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# DESIGN AND DEVELOPMENT OF THE LIQUISOLID COMPACT OF GINGEROL LOADED LOZENGES

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## ABSTRACT

The work was aimed to design and develop liquisolid compact of gingerol loaded lozenges for increasing the solubility of 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 obtained to be above 97.82 %. The lozenges formulation was optimized based on evaluation parameters such as weight variation, hardness, friability, and drug content. Based on the evaluation studies F4 was identified as best formulation. Formulation F4 exhibited a drug release profile of 90.08 % and followed the Higuchi model. The satisfactory results were obtained from the stability studies. This technique aims to enhance the solubility in water and bioavailability of the pure drug 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.[1,2] Medications like lozenges can help prevent nausea. A

drug's permeability through lipophilic membranes and solubility in an aqueous environment determine its bioavailability. Solubilized drug molecules only able to be absorbed by the cellular membranes and reaches in to the desired site.[3]

The selection of non-volatile solvents, carriers, coating materials, and their ratios can enhance solubility and bioavailability.[4] Lozenges are solid dosage forms that are gradually dissolve/disintegrate into the oral cavity. They are flavoured and sweetened to have a pleasing taste, and contains one or more active ingredients. They can contain anesthetic, demulcent, or antiseptic ingredients. Lozenges are chiefly useful for patients having difficulty in swallowing conventional solid dosage forms.[5] In this study, we employed the liquisolid method to enhance the solubility of gingerol, which was then formulated into lozenges to provide a convenient route of administration for patients experiencing motion sickness.

## MATERIALS AND METHODS

Gingerol was gifted by herbal creations, Uttarakhand**,** polyethylene glycol 400, Avicel PH 102 Aerosil-200, glycerin, HPMC K100, sucrose, tween 80, dextrose, menthol, propylene glycol, citric acid, sodium starch glyclolate, talc were supplied by Loba Chemie laboratory reagents and fine chemicals, Mumbai.

## DETERMINATION OF STANDARD CURVE

Dissolve 100 mg of pure 6-gingerol in 10 ml of ethanol. Further sonicated and suitable dilution was made with phosphate buffer pH 6.8. This resulted solution (1 mg/ml) of gingerol was further diluted to obtain serial dilution ranges between 2 µg/ml to 10 µg/ml. The diluted samples were subjected to measure the absorbance using UV spectrophotometer at 280 nm.[6]

## DETERMINATION OF SATURATION SOLUBILITY

Gingerol solubility in different liquid vehicles with excess amount of gingerol was carried out in glycerin, tween-80, polyethylene glycol 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 that, the solutions were subjected to centrifuge 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. The absorbance was measure of all the samples at 280 nm.[7]

## FORMULATION OF LIQUISOLID SYSTEM

The liquisolid systems were compounded based on the mathematical model presented by Spirease. PEG 400 was chosen as liquid vehicle based on its drug solubility, Avicel PH 102 and Aerosil-200 was separately used as carrier material, coating material respectively. The carrier to coating material ratio is termed as excipient ratio of powder (R), defined as

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

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

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

W is the weight of liquid medication and Q is the weight of carrier material. The load factor was further used to calculate the carrier and coating material quantity.[8]

