



## Design and evaluation of pharmacosomes loaded with telmisartan

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### Abstract

The research focused on creating pharmacosomes with telmisartan to enhance its solubility, bioavailability, and reduce toxicity. Using soya phosphatidylcholine in varying ratios, the complex was prepared via solvent evaporation. The optimized formulation (F1, 1:1 ratio) achieved a drug concentration of 96.83% w/w. Characterization through X-ray powder diffraction confirmed complex formation, while scanning electron microscopy showed disc-shaped particles. In *in vitro* dissolution studies, F1 released 94.69% of the drug over ten hours, compared to 60.42% for pure telmisartan. These findings suggest that the phospholipid complex significantly improves telmisartan's solubility and therapeutic potential.

**Keywords:** Telmisartan, bioavailability, pharmacosomes, phospholipid complex, solubility, DSC, XRD, SEM

### Introduction

Pharmacosomes are colloidal dispersions formed by covalently bonding drugs to lipids, combining the Greek words for "drug" and "carrier." They can take various forms, such as vesicular or micellar aggregates, and effectively overcome limitations of traditional systems like transferosomes [1]. Their amphiphilic nature reduces interfacial tension, enhancing drug bioavailability while minimizing gastrointestinal toxicity [2, 3]. Suitable for both hydrophilic and lipophilic drugs, pharmacosomes enable controlled release and targeted delivery, reducing treatment costs and side effects. The unique properties of phospholipids allow for modified drug release rates, making pharmacosomes a promising strategy for improving therapeutic efficacy [4, 5].

### Drugs

Drugs containing active hydrogen atom (-COOH, OH, NH<sub>2</sub>) can be esterified to the lipid, with or without spacer chain and they form amphiphilic complex which in turn facilitate membrane, tissue, cell wall transfer in the organisms [6].

### Solvents

For the preparation of pharmacosomes, the solvents should have high purity and volatile in nature. A solvent with intermediate polarity is selected for pharmacosomes preparation [6].

### Lipids

Phospholipids, primarily phosphoglycerides and sphingolipids, are key components of biological membranes, with phosphatidylcholine being the most common. This amphiphilic molecule consists of a glycerol backbone linked to two hydrophobic acyl chains and a hydrophilic phosphocholine head. Most commercial lecithin products contain about 20% phosphatidylcholine, sourced from plants, animals, and microbes. Pharmacosomes are an innovative drug delivery system that improves the solubility, stability, and bioavailability of poorly soluble active pharmaceutical ingredients (APIs). They facilitate targeted delivery and controlled release while minimizing

side effects and toxicity, allowing for lower effective doses and enhancing the therapeutic potential of medications [6].

### Materials and methods

Following are the list of ingredients and their sources 1. Telmisartan-Kashvi life sciences cuddalore 2. Soya lecithin-oxford fine chem 3. Dichloromethane-sisco research laboratories 4. Methanol-molychem Mumbai 5. Chloroform- oxford fine chem labs.

### Determination of $\lambda$ max [7]

A stock solution of Telmisartan (10 mg in 10 ml methanol) was diluted to 100  $\mu$ g/ml, from which concentrations of 4, 8, 12, 16, and 20  $\mu$ g/ml were prepared. UV absorbances were measured, and a calibration curve was plotted based on the recorded  $\lambda$  max.

### Determination of standard curve [8]

The stock solution was serially diluted to concentrations of 4-20  $\mu$ g/ml using phosphate buffer at pH 7.4, with absorbances measured at 296 nm in a UV spectrometer. A calibration curve was plotted with absorbance on the y-axis and concentration ( $\mu$ g/ml) on the x-axis to determine the slope.

### Preparation of pharmacosomes of telmisartan by solvent evaporation technique [9]

Pharmacosomes of Telmisartan were prepared by acidifying the drug with 0.1 N hydrochloric acid, extracting it with chloroform, and recrystallizing. Telmisartan was then combined with soya lecithin in various molar ratios, refluxed in dichloromethane, and the solvent evaporated before characterization.

**Table 1:** Formulation table of telmisartan pharmacosomes [10]

Ingredients	F1	F2	F3	F4	F5	F6	F7
Telmisartan: Soya lecithin (Molar Ratio)	1:1	1:1.5	1:2	1:2.5	1:3	1:3.5	1:4
Dichloromethane (ml)	20	20	20	20	20	20	20

**Preformulation studies**<sup>[11]</sup>

Pre-formulation testing is a crucial first step in drug development, focusing on the physical and chemical properties of a drug substance, both alone and with excipients. Its main objective is to provide data that assists formulators in creating stable, scalable drug forms. For telmisartan and soya lecithin, these studies evaluate solubility, stability, and compatibility, helping to optimize formulations for effective drug delivery. Understanding these properties enables informed decisions that enhance bioavailability and minimize toxicity.

