individuals have trouble swallowing firm gelatin capsules and tablets. Because of this, people don't follow their prescriptions, which leads to a high rate of non-compliance and unsuccessful treatment [3-5]. It can be challenging to swallow regular tablets in some situations, such as motion sickness, unexpected allergic reactions, coughing, and a lack of water. Patients who are young or elderly in particular find it tough. The Fast Dissolving Tablet can be used to solve such issues. This pill dissolves instantly when put in water, releasing the medication, which then dissolves or spreads in the water. An DT is defined as: "A solid dosage form containing medicinal substances, which disintegrate rapidly, usually within a matter of seconds, [6-10]" by the Center for Drug Evaluation and Research.

Mechanism of DT drugs [11-14].

Fig.1: Disintegration Process Of Dispersible Tablets



Materials Used

Zingiber officinale powder was purchased from the local market of Yeola, MCC (PH-102), Lactose Monohydrate, Sodium starch Glycolate, Magnesium stearate, Croscarmellose Sodium, Sodium Saccharin, Menthol, Propyl Paraben were purchased from SND College of Pharmacy, Yeola.

Preformulation Studies:

It is needed to ensure the development of stable, effective, and safe dosage forms[15,16]

Physical examination of drug substance:

For physical evaluation Moisture content, Total ash content, Acid-insoluble ash, and water-soluble ash were detected by the following methods-

Moisture Content- A weighed quantity of dried rhizome was placed in a hot air oven set to 100°C for an hour. Moisture content was computed using the difference between the initial and end weights[17]

Total Ash Content- The total ash content is the weighted quantity of dry rhizome burned in a muffle furnace for 30 minutes at 550°C. The total amount of ash was calculated from the difference between the initial and final $_{weights}$[17,18]

Acid Insoluble Ash- 25 milliliters of diluted HCl were used to dissolve the weighed quantity of total ash, which was then heated for five minutes in a water bath. It was filtered and repeatedly cleaned with water to get rid of extra acid. After three hours of drying at 100°C, the obtained ash was weighed. Using the total ash content as a reference, the proportion of acid-insoluble ash was determined[19]

Water Soluble Ash- After weighing the whole amount of ash, it was boiled for five minutes in 25 milliliters of water before being filtered through ashless filter paper. cleaned with hot water and heated to 300°C for 15 minutes in a muffle furnace. The proportion concerning total ash was derived by deducting the insoluble content from total $_{ash}$[19,20]

Phytochemical screening of the active ingredients:

The qualitative and quantitative phytochemicals present in Ginger rhizomes were analyzed as follows.

Determination of qualitative phytochemical analysis :

The phytochemical analysis of active ingredients was carried out in the Laboratory of SND Babhulgaon, Yeola. Method was used for the identification tests of the phytochemicals.

Alkaloids: A few drops of Wagners reagent were added to few ml of plant extract along the sides of test tube. A reddish-brown precipitate confirms the present of Alkaloids.

Flavonoids: 0.5 g ginger was mixed with water in a test tube and shaken. Few drops of sodium hydroxide was added, formation of intense yellow colour which becomes colourless on further addition of dilute Hydrochloric acid indicate the presence of flavonoids.

Tannins: 0.5 g of ginger powder was mixed with 20ml of water in a test tube and heated. The mixture was filtered and 0.1%

of ferric chloride was added. Appearance of brownish green colouration indicates the presence of tannins.

Saponins: 0.5 g of ginger was mixed with water in a test tube and heat. Few drops of olive oil wereadded and shaken. Formation of soluble emulsion indicated the presence of Saponins.

Glycosides: Total of 100 mg of the extract was dissolved in 1ml of glacial acetic acid containing one drop of ferric chloride solution, it was then under layered with 1ml of concentrated sulphuric acid, a brown ring obtained at the interface indicate the presence of de-oxysugar characteristic of cardenolides.

Steroids: Analytical method was used to determined 0.5 g of additives and was dissolved in 2ml ofChloroform and few drops of Sulphuric acid was added to form a lower layer. A reddish-brown colour at the interface indicates the presence of steroid.Anthraquinones: 0.5g of the extract was collected in a dry test tube and 5mls of chloroform was added and shaken for 5minutes it was then filtered and the filtrate was shaken with an equal volumeof 100% ammonia solution. A pink violet or red colour in ammonia lower layer indicates the presence of free Anthraquinones.

