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Design and Development of the Liquisolid Compact of Gingerol Loaded Lozenges

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ABSTRACT

The aim of the work is to design and develop liquisolid compact of gingerol loaded lozenges in order to increase the solubility of the poorly soluble drug gingerol. The formulation was characterized for drug-excipient interaction using FTIR, DSC, XRD, and drug content analysis. The drug content for the optimized formulation was found to be above 97.82 %. The lozenges formulation was optimized based on evaluation parameters such as weight variation, hardness, friability, and drug content. Formulation F4 was identified as the optimized formulation based on the evaluation studies. In-vitro drug release of formulation F4 exhibited a release profile of 90.08 % and followed the Higuchi model. The stability studies of the optimized formulation LF4 were also found to be satisfactory. This technique aims to improve the aqueous solubility and bioavailability of the active ingredient, gingerol.

Keywords: *liquisolid compact, gingerol, lozenges, motion sickness.*

INTRODUCTION

Motion sickness is a condition that can cause cold sweats, nausea, and vomiting in individuals who experience it while traveling by car, sea, or air. It can affect anyone, but women and children are more prone to it. To reduce the risk of getting sick while traveling, there are steps that can be taken. Medications like lozenges can help prevent nausea. The bioavailability of a drug depends on its solubility in an aqueous environment and its permeability through lipophilic membranes. Only solubilized drug molecules can be absorbed by cellular membranes and reach the site of drug action. The dissolution properties and release rate of a drug from a dosage form have a significant impact on its bioavailability. Poor dissolution characteristics of water-insoluble drugs pose a challenge for pharmaceutical scientists. The therapeutic effectiveness of a drug relies on its bioavailability, which is influenced by the solubility of drug molecules. Solubility is an important parameter in achieving the desired concentration of a drug in systemic circulation. The dissolution rate is a limiting factor in drug absorption for class II (low solubility and high permeability) and class IV (low solubility and low permeability) drugs as defined in the Biopharmaceutics Classification System (BCS). The selection of non-toxic hydrophilic solvents, carriers, coating excipients, and their ratios can enhance solubility and bioavailability. Lozenges are solid dosage forms designed to dissolve or disintegrate slowly in the mouth. They contain one or more active ingredients and are flavored and sweetened to be pleasant tasting. While they are commonly used for their topical effect, they may also have ingredients that produce a systemic effect. Lozenges are used to medicate the mouth and throat, providing slow administration for digestion or cough remedies. They can contain anesthetic, demulcent, or antiseptic ingredients. Lozenges are particularly useful for patients who have difficulty swallowing other types of solid dosage forms.

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Determination of Standard Curve

To prepare the stock solution of gingerol, 100 mg of pure drug was dissolved in 10 ml of ethanol and sonicated. The volume was then made up to 100 ml with phosphate buffer (pH 6.8). This resulted in a stock solution with a concentration of 1 mg/ml of gingerol. The stock solution was further diluted to obtain solutions with concentrations ranging from 2 µg/ml to 10 µg/ml. This was done through serial dilution. To determine the concentration of the diluted solutions, the absorbance of each solution was measured at 280 nm using a UV spectrophotometer.

Determination of Solubility

To determine the solubility of gingerol in different liquid vehicles, excess quantity of gingerol was added to glycerin, tween-80, polyethylene glycol grade 400, propylene glycol, and distilled water separately. These mixtures were then shaken in a rotary shaker (Remi ISO 9001: 2000, CIS-24BL) for 48 h at a temperature of 25°C. After the shaking period, the solutions were centrifuged for 30 min at 2000 rpm. The supernatant was then filtered, diluted, and observed using a UV-spectrophotometer (SHIMADZU 1800) at a scanning wavelength of 280 nm. By measuring the absorbance at this wavelength, the solubility of gingerol in each liquid vehicle was determined.

Formulation of Liquisolid System

The liquisolid compacts were formulated according to the theory and mathematical model presented by Spirease. According to this model, PEG 400 was used as a liquid vehicle based on its drug solubility, Avicel PH 102 was separately used as carrier material and Aerosil-200 was used as a coating material. According to the theory of liquisolid system carrier and coating material retain a specified quantity of liquid vehicle that ensures acceptable flowability and compressibility. The ratio of carrier to coating material is termed as excipient ratio of powder (R), defined as

$$\mathbf{R} = \frac{Q}{q}$$

Where R is excipient ratio, Q is carrier material weight and q is the weight of coating material used in the formulation. Load factor (L_f) is the ratio between the weight of liquid medication (drug dissolved or dispersed within the liquid vehicle) overweight of carrier material used that produces a powder with acceptable flowability and efficient compression.

$$\mathbf{L_f} = \frac{W}{Q}$$

Where W is the weight of liquid medication and Q is the weight of carrier material. The load factor was further used for the determination of carrier and coating material quantity.

Table 1: Formulation Chart of Liquisolid Technique

Formulation code	Drug (mg)	Vehicle PEG400 (ml)	Carrier Q (mg)	Coating q (mg)	Sodium Starch glycolate (mg)	Talc (mg)	Total (mg)
LF1	100	150	380	76.00	7.06	7.13	720.19
LF2	100	150	664	66.40	9.80	9.80	1000.00
LF3	100	100	304	60.80	5.64	5.70	576.14
LF4	100	100	531	35.10	7.60	7.70	781.40
LF5	100	50	228	45.60	4.20	4.20	432.00
LF6	100	50	398	39.80	5.80	5.90	652.60

F-Liquisolid formulation; L_f - liquid load factor

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Preparation of Candy Lozenges