**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

## PREPARATION OF CANDY LOZENGES

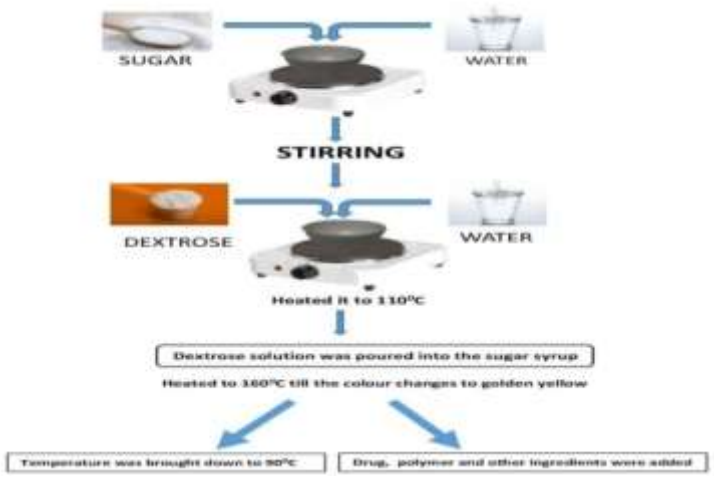



**Figure 1: Schematic representation of preparation of lozenges.**

Syrup of dextrose was poured into sugar syrup and heated to 160 ℃ till the color changes to golden yellow. The temperature was then lowered to 90 ℃. Subsequently liquisolid mixture was added and poured into the mould having 2.8 cm in dm and 6.5 mm thickness. The prepared lozenges were stored in an aluminum foil and kept in a desiccator to avoid from absorption of moisture. The final weight of each lozenge is 3.09 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 |
|---|---|---|---|---|---|---|
| Gingerol liquisolid mixture | 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[9,10]

Evaluation of flow properties including Carr's compressibility index and Hausner's ratio were determined by using the following formula.

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

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 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.[11] The DSC measurements (METTLER TOLEDO) were performed with a temperature range of 0 to 350° C and a scanning rate of 10° C/min.

**Fourier Transform Infrared Spectroscopy (FTIR)**

FTIR experiments were carried out for carrier, coating, physical mixture and gingerol 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.[12]

**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.[13]

## EVALUATION OF PHYSICOCHEMICAL CHARACTERISTICS OF OPTIMIZED GINGEROL LOZENGES

**Average weight and Weight variation test[15]**

The average weight was computed based on the collective weight. The weight of each lozenge was then compared to the average weight to ensure that it was within allowable bounds. For 300 mg tablets, no more than two of the individual weights varied from the average weight by more than 7.5 %, and none by more than twice that amount.

**Friability test**

A friabilitor evaluated 20 tablets from each batch to determine their level of friability. for four minutes at a speed of 25 rpm followed by weighed them again and used the calculation to get the percentage weight reduction.[16]

% Friability = (initial weight. - Wt. after friability) × 100 / initial weight

**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**

In a 50 ml volumetric flask, the required number of lozenges is crushed, dissolved in 5 ml of methanol, and the volume is increased to 50 ml with pH 6.8 phosphate buffer. 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.[17]

**Moisture content analysis**

The crushed lozenges were stored in a desiccator. 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 evaluated by each 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 observed using 100 ml 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.[15]

***In vitro* 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 using USP dissolution test apparatus type II (Paddle). 5 ml of sample solution were collected at a various time interval of 5, 10, 15, 20, 25, and 30 min and an equivalent volume of fresh buffer was replaced to maintain the sink condition. The sample solution was analyzed at 280 nm using a spectrophotometer against a suitable blank.[15]

**Stability studies**

The optimized formulation was 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.[18]

## 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 |

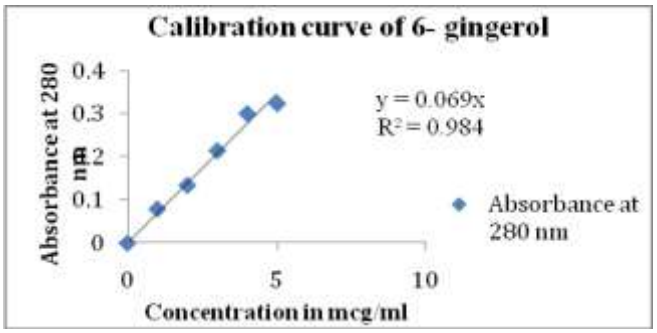



**Figure 2: Calibration curve of Gingerol in phosphate buffer pH 6.8.**

**Solubility of Gingerol in different solvents**

**Table 4: Solubility of Gingerol in different solvents.**

| S.NO | SOLVENTS | SOLUBITITY (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** |

