Int. J. Sci. R. Tech., 2025 2(7)
A Multidisciplinary peer-reviewed Journal
www.ijsrtjournal.com [ISSN: 2394-7063]

Original Article

Formulation and Evaluation Fast Disintegrating Tablet of Telmisartan

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ABSTRACT

Telmisartan, a widely used antihypertensive agent, suffers from poor aqueous solubility, leading to limited oral bioavailability. To overcome this challenge and enhance patient compliance, especially in geriatric and pediatric populations, fast disintegrating tablets (FDTs) offer a promising drug delivery approach by providing ease of administration and rapid onset of action without the need for water. The present study aimed to formulate and evaluate fast disintegrating tablets of Telmisartan using the direct compression method, focusing on achieving rapid disintegration, improved drug release, and acceptable mechanical properties. Four formulations (F1–F4) were prepared using varying concentrations of excipients such as Crospovidone, HPMC and Microcrystalline Cellulose. All ingredients were sieved, blended, and compressed into tablets using a rotary compression machine. The prepared tablets were evaluated for pre- and post-compression parameters, including hardness, friability, disintegration time, swelling index, drug content and in-vitro dissolution. The dissolution study was performed in phosphate buffer (pH 6.8) and drug release was monitored spectrophotometrically. Among all formulations, Formulation F3 exhibited optimal performance, with a disintegration time below 40 seconds, high drug content (99.02%) and rapid drug release (55.6% at 5 min; 99.4% at 30 min). The swelling index and mechanical strength were within acceptable limits, indicating a balanced formulation. Stability studies confirmed that F3 remained stable under ICH-recommended conditions over two months. The optimized formulation F3 demonstrated excellent physicochemical properties, rapid disintegration, and nearly complete drug release, making it a suitable candidate for fast-acting oral antihypertensive therapy. This study highlights the potential of FDTs in improving the therapeutic efficacy and compliance of Telmisartan in target patient populations.

Keywords: Telmisartan, Fast Disintegrating Tablets, Crospovidone, Direct Compression, Dissolution, Patient Compliance, Hypertension

INTRODUCTION

Hypertension, a major risk factor for cardiovascular morbidity and mortality, affects millions globally and requires long-term pharmacological management. Among the various antihypertensive agents, Telmisartan, an angiotensin II receptor blocker (ARB), has garnered significant clinical attention due to its high efficacy, prolonged half-life and favourable safety profile [1]. However, Telmisartan exhibits poor aqueous solubility (Class II drug in BCS classification), resulting in variable and limited oral bioavailability. Traditional oral dosage forms like tablets or capsules often present challenges for geriatric and pediatric patients, especially those suffering from dysphagia, leading to poor adherence and delayed therapeutic response [2]. To address these issues, fast disintegrating tablets (FDTs) have emerged as a novel and patient-friendly drug delivery system. FDTs disintegrate or dissolve rapidly in the saliva within seconds without the need for water, ensuring swift drug release and absorption [3]. This dosage form not only improves patient compliance but also facilitates faster onset of therapeutic action, particularly advantageous in conditions like hypertension where timely blood pressure control is crucial. The formulation of FDTs is technically challenging and demands a careful selection of excipients and optimization of formulation parameters. Super disintegrants play a pivotal role in ensuring rapid disintegration by facilitating swelling, wicking, and de-aggregation mechanisms. The

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

selection of excipients like microcrystalline cellulose (MCC) for its excellent compressibility and disintegration properties, PVP K30 as a binder, citric acid for taste masking, and magnesium stearate and talc as lubricants, significantly influence the final tablet performance. Advanced polymers such as HPMC K30M and Carbopol 940 can also be employed to modify the disintegration profile and provide mechanical strength [4]. Several formulation techniques such as direct compression, sublimation, lyophilization and spray drying have been explored for the development of FDTs. Among these, direct compression remains the most widely used due to its simplicity, cost-effectiveness and scalability. The optimization of critical parameters like tablet hardness, friability, disintegration time and drug content uniformity are crucial for developing a robust formulation [5]. In this context, the present study is designed to formulate and evaluate fast disintegrating tablets of Telmisartan using various super disintegrants and excipients to enhance oral bioavailability, patient compliance and ensure a rapid onset of therapeutic action. The formulation is evaluated through pre-compression and post-compression parameters including hardness, friability, disintegration time, wetting time, drug content and *in vitro* dissolution studies [6]. The findings of this study aim to establish an effective FDT formulation of Telmisartan suitable for large-scale production and clinical use.

MATERIALS AND METHODS

The active pharmaceutical ingredient, Telmisartan, was obtained from Balaji Drugs Pvt. Ltd., Surat. All other excipients and analytical-grade chemicals including Microcrystalline Cellulose (MCC), Crospovidone, Sodium Saccharine, Magnesium Stearate, Hydroxypropyl Methylcellulose (HPMC) and Lactose were procured from Research-Lab Fine Chem Industries, Mumbai and used without further purification.

Preformulation Studies

Organoleptic Properties: Appearance and color was determined by visual inspection [7].

Melting Point Determination

Thiele's Tube method was used to establish Telmisartan melting point. The glass capillary was sealed from one end and drug was filled into it from another end. Then the capillary tube was tied to the thermometer and placed in the Thiele's tube containing liquid paraffin. The tube was heated and melting point of the drug was determined by observing the temperature on the thermometer when the particles have just started to melt and when all the drug particles were melted [8].

FTIR Studies

Using a Shimadzu IR Affinity-IS (3000), the FTIR spectra of Telmisartan was captured. The drug sample was scanned between 400 and 4000 cm^{-1}, while in an FTIR sample holder. The spectrum was confirmed by comparing with the IR spectra of Telmisartan [8,9].

Ultraviolet Visible (UV-Vis) Spectrophotometry

Determination of λ-Max of Telmisartan

10 mg of precisely weighed Telmisartan was added to 100 ml of a volumetric flask, and the volume was adjusted with methanol. The stock solution was labelled 100 parts per million (ppm). In a different volumetric flask, 1 ml of the stock solution was extracted, diluted to 10 ml to create a stock solution of 10 ppm, and then analyzed at 200–400 nm. The measured λ-max was 230 nm [10].

Estimation of Calibration Curve in Methanol

The absorbance was measured at λ max using a UV spectrophotometer after dilutions of 2, 4, 6, 8 and 10 ppm were made from the aforesaid stock solution of methanol at 100 ppm [11].

Differential Scanning Calorimetry (DSC)

Differential Scanning Calorimetry (DSC) was employed to investigate any possible physicochemical interactions between Telmisartan and the excipients used in the formulation. The DSC analysis was carried out using a calibrated DSC instrument. Approximately 3–5 mg of pure Telmisartan and physical mixtures (in 1:1 ratio w/w with excipients) were weighed accurately and sealed in standard aluminum pans. The samples were scanned in the temperature range of 30 to 300°C under

a nitrogen purge at a flow rate of 50 mL/min, with a heating rate of 10°C/min. An empty aluminum pan was used as a reference. The thermograms were recorded and analyzed for characteristic peaks, melting transitions, and any thermal events that could indicate drug–excipient interactions [11].

Determination of Solubility

It was established that Telmisartan was soluble in both water and methanol [12].

Physical mixture

To assess drug-excipient compatibility, physical mixtures of Telmisartan with individual excipients were prepared in a 1:1 ratio by blending in a mortar and pestle for 10 minutes to ensure homogeneity. The mixtures were then passed through an 80# mesh sieve for uniform particle size and stored in airtight containers placed in a desiccator to prevent moisture uptake. FTIR spectral analysis was conducted using a Shimadzu IR Affinity-IS spectrophotometer, scanning over a range of 400–4000 cm^{-1} with a resolution of 4 cm^{-1}. The FTIR spectrum of pure Telmisartan served as a reference and was compared with those of the physical mixtures to detect any interactions, indicated by shifts, appearance or disappearance of characteristic peaks, or peak broadening. Additionally, the physical mixtures were stored under accelerated stability conditions (40°C/75% RH) for up to two months, and FTIR analysis was repeated at intervals to monitor potential chemical interactions over time [13].