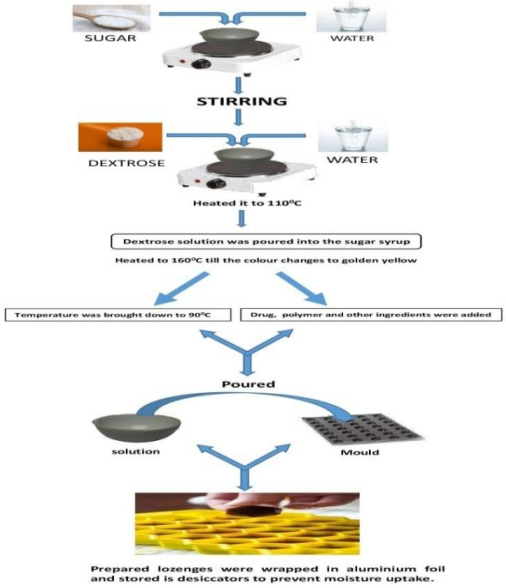

Fig .1 Schematic representation of preparation of lozenges

Required quantity of sugar syrup was prepared mixing sugar and water. Dextrose was dissolved in small quantity of water and heated it to 110 ℃ till dextrose dissolves completely forming as clear viscous syrup. Then the dextrose solution was poured into the sugar syrup and heated to 160 ℃ till the color changes to golden yellow. The temperature was bought down to 90 ℃ and drug, polymer and other ingredients were added. The solution was poured into the mold having 2.8 cm diameter and 6.5 mm thickness. The prepared tablets were stored wrapped in aluminum foil and stored in desiccators to prevent moisture uptake. The final weight of each lozenge is 3 g. The details of formulations are given in Table 2.

Table 2: Preparation of drug loaded lozenges formulation

Ingredients (mg)	F1	F2	F3	F4	F5	F6
Drug	10	10	10	10	10	10
HPMC K100	16	32	48	16	32	48
Sucrose	1966	1950	1934	1966	1950	1934
Dextrose	974	974	974	974	974	974
Citric acid	32	32	32	32	32	32
Menthol	1	1	1	1	1	1
Total	3090	3090	3090	3090	3090	3090

PRE-COMPRESSION PARAMETERS

Flow properties evaluation powder flow is of prime importance at the industrial level because it ensures efficient compression. In current research work, basic flow ability parameters were evaluated including Carr's compressibility index and Hausner's ratio. Bulk and tapped densities were determined by taking a suitable quantity of powder in the graduated cylinder and volume occupied before and after tapping was observed. Carr's compressibility index was determined using the following formula.

$$\text{CI \%} = \frac{Pt - Pb}{Pt} \times 100$$

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Where P_t tapped density and P_b is bulk density. British Pharmacopeia (BP) categorizes the CI % less than 25 in an acceptable range of flow properties. Whereas Hausner's ratio was calculated by dividing the tapped density value over bulk density. The angle of repose was determined using the fixed funnel method. The funnel was fixed at a suitable height; the powder was allowed to fall through funnel orifice which forms a heap with a horizontal surface. The angle of repose was determined by employing the following formula.

$$\Theta = \tan^{-1} (h/r)$$

Where h is pile height and r is the distance between the pile center and edge.

Differential Scanning Calorimetry (DSC)

An accurately weighed 2 mg of liquisolid powder was sealed tightly in the aluminum pan against an empty aluminum pan as the reference standard. The DSC (METTLER TOLEDO) measurements were carried out at a scanning rate of 10 °C/min and a temperature range between 0 and 350 °C.

Fourier Transform Infrared Spectroscopy (FTIR)

FTIR studies were conducted to check out drug-excipients interaction. The sustained release liquisolid formulation, carrier material, coating material, physical mixture and active drug were analyzed using IR spectrophotometer (JASCO 4600). The method adopted was the ATR IR method at a scanning time of 3 min. The spectra were recorded at a scanning range of (4000 cm^{-1} and 400 cm^{-1}). The recorded spectra were evaluated and compared for any spectral changes.

X-Ray Crystallography (XRD)

The cross section of samples was exposed to X-ray radiation (Cu Kα) with wavelength of 1.5406 °A. The rate of the scanning was 0.6 °/min. Samples, ground into powders with an agate mortar and pestle, were measured on a low background quartz plate in an aluminum holder.

Evaluation of Physicochemical Characteristics of Optimized Gingerol Lozenges

Average weight and Weight variation test:

20 lozenges were selected and weighed collectively and individually on an electronic balance. From the collective weight, average weight was calculated. Each lozenge weight was then compared with average weight to assure whether it was within permissible limits or not. Not more than two of the individual weights deviated from the average weight by more than 7.5% for 300 mg tablets and none by more than double that percentage.

Friability Test

The friability of the 20 tablets from each batch was tested by a fribilator. At a speed of 25 rpm for 4 min. The lozenges were then deducted, reweighed and percentage weight loss was calculated by the equation,

$$\% \text{ Friability} = (\text{initial weight.} - \text{Wt. after friability}) \times 100 / \text{initial weight}$$

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Disintegration Test

The disintegration test was carried out in 6.8 pH phosphate buffer at 37 °C ± 0.5°C and the time taken for the disintegration of lozenges were noted. Experiments were performed in triplicate.

Drug Content

Appropriate number of lozenges are crushed and dissolved in 5 ml of methanol in 50 ml volumetric flask and volume made up of 50 ml with phosphate buffer pH 6.8. From this solution 1 ml was taken and diluted with phosphate buffer pH 6.8 in 50 ml volumetric flask then sonicated for 30min and then filtered using filter paper. The absorbance of the solution is measured spectrophotometric ally at 280 nm. The drug content of gingerol lozenges was calculated using calibration curve.

Moisture Content Analysis

The sample was weighed and crushed in a mortar. From this 1 gm of sample was weighed and placed in a desiccator for 24 h. After 24 h the sample was weighed. The moisture content was determined by subtracting the final weight from initial weight of lozenges.

***In vitro* Mouth Dissolving Time**

Mouth Dissolving Time was determined by each batch formulation using USP disintegration apparatus, where lozenges were placed in each tube of the apparatus and time taken for the lozenges to dissolve completely was noted by using 100ml phosphate buffer of pH 6.8 at 37 ºC. This test was done in triplicate. The average dissolving time for lozenges was calculated and presented with standard deviation.

***In vitro* Dissolution Studies**

USP dissolution test apparatus type II (Paddle) was used for dissolution studies. A dissolution test was carried out using 900 ml of phosphate buffer 6.8 pH at 37 ± 0.5 °C and 100 rpm. 5 ml sample solutions were collected at a precise time interval of 5, 10, 15, 20, 25, and 30 min and an equivalent volume of fresh solution was added to maintain the sink condition. The sample solution was analysed at 280 nm using a spectrophotometer against a suitable blank.