1. Organoleptic properties
2. Preliminary solubility analysis

**Compatibility studies****FTIR**<sup>[11]</sup>

The IR spectra matching approach was used to assess potential chemical interactions between the drug and excipient. A physical mixture of the drug and soya lecithin was compressed with potassium bromide into a pellet and scanned using a Perkin Elmer FTIR spectrophotometer. Comparing the IR spectra of the pure drug and the mixture helped identify any changes in peak appearance, indicating possible interactions.

**Angle of repose**<sup>[12]</sup>

The angle of repose measures the maximum angle between a powder pile and the horizontal plane, indicating resistance to particle flow. It was determined using the fixed funnel method, where the funnel's tip touches the powder heap. After allowing the powder to flow, the height (h) and radius (r) of the cone were measured. The angle ( $\theta$ ) was calculated using the formula.

$$\theta = \tan^{-1} \left( \frac{h}{r} \right)$$

**Bulk density**<sup>[6]</sup>

Bulk density is the weight-to-volume ratio of a powder, expressed in g/mL, and helps determine container size for handling. A weighed quantity of powder (W) is placed in a graduated cylinder, and the volume occupied ( $V_0$ ) is measured. Bulk density is calculated using the formula:

$$\text{Bulk Density} = \frac{W}{V_0}$$

**Tapped density**<sup>[13]</sup>

Tapped density is the weight-to-volume ratio of a powder after compaction, expressed in g/ml. It is determined by tapping a graduated cylinder containing the powder until no further volume change occurs. The final volume ( $V_f$ ) is measured, and tapped density is calculated using the formula:

$$\text{Tapped Density} = \frac{W}{V_f}$$

**Hausner's ratio**<sup>[13]</sup>

It is the ratio of a powder's tapped bulk density to its poured bulk density. It was calculated using the formula

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

**Carr's index**<sup>[13]</sup>

$$C_i = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

**Differential scanning calorimetry (DSC)**<sup>[14]</sup>

DSC measures the amount of heat energy absorbed or released by a sample, as it is heated, cooled or held at a constant temperature which intern provides the melting point of a sample. Thermal properties of the pure drug and the physical mixture of drug and excipients were analyzed by Perkin Elmer Differential Scanning Calorimeter. The samples were heated in a hermetically sealed aluminium pan. Heat runs for each sample were set from 30<sup>0</sup> C to 100<sup>0</sup>C at a heating rate of 3<sup>0</sup>C/min, during the measurement, inert nitrogen gas was purged into the system.

**Evaluation of pharmacosomes****Drug content determination**<sup>[15]</sup>

To determine the drug content in Telmisartan pharmacosomes, a 50 mg sample was added to a 100 ml volumetric flask with pH 7.4 phosphate buffer and stirred for 24 hours. Afterward, suitable dilutions were made, and the drug content was measured at 296 nm using UV spectrophotometry.

**X-ray powder diffraction (XRD) analysis**<sup>[16]</sup>

The crystalline state of Telmisartan in various samples was analyzed using a Rigaku X-ray powder diffractometer at Vignan Bhavan, University of Mysuru. The powder sample was placed in an aluminium holder, with the X-ray generator operated at 40 kV and 30 mA using Cu K $\alpha$  radiation. Scanning was conducted from 10<sup>0</sup> to 90<sup>0</sup> at a speed of 10<sup>0</sup>/min, analysing the drug, phosphatidylcholine, and the pharmacosome.

**Scanning electron microscopy (SEM) analysis**<sup>[17]</sup>

To analyze the surface morphology of the pharmacosome, SEM was conducted using a Zeiss Scanning Electron Microscope at Vignan Bhavan, University of Mysuru. The sample was mounted on an SEM stub with double-sided adhesive tape and coated for 6 minutes at 50 mA using a KYKY SBC-12 sputter coater. Digital images were captured using a secondary electron detector.

**In vitro dissolution study**<sup>[15]</sup>

The dissolution test was performed using the USP XXIV Type I apparatus at 75 RPM and 37<sup>0</sup>C  $\pm$  0.5<sup>0</sup>C for 10 hours in 900 ml of pH 7.4 phosphate buffer. Samples (10 ml) were withdrawn at predetermined intervals and replaced with fresh buffer. Absorbance was measured at 296 nm using a Shimadzu double beam spectrophotometer. Cumulative release was calculated using appropriate equations based on a standard curve. This method evaluates the release characteristics of the capsule formulation.