Phenols: The extract (50 mg) was dissolved in 5 ml of distilled water and 2 ml of 1% solution of Gelatin containing 10% NaCl was added to it. The presence of phenol compounds is indicated by a white precipitate.

Oxalates: One milliliter of strong sulfuric acid was added to five milliliters of the extract, which was then left to stand for an hour before two drops of potassium permanganate were added. The development of a consistent red color indicates the presence of oxalate [21].

Solubility analysis:

Adding tiny amounts of solute to a predetermined volume of solvents, such as water, ethanol, chloroform, and acetone, and then monitoring for undissolved particles is known as solubility analysis[22]

pH of Solution:

Weigh 1 g of dried ginger powder. Add it to 10 mL of distilled water in a beaker (1:10 ratio). Stir the mixture thoroughly for 5 minutes. If solids interfere, filter the mixture to obtain a clear extract. Insert the calibrated pH meter electrode into the solution. Wait for the reading to stabilize and record the pH.

Melting point:

The conventional melting point determination method was used to estimate the melting point of the extracted material.

Method:

The dispersible tablets of Zingiber officinale were prepared by direct compression method using two different super disintegrants and formulae are given in Table 1. Dispersible tablets were prepared with a total weight of 150 mg of varying super disintegrants compositions and fixed quantity of Zingiber officinale powder of 10 mg. The specified quantity of API and super disintegrants were weighed accurately, mixed and passed through sieve #40. All the materials were transferred to mortar in geometrical order and blended upto 10 minutes, except magnesium stearate and Glyceryl Behanate. Before the compression the magnesium stearate was added and mixed gently for 2-3 min. The tablets were punched with B tooling. The compression force was adjusted to give tablet hardness in the pharmacopeial range of Dispersible tablets (2 – 4 kg/cm3)

Table 1: Zingiber Officinale Extract oral disintegrating tablet formulation utilizing synthetic disintegrants

Ingredients(mg per tablet)	F1	F2	F3	F4	F5	F6
Zingiber Officinale Extract	10	10	10	10	10	10
Lactose Monohydrate	80	80	80	80	80	80
MCC PH-102	45	40	35	45	40	35
Croscarmellose Sodium	5	10	15	---	---	---
Sodium Starch Glycolate	---	----	---	5	10	15
Sodium Saccharin	1.8	1.8	1.8	1.8	1.8	1.8
Menthol	1.5	1.5	1.5	1.5	1.5	1.5
Magnesium Stearate	1.8	1.8	1.8	1.8	1.8	1.8
Glyceryl Behanate	1.8	1.8	1.8	1.8	1.8	1.8
Propyl Paraben	3.1	3.1	3.1	3.1	3.1	3.1
Total Weight	150	150	150	150	150	150

Evaluation of formulated Zingiber officinale dispersible tablets:

The following tests were performed on the prepared tablets to confirm their qualities:

Pre-compression Parameters:[23] Flow properties:

Flow properties were evaluated in terms of angle of repose, bulk density, tapped density, Carr'sindex, and Hausner's ratio.

Angle of Repose:

Tanθ=h/r

Consequently, θ = tan-1 (h/r).

Bulk Density

M/V0 = Pb

Tapped Density

ρtap = M / VT

Carr's index

Compressibility percentage Carr's index = (Vb – Vt) * 100/Vb

Hausner's ratio

Tapped density (pt) / Bulk density(pb) = Hausner's Ratio

Post Compression Parameters:

Weight variation[24]

This test guarantees that the correct dosage of medication is included in every tablet. Twenty pills were weighed separately using an analytical weighing scale. Next, the weight fluctuation percentage and average weight were calculated.