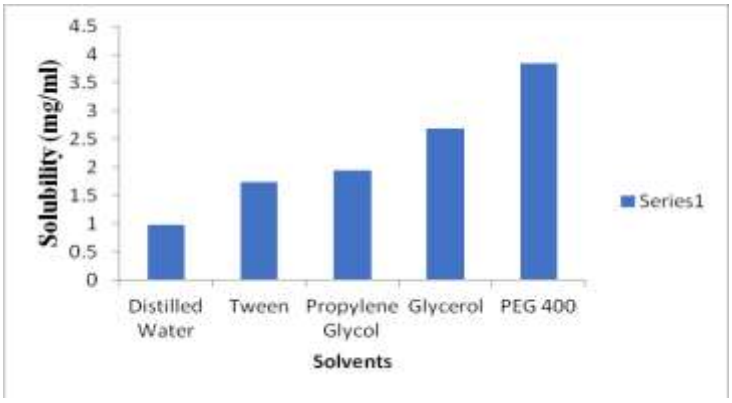



**Figure 3: Solubility of gingerol in different non-volatile solvents.**

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**

The spectra and major peaks of individual compounds and their combinations are given in the figures below. From the following spectrums it is clear that there was no interaction between the drug and excipients. Hence the selected excipient was proved to be compatible with the gingerol.

