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Formulation and Evaluation of Fast Dissolving Telmisartan Tablets

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ABSTRACT
Rapid response is crucial in such situations since individuals with sudden increases in blood pressure have significantly reduced functional abilities and are very restless. Therefore, utilising a fast dissolving drug delivery mechanism would help the patients receiving acute treatment. Because telmisartan, an anti-hypertensive medication, is insoluble in water, it may dissolve slowly or not at all in the gastrointestinal tract. Because of this, the rate of dissolution is slower, and its bioavailability is lower (42%). In this study, an effort has been made to get ready. Superdisintegrants Crosscarmellose Sodium, Doshion, and Sodium Starch Glycolate are added to Telmisartan tablets in order to speed up the drug's release from the dosage form, hence increasing the drug's bioavailability. The blend and tablets were made using direct compression techniques, and their physicochemical characteristics and dissolution study were assessed. Weight variation, thickness, hardness, disintegrating time, wetting time, and an in-vitro drug release and stability study were among the evaluation tests carried out. The concentration of Superdisintegrants was added, which lengthened the time it took for Fast Dissolving Tablets to dissolve.

INTRODUCTION

For the delivery of the majority of therapeutically active medications, oral drug administration has shown to be one of the most effective and commonly tolerated by patients. Oral administration of numerous dose forms, including tablets, capsules, and liquid formulations, has been used. However, the administration of some medications is impacted by some unsuitable physiological conditions of the gastrointestinal tract, such as relatively poor absorption, the presence of different digestive enzymes of inadequate absorption efflux (caused, for example, by P-glycoprotein, etc.), the gastrointestinal lumen and epithelium, and first pass hepatic enzyme metabolism.

Additionally, it prevents many medications from being used at therapeutic levels. Researchers have therefore been working on intraoral drug delivery systems that will increase the therapeutic drug level, avoid first-pass and gut-wall metabolism, increase the bioavailability of active medication, or improve dosing convenience in order to reduce the issues associated with drug absorption through gastro-intestinal membrane. The buccal, sublingual, periodontal, tongue, and gum areas of the oral cavity are among the target sites for local medication administration.[1] In addition to the oral cavity, the pharynx, larynx, adenoids, and tonsils are all desirable targets.[2]

Three types of medication transport through the oral cavity's membranes are categorised within the oral cavity:

Sublingual delivery involves administering drugs to the systemic circulation through the mucosal membranes lining the floor of the mouth; buccal delivery involves administering drugs to the systemic circulation through the mucosal membranes lining the cheeks and the space between the gums and upper and lower lips; and local delivery involves administering drugs to the periodontal, gingival, and odontal tissues for the local treatment of aphthous ulcers.

Fast Dissolving Tablet: New drug delivery systems have recently been developed with the goal of improving patient compliance while also improving the safety and efficacy of the therapeutic molecule [3]. One such tactic is the use of "fast disintegrating tablets".

The oral route is still the best way to provide therapeutic drugs since it is simple to administer, has cheap manufacturing costs, and results in high patient compliance. Many patients have trouble swallowing pills and thick gelatin capsules, which prevents them from taking their prescriptions as directed.[4]

This issue, which is thought to affect 50% of the population, causes a high prevalence of noncompliance and poor therapy. Particularly in the paediatric and geriatric markets, there is a high demand for solid dosage forms that can be chewed, dissolved quickly in the mouth, or suspended in water. This demand also extends to other patients who prefer the convenience of a readily administered dosage form.

Less frequently, they are intended to be absorbed as the saliva passes into the stomach through the buccal and esophageal mucosa. In the latter scenario, a drug's bioavailability from fast-dissolving formulations may surpass that seen with conventional dose forms.[5]

A solid dose form that can break down into tiny grains that dissolve gradually in the mouth is known as a fast-dissolving tablet. Depending on the formulation and tablet

size, the disintegration time for a fast-dissolving tablet might range from a few seconds to more than a minute.

A solid dosage form that can dissolve or disintegrate in the oral cavity in less than 30 seconds without the need for water administration is referred to as a fast disintegrating system, tablet, or capsule.

The terms "fast disintegrating tablets" and "fast dissolving tablets" are interchangeable. They also refer to melt-in-your-mouth tablets, rapimelts, porous tablets, orodispersible pills. Recently, European Pharmacopoeia adopted the term "Orodispersible tablet" as a tablet that should be placed in the mouth where it quickly disperses, before swallowing. The significance of this drug delivery system includes administration without water, accuracy dosage, easy portability, an alternative to liquid dosage forms ideal for paediatrics' & geriatric patients, and rapid onset of action.[6]

MATERIALS

Table 1: Materials

Si no	Materials	Source
1	Telmisartan	Xenon Pharma Pvt. Ltd., Delhi
2	Mannitol	Truworth Healthcare, Delhi
3	Magnesium stearate	Shilex Chemicals Pvt. Ltd., Delhi
4	Sodium stearate	Ajit International Pvt. Ltd., Delhi
5	Croscarmellose sodium	Anil Enterprises, Delhi
6	Crospovidone	Atulya Chemicals, Delhi
7	Sodium starch glycolate	Anil Enterprises, Delhi
8	Sodium lauryl sulphate	Shree Radhey Enterprises, Samay Pur, Delhi

Table 2: Equipments

Si no	Equipment
1	Tablet compression machine
2	Hardness tester
3	Friability Test Apparatus
4	Tablet Dissolution Test Apparatus
5	Single pan digital balance
6	pH Meter
7	UV Visible spectrophotometer
8	FT-IR Spectrometer

FORMULATION

100 mg of pure medicine were dissolved in 100 ml of 0.1 N HCl in a volumetric flask to produce a concentration of 1 mg/ml.1N HCl, a standard calibration curve for telmisartan was produced.

From the standard solution, a stock solution was made with a 100 mcg/ml concentration in 0.1 N HCl.Pipets were used to transfer 1.2 ml into 10 ml volumetric flasks after dividing the stock solution into aliquots of 0.2, 0.4, 0.6, 0.8, and 1.0.Solvent was used to increase the volume to the desired level. Following dilution, the concentrations of telmisartan are as follows: 2, 4, 6, 8, 10, and 12 mg/ml.

The absorbance of a prepared solution of telmisartan in HCl was measured at 296 nm using a UV-visible spectrophotometer from PG Instruments, with 0.1N HCl acting as the reference. The medicine complies with Beer's law in the concentration range of 4 to 14 mcg/ml, as shown by the calibration curve's absorbance data, which yields a straight line.