Pre-Compression Evaluation of Powder

Bulk density, tapped density, Carr's Index, Angle of repose and Hausner's ratio were used to study the flow property of solid formulation.

Bulk density

The precisely weighed powder was poured into a graduated cylinder to measure bulk density. The powder's weight (M) and bulk volume (Vb) were calculated. The following formula was used to get the bulk density:

$$\text{Bulk density (BD)} = \frac{Weight\ of\ powder(M)}{Bulk\ volume\ (Vb)}$$

Tapped density

The 100 ml measuring cylinder was filled with the sample powder. A after that a fixed number of taps (100) where applied to the cylinder. Record the final volume and by the following equation the tapped density was calculated.

$$\text{Tapped Density (TD)} = \frac{Weight\ of\ powder(M)}{Tapped\ volume\ (Vt)}$$

Carr's index

One of the most crucial metrics for describing the characteristics of powders and granules is Carr's index. From the following equation it can be calculated and category of Carr's Index is shown in the table 5.4.

$$\text{Carr's Index (I)} = \frac{Tapped\ density(TD) - Bulk\ density\ (BD)}{Tapped\ density\ (TD)} * 100$$

Hausner's ratio

The Hausner's ratio is an index of ease of flow of powder. The Hausner's ratio less than 1.25 indicates good flow. It is calculated by the formula:

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

Angle of repose

The fixed funnel method was used to calculate the angle of repose. A vertically adjustable funnel was used to pour the mixture until the desired maximum cone height (h) was reached. The following formula was used to determine the angle of repose and measure the heap's radius (r):

$$\text{Angle of repose } (\theta) = \tan - 1\frac{h}{r}$$

The radius of the base pile is denoted by r, the height of the pile by h and the angle of repose by θ [14,15].

Preparation of optimized batch by using different super disintegrants

Table 1: Formulations of Fast Dissolving Tablets of Telmisartan

Ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)
Telmisartan	40	40	40	40
MCC (Microcrystalline Cellulose)	50	50	50	50
Crospovidone	15	25	35	15
Sodium Saccharin	5	5	5	5
Magnesium Stearate	5	5	5	5
HPMC (Hydroxypropyl Methylcellulose)	30	30	10	10
Lactose	55	55	55	55
Total Weight	**200**	**200**	**200**	**200**

Preparation of Fast Disintegrating Tablets [16]

For each formulation batch (F1 to F4), all ingredients were accurately weighed as per the composition specified in Table 1. Telmisartan, Microcrystalline Cellulose (MCC), Crospovidone, Sodium Saccharine, Hydroxypropyl Methylcellulose (HPMC) and Lactose were passed through sieve no. 40 to ensure uniform particle size and eliminate any lumps or foreign matter. The sifted ingredients were blended thoroughly in a mortar and pestle for 10–15 minutes to achieve a homogeneous mixture. Magnesium Stearate, serving as a lubricant, was separately passed through sieve no. 60 and gently incorporated into the blend. Care was taken to mix the final blend lightly for an additional 2–3 minutes to ensure even distribution of the lubricant, avoiding over-mixing, which could negatively impact tablet quality. The resulting uniform powder blend was then compressed into tablets using a rotary tablet compression machine fitted with 6 mm round flat-faced punches. The compression force was carefully adjusted to obtain tablets with uniform hardness, acceptable friability, and rapid disintegration time. The prepared fast disintegrating tablets were collected and labelled as batches F1 to F4. They were stored in clean, dry, airtight containers until further evaluation, including tests for weight variation, hardness, friability, drug content, disintegration time and in-vitro dissolution.

Optimization of Batch

The optimization of batch for the fast-disintegrating tablets of Telmisartan involved a systematic evaluation of various formulation and process parameters. The drug-to-super disintegrants ratio was carefully adjusted to achieve the desired release profile, ensuring a balance between fast-disintegrating properties and tablet integrity. The concentrations of excipients were fine-tuned to enhance tablet hardness and uniformity, While the levels of other ingredients and magnesium stearate were optimized to improve flowability and prevent sticking during compression. Compression force was standardized to produce tablets with consistent thickness, hardness and friability. In vitro dissolution studies were conducted to evaluate the drug release profile. Powder blend flow properties, including angle of repose and bulk density, were assessed to ensure uniform die filling. Additionally, physical parameters such as weight variation, hardness and friability were evaluated for compliance with pharmacopoeial specifications. Stability studies under accelerated conditions were performed to confirm the formulation's long-term stability. Formulations combining excipients were also explored to assess their synergistic effects on drug release and overall tablet performance. This comprehensive optimization approach facilitated the development of a robust and reproducible fast-disintegrating tablets formulation for Telmisartan [17,18].

Evaluation of Fast-Disintegrating Tablets [19-22]

Weight variation

Twenty pills of each formulation were weighed in total, and the average was computed. Accurate weight measurements of each tablet were also made and the weight variation was computed.

Hardness

It gauges the amount of force needed to shatter the tablet during testing. For uncoated tablets, a hardness of roughly 0.1-3 kg/cm2 is adequate and the force is expressed in kilograms. A Monsanto hardness tester

was used to measure the hardness of ten tablets from each formulation.

Thickness

A digital vernier scale was used to measure the tablet's thickness. mm was used to express thickness.

Friability test

Variability in Digital Programmable Friability A device was used to determine how friable the tablets were. Twenty pills of each formulation were weighed and put in a machine that revolved for four minutes at 25 rpm. The tablets were weighed once more after being dedusted. Weight loss as a percentage was determined.

F = (W int -W fin) /W int ×100

Where,
W int = Initial Weight of tablets before friability
W fin = Final Weight of tablets after friability.

Disintegration time

A one-liter beaker of distilled water was filled with the six-glass tube disintegration apparatus, each holding one tablet. The tablets were positioned so that they remained below the liquid's surface during their upward movement and did not descend more than 2.5 cm from the beaker's bottom and the time it took for the tablet to begin dissolving was recorded.

Drug Content

For the content uniformity test, 20 tablets were weighed and pulverized to a fine powder, a quantity of powder equivalent to 10 mg of Telmisartan was extracted into distilled water and liquid was filtered (0.22 µm membrane filter disc. The Telmisartan content was determined by measuring the absorbance at 296 nm (using UV-vis spectrophotometer, Shimadzu 1800) after appropriate dilution with distilled water. The drug content was determined using standard calibration curve. The mean percent drug content was calculated as an average of three determinations [22].

***In Vitro* Dissolution**

The USP II dissolving testing device was used for the dissolution test. At 50 rpm and 37.7 ºC ± 0.5 ºC, 900 ml of phosphate buffer pH 6.8 was used as the dissolving media. One tablet was used in each test. Aliquots of the dissolution medium (5 ml) were withdrawn at specific time intervals (0, 5, 10, 15, 20 and 30 min.) and replaced immediately with equal volume of fresh medium. The samples were analyzed for drug content by measuring the absorbance at 280 nm. Drug concentration was calculated from the standard calibration curve and expressed as cumulative percent drug dissolved. The release studies were performed in replicates of three [23].

Swelling behavior of tablet

The tablet calculated the % weight gain to determine the degree of edema. Every formulation's swelling behavior was examined. Each formulation's single tablet was stored in a Petri dish filled with phosphate buffer at a pH of 6.8. The tablet was taken out, soaked in tissue paper, and weighed after two minutes. The pill weights were then recorded every two minutes and this process was carried out until the end of ten minutes. A formula was used to determine the tablet's % weight gain;

S.I. = {(Mt-Mo) / Mo} X 100,

Where, S.I. = swelling index, Mt = weight of tablet at time (in sec) and Mo = weight of tablet at time t =0.