Stability Studies

All the prepared formulations were subjected to stability studies at temperature and 40° C / 75 % RH for a period of 3 month. After 1month drug content, hardness and moisture content were determined.

RESULTS AND DISCUSSION

Construction of Calibration Curve

Calibration curve of gingerol was taken in phosphate buffer 6.8 at 280 nm . The absorbance value in the range of 1-5 µg/ml and their calibration curve were given in the Table 3. The drug was found to obey Beer's Lambert's law with regression coefficient (R^2) values of 0.9858 in phosphate buffer pH 6.8.

Table 3: Calibration curve of Gingerol

Concentration (µg/ml)	Absorbance at 280 nm
0	0
1	0.079

2	0.134
3	0.214
4	0.300
5	0.323

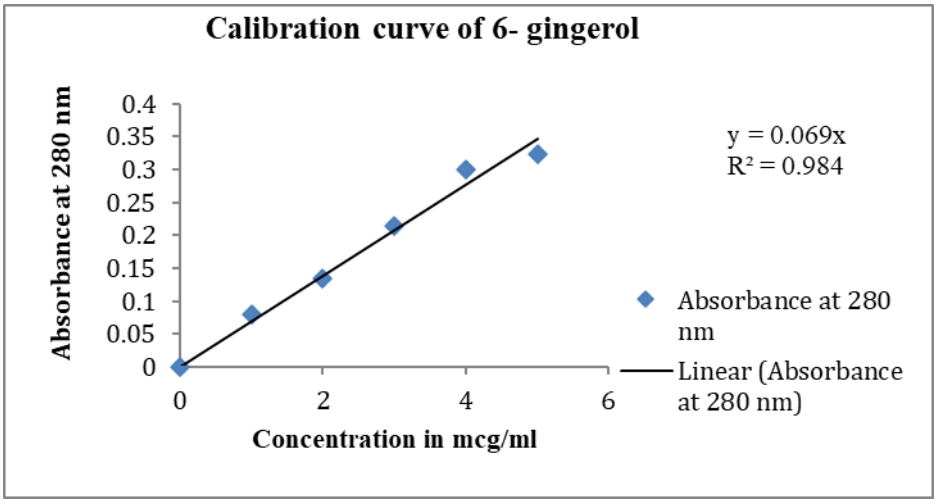

Fig. 2: Calibration curve of Gingerol in phosphate buffer pH 6.8

Solubility of Gingerol in Different Solvents

Table 4: Solubility of Gingerol in different solvents

S.NO	Solvents	Solubility (mg/ml)
1.	Distilled Water	0.98
2.	Tween	1.74
3.	Propylene Glycol	1.95
4.	Glycerol	2.68
5.	**PEG 400**	**3.85**

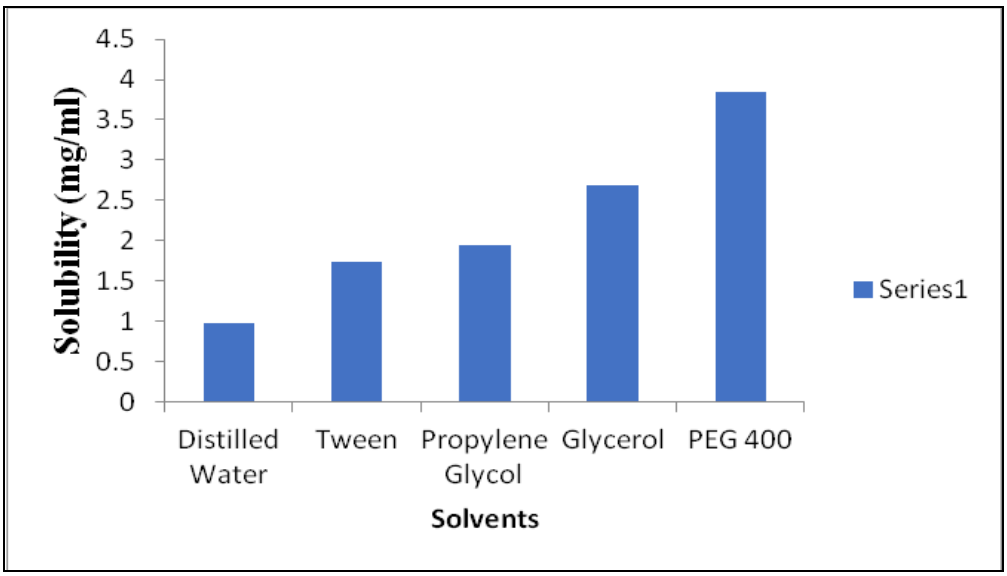

Fig.3 Solubility of gingerol in different non-volatile solvents

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The solubility was determined by dissolving in different solvents like Distilled water, Tween80, propylene glycol, Glycerol and PEG400. PEG 400 was exploited as a non-volatile liquid vehicle for gingerol liquisolid system.

Compatibility Studies using FT-IR Spectroscopy

FTIR spectra of drug, excipients and their mixtures were analyzed to check the interactions between them. The spectra and major peaks of individual compounds and their combinations are given in the figures below. From the spectra it is clear that there is no interaction between the drug and excipients. Hence the selected excipient was found to be compatible with the selected drug.

Table 5: FTIR studies of Pure gingerol powder

S.NO	Functional group assignment	Wave number (cm^{-1}) of gingerol
1	C=C bond	1600-1680
2	O-H bond(alcohol)	3200-3600
3	C=C stretching (aromatic)	1500-1600
4	C-H Stretching(aromatic)	3000-3100