Table 3: Telmisartan's standard calibration curve in 0.1 N HCL at 296 nm

Si. no.	Concentration (mcg/ml)	Absorbance
1	00	0.000
2	02	0.181
3	04	0.249
4	06	0.372
5	08	0.471
6	10	0.612
7	12	0.59

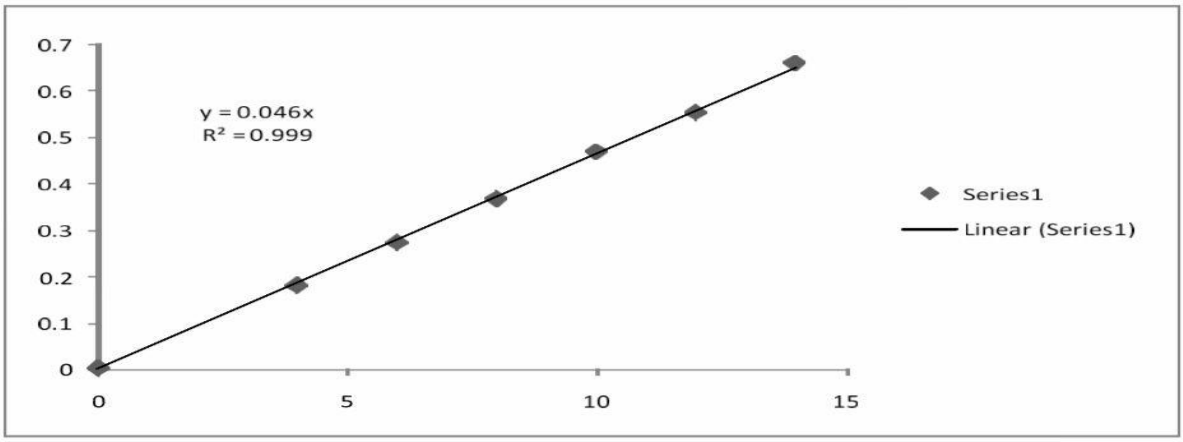


Figure 1: Standard calibration curve of Telmisartan in 0.1N HCl at λ_{max} 296nm

Table 4: Materials used in the study with their property

Si. No.	Materials	Properties
1	Telmisartan	Antihypertensive
2	Crospovidone	Disintegrant
3	Croscarmellose sodium	Disintegrant
4	Sodium starch glycolate	Disintegrant
5	Microcrystalline cellulose	Diluent
6	Lactose	Diluent
7	Talc	Glidant
8	Mg stearate	Lubricant

Table 5: Parameters fixed for the fast dissolving tablets

Si. no.	Test	Limit
1	Physical appearance	White circular
2	Average weight	150 mg
3	Diameter	7 mm
4	Thickness	3 mm
5	Hardness	2-4 kg
6	Friability	NMT 1%
7	Disintegration time	NMT 180 sec

Precompression studies

1. Angle of repose(θ) : The angle of repose is the maximum angle that can be created between the surface of a pile of powder and a horizontal plane. One can calculate the frictional force present in loose powder or grains by measuring the angle of repose.

Tan-1 (h/r) = Tan(h/r)

where h is the pile's height and is the angle of repose.
R stands for the pile's base radius.

2. Bulk Density: The bulk density is defined as the mass of a powder divided by the bulk volume. The primary factors affecting a powder's bulk density are its distribution of particle size, shape, and tendency to adhere to other particles.

3. True Density: The true density of the granules is ascertained using the specific gravity bottle.
Calculate W1, the empty bottle's weight, first.
After that, add 3/4 of the liquid, or W_2, its weight.
1/4 of the powder should be added. Weigh the outcome, W_3.
The container, the liquid, and the powder should all be weighed last.

Formula for calculation:
True Density is equal to (w2-w1)-(w4-w3)/[(w2-w1)-(w4-w3)/]

4. Percentage Porosity: This is calculated as Percentage Porosity = 1- (Bulk Density/True Density) * 100 by adding the values of bulk density and actual density.

Post-compression parameters
1. Dimensions and Form: The created tablets were round and had a 7 mm diameter.
2. Colour: It was found that the fast-dissolving telmisartan tablets were white in colour.

3. Hardness Test: Tablets need to have a certain degree of strength, or hardness, and resistance to friability to withstand mechanical shocks of handling during manufacture, packaging, and shipment. Using a Monsanto Hardness tester, the tablets' hardness was assessed. Kg/cm2 is the measuring unit. Three tablets were randomly selected from each formulation, and the mean and standard deviation values were calculated.
4. Friability Test: This is a condition where tablet surfaces are damaged and/or exhibit evidence of lamination or fracture when exposed to mechanical shock or attrition.

Tablet friability was evaluated using the Veego Friabilator. The value is given as a percentage (%). Twenty tablets were weighed and then put in the friabilator (Winitial). Up to 100 revolutions per minute, or 25 rpm, were applied to the friabilator for 4 minutes. The tablets were once more weighed (Wfinal).
The% friability was then calculated using,

F = Initial Weight x 100/(Initial Weight - Final Weight)

Tablets with a friability of less than 1% are acceptable.
5. Weight Variation Test: Pills from each formulation were randomly selected and weighed separately to check for weight variance. Some variation in pill weight is allowed by the US Pharmacopoeia.

6. Drug Content Uniformity: Twenty tablets were weighed and crushed in a mortar. 100 mg of the drug has been diluted in 100 ml of 0.1 N HCL and then been added to the powder.
It has a 1000 mcg/ml concentration. 10 ml of this stock solution are diluted to 0.1 N HCL to create 100 g/ml. The diluted 0.6ml stock solution was then added to 10ml. Measurement of absorbance at 296 nm.

7. Disintegration Time: The term "disintegration" refers to the process by which a tablet disintegrates into smaller fragments. The disintegration time was measured using disintegration test equipment in line with I.P. norms.
8. Dissolution studies: The dissolution rate was examined using a USP type-II device (dissolving Test device at 50 rmp) and 900 ml of 0.1 N HCl as the dissolving medium.
At intervals of one minute, a part of the dissolving medium was taken out and filtered while maintaining the temperature of the dissolution medium at 37 0.5 °C. The filtered solution's absorbance was measured at 296 nm using a UV spectrophotometric technique, and the drug concentration was determined using a standard calibration curve.

Details of drug release studies
1. Dissolving test equipment for USP II was used.
2. Dissolution medium 0.1 N HCl
3. The dissolving medium volume is 900 ml.
4. 37.4°C, with a tolerance of 0.5°C
The speed of the basket paddle is 5. 50 rpm.
6. One-minute sample periods
7. A withdrawal of a 5 ml sample
8. 296 nm for the measured absorbance

FTIR study on drug-polymer interactions:
The infrared (IR) spectra of pure drug, formulations Telmisartan, Crospovidone, and F6, were captured using a Fourier transform infrared (FTIR) spectrophotometer (Shimadzu corporation 8600, Japan).