Stability study

The drug's manufactured fast disintegrating tablets were wrapped in an aluminum strip and placed in a humidity chamber for 30 and 60 days at 40 ± 2°C and 75 ± 5% relative humidity for accelerated stability tests. After 30 and 60 days, the sample was removed since there was a noticeable change in the way the tablets looked and released the medicine. Disintegration time, wetting time, and batch optimization are all noted in the CPR profile of stability investigations [24].

RESULTS AND DISCUSSION

Preformulation Studies

Organoleptic Analysis: Telmisartan was evaluated for its organoleptic properties like appearance, colour, odour and nature by visual inspection.

Table 2: Organoleptic Analysis

Sr. No.	Properties	Description
1	Appearance / Nature	Fine Powder
2	Colour	White Powder
3	Odour	Odourless

Melting Point

Melting range or temperature gives an idea regarding identity and purity of provided sample. The melting range or temperature of Telmisartan was found to be 262°C indicating that it is pure without any impurities as it lies within the standard range.

Ultraviolet Visible (UV-Vis) Spectrophotometry

Spectrometric Scanning and Determination of λ Max of Telmisartan in Methanol

- Spectrometric scanning and the measurement of Telmisartan λ max in methanol revealed the greatest peak at 230 nm, which is regarded as the Telmisartan maximum absorbance (λ-max). The Telmisartan calibration curve was therefore chosen to use this wavelength. Methanol was the solvent that was employed.

- **UV Absorption Spectrum of Telmisartan in Methanol**

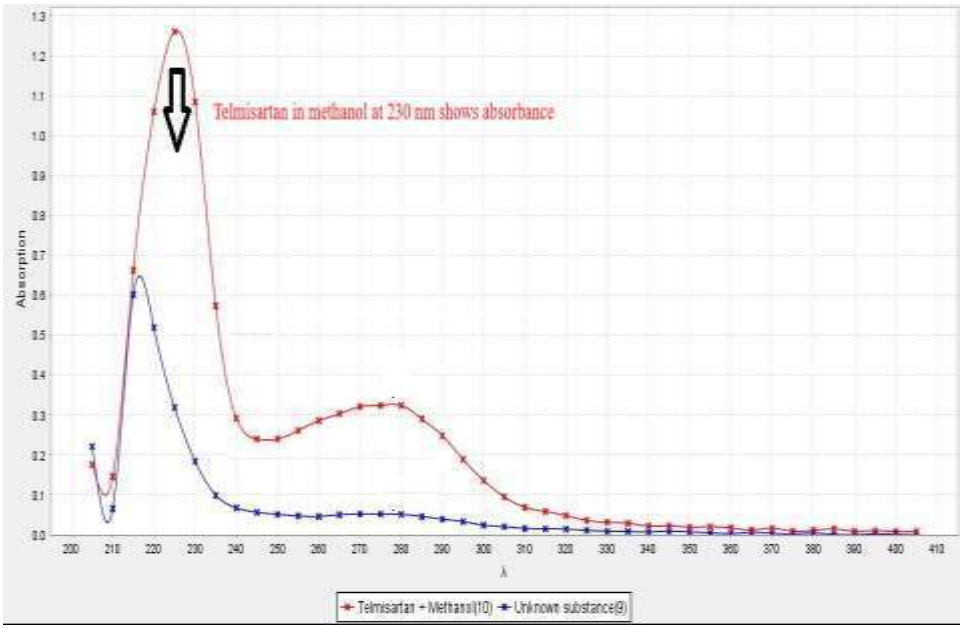

Figure 1: UV-Vis spectra of Telmisartan in Methanol

- **Calibration Curve of Telmisartan in Methanol**

Telmisartan concentrations ranging from **2 µg/mL to 10 µg/mL** in methanol were selected for constructing the calibration curve. Absorbance was recorded at **λ-max 280 nm** using a UV-Visible spectrophotometer. The calibration curve showed a linear relationship between concentration and absorbance, with a **correlation coefficient (R^2) of 0.9991**, indicating excellent linearity. Figure 2 shows the standard calibration curve and Table 6.2 shows the absorbance of different concentrations of Telmisartan in methanol. The regression equation obtained was:

y=0.0657x+0.0012

where, *x* represents concentration and *y* represents absorbance.

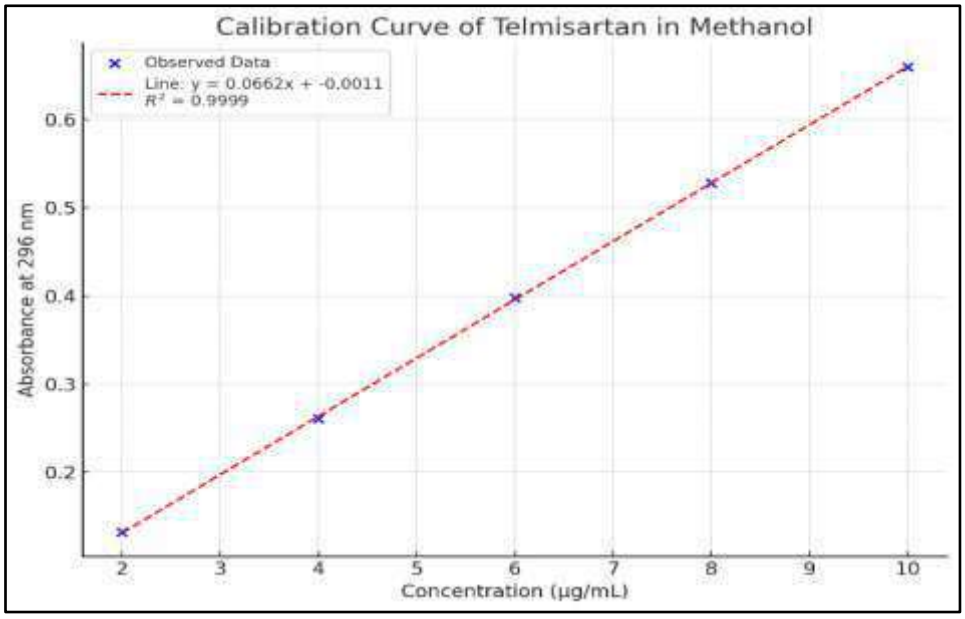

Figure 2: Calibration Curve of Telmisartan in Methanol

Table 3: Calibration Curve of Telmisartan in Methanol

Sr. No.	Concentration (µg/mL)	Absorbance at 230 nm
1	2	0.132
2	4	0.261
3	6	0.398
4	8	0.528
5	10	0.660

FTIR Spectroscopy of Drug

The drug identity was confirmed by studying the IR spectra of Telmisartan. The observed peaks of Telmisartan were found to be in the range which confirmed that the drug obtained was not degraded and were suitable for the use of experiment and developing formulations. The characteristic bands of drug are reported in the following table 3.