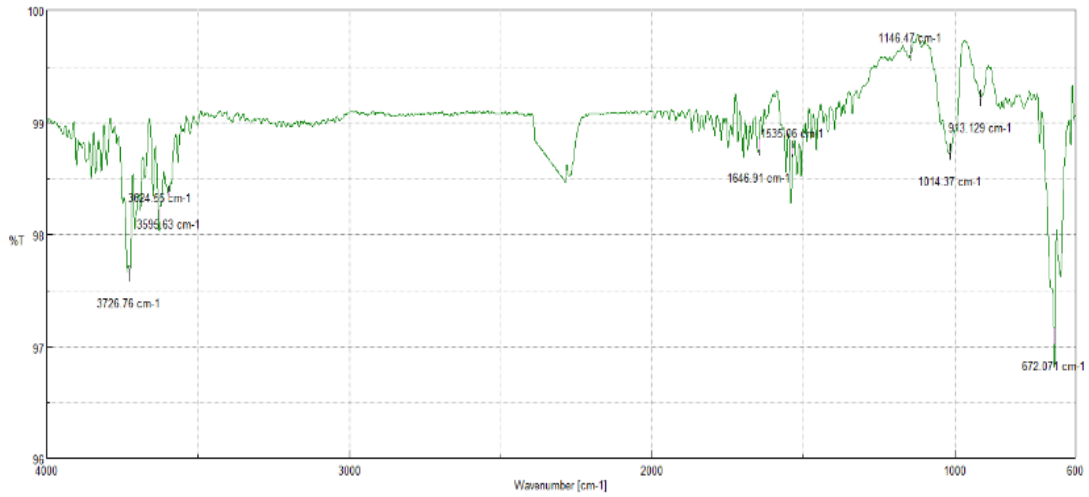

Fig. 4 FTIR studies of Pure gingerol powder

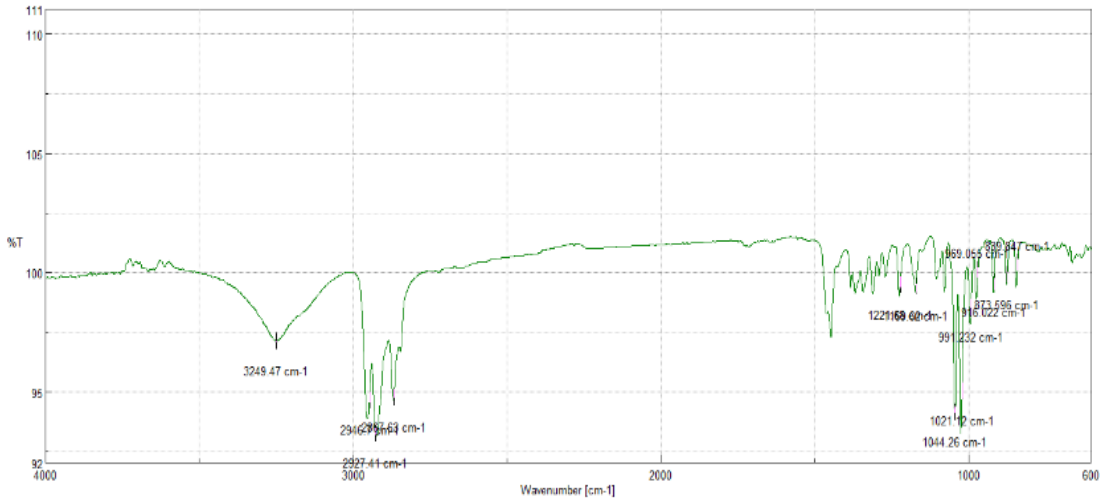

Fig.5 FTIR Studies of drug with Avicel PH102

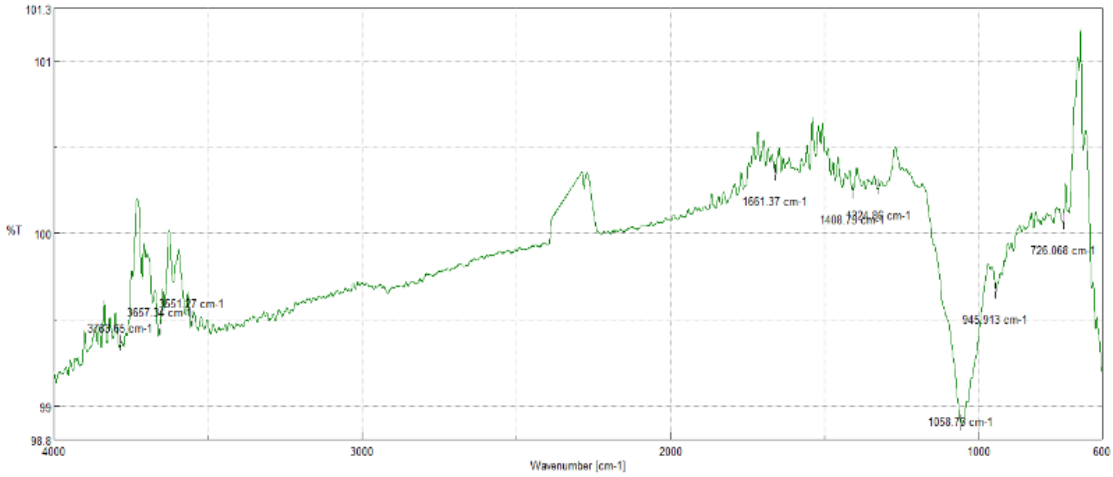

Fig. 6 FTIR studies of Drug with Aerosil 200

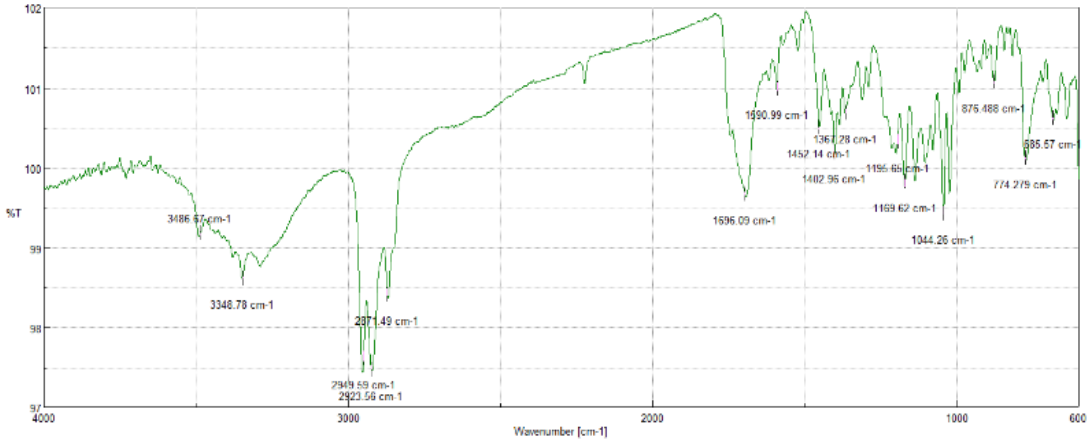

Fig. 7 FTIR studies of Drug with sodium starch glycolate

Quantification of Gingerol in Ginger Powder using HPTLC

Table 6: Result of HPTLC

S.No.	Parameters	Results
1	Appearance	Brown coloured powder
2	Quantification of Gingerol (By HPTLC)	1.21 % w/w