Table 6: Formulation of direct compression-prepared telmisartan fast-dissolving tablets

Ingredient	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9	F_{10}	F_{11}	F_{12}
Telmisatan	20	20	20	20	20	20	20	20	20	20	20	20
Croscarmellose sodium	5	10	15	---	---	---	---	---	---	---	5	5
Crospovidone	---	---	---	5	10	15	---	---	---	5	5	---
Sodium starch glycolate	---	---	---	---	---	---	5	10	15	5	---	5
Microcrystalline cellulose	36	31	26	36	31	26	36	31	26	31	31	31
Lactose	75	75	75	75	75	75	75	75	75	75	75	75
Talc	7	7	7	7	7	7	7	7	7	7	7	7
Mg stearate	7	7	7	7	7	7	7	7	7	7	7	7
Total	150	150	150	150	150	150	150	150	150	150	150	150

Table 7: Formulation of Telmisartan fast dissolving tablets prepared by direct compression method (60 tablets)

Ingredient	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9	F_{10}	F_{11}	F_{12}
Telmisatan	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200
Crospovidone	250	490	730	---	---	---	---	---	---	370	370	370
Croscarmellose sodium	---	---	---	250	490	730	---	---	---	---	---	---
Sodium starch glycolate	---	---	---	---	---	---	250	490	730	350	350	350
Microcrystalline cellulose	2050	2110	1570	2050	1810	1570	2050	1810	1570	1580	1580	1580
Lactose	4900	4900	4900	4900	4900	4900	4900	4900	4900	4900	4900	4900
Talc	300	300	300	300	300	300	300	300	300	300	300	300
Mg stearate	300	300	300	300	300	300	300	300	300	300	300	300
Total	**9000**	**9000**	**9000**	**9000**	**9000**	**9000**	**9000**	**9000**	**9000**	**9000**	**9000**	**9000**

RESULTS

Granule Parameter Evaluatio

Table 8: Granule Parameters for Telmisartan Formulation

Formulation code	Bulk Density gm/cc	True Density	Angle of Repose	Percentage Porosity
F_1	0.52	1.31	27.91	55
F_2	0.51	1.51	30.2	56
F_3	0.56	1.30	29.90	55.5
F_4	0.53	1.08	29.20	56
F_5	0.52	1.31	29.11	55.2
F_6	0.49	1.90	30.20	56.5
F_7	0.52	1.51	30.91	57
F_8	0.53	1.81	27.91	55
F_9	0.51	1.71	26.10	55.8
F_{10}	0.53	1.31	29.60	55.9
F_{11}	0.51	1.81	27.10	56.2
F_{12}	0.50	1.21	26.50	57

Hardness Test

Table 9: Hardness Test for Telmisartan Formulation

Formulation code	Hardness in* Kg/cm^2 +-SD
F_1	20.0±2.91
F_2	81±2.98
F_3	22.0±3.22
F_4	39.0±3.32
F_5	62.0±2.8
F_6	24.0±2.78
F_7	21.0±2.95
F_8	9.0±2.81
F_9	40.0±2.89
F_{10}	00.0±4.0
F_{11}	22.0±3.5
F_{12}	81.0±3.8

***Average of three determinations**

Friability Test

Formulation code	Friability (%)
F_1	0.53
F_2	0.53
F_3	0.55
F_4	0.59
F_5	0.60
F_6	0.58
F_7	0.59
F_8	0.65
F_9	0.69
F_{10}	0.85
F_{11}	0.80
F_{12}	0.58

Dispersion Test

Table 10: Dispersion Time for Telmisartan Formulation

Formulation code	Time in seconds +-SD
F_1	2.4±74.0
F_2	1.3±59.0
F_3	1.9±36.0
F_4	0.8±57.0
F_5	0.5±40.0
F_6	0.6±17.0
F_7	1.2±108.0
F_8	1.5±88.0
F_9	0.9±69.0
F_{10}	1.0±90.0
F_{11}	0.8±65.0
F_{12}	0.8±47.0

Table 11: Weight Variation of Telmisartan Formulation

Sr. No.	(F_1) Weight in mgs	(F_1) Difference in weight	(F_1) Percent Deviation	(F_2) Weight in mgs	(F_2) Difference in weight	(F_2) Percent Deviation	(F_3) Weight in mgs	(F_3) Difference in wight	(F_3) Percent Deviation
1	149	1.2	0.79	148	4.2	2.5	152	2.1	1.2
2	150	2.2	1.3	150	2.5	1.5	151	1.3	0.8
3	150	0.8	0.5	151	2.5	1.5	149	1.1	0.8
4	153	3.9	2.5	150	0.3	0.25	151	0.9	0.5
5	151	2.8	1.7	148	2.5	1.5	151	0.9	0.5
6	149	1.5	0.93	149	2.5	1.5	152	2.1	1.35
7	149	0.4	0.21	150	1.5	0.9	150	1.1	0.75
8	150	1.5	0.92	149	0.3	0.25	148	1.9	1.12
9	148	0.4	0.20	153	2.5	1.5	149	3.5	2.41
10	151	1.5	0.90	152	3.3	2.2	151	0.8	0.48
	Average of	**10 tablets**	**150.5 mg**	**Average of**	**10 Tablets**	**149.7 mg**	**Average of**	**10 tablets**	**149.5 mg**

Table 12: Weight Variation of Telmisartan Formulation

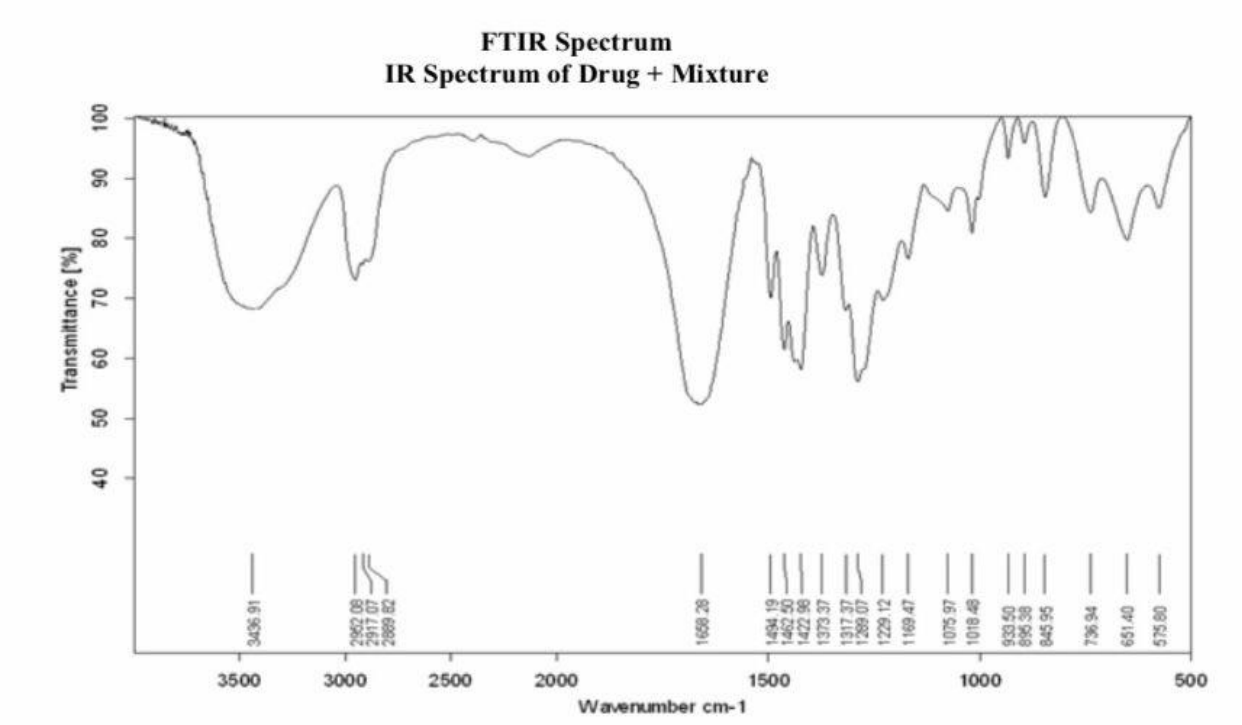
Sr. No.	(F_4) Weight in mgs	(F_4) Difference in weight	(F_4) Percent Deviation	(F_5) Weight in mgs	(F_5) Difference in weight	(F_5) Percent Deviation	(F_6) Weight in mgs	(F_6) Difference in wight	(F_6) Percent Deviation
1	149	1.0	0.71	152	0.8	0.50	151	0.75	0.50
2	153	3.9	2.45	148	1.2	0.85	154	1.9	1.15
3	150	3.0	1.75	149	3.4	1.90	149	0.3	0.15
4	148	0.9	0.60	147	1.2	0.75	148	0.9	0.50
5	151	1.2	0.70	153	1.2	0.75	153	0.9	0.50
6	149	2.2	1.20	155	0.4	0.20	148	1.9	1.15
7	155	2.2	1.20	153	1.8	1.05	149	3.1	2.0
8	149	4.0	2.5	147	2.8	1.71	152	2.1	1.28
9	150	1.8	1.1	148	3.8	2.40	147	1.3	0.78
10	148	0.8	0.6	150	1.2	0.90	149	0.9	0.5
	Average of	**10 tablets**	**149.8 mg**	**Average of**	**10 tablets**	**150.4 mg**	**Average of**	**10 tablets**	**151.2 mg**