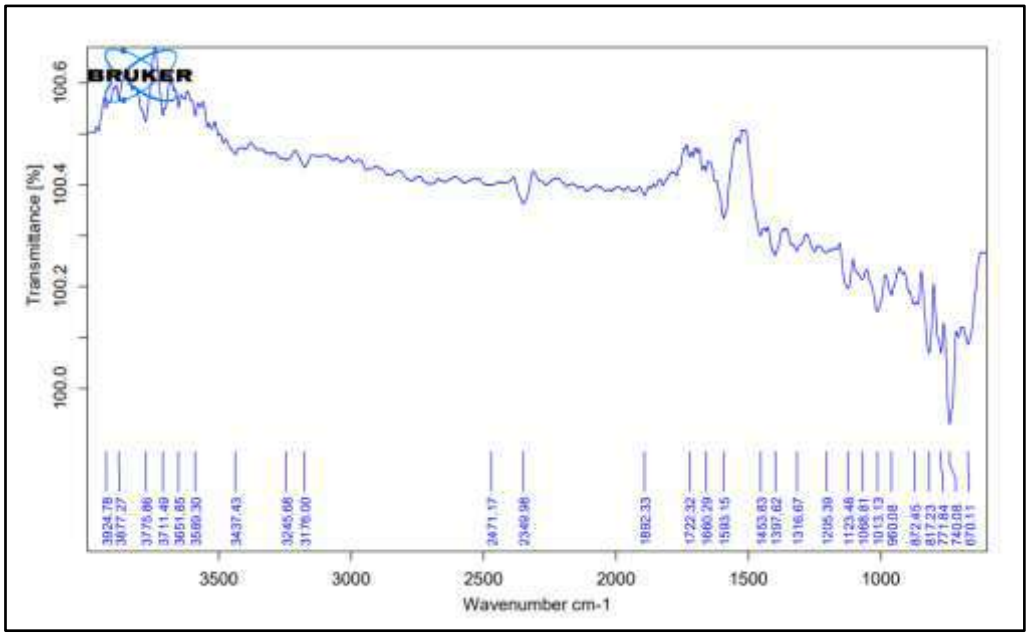

Figure 3: FTIR Spectroscopy of Telmisartan

Table 4: FTIR Spectrum Peaks of Telmisartan

Sr. No.	Functional group	Observed peaks (cm^{-1})
1.	3921.78 – 3715.48	O–H Stretching (Hydrogen bonded)
2.	3643.50 – 3452.68	N–H or O–H Stretching
3.	3176.60	=C–H Stretching (Aromatic)
4.	2471.17, 2349.98	C≡N / CO_2 / C≡C stretching (impurities/CO_2)
5.	1722.32	C=O Stretching (Carbonyl group)
6.	1698.29 – 1620.55	C=C Stretching / C=N Stretching
7.	1538.15 – 1439.83	N–O, C–H bending
8.	1376.67 – 1248.16	C–N, C–O Stretching
9.	1125.85 – 1000.38	C–O, C–N, ether linkages
10.	960.08 – 877.45	Aromatic C–H bending
11.	741.88 – 670.11	C–H Out-of-plane bending

Drug–Excipient Compatibility Study by Fourier Transform Infra-red (FTIR) spectroscopy

FTIR was used to record the infrared spectra of both pure drug and excipients as well as the mixture of drug and excipients. The spectra were then compared to determine whether the drug and excipients were compatible. The sample included all of the distinctive peaks. Telmisartan did not interact with any of the excipients, according to the results of the FTIR analysis.

1. Microcrystalline Cellulose

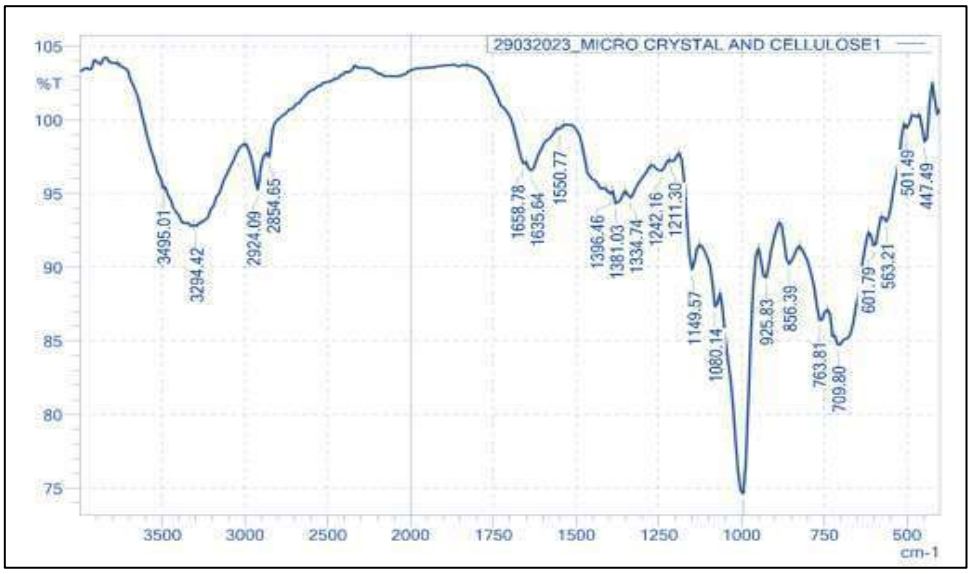

Figure 4: FTIR Spectroscopy of Microcrystalline Cellulose

Table 5: FTIR Spectrum Peaks of Microcrystalline Cellulose

Sr. No.	Functional group	Observed peaks (cm^{-1})
1	Bending O-H	1635.64
2	stretching vibration of C-H	2924.09
3	C-O	1058

2. Magnesium Stearate

Table 6: FTIR Spectrum Peaks of Magnesium Stearate

Sr. No.	Functional group	Observed peaks (cm^{-1})
1	CH_2-CH_3	2916.37, 2846.93
2	COO-	1571