Estimation of Gingerol in Ginger powder by HPTLC
Photo documentation under UV visible spectrophotometer

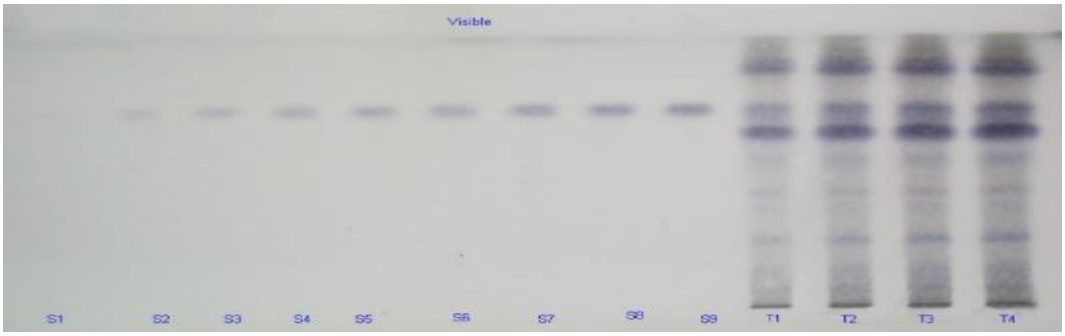

Fig. 8 Photo documentation under UV Visible spectrophotometer

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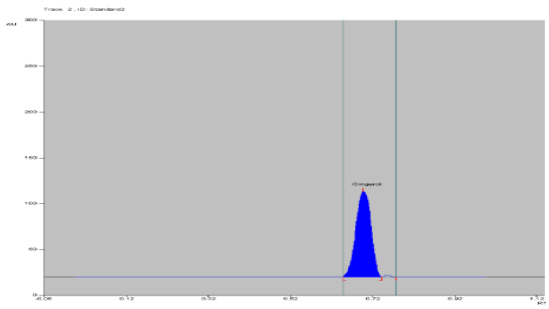

Fig. 9. Denstiogram of standard Preparation (R_f=0.73)

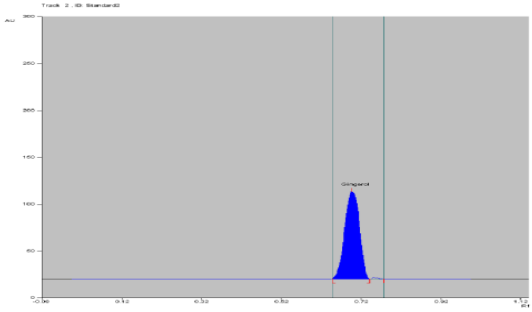

Fig. 10. Denstiogram test sample (R_f=0.73)

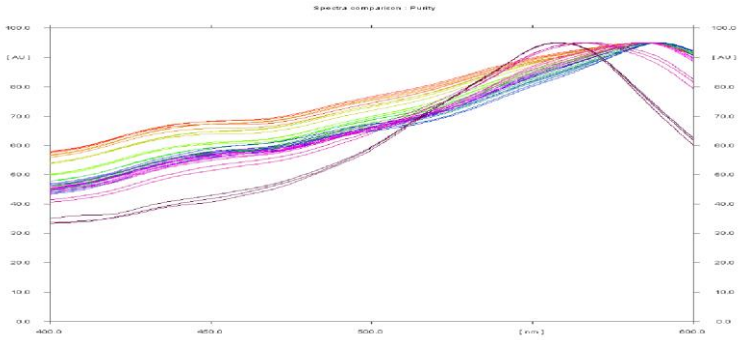

Fig. 11. Spectral comparison for purity

RESULTS

The amount of Gingerol in Herbal powder was found to be 1.21 % w/w.

DSC Curve of 6-Gingerol and Liquisolid Compact Mixture

DSC thermogram of the pure drug (gingerol) displayed a sharp endothermic peak at 215.5°C, indicating the melting transition temperature and decomposition of gingerol. This peak suggests that the 6-gingerol used was in a pure crystalline state. In contrast, the DSC thermogram of the physical mixture (liquisolid compact) showed the complete disappearance of the characteristic peak at 221°C. This observation aligns with the formation of a drug solution within the liquisolid powdered system, indicating that the drug was molecularly dispersed within the liquisolid matrix. The disappearance of the drug peak in the liquisolid formulation is consistent with the findings of an article by Mura et al, which stated that the complete suppression of all drug thermal features indicates the formation of an amorphous solid solution.