**Results and discussion****Preformulation studies of Telmisartan**

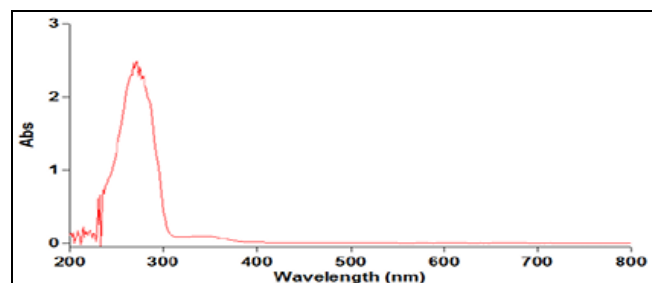
**Table 2:** Organoleptic properties and characteristics of Telmisartan

Properties	Reported	Observed
Appearance	White powder	White powder
Odour	Odourless	Odourless
Solubility	Ethanol	Soluble
	Methanol	Soluble
	Chloroform	Insoluble
	Ethyl ether	Insoluble
	Water	Sparingly soluble
	Glycerol	Sparingly soluble

- a. Organoleptic evaluation:** Organoleptic evaluation like general description, odour and colour of telmisartan were evaluated. It was found that telmisartan was odourless and white powder the results obtained are shown in table No.02.
- b. Solubility study:** The study of Telmisartan was carried out in ethanol, methanol, was insoluble in chloroform, ethyl ether, and sparingly soluble in glycerol and water. The telmisartan was soluble in ethanol, methanol, and ethyl ether and insoluble in water and glycerol. The results of solubility studies obtained were shown in Table No.07.

#### Determination of $\lambda_{max}$

Solution of Telmisartan (100  $\mu\text{g/ml}$ ) was prepared using methanol and this solution was scanned for absorbance 200-800 nm using Shimadzu UV spectrophotometer. The absorption maximum ( $\lambda_{max}$ ) was found 296 nm. This value was selected for rest of the UV spectrophotometric analysis.



**Fig 1:** Peak representing the absorption maximum ( $\lambda_{max}$ ) of Telmisartan at 296nm

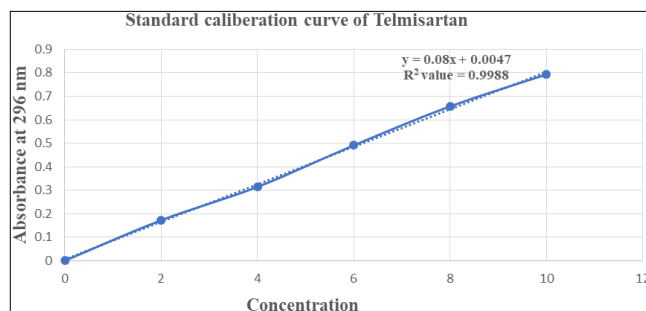
#### Standard calibration plot

Absorbances of all the solution were measured at 296 nm against blank and calibration curve was constructed by taking concentration on x-axis and absorbance on y-axis. As shown in fig. 2.

**Table 3:** Standard calibration table of Telmisartan

Sl. no	Concentration ( $\mu\text{g/ml}$ )	Absorbance
1	2	0.172 $\pm$ 0.0041
2	4	0.314 $\pm$ 0.0159
3	6	0.491 $\pm$ 0.0032
4	8	0.657 $\pm$ 0.0017
5	10	0.793 $\pm$ 0.0031

\*All the Values represents are mean of 3 readings (n=3)  $\pm$ SD-Standard deviation

**Fig 2:** Calibration curve Telmisartan

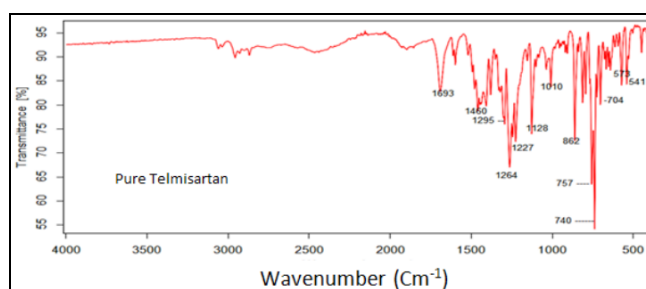
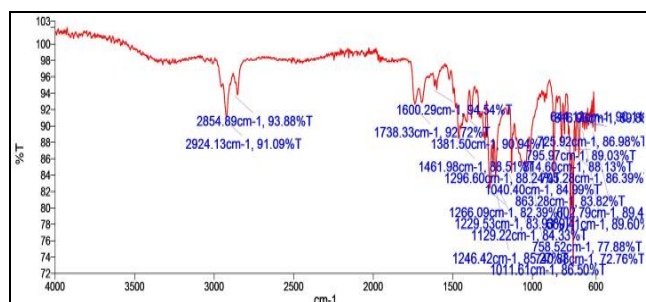
A drug solution ranging from 2  $\mu\text{g/ml}$  to 10  $\mu\text{g/ml}$  was prepared using methanol, and absorbance was measured at the absorption maximum ( $\lambda_{max}$ ) of 296 nm using a UV spectrophotometer. The absorbance data plotted against concentration showed linearity, obeying Beer's Law in the range of 0-7  $\mu\text{g/ml}$ , with a slope of  $y = 0.08x + 0.0047$  and an  $R^2$  value of 0.9988. Absorbance values at different concentrations are provided in Table 6, and the standard plot is illustrated in Figure 2.