{(Individual Weight - Average Weight)/Average Weight} X 100 = % Weight Variation

Hardness

It is a method for determining a tablet's breaking point and structural integrity. It is used to determine the strength of the granules. The tablet's hardness is measured using the Monsanto hardness tester. Compared to conventional tablets, dispersible tablets are softer[25]

Wetting time - The wetting time of the tablets can be measured using a simple procedure. Five circular tissue papers of 10 cm diameter are laid in a petri dish with a 10-cm diameter. Ten milli-liters of water-soluble dye (eosin) solution is added to petri- dish. A tablet is carefully laid along the airfoil of the tissue paper. The time needed for water to reach the upper surface of the tablet is noted as the wetting time [26].

Water absorption ratio - For measuring the water absorption ratio the weight of the tablet of sample is noted before continuing in the petri dish containing water and then the wetted tablet is removed from the petri dish and reweighed. The

water absorption ratio, or can be defined by the following equation [27].

R = 100 (Wa – Wb) / Wb

Where, Wa = Weight of tablet after absorption Wb = Weight of tablet before absorption

Assay determination

After the pills were broken up, 50 milliliters of water were used to dissolve 10 milligrams of the powder. Following 20 minutes of sonication, the samples were analyzed using spectrophotometry, and a calibration curve was utilized to determine the drug level.

Friability Test:

The Roche friabilator (Electrolab, Mumbai) was used to do this. A weighted sample of the powder and 25 steel balls, each with a diameter of 2 mm, were placed within the friabilator. The percentage mass loss between the sample's initial and final weights was used to determine the friability following 100 spins at 25 rpm for four minutes.

Friability as a percentage =

{(W1 - W2)/W1} X 100

Where, W1 = The Weightofthe tablets before the test

W2 = The Weight of tablets after the test[28]

Tablets Disintegration test

Distilled water was utilized as the dissolution medium, and the device was maintained at 37°C ± 2°C with an average of 28 to 32 cycles per minute. Each plastic disc contained 100 mg of the material, and the disintegration time was noted. For every formulation, the test was run three times in a row[29]

In vitro dispersion time test

To determine dispersion time, a 10 ml measuring cylinder is taken, to which 6 ml of distilled water is added, and then a sample tablet is dropped in it. The time needed for complete dispersion was determined [30].

Tablets Dissolution test

100 mg of tablets were dissolved in 900 mL of distilled water at 37°C and 50 rpm using a USP Type 2 paddle device. To calculate the proportion of drug release, samples were taken out at predetermined intervals and their absorbance at 280 nm was evaluated[31]

Accelerated stability studies:

The disintegrating tablets are carried in suitable packaging and stored under the following conditions for a period as prescribed by the ICH guidelines for accelerated studies. (1) 40 ± 10 C (2) 50 ± 10 C (3) 37 ± 10 C and Relative Humidity = 75% ± 5. The tablets are removed after a period of 15 days and analyzed for physical characterization (Visual defects, Hardness, Friability, Disintegration, Dissolution, etc.) and drug content. The information obtained is fitted into the first-order equation to define the kinetics of degradation. Accelerated stability data are plotted according to the Arrhenius equation to determine the shelf life at 25 0 C [32,33].

2. RESULTS &DISCUSSION

Results:

Physical Appearance:

Table 2: Results of the Physical Appearance Tests of Zingiber officinale Powder

Sr. No.	Tests	Observation
1	Color	Earthy Brown
2	Taste	Pungent
3	Odor	Aromatic
4	Moisture	5.15±0.15%
5	Total Ash Contents	3.69±0.08%

6	Acid Insoluble Ash	0.40±0.11%
7	Water Soluble Ash	2.31%

Phytochemical screening of ginger Qualitative phytochemicals:

Table 3 presents the qualitative screening of ginger (Zingiber officinale). While there were no excess bioactive compounds in the water extract, there were alkaloids and flavonoids in the ginger ethanol extract. Ginger water extract had moderate levels of flavonoids, saponins, and alkaloids, while ginger ethanol extract had moderate levels of phenol and phytate. Ginger water extract included trace amounts of phenol and tannin, while ginger ethanol extract contained trace amounts of steroids, anthraquinones, tannin, and saponin. While glycosides, steroids, anthraquinone, phytate, and oxalate were uncommon in ginger water extract, they were uncommon in ginger ethanol extract.