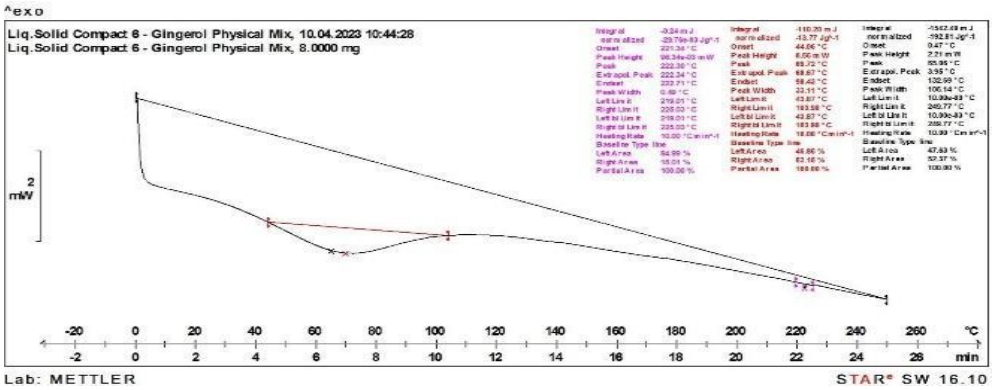

Fig. 12 Differential scanning calorimetry of gingerol

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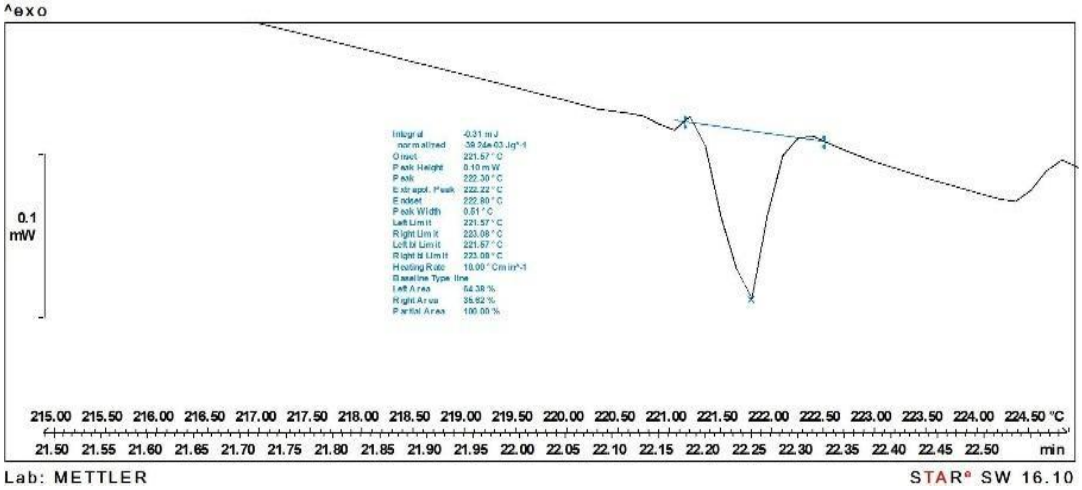

Fig. 13 Differential scanning calorimetry of optimized formulation

X-Ray diffractograms of pure gingerol and optimized formulation

The absence of characteristic peak 6- gingerol in the liquisolid compact formulation shows the conversion of drug to an amorphous or solubilized form. The absence of crystallinity in the liquisolid compact system is due to the solubilization of drug in the liquid vehicle