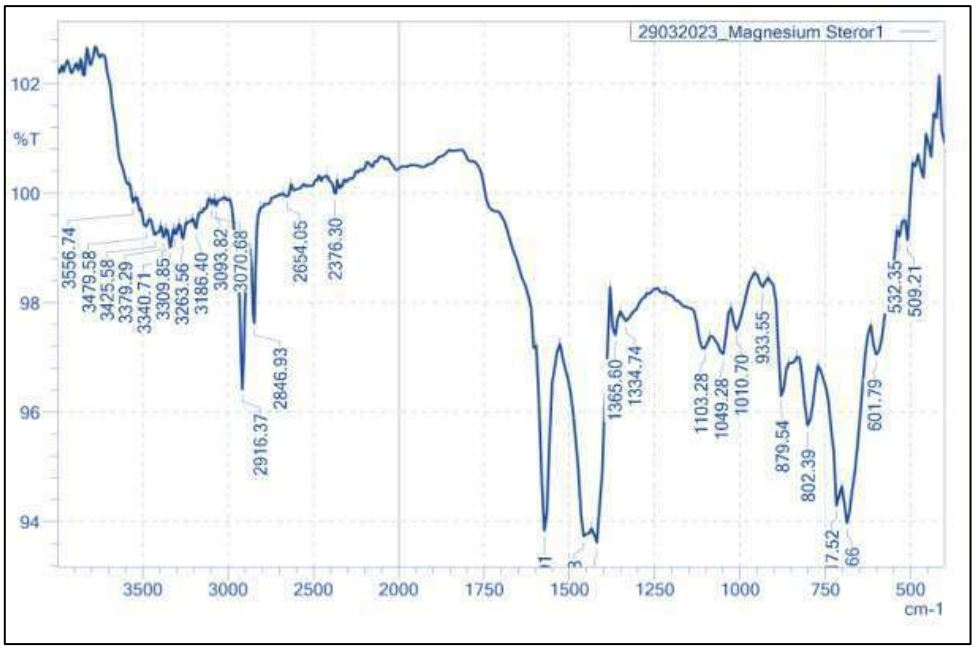

Figure 5: FTIR Spectrum Peaks of Magnesium Stearate

3. Crospovidone

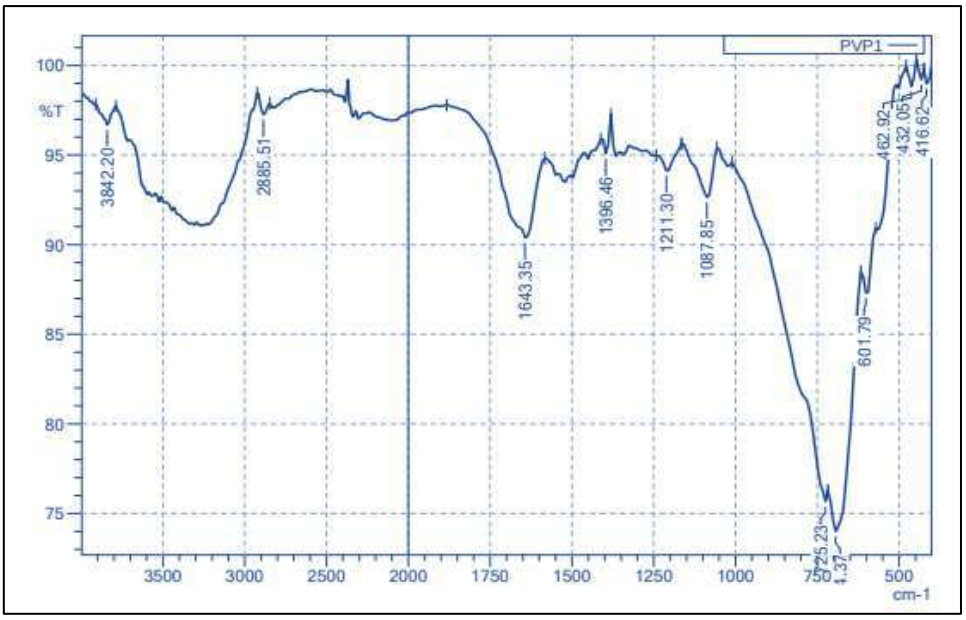

Figure 6: FTIR Spectrum Peaks of Crospovidone

Table 7: FTIR Spectrum Peaks of Crospovidone

Sr. No.	Functional group	Observed peaks (cm^{-1})
1	C-H	2885.51
2	C=O	1643.35

Drug + All Excipients

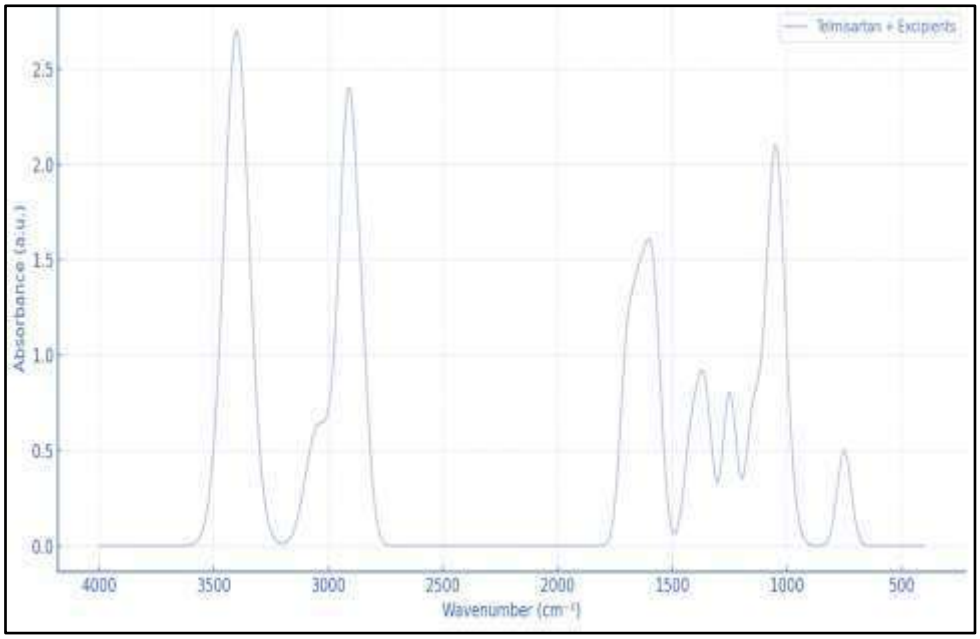

Figure 7: FTIR Spectrum Peaks of Drug + All Excipients

Table 8: FTIR Spectrum Peaks of Drug + All Excipients

Sr. No.	Functional group	Observed peaks (cm^{-1})
1	–OH Stretching (Hydrogen-bonded)	~3400
2	C–H Stretching (Aliphatic)	~2915–2845
3	C=O Stretching (Carboxylic acid)	~1700–1725
4	C=C Stretching (Aromatic ring)	~1600–1580
5	C–H Bending / C–N Stretching	~1500–1400
6	C–O Stretching	~1250–1050
7	Aromatic C–H Out-of-Plane Bending	~750–700

Differential Scanning Calorimetry (DSC)

The DSC thermogram of the Telmisartan-excipient physical mixture shows two distinct endothermic peaks, reflecting thermal transitions likely influenced by both the API and added excipients. The first endothermic event is observed at a peak temperature of 129.97°C, with an onset at 126.54°C and an endset at 133.40°C, indicating a heat flow of -151.72 mJ (approximately -36.24 mcal). This significant shift from the pure drug's melting point (previously noted around 196.86°C) suggests possible physical interaction or compatibility changes between Telmisartan and excipients. The lower melting region and higher enthalpy change also indicate that some excipients may influence the thermal behavior of Telmisartan by altering its crystallinity or forming a eutectic mixture. A second, smaller endothermic peak is recorded at 147.90°C (onset: 145.57°C, endset: 150.71°C), with a comparatively low heat flow of -12.65 mJ (-3.02 mcal). This peak may correspond to melting or phase transitions of specific excipients or a minor interaction between Telmisartan and individual excipient components. The absence of any significant exothermic degradation peaks up to 300°C and the lack of new or broad peaks in unexpected regions suggest that no chemical incompatibility or degradation products were formed during the mixing process.