Table 13: Weight Variation of Telmisartan Formulation

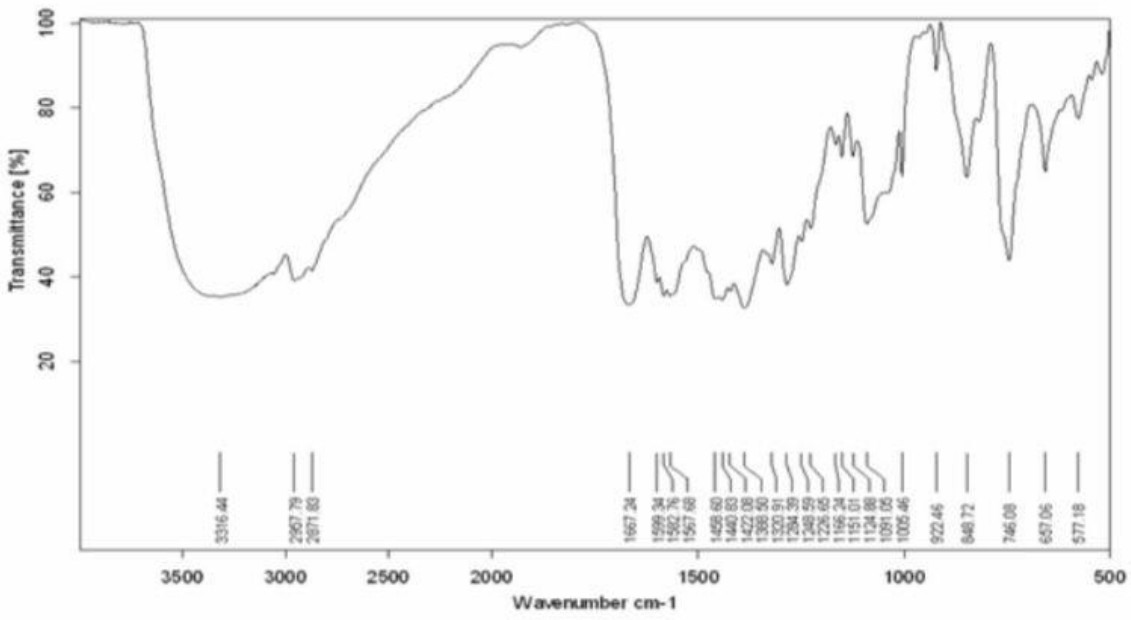
Sr. No.	(F_7) Weight in mgs	(F_7) Difference in weight	(F_7) Percent Deviation	(F_8) Weight in mgs	(F_8) Difference in weight	(F_8) Percent Deviation	(F_9) Weight in mgs	(F_9) Difference in wight	(F_9) Percent Deviation
1	150	0.75	0.50	149	0.2	0.07	154	1.2	0.75
2	151	1.75	1.20	150	1.2	0.7	151	2.4	1.36
3	152	2.5	0.78	148	3.2	1.82	153	1.8	0.90
4	148	1.3	0.81	153	1.8	0.70	149	2.8	1.72
5	147	2.3	0.28	150	2.8	1.95	149	1.2	0.81
6	146	3.4	2.0	148	1.2	0.72	147	2.4	1.39
7	154	1.1	0.73	148	3.0	1.78	151	2.8	1.72
8	153	0.3	0.15	149	1.2	1.74	148	1.6	0.91
9	151	0.9	0.5	152	2.8	1.9	152	0.4	0.17
10	150	1.9	1.14	153	1.8	1.20	151	1.4	0.75
	Average of	**10 tablets**	**150.1 mg**	**Average of**	**10 tablets**	**150.3 mg**	**Average of**	**10 tablets**	**150.6 mg**

Table 14: Weight Variation of Telmisartan Formulation

Sr. No.	(F_{10}) Weight in mgs	(F_{10}) Difference in weight	(F_{10}) Percent Deviation	(F_{11}) Weight in mgs	(F_{11}) Difference in weight	(F_{11}) Percent Deviation	(F_{12}) Weight in mgs	(F_{12}) Difference in wight	(F_{12}) Percent Deviation
1	152	0.6	0.33	151	0.8	0.61	151	2.1	1.21
2	151	1.6	1.0	152	2.0	1.21	149	0.8	1.12
3	154	2.7	1.42	147	3.0	1.29	150	1.2	0.61
4	147	2.7	0.92	148	1.2	0.07	148	3.2	0.72
5	148	1.6	0.92	150	2.2	1.32	147	2.2	2.1
6	150	1.6	1.60	152	0.2	0.07	149	1.9	1.2
7	152	2.7	1.60	149	2.2	1.29	152	2.1	1.22
8	152	2.7	0.92	149	1.3	1.29	151	3.1	1.93
9	149	1.6	0.32	148	3.0	0.71	148	1.2	1.78
10	153	0.8	0.87	152	2.4	1.72	153	2.0	1.2
	Average of	**10 tablets**	**150.4 mg**	**Average of**	**10 tablets**	**150.2 mg**	**Average of**	**10 tablets**	**150.4 mg**