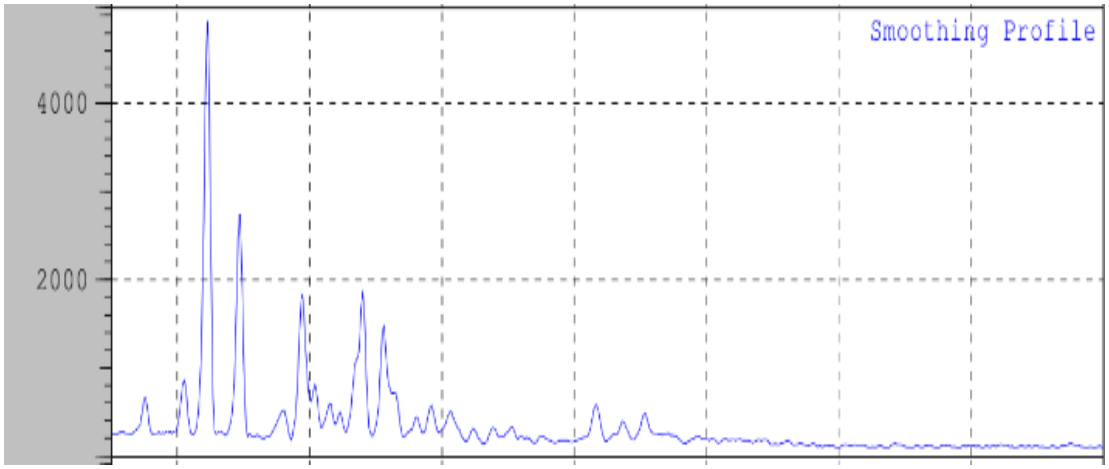

Fig. 14 X-Ray diffractograms of pure gingerol

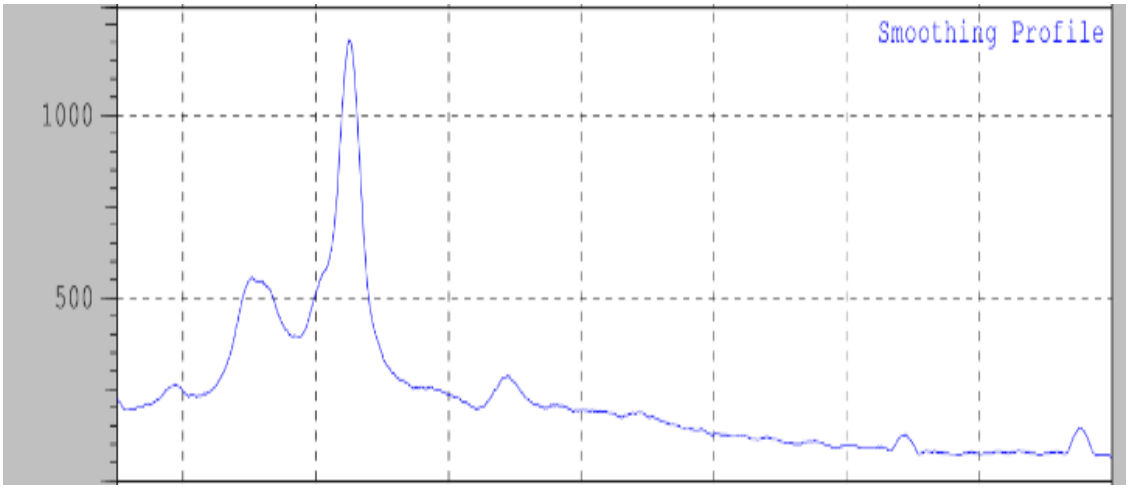

Fig. 15 X-Ray diffractograms of optimized formulation

Preparation of liquisolid compact

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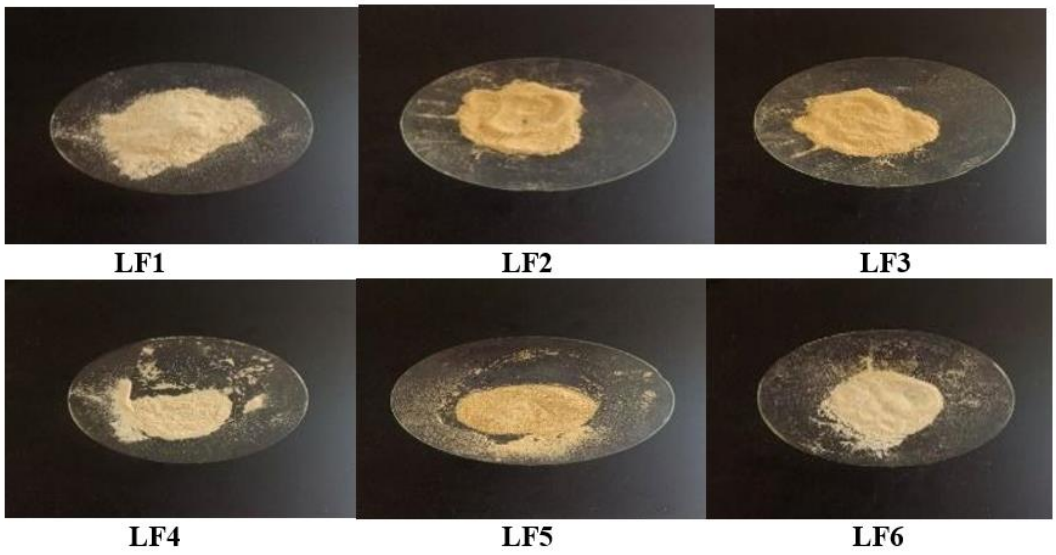

Fig.16 Preparation of liquisolid compacts of F1, F2, F3, F4, F5 and F6

Precompression Parameters

The drug and the formulated powders of gingerol formulation were evaluated for precompression parameters. Table 7 revealed that all the powders of liquisolid compact systems prepared had a satisfactory inflow according to the attained results of measuring the angle of repose. The angle of repose ranges from 24.65 to 28.85°. The set gingerol powder systems can be arranged in thrusting order, regarding the angle of repose measures as follows LF5 < LF3 < LF6 < LF1 < LF4 < LF2. Table 7 also illustrated the bulk and tapped density for gingerol formulation powders and the mean consistence of powders ranges from 0.3608 to 0.413 g/ml for bulk density and from 0.4811 to 0.6015 g/ml for tapped density.

The results attained from Table 7 for Carr's index and Hauser's ratio were calculated. These results revealed that LF1 and LF3 had Hausner ratio of 1.13 and 1.16 respectively, which were lower than 1.2 and suggested with good flowability and the rest formulations had low flowability because it has hausner's ratio greater than 1.2. Formulations LF2, LF4, LF5 and LF6 had Carr's index values of lower than 21 which supports the fact that these phrasings have good inflow. The results are given in the table below.

Table 7: Precompression Parameters

LS-Formulation	Angle of Repose θ°	Bulk density (g/ml)	Hausner's Ratio	Tapped density (g/ml)	Carr's index (%)
LF1	26.43	0.4137	1.13	0.5433	22.0
LF2	28.85	0.4829	1.25	0.6025	25.0
LF3	25.12	0.4142	1.16	0.4833	17.0
LF4	28.34	0.3968	1.26	0.5026	28.2
LF5	24.65	0.3608	1.33	0.4811	25.06
LF6	25.45	0.4135	1.40	0.5079	21.95

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Preparation of Lozenges

Fig.17 Preparation of lozenges

In vitro Disintegration Time

As shown in Table 8 LF4 formulation was set up to be disintegrated (660 seconds) the fastest followed by LF1, LF2, LF3, LF5, LF6, with disintegration times of 720 sec, 840 sec, 720 sec, 720 sec, 840 sec respectively. Among all this formulation, F4 shows the lower disintegrating time (660 sec) and showed a rapid release.

Table 8: Disintegration Time

LS- Formulation	Disintegration Time (sec)
LF1	720
LF2	840
LF3	720
LF4	660
LF5	720
LF6	840

Precompression Studies of Lozenges

From Table 9 the hardness of the lozenges was evaluated. The lozenges formulation LF1, LF2 and LF3, was having the mean hardness of 10, 10.23 and 11.18 kg/cm^2 respectively. Also, formulation LF4 and LF5, LF6 were having hardness of 10.32, 10.52 and 10.48 kg/cm^2. The friability test indicated that all the liquisolid lozenges complied with the British Pharmacopeia specifications as no tested formulations recorded percentage lost exceeding 1 % showed the weight variation of lozenges comply with the test for uniformity of weight. Percentage moisture loss was determined and results are given in Table 9. It was determined to know about the lozenges stability nature and ability of lozenges to withstand its physiochemical properties under normal conditions. Percentage moisture loss of the lozenges LF1**, LF2** was found to be 0.6 to 0.7. Percentage moisture loss of the lozenges **LF3, LF4**was found to be 0.6 to 0.8. Percentage moisture loss of the lozenges L**F5, LF6** was found to be 0.8 to 0.6. Among all these 6 formulations, LF**2** and **LF5** shows the maximum value which indicates the percent moisture loss increases with increase in the percentage of polymer, this may be due to hydrophilic character of the polymer. All the formulations are within the acceptable limits and the results were similar. Where all the formulations were within the range of 90.11 % and 95.10 %.

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Table 9: Post compression characteristics of lozenges

Formulation	Hardness (kg/cm^2)	Friability (%)	Weight Variation (mg)	Drug Content
LF1	10.00 ± 0.002	0.63 ± 0.04	803 ± 18	92.47±0.005
LF2	10.23 ± 0.005	0.59 ± 0.01	801 ± 23	90.11±0.006
LF3	11.18 ± 0.008	0.42 ± 0.06	798 ± 11	95.10±0.004
LF4	10.32 ± 0.006	0.59 ± 0.04	795 ± 20	97.82±0.008
LF5	10.52 ± 0.003	0.58 ± 0.02	800 ± 19	94.40±0.005
LF6	10.48 ± 0.005	0.54 ± 0.10	793 ± 15	92.01±0.002

Mean SD, n=3

***In vitro* dissolution of lozenges**

For i*n vitro* dissolution study of Table 10 showed the dissolution profile of the formulations. It determines that LF5 as more dissolution release rate 90.08 in 60 min. Among all, optimized LF4 showed advanced release rate 97.82 %. The dissolution rates were increased by the proper carriers that used for the lozenges formulations. The advanced dissolution rate displayed by liquisolid compacts will ameliorate the immersion of medicine from the GI tract.