**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 |

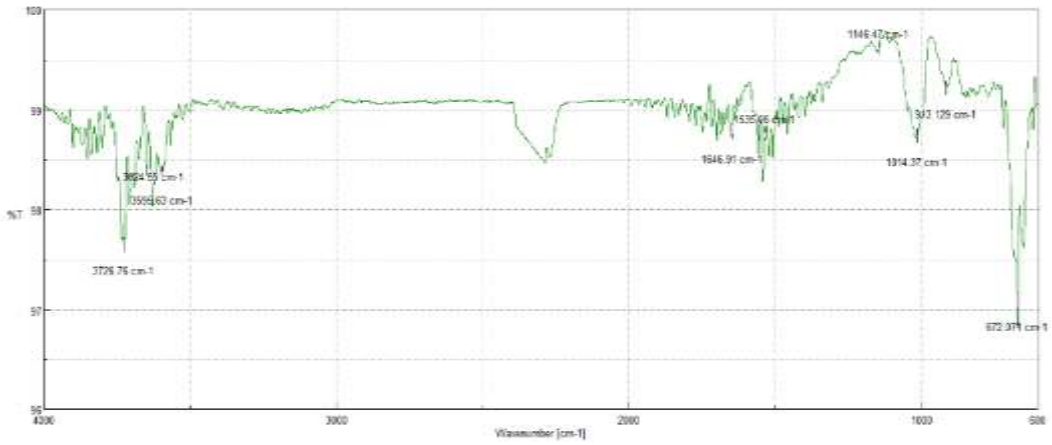


**Figure 4: FTIR spectrum of Pure gingerol powder.**

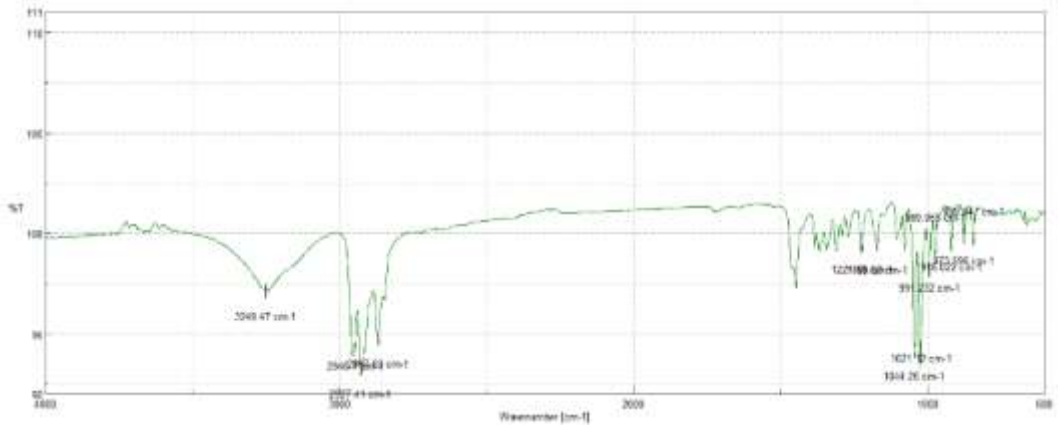


**Figure 5: FTIR Spectrum of drug with Avicel PH102.**

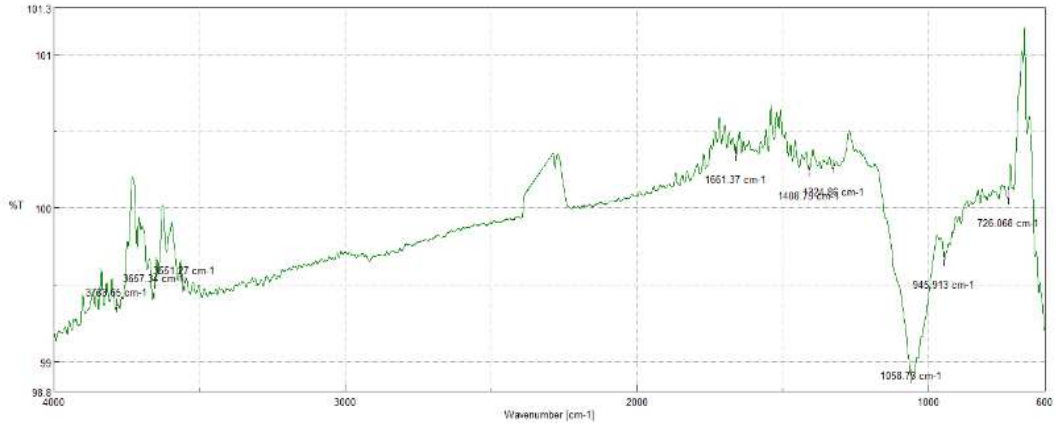



**Figure 6: FTIR Spectrum of Drug with Aerosil 200.**

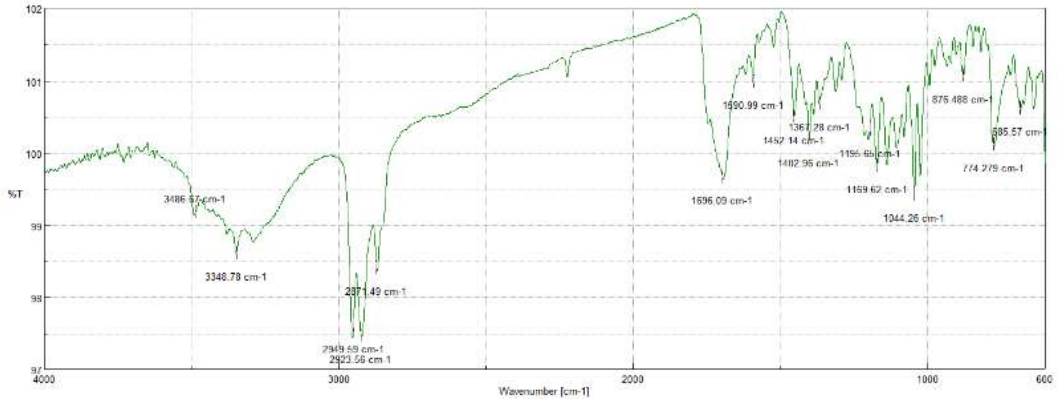



**Figure 7: FTIR Spectrum of Drug with sodium starch glycolate.**

**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.

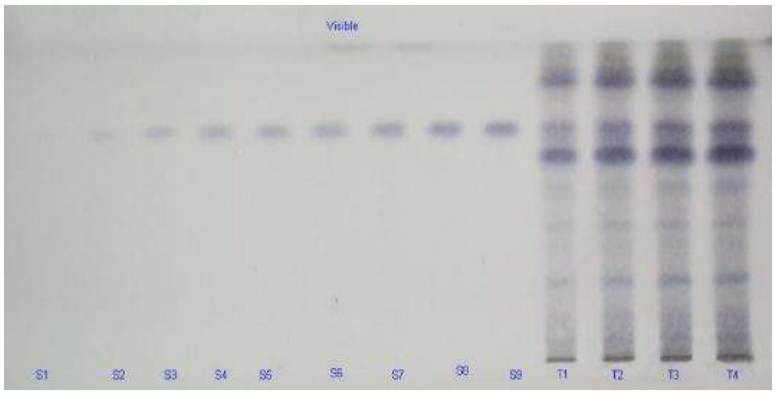



**Figure 8: Photo documentation under UV Visible spectrophotometer.**

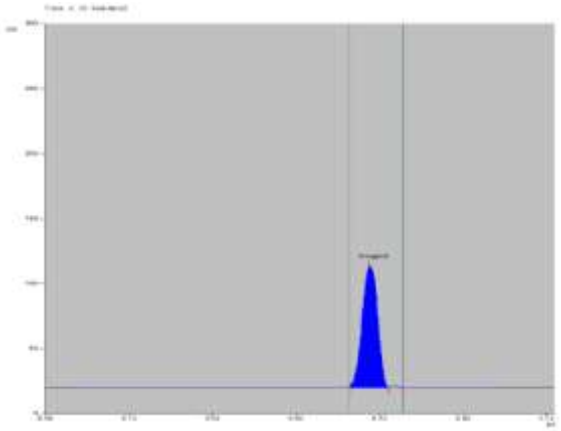