FTIR Spectrum
IR Spectrum of Pure Drug Telmisartan



FTIR Spectrum
IR Spectrum of Formulation F_6

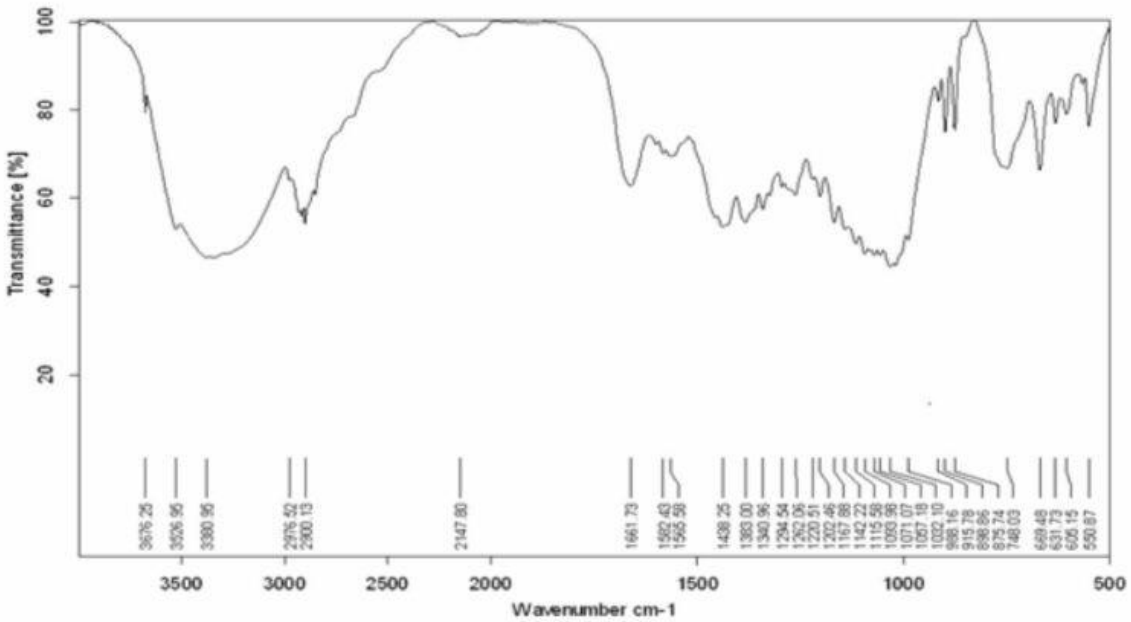


Table 15: Drug content of Telmisartan Formulation

Sr. no.	Formulation code	Absorbance	Concentration in mcg/ml	Average Content SD±(%)
1	**F_1**	**1.198**	**20**	0.180±100.5
2	**F_2**	**1.201**	**19.6**	0.280±99.5
3	**F_3**	**1.187**	**19.5**	0.170±98.0
4	**F_4**	**1.172**	**19.1**	0.440±95.0
5	**F_5**	**1.210**	**20.02**	0.355±98.3
6	**F_6**	**1.199**	**19.8**	0.160±99.5
7	**F_7**	**1.162**	**19.0**	0.260±96.5
8	**F_8**	**1.198**	**19.7**	0.239±98.5
9	**F_9**	**1.181**	**19.8**	0.155±98.0
10	**F_{10}**	**1.170**	**19.4**	0.125±97.0
11	**F_{11}**	**1.212**	**19.8**	0.428±98.3
12	**F_{12}**	**1.72**	**18.9**	0.139±99.5

Table 16: Drug release Telmisartan Fast dissolving Tablet F_1

Time in Minute	Absorbance	Concentration in mg	% Drug Release SD±
01	0.075	2.98	14.98+-0.11
02	0.145	5.36	26.98+-0.28
03	0.232	8.12	40.22+-0.22
04	0.268	9.81	48.82+-0.28
05	0.338	11.98	59.95+-0.24
06	0.402	14.62	73.10+-0.22
07	0.460	15.94	82.12+-0.61
08	0.506	18.42	92.20+-0.46
09	0.523	19.2	95.5+-0.22
10	0.542	19.62	96.95+-0.52

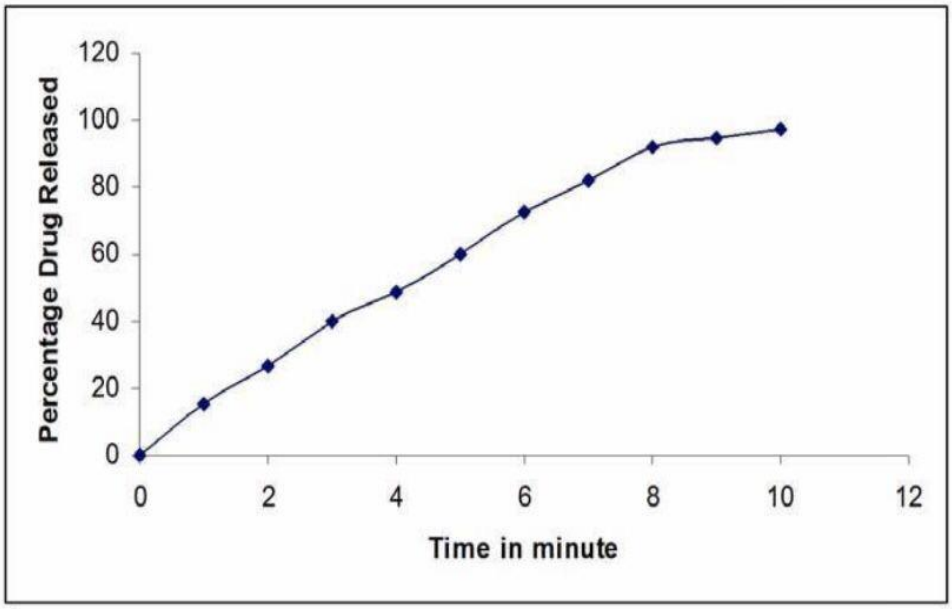


Figure 2: Telmisartan Fast Dissolving Tablet F_1 Drug Release

Table 17: Drug release Telmisartan Fast dissolving Tablet F_2

Time in Minute	Absorbance	Concentration in mg	% Drug Release SD±
01	0.078	2.78	14.5+-0.15
02	0.155	5.82	29.10+-0.41
03	0.225	8.20	40.10+-0.58
04	0.270	9.72	47.95+-0.43
05	0.355	12.48	61.4+-0.72
06	0.410	14.54	71.85+-0.72
07	0.470	17.22	83.12+-0.45
08	0.530	19.13	94.12+-0.15
09	0.540	19.54	96.85+-0.22
10	0.550	19.69	97.8+-0.01