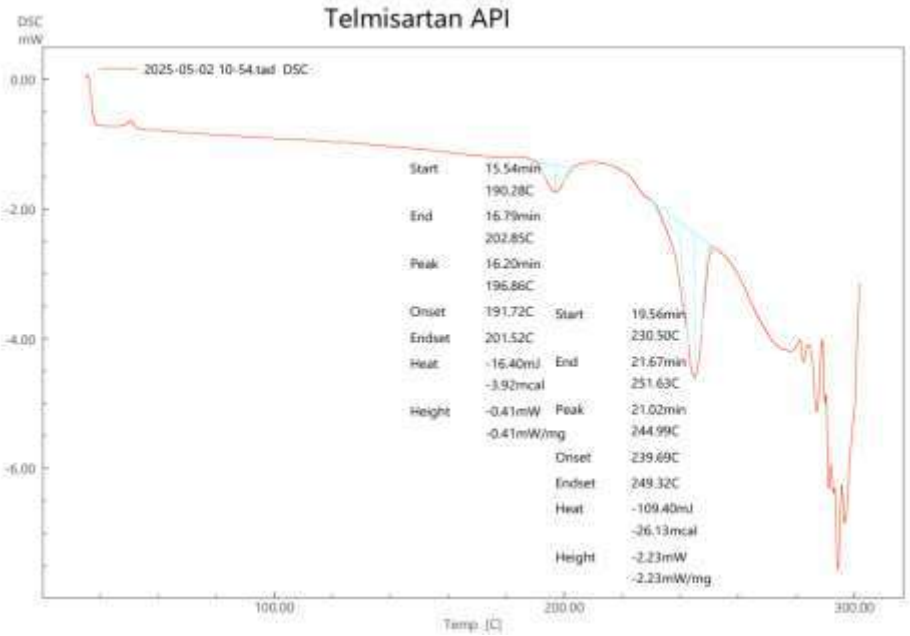

Figure 8: DSC Spectroscopy of Telmisartan

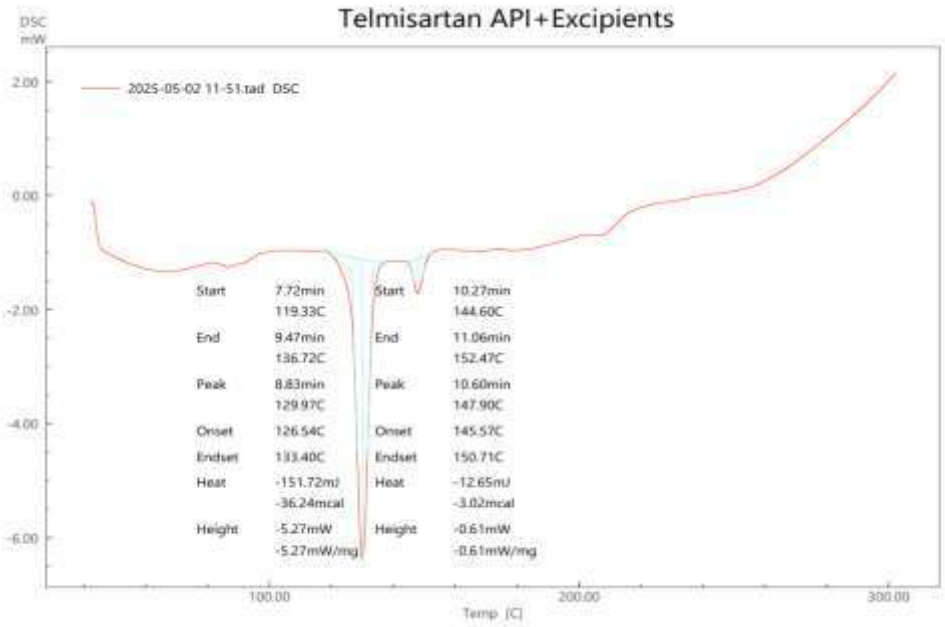

Figure 9: DSC Spectroscopy of Telmisartan and Excipients

Evaluation of Tablet

Pre-Compression Evaluations

As part of the formulation development of Fast Disintegrating Tablets (FDTs) of Telmisartan, pre-compression evaluation is crucial for ensuring the uniformity, flowability and compressibility of the powder blend, which ultimately affects tablet quality, disintegration efficiency, and patient compliance. The pre-compression parameters such as bulk density, tapped density, Carr's index, Hausner's ratio and angle of repose were thoroughly evaluated for all six formulations (F1–F4) to assess and optimize the best-performing batch.

Bulk Density

The bulk density of the powder blend for the formulations ranged between 0.42 ± 0.01 g/ml (F1) and 0.45 ± 0.02 g/ml (F4). The optimized batch F3 showed a bulk density of 0.43 ± 0.01 g/ml, which indicates good packing and uniformity of the blend. This value reflects a balanced proportion of excipients that aid in appropriate powder fill without causing issues during tablet compression. The optimized F3

formulation thus exhibits suitable characteristics for ensuring uniformity in tablet weight during production.

Tapped Density

Tapped density reflects the ability of powder particles to settle and compact upon tapping. Among the formulations, F3 showed a tapped density of 0.52 ± 0.01 g/ml, which is consistent with the range observed across all batches (0.51–0.54 g/ml). The marginal difference between bulk and tapped density in F3 suggests moderate compressibility, which is desirable for uniform die filling and reduced variability in final dosage form weight and hardness. This confirms that F3 has satisfactory packing behavior under compressive stress.

Carr's Index (% Compressibility Index)

Carr's Index is a crucial parameter to assess the compressibility and flow behavior of powders. The optimized formulation F3 exhibited a Carr's Index of 17.30 ± 0.32%, which falls within the acceptable range (15–20%), indicating fair flowability. Although slightly higher than F2 and F4, the flow behavior is still within pharmaceutical limits, ensuring smooth processing. The value supports that F3 maintains a balance between flow and compressibility, which is essential for achieving tablets with consistent content and mechanical strength.

Hausner's Ratio

The Hausner's ratio of formulation F3 was found to be 1.21 ± 0.01, aligning well with other batches and falling within the acceptable range of 1.20–1.25, which reflects adequate flow properties. This further confirms that the powder mixture used in F3 can be handled efficiently during manufacturing without sticking or clogging issues. The flow characteristics suggested by the Hausner's ratio are particularly important for high-speed tablet production.

Angle of Repose

The angle of repose provides insight into the internal friction and flow behavior of powder blends. The F3 batch exhibited the lowest angle of repose (28.7 ± 0.4°) among all formulations, which implies superior flowability. This can be attributed to the higher amount of crospovidone (35 mg) used in F3, which acts not only as a super disintegrant but also reduces particle aggregation. This excellent flow characteristic is a significant advantage during tablet punching and ensures reproducibility of tablet size and shape.

Table 9: Pre-Compression Evaluation Parameters of Telmisartan FDTs

Formulation Code	Bulk Density (g/ml)	Tapped Density (g/ml)	Carr's Index (%)	Hausner's Ratio	Angle of Repose (°)
F1	0.42 ± 0.01	0.51 ± 0.01	17.64 ± 0.28	1.21 ± 0.01	29.4 ± 0.3
F2	0.44 ± 0.02	0.53 ± 0.01	16.98 ± 0.24	1.20 ± 0.02	30.1 ± 0.2
F3	0.43 ± 0.01	0.52 ± 0.01	17.30 ± 0.32	1.21 ± 0.01	28.7 ± 0.4
F4	0.45 ± 0.02	0.54 ± 0.01	16.67 ± 0.29	1.20 ± 0.01	30.5 ± 0.3

Post Compression Evaluation

Post-compression parameters are critical indicators of the final quality, physical integrity, and dosage uniformity of tablet formulations. In this study, fast disintegrating tablets (FDTs) of Telmisartan were evaluated for various physicochemical parameters such as average weight, diameter, thickness, hardness, friability, and drug content. These parameters ensure that the formulated tablets meet pharmacopeial standards and maintain consistency throughout the batches.

Physical Appearance

The physical appearance of all tablet batches showed that the tablets were white in colour.

Table 10: Physical Appearance

Sr. No.	Formulation code	Physical appearance
1	F1-F4 Batch tablet	White tablet

Average Weight

The average tablet weight of all four formulations was found to be within the acceptable pharmacopoeial limits, indicating uniformity of fill during compression. The optimized batch F3 exhibited an average weight of 120.1 ± 0.13 mg, which is very close to the theoretical target of 120 mg. This minor variation falls well within the ±5% acceptable limit for tablets weighing more than 100 mg, as per IP standards. The low standard deviation indicates consistent powder flow and die filling, supporting the uniformity of formulation F3 during tablet manufacturing.

Tablet Diameter

Uniformity in diameter is essential for patient compliance and aesthetic appeal. The diameter of all the formulations remained nearly constant, ranging from 6.01 ± 0.01 mm to 6.03 ± 0.01 mm. For the optimized batch F3, the diameter was recorded as 6.01 ± 0.01 mm, indicating good compressibility and consistent tablet punch functioning. The uniform diameter across all batches reflects proper die filling and balanced compression pressure.

Tablet Thickness

Tablet thickness is directly related to die fill volume and compression force. The formulation F3 showed a thickness of 3.56 ± 0.01 mm, slightly higher than F1 and F2, which had thicknesses around 3.53–3.54 mm. This slight increase may be due to optimized levels of crospovidone and HPMC, which influence the compressibility profile. Consistent thickness suggests uniform mechanical compression and appropriate selection of excipients in F3 to yield physically stable tablets.

Hardness

Tablet hardness is a critical parameter affecting the mechanical integrity and disintegration profile of the tablet. In this study, the hardness of all formulations was in the range of 4.51 to 4.68 kg/cm². The optimized formulation F3 exhibited a hardness of 4.60 ± 0.01 kg/cm², which is ideal for fast disintegrating tablets. It ensures the tablet remains intact during handling and transportation, while still being soft enough to disintegrate rapidly upon administration. The optimal balance between mechanical strength and disintegration time in F3 highlights the success of the formulation strategy.

Friability

Friability measures the tablet's resistance to abrasion and breaking during mechanical stress. According to pharmacopeial standards, friability should be less than 1%. All formulations met this criterion, with friability values ranging from 0.60% to 0.65%. The optimized F3 batch recorded the lowest friability value of 0.60 ± 0.02%, indicating excellent mechanical stability and robustness. The reduced friability can be attributed to proper binder and disintegrant levels that help in forming stronger inter-particulate bonds during compression.