**Figure 9. Denstiogram of standard Preparation (Rf=0.73)**

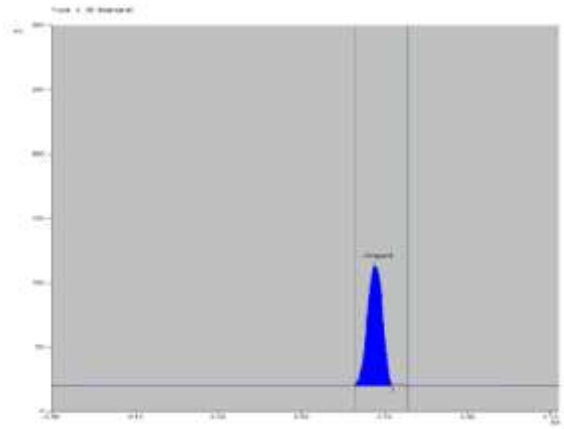


**Figure 10. Denstiogram test sample(Rf=0.73)**

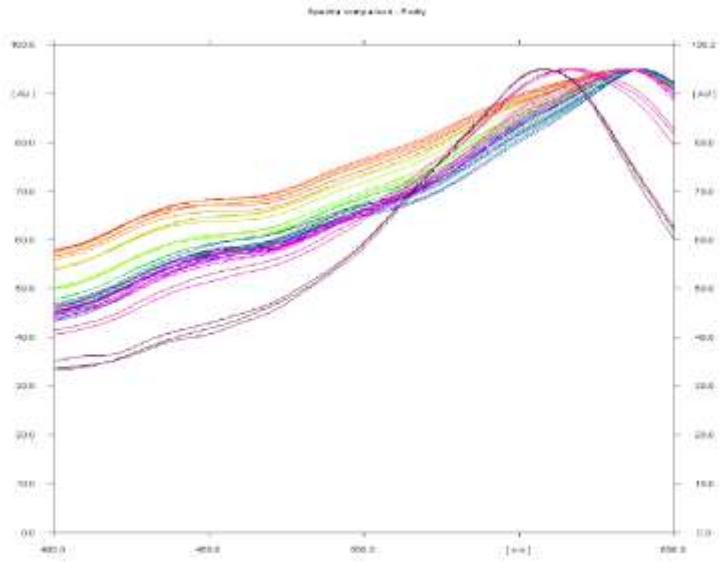


**Figure 11: Spectral comparison for purity.**

## 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℃, indicating the melting transition temperature and decomposition of gingerol. This peak confirmed that the 6-gingerol was in a pure crystalline state. In contrast, DSC thermogram of the physical mixture (liquisolid compact) showed the complete disappearance of the characteristic peak at 221℃. 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.