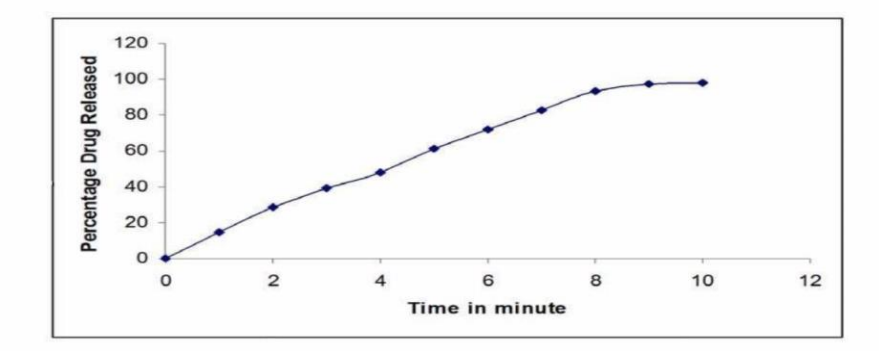


Figure 3: Telmisartan Fast Dissolving Tablet F_2 Drug Release

Table 18: Drug Release of Telmisartan Fast dissolving Tablet F_3

Time in Minute	Absorbance	Concentration in mg	% Drug Release SD±
01	0.89	3.280	16.65+-0.35
02	0.189	7.12	33.38+-0.11
03	0.258	9.52	46.95+-0.25
04	0.325	11.65	58.20+-0.45
05	0.418	14.98	75.80+-0.55
06	0.466	17.12	84.20+-0.35
07	0.527	18.26	95.75+-0.18
08	0.552	19.82	99.18+-0.68
09	0.552	19.82	99.18+-0.10
10	0.552	19.82	99.18+-0.08

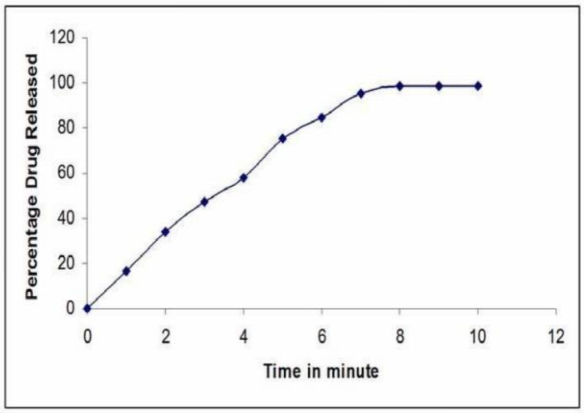


Figure 4: Telmisartan Fast Dissolving Tablet F_3 Drug Release

Table 19: Drug Release of Telmisartan Fast dissolving Tablet F_4

Time in Minute	Absorbance	Concentration in mg	% Drug Release SD±
01	0.108	3.982	20.80+-0.35
02	0.228	8.281	39.55+-0.18
03	0.318	11.665	56.55+-0.45
04	0.403	14.25	68.20+-0.55
05	0.465	16.20	78.75+-0.77
06	0.490	17.0	85.65+-0.11
07	0.502	18.20	88.00+-0.20
08	0.518	19.20	94.20+-0.20
09	0.540	20.10	98.65+-0.11
10	0.549	20.40	99.20+-0.11

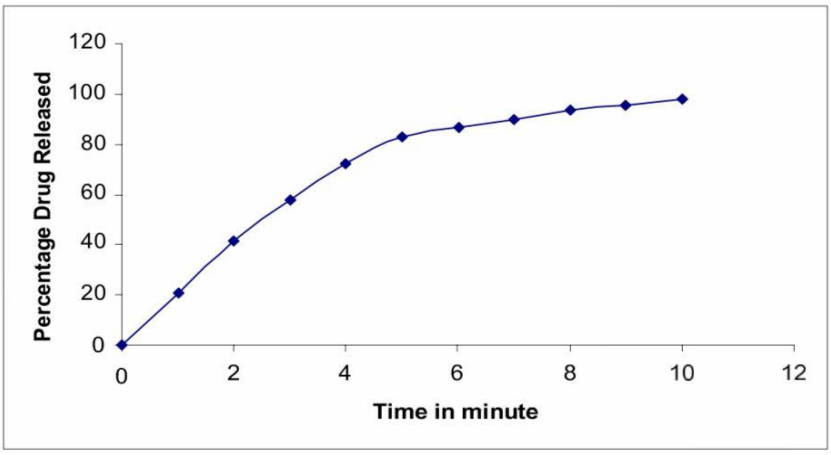


Figure 5: Telmisartan Fast Dissolving Tablet F_4 Drug Release

Table 20: Drug Release of Telmisartan Fast dissolving Tablet F_5

Time in Minute	Absorbance	Concentration in mg	% Drug Release SD±
01	0.110	4.252	22.20+-0.15
02	0.225	7.104	32.12+-0.25
03	0.332	9.120	45.33+-031
04	0.362	10.342	58.10+-0.42
05	0.380	12.743	68.85+-0.30
06	0.407	15.100	76.93+-0.22
07	0.452	16.558	81.0+-0.20
08	0.480	17.102	87.93+-0.15
09	0.520	17.952	92.12+-0.22
10	0.552	19.662	99.60+-0.01

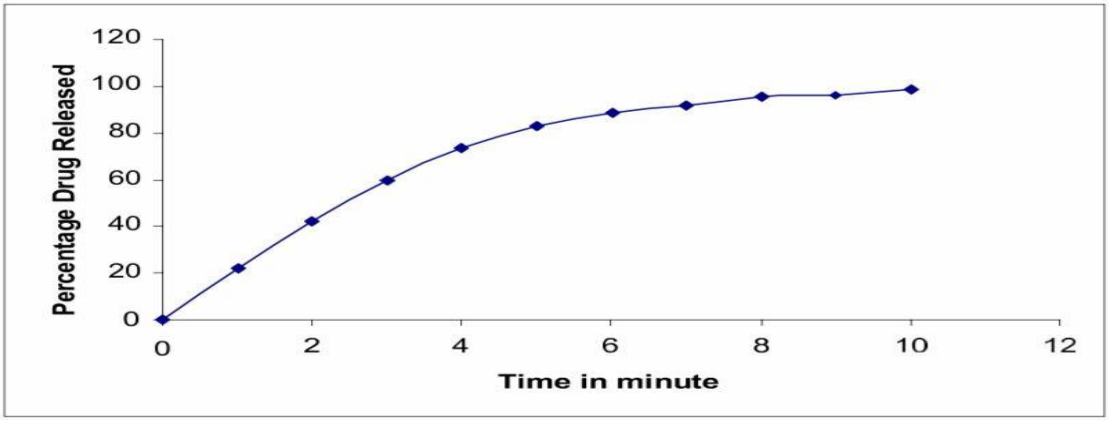


Figure 6: Telmisartan Fast Dissolving Tablet F_5 Drug Release

Table 21: Drug Release of Telmisartan Fast dissolving Tablet F_6

Time in Minute	Absorbance	Concentration in mg	% Drug Release SD±
01	0.151	5.28	26.20+-0.52
02	0.291	10.65	51.98+-0.47
03	0.398	15.10	69.43+-0.15
04	0.528	18.88	92.94+-0.13
05	0.563	19.65	99.9+-0.00