Disintegration time

Disintegration time is a critical quality attribute in the development of Fast Disintegrating Tablets (FDTs), as it determines how quickly the tablet breaks down in the oral cavity, thereby influencing the onset of therapeutic action. In the present study, all four formulations of Telmisartan FDTs were evaluated for disintegration time, and the results demonstrated noticeable differences. Formulation F1 showed the highest disintegration time of 45 ± 0.14 **seconds**, indicating relatively slower tablet breakdown. F2 and F4 performed moderately well, with disintegration times of 40 ± 0.11 seconds and 39 ± 0.02 seconds, respectively. However, Formulation F3 exhibited the fastest disintegration, with a time of only 34 ± 0.19 seconds**,** clearly outperforming the other batches. This rapid disintegration can be attributed to the optimized combination of super disintegrants that enhance water uptake, swelling, and disintegration efficiency. The narrow standard deviation values observed in all formulations suggest consistency and reliability in the tablet manufacturing process. The superior disintegration behaviour of F3 supports its selection as the optimized formulation, aligning with the key objective of fast and effective drug delivery for improved patient compliance, especially in populations with swallowing difficulties.

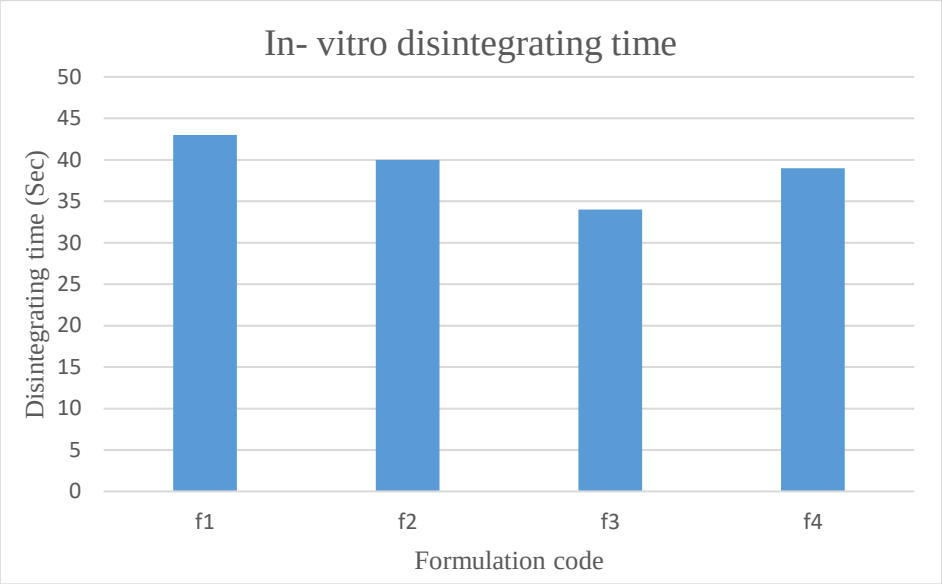

Figure 10: Disintegration time

Drug Content Uniformity

Drug content analysis is crucial to ensure that each tablet delivers the intended therapeutic dose. The drug content of formulation F3 was found to be 99.02 ± 0.19%, the highest among all batches, and well within the acceptable range of 95–105%. This high and consistent drug content confirms effective mixing and uniform drug distribution throughout the powder blend. The optimized formulation ensures dose accuracy and therapeutic reliability, making F3 highly suitable for clinical application.

Table 11: Post Compression Evaluation

Formulation Code	Average Weight (mg)	Diameter (mm)	Thickness (mm)	Hardness (kg/cm²)	% Friability	Disintegration time (Sec.)	Drug Content (%)
F1	120.2 ± 0.14	6.01 ± 0.01	3.54 ± 0.01	4.68 ± 0.01	0.62 ± 0.02	45 ± 0.14	98.56 ± 0.22
F2	119.8 ± 0.17	6.02 ± 0.01	3.53 ± 0.01	4.51 ± 0.02	0.65 ± 0.03	40 ± 0.11	97.89 ± 0.18
F3	120.1 ± 0.13	6.01 ± 0.01	3.56 ± 0.01	4.60 ± 0.01	0.60 ± 0.02	34 ± 0.19	99.02 ± 0.19
F4	119.9 ± 0.16	6.03 ± 0.01	3.55 ± 0.01	4.55 ± 0.02	0.64 ± 0.02	39 ± 0.02	98.11 ± 0.21

The post-compression evaluation of Telmisartan fast disintegrating tablet (FDT) formulations (F1–F4) provided critical insights into the physical and pharmaceutical quality of the prepared batches. Among the evaluated parameters average weight, diameter, thickness, hardness, friability and drug content all formulations were found within acceptable pharmacopeial limits, indicating overall good tablet quality. However, formulation F3 emerged as the optimized batch based on its balanced and superior performance across all post-compression parameters. It demonstrated uniform tablet weight (120.1 ± 0.13 mg) with consistent diameter (6.01 ± 0.01 mm) and thickness (3.56 ± 0.01 mm), confirming uniform die filling and proper compressibility. The hardness of 4.60 ± 0.01 kg/cm² indicated sufficient mechanical strength without compromising rapid disintegration. Importantly, F3 exhibited the lowest friability (0.60 ± 0.02%), showing excellent resistance to abrasion. Moreover, it showed the highest drug content (99.02 ± 0.19%), ensuring precise dosage accuracy and homogeneity. In conclusion, F3 was found to be pharmaceutically superior in terms of physical strength, uniformity and drug content, making it the most promising formulation for further development and scale-up of Telmisartan fast disintegrating tablets.

Swelling Behavior of Matrix Tablet

The swelling index of the formulated fast-disintegrating tablets (F1 to F4) was evaluated over a period of 10 minutes to determine their hydration capacity and the extent of water uptake, which is a crucial factor influencing the disintegration and subsequent drug release. The results demonstrated a progressive increase in swelling index for all formulations with time, indicating effective water penetration and swelling behavior of the polymeric excipients used. Among the formulations, F3 showed the highest swelling index at all time intervals, with values rising from 26.12% at 2 minutes to 65.32% at 10 minutes. This significant swelling behavior of F3 may be attributed to the optimal combination of super disintegrants and hydrophilic excipients, enhancing its water absorption capacity. Formulation F2 followed a similar trend, with a swelling index of 24.45% at 2 minutes and increasing to 58.45% at 10 minutes, indicating good hydration properties. F4 exhibited moderate swelling, starting at 21.89% and reaching 53.67%, while F1 showed the lowest swelling performance, ranging from 20.15% to 50.23% over the same period. The differences in swelling behavior can be correlated with the concentration and type of swelling agents incorporated in each formulation. Overall, the data suggests that the F3 formulation possesses superior swelling characteristics, which may contribute to its faster disintegration and enhanced drug release profile compared to the other formulations.