Table 3: Qualitative phytochemical screening of the studied herbs

Phytochemicals	Ginger ethanol	Ginger water
Alkaloid	+++	++
Flavonoid	+++	++
Tannins	+	+
Saponins	+	++
Glycosides	-	-
Steroid	+	-
Anthraquinone	+	-
Phenolics	++	+
Phytate	++	-
Oxalate	++	-

Solubility analysis:

Table 4: Results of the Solubility Analysis Of Zingiber officinale Powder

Sr. No.	Solvents	Solubility Behaviours
1	Distilled Water	Soluble
2	Acetone	Insoluble
3	Toluene	Insoluble
4	Chloroform	Soluble
5	Ethanol	Soluble
6	Methanol	Soluble
7	DMSO	Soluble
8	Benzene	Soluble
9	Ether	Sparingly Soluble

pH of Solution:

The pH value of Zingiber officinale Powder (1% solution) was recorded as 4.96±0.07.

Determination of Melting Point:

It was discovered that the ginger extract had a melting point of 32 °C.

Calibration curve for the Ginger Extract

Table 5: Estimation of Zingiber Officinale Extract at 205 nm.

Concentration (µg\mL)	Absorbance
2	0.133
4	0.256
6	0.345
8	0.464
10	0.565
12	0.681
16	0.828
20	1.083

Fig 2: Zingiber Officinale Extract calibration curve at 205 nm in pH 6.8 phosphate buffer

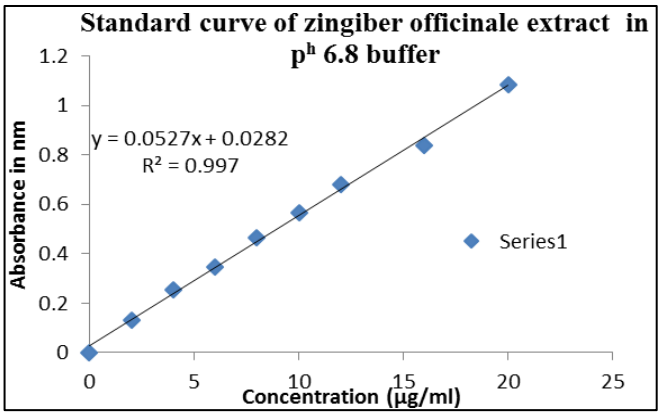


Table 6: Evaluation of flow properties of the blends of all formulations

Formulations	Angle of repose	Bulk density	Tapped density	Carr's index	Hausner's ratio	Flowability
F1	33	0.58	0.67	16.86	1.18	Fair
F2	31	0.68	0.76	11.10	1.14	good
F3	32	0.71	0.77	12.14	1.13	good
F4	29	0.57	0.66	10.16	1.11	Excellent
F5	31	0.65	0.74	11.13	1.15	Good
F6	27	0.70	0.78	8.16	1.07	Good

Table 7: Tests of quality control for Zingiber Officinale Extract oral disintegrating tablets

Formulations	Avarage Weight	Hardness (Kg/cm$^{2)}$	Friability (%)	Wetting time	Water absorbtion ratio
F1	152±0.16	3.6±0.128	0.51±0.173	23.14±0.135	39±0.115
F2	150.8±0.16	3.8±0.133	0.44±0.167	20.55±0.155	41±0.255
F3	153.4±1.64	3.7±0.192	0.53±0.223	19.04±0.253	40±0.133
F4	154.7±0.99	3.7±0.132	0.50±0.189	10.55±0.189	27±0.145
F5	150.9±1.04	3.5±0.222	0.58±0.180	8.34±0.177	31±0.235
F6	152.5±1.96	3.6±0.321	0.61±0.168	7.24±0.146	34±0.213

*Avarage of three determinants (n=3)

Table 8: Tests of quality control for Zingiber Officinale Extract oral disintegrating tablets

Formulations	Disintegration time (sec)	Drug content (%)	Percentage Drug Dissolved After 10 Min.	Invitro dispersion time (s)
F1	49.28±0.763	98.14±1.24	75.15±0.57	52±0.14
F2	48.58±0.823	97.58±1.03	80.57±0.94	50±0.57
F3	46.69±0.791	98.9±0.94	84.23±0.48	49±0.48
F4	17.37±0.548	97.5±0.91	86.06±0.87	15±0.24
F5	14.56±0.670	96.59±1.73	91.45±0.48	13±0.58
F6	12.70±0.765	99.10±0.88	96.88±0.87	11±0.88