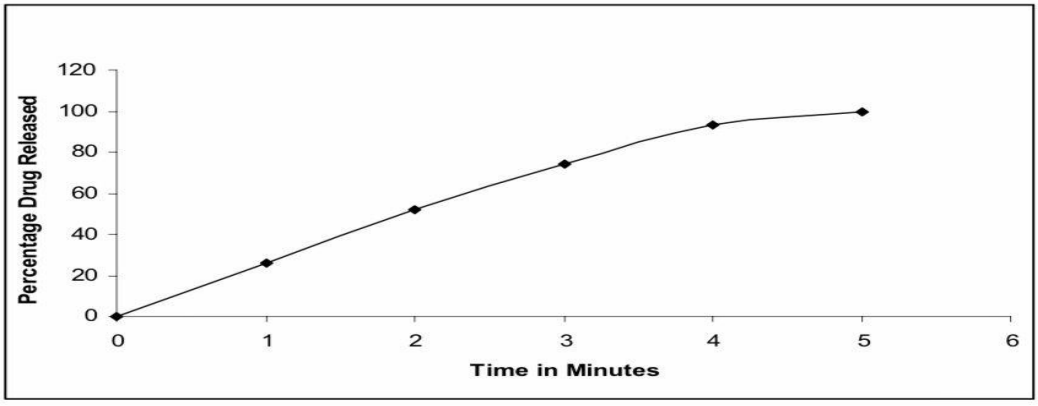


Figure 7: Telmisartan Fast Dissolving Tablet F_6 Drug Release

Table 22: Drug Release of Telmisartan Fast dissolving Tablet F_7

Time in Minute	Absorbance	Concentration in mg	% Drug Release SD±
01	0.82	2.768	14.11+-0.14
02	0.151	5.18	25.98+-0.38
03	0.238	8.68	44.22+-0.55
04	0.309	10.95	56.20+-0.35
05	0.331	11.83	59.22+-0.71
06	0.360	12.62	64.0+-0.11
07	0.425	.15.05	75.84+-0.35
08	0.501	17.64	89.88+-0.38
09	0.511	18.55	92.85+-0.27
10	0.525	18.75	93.95+-0.48

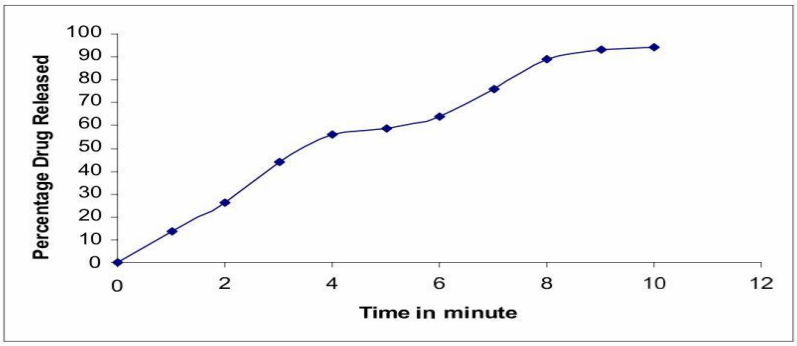


Figure 8: Telmisartan Fast Dissolving Tablet F_7 Drug Release

Table 23: Drug Release of Telmisartan Fast dissolving Tablet F_8

Time in Minute	Absorbance	Concentration in mg	% Drug Release SD±
01	0.071	2.229	12012+-0.82
02	0.142	4.842	24.52+-0.70
03	0.202	7.346	35.22+-0.55
04	0.272	9.123	46.95+-0.27
05	0.298	11.524	57.18+-0.39
06	0.382	14.285	67.96+-0.23
07	0.451	16.122	78.85+-0.15
08	0.482	17.323	86.14+-0.21
09	0.502	18.408	90.96+-0.98
10	0.536	19.221	94.65+-0.13

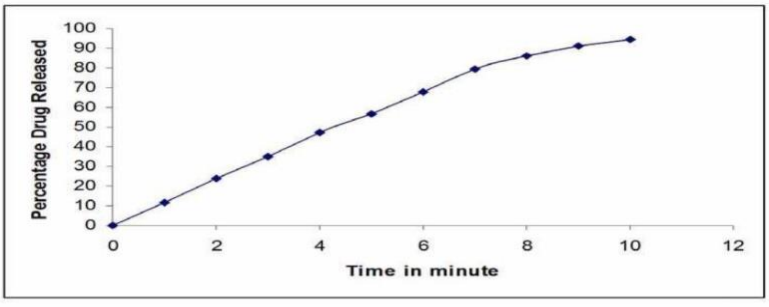


Figure 9: Telmisartan Fast Dissolving Tablet F_8 Drug Release

Table 24: Drug Release of Telmisartan Fast dissolving Tablet F_9

Time in Minute	Absorbance	Concentration in mg	% Drug Release SD±
01	0.068	2.602	13.12+-0.28
02	0.139	5.205	26.10+-0.35
03	0.235	8.348	42.88+-0.17
04	0.302	10.695	54.22+-0.14
05	0.382	13.502	67.95+-0.14
06	0.438	16.206	79.15+-0.26
07	0.503	18.117	90.23+-0.23
08	0.518	18.988	93.85+-0.18
09	0.525	19.127	94.98+-0.22
10	0.503	18.323	91.25+-0.06

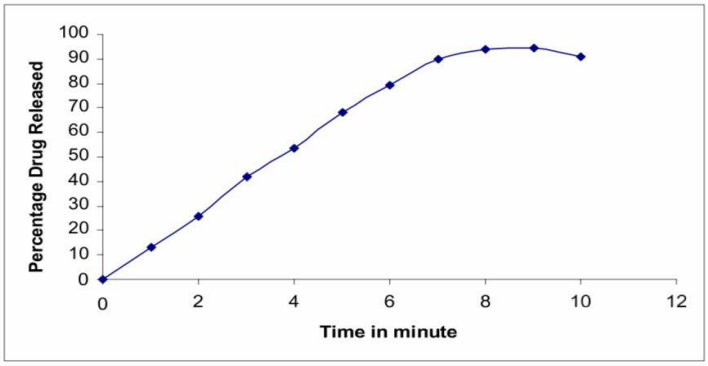


Figure 10: Telmisartan Fast Dissolving Tablet F_9 Drug Release

Table 25: Drug Release of Telmisartan Fast dissolving Tablet F_{10}

Time in Minute	Absorbance	Concentration in mg	% Drug Release SD±
01	0.082	2.617	13.758+-0.12
02	0.142	4.795	25.22+-0.09
03	0.181	6.413	32.10+-0.06
04	0.250	8.884	44.23+-0.04
05	0.299	11.121	55.45+-0.11
06	0.376	12.852	66.11+-0.25
07	0.428	15.483	77.85+-0.25
08	0.479	16.958	87.55+-0.12
09	0.510	18.204	92.14+-0.42
10	0.530	18.998	94.95+-0.11