#### Compatibility studies using FT-IR

Compatibility of drug in physical mixture and formulation was analysed by FT-IR. The prominent functional groups were observed and interpreted and is shown in Table. 04.

**Table 4:** Interpretation of theoretical and observed FTIR peaks

S.no	Functional group	Characteristic Peaks	Observed peaks	
			Telmisartan	Telmisartan+soya lecithin
1	C=C	1450-1600	1460	1461
2	C-H	2850-2975	2920	2924.13
3	C-N	1342-1266	1295	1266.09
4	C-O	1075-1010	1010	1040.40
5	N-H	3300-3350	—	—
6	O-H	1320-1210	1264	1229

**Fig 3:** FTIR spectra of Pure Telmisartan**Fig 4:** FTIR spectra of Telmisartan + soya lecithin [Drug + Exipient]

The compatibility of Telmisartan with excipients was assessed using FT-IR spectroscopy. The IR spectra showed characteristic peaks consistent with literature, indicating no new peaks or loss of existing ones in the drug-loaded particles. This confirms that the polymer did not alter the drug's performance characteristics, demonstrating compatibility between Telmisartan and the lipid used, as illustrated in figures 3&4.

### Micromeritic study

**Table 5:** Micromeritic properties of pharmacosome powder

Formulation code	Angle of repose ( $\theta^\circ$ )	Bulk Density (gm/ml)	Tapped Density (gm/ml)	Carr's index (%)	Hausner Ratio
F1	24°15'	0.554	0.624	11.21	1.12
F2	26°53'	0.401	0.453	11.47	1.12
F3	24°82'	0.500	0.570	14.0	1.14
F4	27°08'	0.433	0.500	13.40	1.15
F5	28°30'	0.454	0.525	13.52	1.15
F6	27°56'	0.415	0.500	17.0	1.20
F7	27°63'	0.500	0.624	19.87	1.24

The angle of repose, Bulk density, tapped density, Carr's index and Hausner's ratio was found within the passable limits thus it shows good flow properties.

### Drug content studies

The drug content of telmisartan in the pharmacosomes was estimated by UV spectrophotometry at 296 nm using pH 6.8 phosphate buffer.

**Table 6:** Results of drug content studies

Formulation	Drug content
F1	96.83
F2	96.12
F3	93.38
F4	93.56
F5	90.81
F6	90.04
F7	88.60

The drug content of Telmisartan in the complex ranged from 88.60% to 96.83%, indicating acceptable levels in the formulations. Pharmacosomes demonstrated high drug loading, which decreased with increased lipid concentration. Formulation F1 achieved the maximum drug content of 96.83%, highlighting the formulation's effectiveness in maintaining drug levels.

### Solubility studies

The change in solubility of telmisartan due to complexation was determined by evaluating its solubility in water, pH 6.8. Phosphate buffer and n-octanol solutions and was estimated by UV spectrophotometry at 296nm.

**Table 7:** Solubility profile in different media

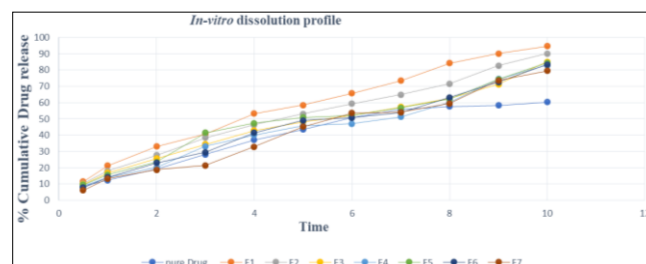
Formulation	Solubility in Water (mg/ml)	Solubility in pH 7.4 phosphate Buffer (mg/ml)	Solubility in n-Octanol (mg/ml)
Pure Drug	0.143	0.196	0.230
F1	0.787	5.272	5.975
F2	0.780	5.150	5.641
F3	0.651	4.836	5.283
F4	0.693	3.950	4.568
F5	0.527	3.751	4.190
F6	0.572	3.863	4.236
F7	0.616	4.355	4.586

The solubility of Telmisartan pharmacosomes was significantly higher than that of the pure drug, attributed to micelle formation and the complex's amorphous nature. Amphiphilic surfactants (phospholipids) enhanced drug solubility through their wetting and dispersion properties. Formulation F1 showed the highest degree of solubility, highlighting the effectiveness of this approach in improving bioavailability.