*Average of three determinants (n=3)

Table 9: Dissolution characteristics of Zingiber Officinale Extract oral disintegrating tablets

Batch code			Cumulative % drug dissolved (min)			
	0	2.5	5	10	15	20
F1	0	40.7±1.26	63.4±0.27	75.16±0.56	86.36±0.22	94.04±0.34
F2	0	43.9±1.49	66.10±0.58	80.58±0.92	94.8±0.37	96.54±0.18
F3	0	45.3±3.17	78.8±0.37	82.24±0.47	94.66±0.18	97.59±0.45
F4	0	47.5±0.99	81.4±0.51	84.06±0.86	98.13±0.87	98.07±0.97
F5	0	48.7±1.97	79.6±0.58	89.45±0.45	99.09±0.49	98.45±0.64
F6	0	53.5±1.47	84.8±0.67	94.86±0.21	100.7±0.87	100.70±0.59

Fig 3: Comparative dissolving profile of oral disintegration tablets with varying amounts of croscarmellose sodium as a super disintegrant in Zingiber Officinale Extract

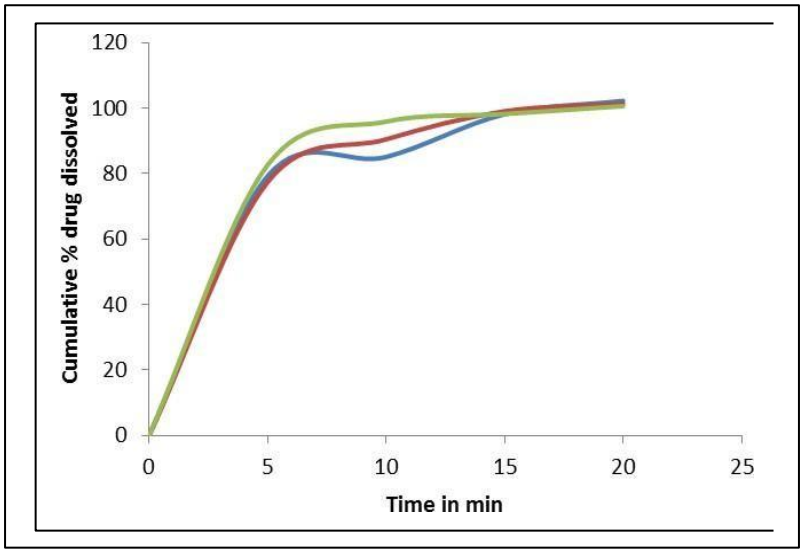


Fig 4: Comparative dissolving profile of oral disintegration tablets with varying amounts of Sodium Starch Glycolate asa super disintegrant in Zingiber Officinale Extract