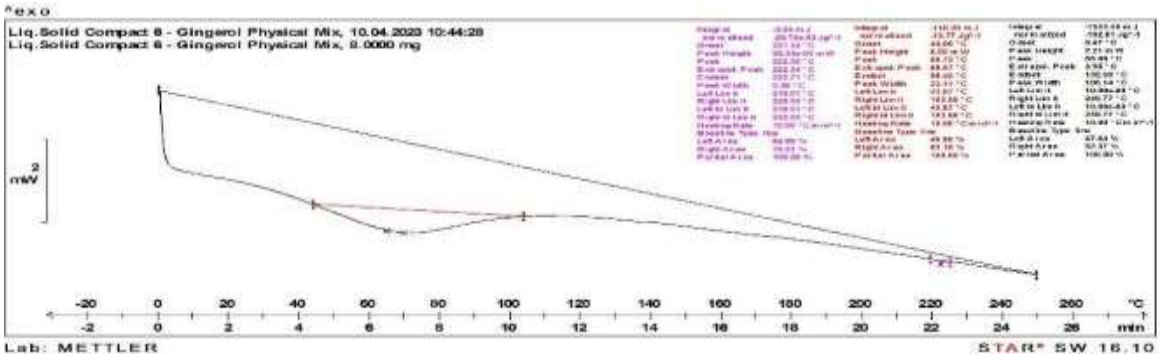



**Figure 12. Differential scanning calorimetry of gingerol.**

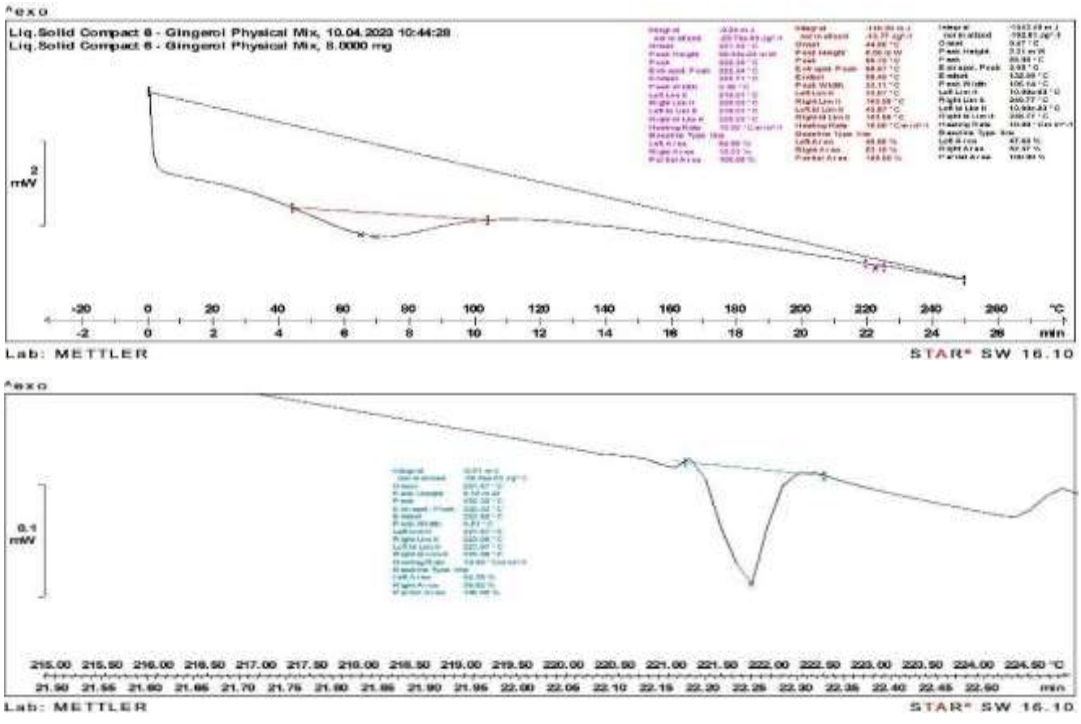



**Figure 13: Differential scanning calorimetry of optimized formulation.**

**X-Ray diffractograms of pure gingerol