### In-Vitro Dissolution studies

**Table 8:** *In vitro* drug release of telmisartan pharmacosomes

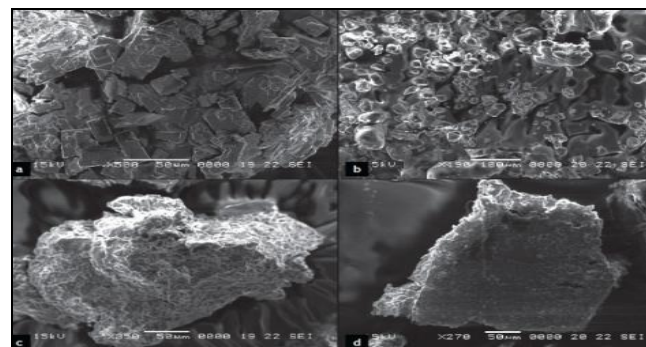
Time (hrs)	Pure Drug	% Cumulative Release						
		F1	F2	F3	F4	F5	F6	F7
0.5	8.66	11.58	10.37	9.88	8.64	9.54	7.85	6.19
1	12.33	21.29	18.07	16.94	14.21	15.73	14.26	13.42
2	19.27	33.16	27.68	25.65	20.14	23.46	23.02	18.85
3	28.21	40.64	38.42	34.49	33.24	41.51	29.51	21.52
4	37.10	53.21	46.63	42.92	40.23	47.43	41.46	32.94
5	43.54	58.55	53.17	48.19	45.75	50.85	49.00	45.18
6	50.98	65.77	59.40	52.08	46.98	52.30	50.76	53.62
7	55.88	73.50	64.81	57.30	51.27	56.74	53.95	54.05
8	57.62	84.16	71.54	62.69	60.20	62.25	63.16	59.54
9	58.27	90.19	82.79	71.20	74.48	74.25	72.60	73.60
10	60.42	94.69	90.05	85.07	83.05	84.44	83.34	79.49



**Fig 5:** *In vitro* comparative dissolution profile of pharmacosomes containing Telmisartan

The pharmacosomes of Telmisartan showed better dissolution profile than the pure drug. Unlike the free telmisartan (which showed a total of only 60.42% drug release at the end of the 10 hour), all the formulation showed the percentage cumulative drug release in the range of 79.49–94.69%. The formulation F1 with drug: soya lecithin ratio of 1:1 showed the maximum release of 94.69% at the 10th hour.

### Scanning electron microscopy analysis

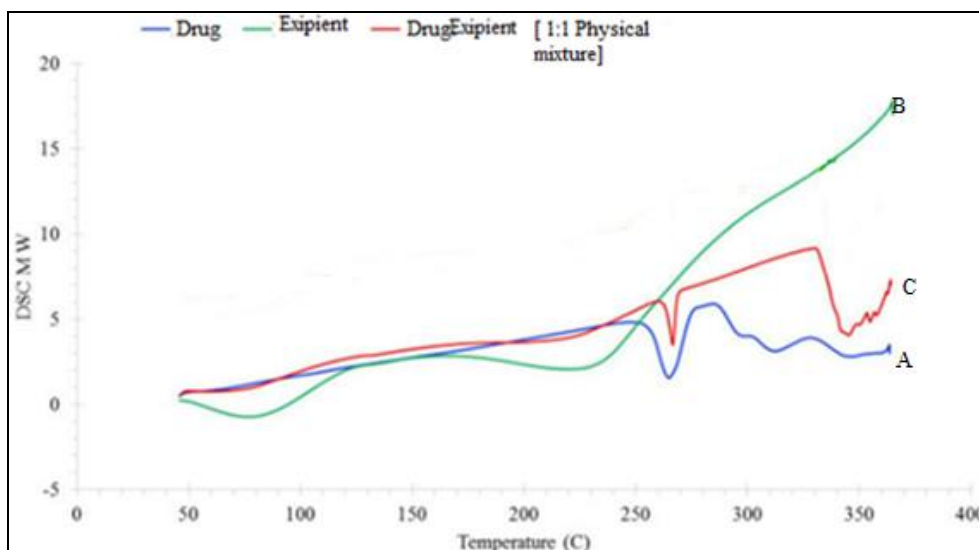


**Fig 6:** Scanning electron microscopy images of Telmisartan and Pharmacosomes (a) Telmisartan (b) Phospholipid (c) Pharmacosomes of Telmisartan 1:1 (drug: lipid ratio) (d) Pharmacosome of telmisartan 1:2.5 (drug: lipid ratio).