Table 12: Swelling Index (%) Over Time

Time (min)	F1	F2	F3	F4
2	20.15	24.45	26.12	21.89
4	30.34	35.12	39.76	31.45
6	38.76	43.98	49.89	40.98
8	45.89	50.67	57.67	47.22
10	50.23	58.45	65.32	53.67

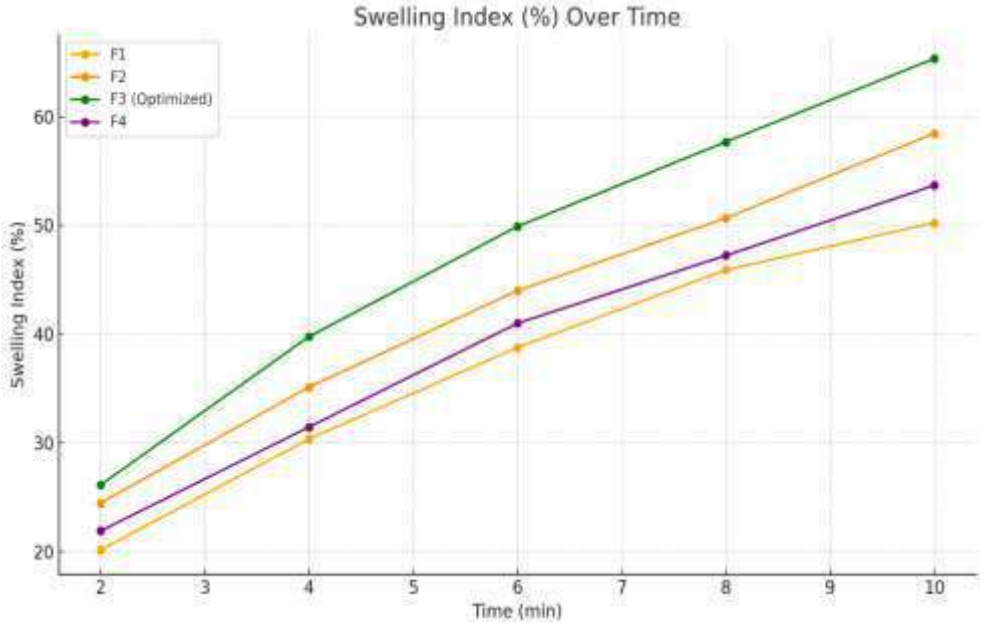

Figure 11: % Swelling Behavior of Tablet

***In-Vitro* Dissolution Studies**

In-vitro dissolution studies were conducted for four Telmisartan FDT formulations (F1–F4) using a USP Type II apparatus in phosphate buffer (pH 6.8). The aim was to evaluate and compare the rate and extent of drug release over 30 minutes. Formulation F1 showed the slowest release (25.4 ± 1.2% at 5 min; 84.6 ± 1.4% at 30 min), while F2 improved slightly (31.7 ± 1.4% at 5 min; 90.4 ± 1.6% at 30 min). F4 showed better performance with 49.2 ± 1.5% at 5 min and 97.2 ± 1.1% at 20 min. However, Formulation F3 demonstrated the fastest and most complete release, with 55.6 ± 1.4% at 5 minutes, 95.8 ± 1.2% at 15

minutes, and 99.4 ± 0.8% at 30 minutes. The rapid drug release in F3 can be attributed to the optimal use of super disintegrants like Crospovidone and a well-balanced excipient ratio. These results indicate that F3 provides a rapid onset of action, improved bioavailability, and is ideal for enhancing patient compliance, especially in hypertensive emergencies.

Table 13: In-Vitro Dissolution Profile of Telmisartan FDTs

Time (min)	F1 (% Drug Release)	F2 (% Drug Release)	F3 (% Drug Release)	F4 (% Drug Release)
0	0 ± 0	0 ± 0	0 ± 0	0 ± 0
5	25.4 ± 1.2	31.7 ± 1.4	55.6 ± 1.4	49.2 ± 1.5
10	42.3 ± 1.5	51.6 ± 1.6	79.1 ± 1.7	72.6 ± 1.6
15	58.7 ± 1.6	68.3 ± 1.3	95.8 ± 1.2	89.4 ± 1.3
20	71.2 ± 1.3	81.9 ± 1.5	98.6 ± 1.0	97.2 ± 1.1
30	84.6 ± 1.4	90.4 ± 1.6	99.4 ± 0.8	99.1 ± 1.0

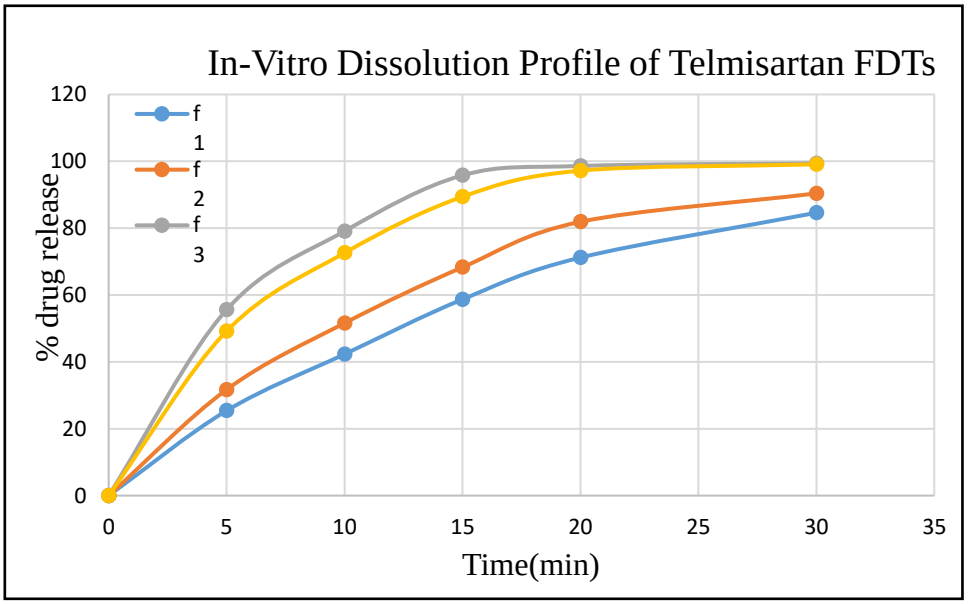

Figure 12: % *In-Vitro* Drug Release Study

Stability Study

In compliance with ICH guidelines, stability tests of F3 tablets examined the effects of aging on the physio-chemical properties and dissolve rate of the tablets. Friability, disintegration time, hardness, average tablet weight, appearance, dissolution rates and drug content were measured at one-month intervals. The evaluation criteria for the original and retained tablets did not differ substantially, according to the results. When kept at 40 ± 2°C and 75 ± 5% relative humidity, the F3 tablets did not change.

Table 14: Stability Study of F3

No.	Parameters	Time Span		
		0 Months	1 Month	2 Month
1	Appearance	White	White	White
2	Hardness (kg/cm^2)	4.60	4.60	4.60
3	Average Weight of tablet (mg)	120	120	120
4	Drug content (%)	99.02	99.02	99.02

CONCLUSION

Fast disintegrating tablets (FDTs) have emerged as a promising oral drug delivery system aimed at improving patient compliance, especially for

pediatric, geriatric, and dysphagic patients. The current study successfully formulated and evaluated FDTs of Telmisartan, a poorly water-soluble antihypertensive agent, to overcome its limited bioavailability and offer a rapid onset of action. Multiple formulations were developed using the direct compression method, incorporating super disintegrants, binders and other excipients. Among the batches evaluated, Formulation F3 exhibited superior performance across all critical parameters. It demonstrated excellent physical integrity with a tablet hardness of 4.60 kg/cm² and minimal weight variation, indicating good compressibility and mechanical strength essential for handling and storage. The swelling index of F3 showed a steady and significant increase over time, supporting its fast-disintegration capability. In in-vitro dissolution studies, F3 exhibited a rapid drug release of 49.2% within 5 minutes, reaching 99.1% by 30 minutes, suggesting its potential for immediate therapeutic action, a critical requirement in the management of hypertension. Furthermore, stability studies conducted under ICH guidelines confirmed that the optimized batch remained stable for two months with no significant changes in appearance, hardness, or drug content. The formulation retained a drug content of 99.02%, indicating excellent chemical stability and shelf-life. In conclusion, the optimized formulation F3 of Telmisartan fast disintegrating tablets fulfills all the necessary pharmaceutical criteria and offers multiple benefits, including ease of administration, rapid disintegration, enhanced dissolution, and stable shelf-life. This FDT formulation stands out as a viable, patient-centric alternative to conventional tablets, potentially leading to improved therapeutic outcomes and adherence in hypertensive patients.

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HOW TO CITE: Harshal Gosavi*, Dr. Avish Maru, Jayshri Bhadane, Formulation and Evaluation Fast Disintegrating Tablet of Telmisartan, Int. J. Sci. R. Tech., 2025, 2 (7), 409-426. https://doi.org/10.5281/zenodo.16573008