and optimized formulation**

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

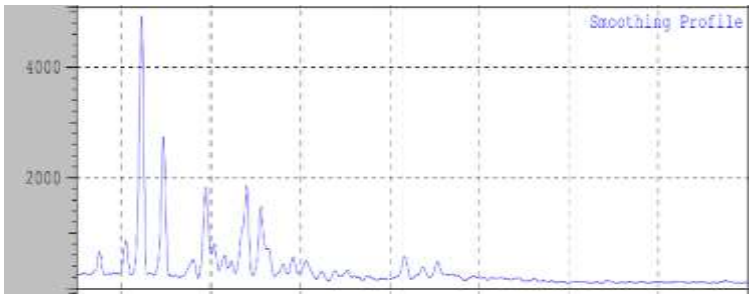



**Figure 14: X-Ray diffractograms of pure gingerol.**

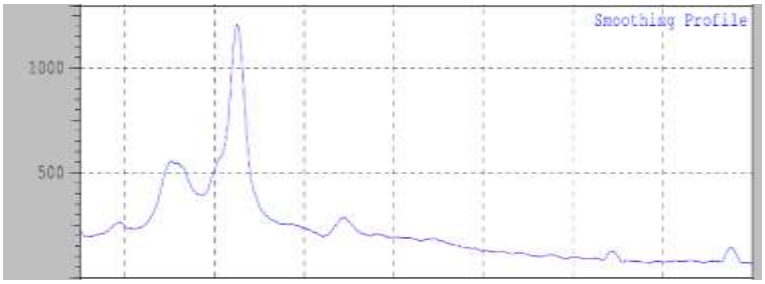
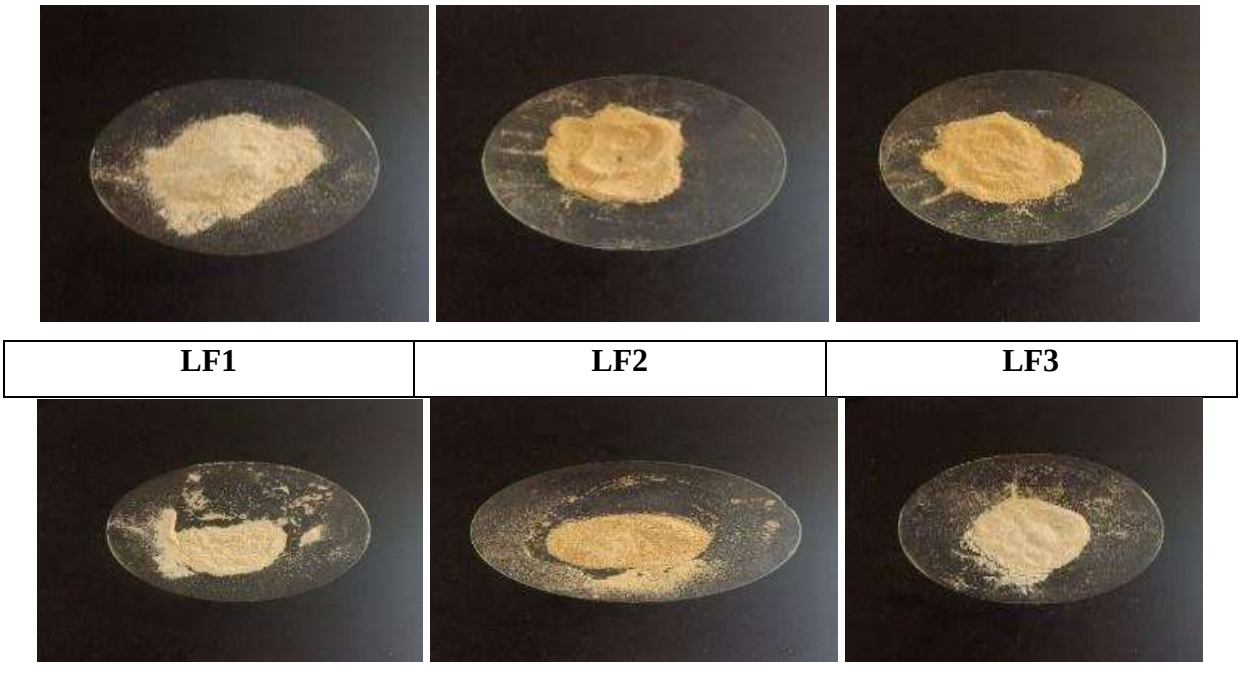