Particle morphology was determined by scanning electron microscopy. The SEM image showed that the pharmacosomes were roughly disc shaped. Scanning Electron Micrographs of the complex are shown in fig no: 06.

### Differential Scanning Calorimetry (DSC)

DSC analysis of Telmisartan pharmacosomes showed a sharp endothermic peak at 230 °C for the pure drug and 265 °C for the optimized formulation. While there was no significant shift in peak position, changes in peak intensities indicated reduced drug crystallinity. This suggests that the drug is physically entrapped without interaction with the lipid.



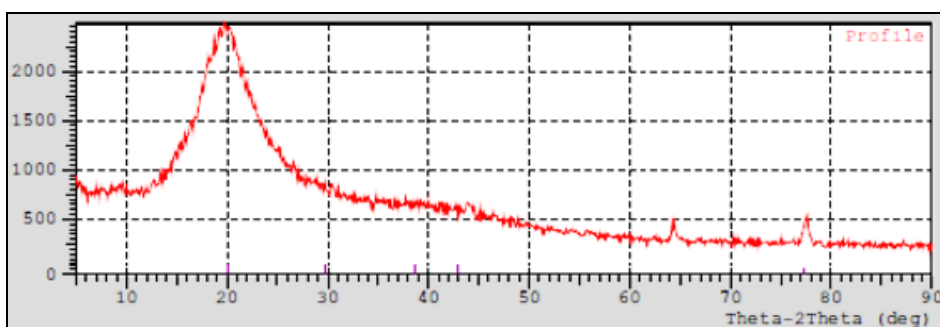
**Fig 7:** DSC Thermogram showing A. Drug (Telmisartan) B. Excipient (phosphatidylcholine) C. Drug excipient mixture (1:1 ratio)

**Table 9:** Interpretation of DSC thermogram from the figure.12

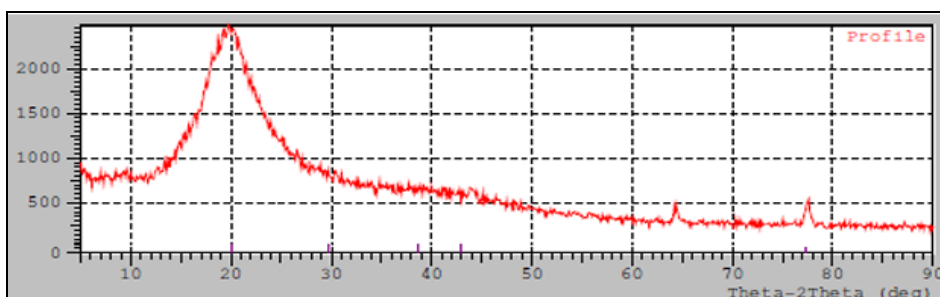
Sample	Tp onset °C	Tp peak °C	Tp End °C
Telmisartan	210°C	230 °C	240 °C
Soya lecithin	260°C	265 °C	270°C
Telmisartan soya lecithin complex	250 °C	265 °C	275 °C

The XRD pattern of the pure drug (telmisartan), soya lecithin and the selected formulation ( $F_1$ ) are shown in Fig: 08 Fig: 09 and Fig: 10. Characteristic diffraction peaks were observed for telmisartan. On the other hand, the formulation  $F_1$  was characterized by less intensity of the diffraction peak when compared to that of the pure drug. This clearly indicates the reduction in the crystallinity of Telmisartan in pharmacosomes.