Table 10: *In vitro* Dissolution rate of lozenges

Formulation (%)	Time (min)					
	10	20	30	40	50	60
LF1	29.19	42.72	55.69	71.33	80.53	83.68
LF2	56.39	62.54	69.17	78.53	86.72	89.98
LF3	48.56	79.73	65.19	72.39	81.92	85.97
LF4	25.96	39.52	48.42	59.37	70.69	76.38
LF5	58.79	65.96	70.21	79.49	87.83	90.08
LF6	52.92	61.43	67.66	76.96	83.64	88.62

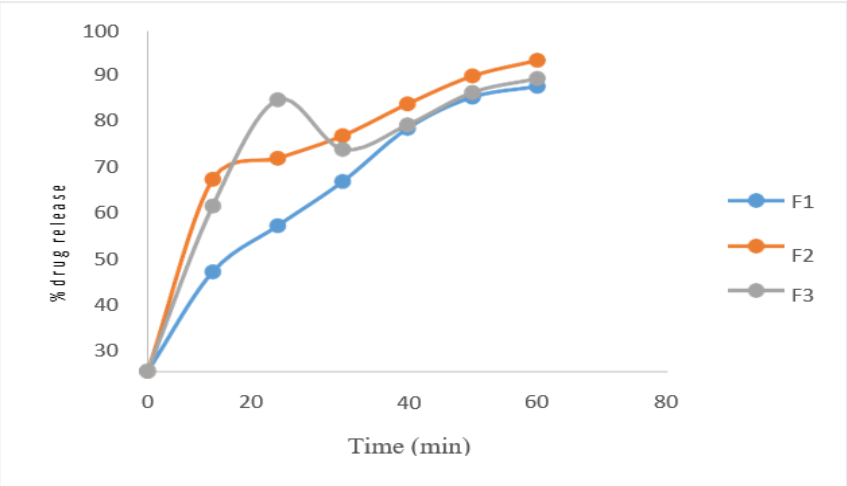

Fig. 18: In vitro dissolution of formulations F1, F2 and F3

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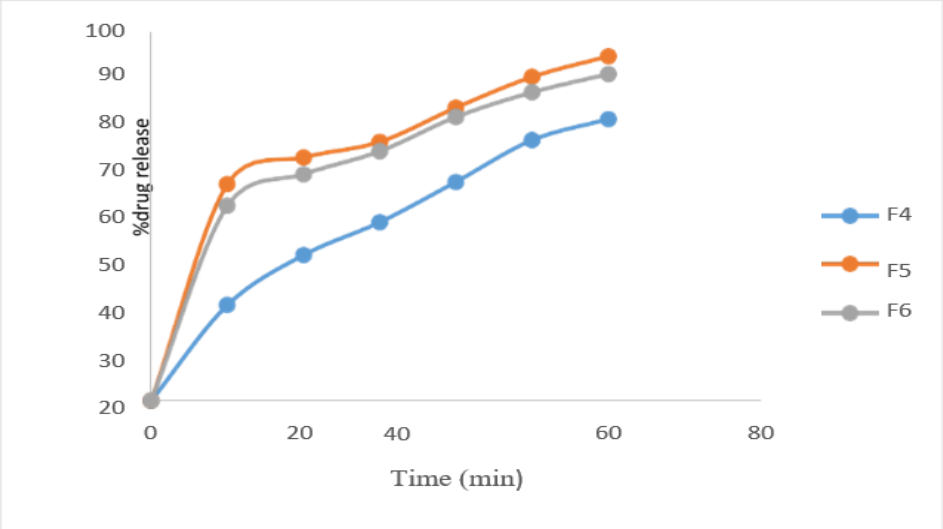

Fig. 19. In vitro dissolution of formulations F4, F5 and F6

In vitro Drug Release Kinetics

Table 11: Kinetics analysis of *in-vitro* drug release data of F4 formulation

Formulation Code	Zero order R^2	First order R^2	Higuchi model R^2	Korsmeyer- peppas equation R^2
LF4	0.9173	0.7699	0.9874	0.7032

In order to determine the release kinetics, the *in-vitro* drug release data were analyzed in zero order, first order and higuchi model. The preference of a certain mechanism was based on the coefficient of determination for the parameters studied, where the highest coefficient of determination is preferred for the selection of the order of release. However, in many experimental situations the mechanism of drug diffusion deviates from the Fickian equation and follows a non-Fickian (anomalous) behavior. In some cases, the Korsemeyer-peppas model was used to analyze the release kinetics. Using the Korsemeyer- Peppas model, n = 0.45 indicates case I or Fickian diffusion, 0.45< n> 0.89 indicates anomalous behavior or non-Fickian transport, n = 0.89 indicates case II transport and n greater than 0.89 indicates super case II transport. Release of all the formulations followed Higuchi model, exhibited diffusion-controlled mechanism as indicated from the highest coefficient of determination (r^2). According to the Korsemeyer-peppas model anomalous (non- Fickian release) was observed in F4 formulation as indicated from the release exponent which was 0.9874. It was found that F4 formulation follows Higuchi model as it had highest R^2 value with Korsemeyer – Peppas mechanism.

Stability Studies of Optimized Formulation

The stability study of liquisolid compact was performed at , 40 ± 2 °C, 75 % RH (in stability chamber) and room temperature (27 °C± 2 °C) for 1 month. The physical appearance, drug content was evaluated after 1 day and 3rd month of storage. There was no significant change observed in the hardness and drug content of the liquisolid compact over 3 months at any temperature condition.

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Table 12. Stability Studies of Optimized Formulation

Day of sample withdrawing	Temperature	Hardness (kg/cm^2)	Drug content (%)
Day1	40 ºC ± 2 ºC	10.32 ± 0.006	97.82 ± 0.008
	Room Temperature	10.30 ± 0.006	97.70 ± 0.006
Day 30	40ºC ± 2 ºC	10.25 ± 0.003	97.62 ± 0.008
	Room Temperature	10.35 ± 0.003	97.72 ± 0.005

Mean SD, n=3

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