**Figure 15: X-Ray diffractograms of optimized formulation.**

**Preparation of liquisolid compact**



| LF1 | LF2 | LF3 |
|---|---|---|
| LF4 | LF5 | LF6 |

**Figure 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 |

**Preparation of lozenges**

**Figure 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 showed the disintegrated with a short interval i.e.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 %.

**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 |

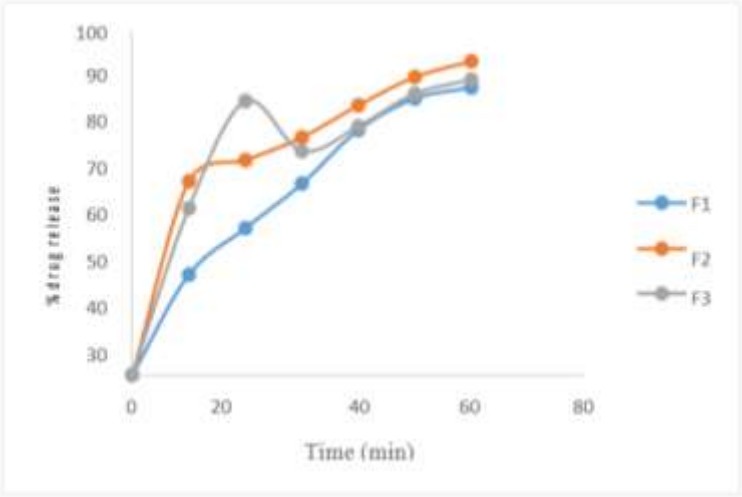



**Figure 18: *In vitro* dissolution of formulations F1, F2 and F3.**

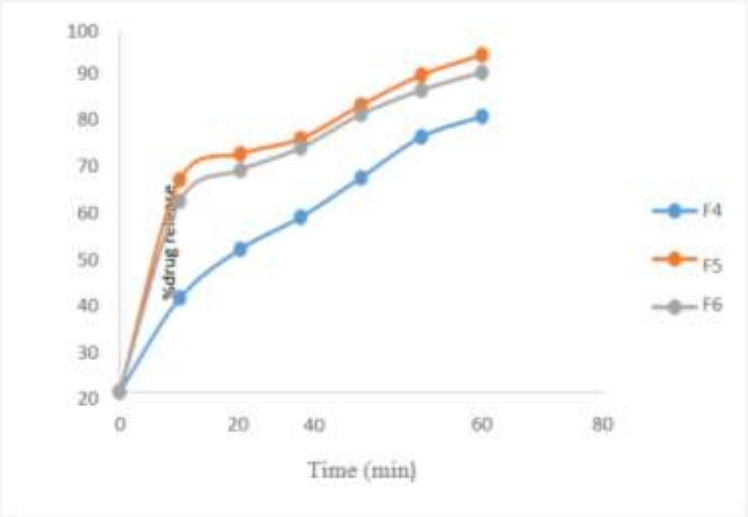



**Figure 19: *In vitro* dissolution of formulations F4, F5 and F6.**

***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 coefficient of determination for the parameters under study determined which method was favored, with the highest coefficient of determination being used to determine the release order. 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 were 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 month at any temperature condition.

**Table 12: Stability studies of optimized formulation.**

| Day of sample withdrawing | Temperature | Hardness ($kg/cm^2$) | Drug content (%) |
|---|---|---|---|
| Day1 | 40 ºC ± 2 | 10.32 ± 0.006 | 97.82 ± 0.008 |
| | Room Temperature | 10.3 ± 0.006 | 97.70 ± 0.006 |
| Day 30 | 40ºC ± 2 | 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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