### X-RAY Powder Diffraction (XRD) analysis



**Fig 8:** XRD pattern of pure drug (Telmisartan)



**Fig 9:** XRD pattern of Soya lecithin

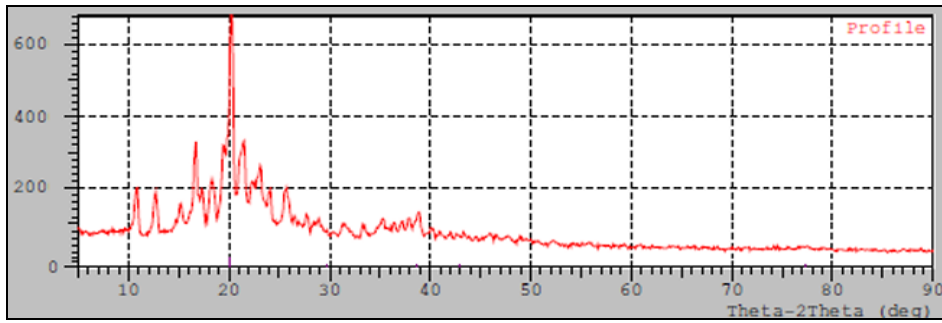


Fig 10: XRD pattern of Telmisartan Pharmacosomes

**Release kinetic analysis**

The optimal formulation, F1, was assessed for release kinetics using *in-vitro* drug release data. Cumulative release was analyzed with various models, including Korsmeyer-Pappas for release mechanism and Zero-order, First-order,

and Higuchi models for release pattern. The best-fitting model was selected based on regression coefficient values, aiding in understanding the drug release behaviour from the pharmacosomes.