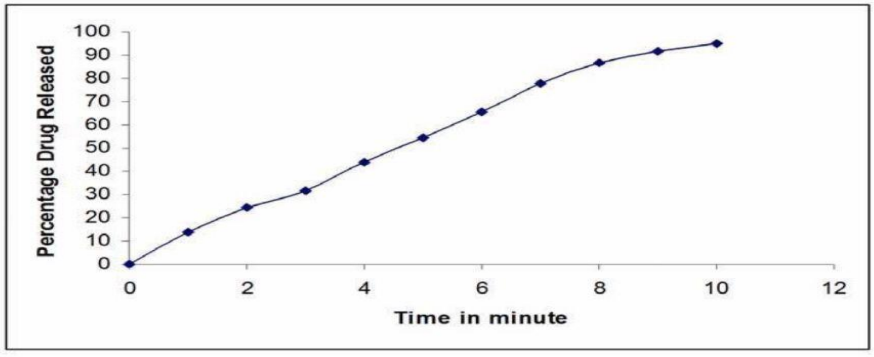


Figure 11: Telmisartan Fast Dissolving Tablet F_{10} Drug Release

Table 26: Drug Release of Telmisartan Fast dissolving Tablet F_{11}

Time in Minute	Absorbance	Concentration in mg	% Drug Release SD±
01	0.081	2.78	14.21+-0.28
02	0.145	4.95	25.88+-0.22
03	0.198	7.25	37.12+-0.78
04	0.250	8.85	44.78+-0.05
05	0.321	11.67	58.0+-0.12
06	0.369	12.96	66.82+-0.07
07	0.433	15.71	77.95+-0.00
08	0.490	17.65	87.94+-0.00
09	0.512	18.48	93.10+-0.01
10	0.529	18.98	94.96+-0.03

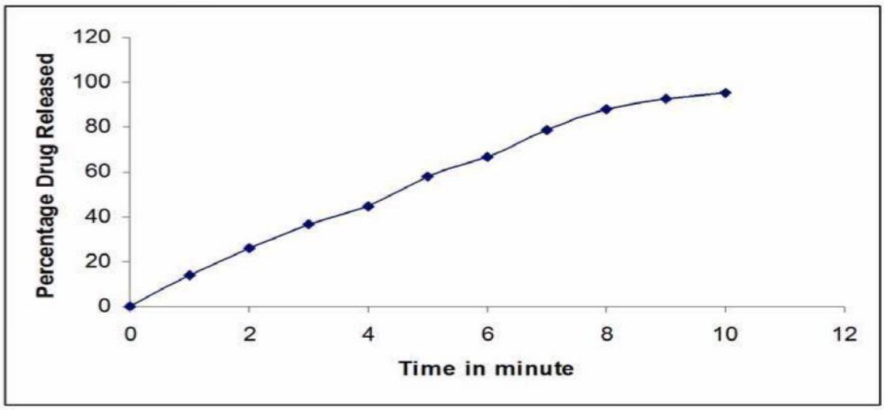


Figure 12: Telmisartan Fast Dissolving Tablet F_{11} Drug Release

Table 27: Drug Release of Telmisartan Fast dissolving Tablet F_{12}

Time in Minute	Absorbance	Concentration in mg	% Drug Release SD±
01	0.121	4.121	20.95+-0.11
02	0.180	6.248	32.35+-0.33
03	0.252	8.849	44.0+-0.22
04	0.318	11.552	57.94+-0.08
05	0.356	12.997	65.35+-0.07
06	0.432	15.232	76.92+-0.05
07	0.491	17.237	85.55+-0.16
08	0.498	17.974	90.65+-0.06
09	0.526	18.643	94.65+-0.05
10	0.532	18.955	95.97+-0.08

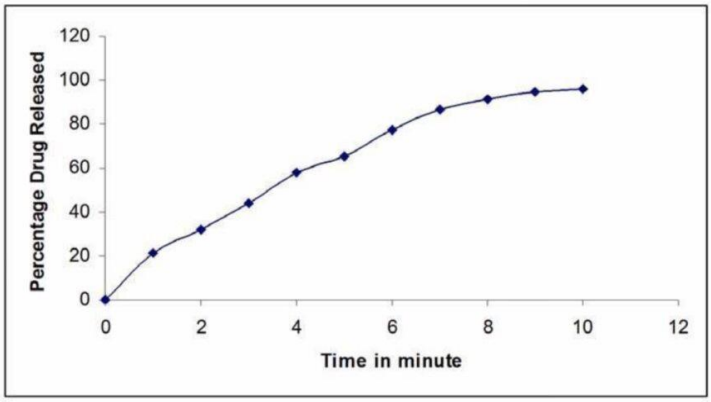
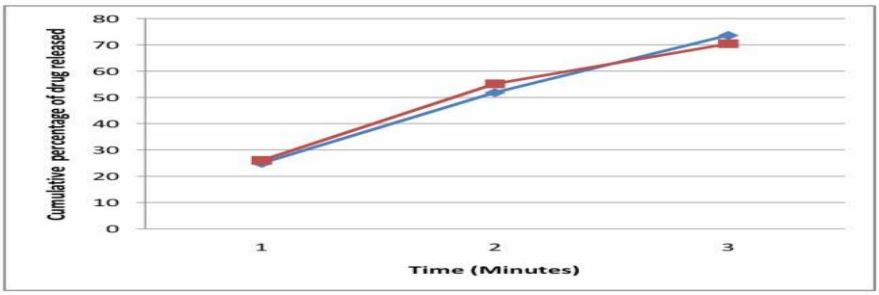


Figure 13: Telmisartan Fast Dissolving Tablet F_{12} Drug Release

Accelerated Stability Research

Due to its in vitro dispersion duration and% drug release, the formulation F6 was chosen for stability studies. Stability tests lasting up to 30 days were carried out at 40 2 °C and 75 5%RH. Next, the tablets' physical attributes, medicine content as a percentage, and in vitro dispersion time were investigated. Tables 29 of the gathered data display them. Table 30 presents the findings of in vitro drug release experiments.

Table 28: Analysis of Telmisartan Fast Dissolving Tablet F_6 for Drug Content, In Vitro Dispersion Time, and Drug Release Stability Studies



DISCUSSION

The purpose of the current study was to develop and assess Fast Dissolving Telmisartan tablets employing the direct compression method and the inclusion of superdisintegranting agents. Utilising the addition of Superdisintegrants at three different concentrations will enhance the dissolution rate of the weakly soluble medication Telmisartan.

Initial preformulation research was done, and the findings guided the rest of the formulation process. Telmisartan's solubility was improved by using surfactants. Physical characteristics like hardness, thickness, weight variation, friability, disintegration, wetting time, and dissolution were assessed for the tablets.

Duration of disintegration of an improved formulation was put up against other formulations, it was discovered that the improved formulation batch's disintegration time was 29 seconds. The effect of surfactants on dissolution was studied.

The optimised formulation underwent a stability assessment at 2-8° C (controlled sample), room temperature, and 40°C/75% RH for one month in accordance with ICH guidelines. After a month, tablets were assessed for assay, disintegrating time, and drug release profile. Improved formulation was determined to be stable. The findings indicated that the tablet's physical and chemical parameters had not changed much.

CONCLUSION

According to the findings of the current study, Telmisartan fast-dissolving tablets might serve as an alternative to the medicine's tablet form, and because the dosage form's rate of drug release increased, the dissolution rate also rose. Additionally, telmisartan's bioavailability has increased. The preparation process is easy, affordable, and scalable.

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