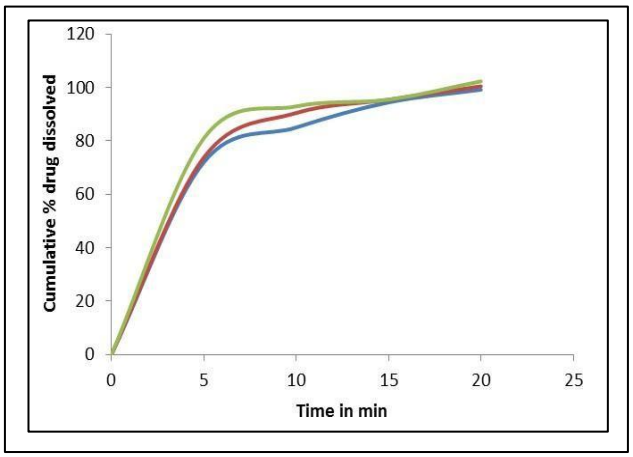


Fig 5: FTIR of Zingiber officinale

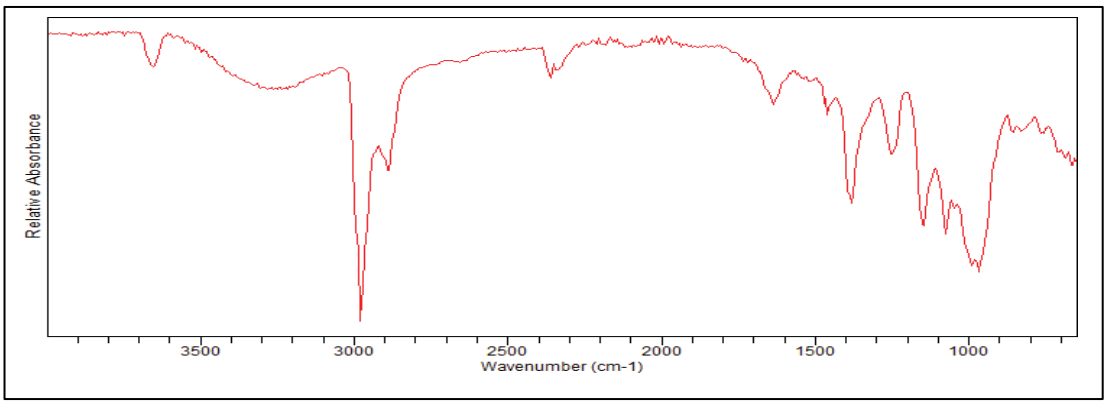


Fig 6: FTIR of Crosscarmellose Sodium

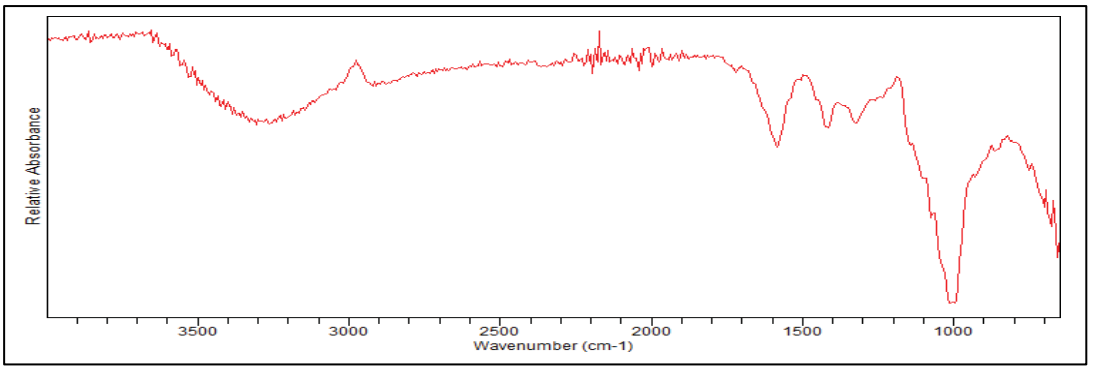


Fig 7: FTIR of Sodium starch glycolate

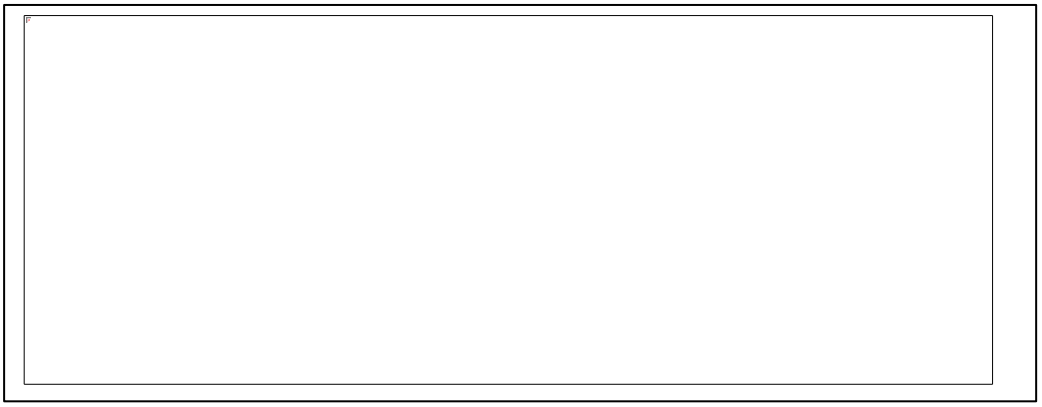


Fig 8: FTIR of optimised formulation

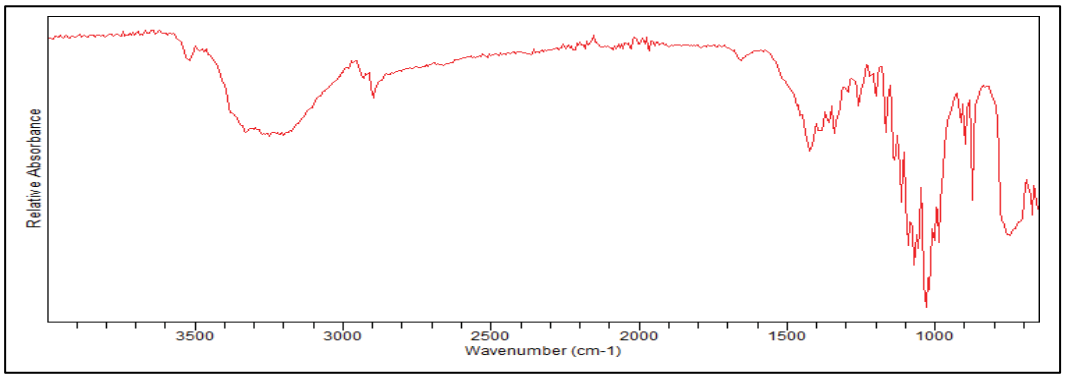


Table 10: Stability analysis for Optimized Formulation (F6)

Formulation	No of days	25˚C & 60%RH		40˚C &75% RH	
		Wetting time(s)	Disintegration time(s)	Wetting time (s)	Disintegration time (s)
F6	0	8.49±0.126	10.70±0.228	8.49±0.227	10.70±0.149
	15	8.47±0.150	10.67±0.448	8.47±0.259	10.63±0.230
	30	8.50±0.348	10.68±0.426	8.48±0.157	10.61±0.448
	45	8.45±0.148	10.66±0.570	8.46±0.659	10.64±0.360
	60	8.46±0.216	10.64±0.148	8.45±0.171	10.67±0.190

Table 11: Drug content for Optimized Formulation (F6)

Formulation	No of days	25˚C / 60%RH	40˚C / 75% RH
F6	0	99.09±0.87	99.10±0.87
	15	98.14±0.59	98.77±0.27
	30	98.77±0.25	98.09±0.37
	45	98.36±0.37	97.87±0.29
	60	98.27±0.19	97.59±0.45

3. DISCUSSION

Six Zingiber Officinale Extract formulations (F1-F6) were prepared using different concentrations of Two super disintegrants: croscarmellose sodium, sodium starch glycollate. Microcrystalline cellulose was used as a filler, while magnesium stearate, and glyceryl behenate improved lubrication and flow . FTIR confirmed no drug-excipient interaction.

Pre-compression tests showed good flow properties with a Hausner's ratio of (1.18–1.07), Carr's index (16.86– 8.16%), and an angle of repose (23˚-35˚). Tablets were made by direct compression, with hardness (3.4–4.0 kg/cm²) and drug content (97.56–101.3%). Wetting and disintegration times ranged from 7.24–23.14 sec and 12.70–49.28 sec, respectively. F6 (croscarmellose sodium) had the fastest disintegration. Dissolution order: croscarmellose sodium > sodium starch glycollate.

Stability tests (40˚C/75% RH and 25˚C/60% RH) for F6 over 60 days showed no significant changes in tablet properties.

4. CONCLUSION

It was discovered that the Zingiber Officinale Extract oral disintegrating pills were aesthetically pleasing and did not chip, fracture, or laminate. Fast disintegration and an in vitro dispersion duration of 11 sec were demonstrated by the promising formula (F6). It was discovered that the optimized formulations (F6) had a faster rate of dissolving than the other formulations. F6 was determined to be the most promising DT formulation out of all of them.

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