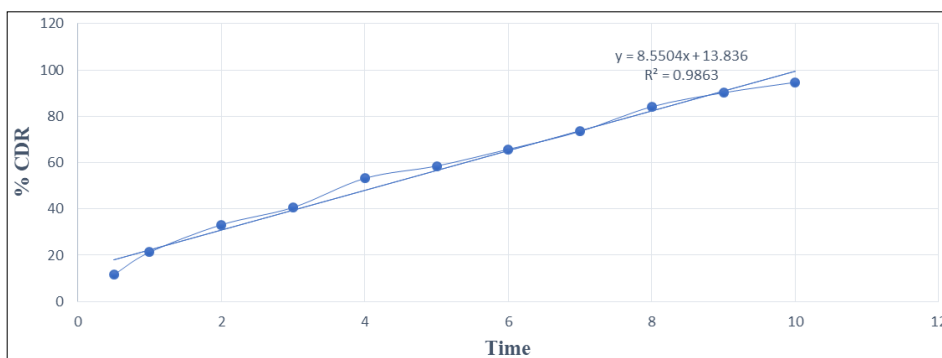


Fig 11: Zero order plot for F1 formulation

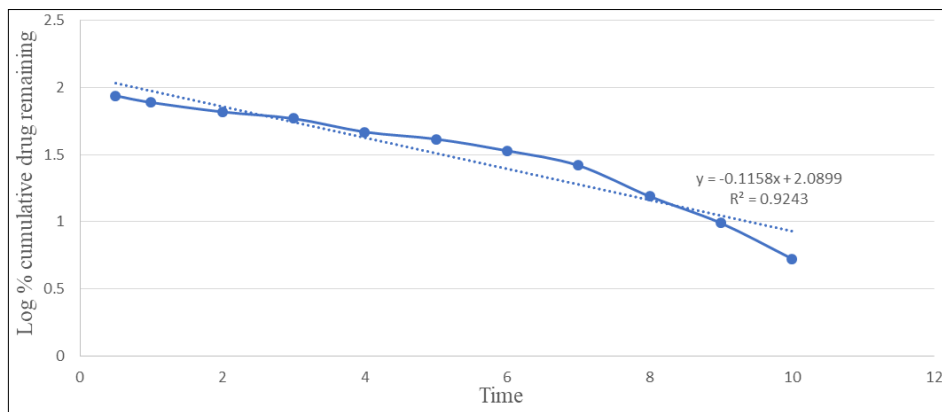


Fig 12: First order plot for F1 formulation

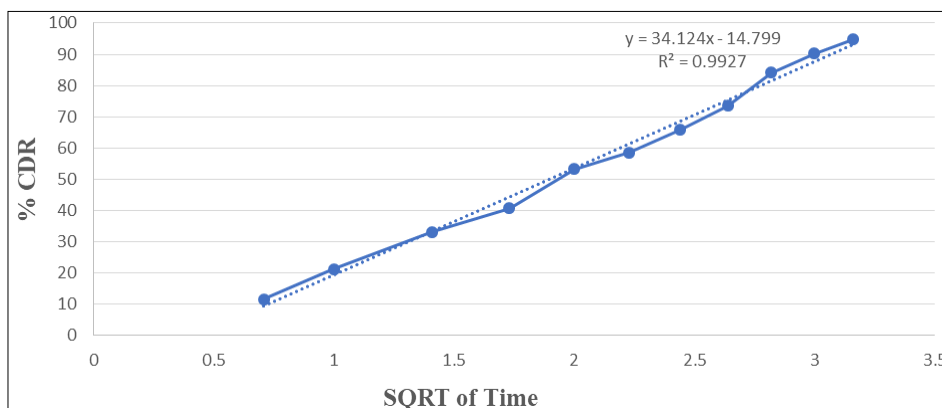


Fig 13: Higuchi model for F1 formulation

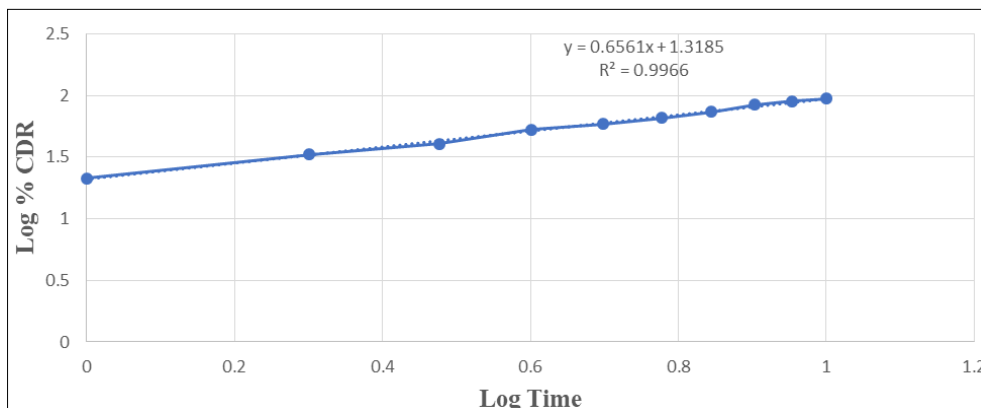


Fig 14: Korsmeyer-Peppas model of F1

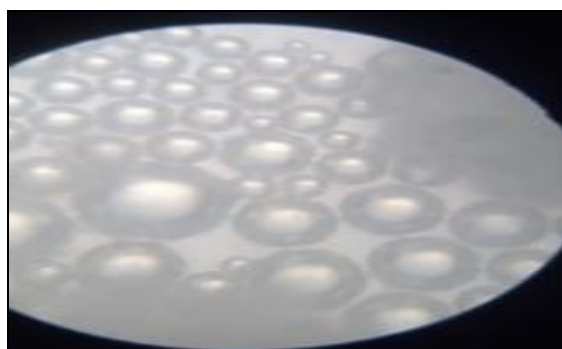
Table 10: Result of kinetic analysis

Formulation	Zero order	First order	Higuchi model	Korsmeyer Peppas model	
	R <sup>2</sup>	R <sup>2</sup>	R <sup>2</sup>	R <sup>2</sup>	N
F1	0.9863	0.9243	0.9927	0.9966	0.6561

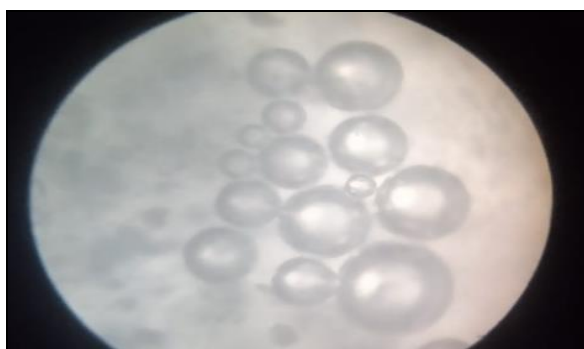
From the regression coefficient values obtained, it was found out that the formulation follows the near korsmeyer peppas model. The slope value (n) obtained from peppas plot was 0.6561, which indicates that the formulation

followed Non-Fickian diffusion mechanism of drug release which involves diffusion followed by polymer relaxation.

**Microscopic images of pharmacosomes: [Fig no. 20]**



F1 Image



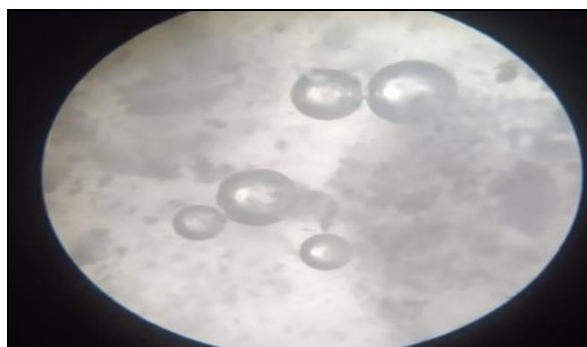
F2 Image



F3 Image



F4 Image



F5 Image



F6 Image

## Conclusion

Study reveals that pharmacosomes formulation offers yet other opportunities for poorly water-soluble drugs to enhance its solubility, absorption hence bioavailability. Telmisartan can be formulated into pharmacosomes with lecithin as vesicle forming agent in the ratio of 1:1.

## Scope for future studies

Further studies can be carried using other techniques and Excipients

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