

PREPARATION AND EVALUATION OF TELMISARTAN SUSTAINED RELEASE TABLETS BY USING EUDRAGIT POLYMERInturi Ramya^{1*}, Dr. M. Dhanalakshmi² and D. Ramchakradhar³

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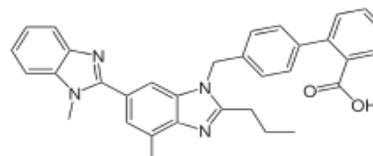
ABSTRACT

The aim of the present study was to develop Telmisartan Sustained release tablets to maintain constant therapeutic levels of the drug for over 24 hrs. Eudragit RSPO, Eudragit RLPO were used as polymers. All the formulations were passed various physicochemical evaluation parameters such as bulk density, tapped density, carrs index, hausners ratio, angle of repose, weight variation, hardness, thickness, friability and drug content. From the dissolution studies it was evident that the formulation F10 showed better and desired drug release pattern i.e., 98.96 % in 12 hours. It contains the Eudragit RLPO as polymer. It followed Peppas release kinetics mechanism.

KEYWORDS: Telmisartan, Eudragit RSPO, Eudragit RLPO and Sustained release tablets.**INTRODUCTION**

Sustained release technology is relatively new field and as a consequence, research in the field has been extremely fertile and has produced many discoveries. With many drugs, the basic goal is to achieve a steady state blood level that is therapeutically effective and non-toxic for an extended period of time. The design of proper dosage form is an important element to accomplish this goal. Sustained release, sustained action, prolonged action, controlled release, extended action, timed release and depot dosage form are term used to identify drug delivery system that are designed to achieve prolonged therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose. In the case of oral sustained released dosage form, an effect is for several hours depending upon residence time of formulation in the GIT. Telmisartan is an angiotensin II receptor antagonist (ARB) used in the management of hypertension. Generally, angiotensin II receptor blockers (ARBs) such as telmisartan bind to the angiotensin II type 1 (AT1) receptors with high affinity, causing inhibition of the action of angiotensin II on vascular smooth muscle, ultimately leading to a reduction in arterial blood pressure. Recent studies suggest that telmisartan may also have PPAR-gamma agonistic properties that could potentially confer beneficial metabolic effects. Telmisartan is an orally active nonpeptide angiotensin II antagonist that acts on the AT1 receptor subtype. It has the highest affinity for the AT1 receptor among commercially available ARBs and has minimal affinity for the AT2 receptor. New studies suggest that telmisartan may also have PPAR γ agonistic properties

that could potentially confer beneficial metabolic effects, as PPAR γ is a nuclear receptor that regulates specific gene transcription, and whose target genes are involved in the regulation of glucose and lipid metabolism, as well as anti-inflammatory responses. This observation is currently being explored in clinical trials. Angiotensin II is formed from angiotensin I in a reaction catalyzed by angiotensin-converting enzyme (ACE, kininase II). Angiotensin II is the principal pressor agent of the renin-angiotensin system, with effects that include vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation, and renal reabsorption of sodium. Telmisartan works by blocking the vasoconstrictor and aldosterone secretory effects of angiotensin II. Literature review of Telmisartan shown that there were several methods for formulation like immediate release tablets,^[1] conventional release tablets,^[2] fast disintegrating tablets,^[3] sublingual tablets,^[4] and mini tablets.^[5] The aim of the present study was to formulate and evaluate sustained released^[6-17] tablet of telmisartan using eudragit polymer.

**Figure 1: Structure of Telmisartan.****MATERIALS AND METHODS****Chemical reagents used**

Telmisartan pure drug procured From Hetero Drugs Pvt Ltd, Hyderabad, India provided by SURA LABS,

Dilsukhnagar, and Hyderabad. Eudragit RSPO, Talc, Eudragit RLPO, Lactose from MERCK Specialities Pvt Ltd, Mumbai, India. Magnesium stearate from YARROW Chem. Products, Mumbai, India.

Equipments

Tablet Compression Machine (Multistation)- Lab Press Limited, India. Weighing Balance- Sartorius, Hardness tester- Monsanto, Mumbai, India. Vernier calipers- Mitutoyo, Japan. Roche Friabilator- Labindia, Mumbai, India. Dissolution Apparatus- Labindia, Mumbai, India. UV-Visible Spectrophotometer and pH meter-Labindia, Mumbai, India. FT-IR Spectrophotometer- Bruker.

Analytical method development

Determination of Wavelength

10mg of pure drug was dissolved in 10ml methanol (primary stock solution - 1000 µg/ml). From this primary stock solution 1 ml was pipette out into 10 ml volumetric flask and made it up to 10ml with the media (Secondary stock solution – 100µg/ml). From secondary stock solution again 1ml was taken it in to another volumetric flask and made it up to 10 ml with media (working solution - 10µg/ml). The working solution was taken for determining the wavelength.

Determination of Calibration Curve

10mg of pure drug was dissolved in 10ml methanol (primary stock solution - 1000 µg/ml). From this primary stock solution 1 ml was pipette out into 10 ml volumetric flask and made it up to 10ml with the media (Secondary stock solution – 100µg/ml). From secondary stock solution required concentrations were prepared (shown in Table 5 and 6) and those concentrations absorbance were found out at required wavelength.

Formulation development of Tablets

All the formulations were prepared by direct compression. The compositions of different formulations are given in Table 1. The tablets were prepared as per the procedure given below and aim is to prolong the release of Telmisartan. Total weight of the tablet was considered as 200mg.

Procedure

- 1) Telmisartan and all other ingredients were individually passed through sieve no ≠ 60.
- 2) All the ingredients were mixed thoroughly by triturating up to 15 min.
- 3) The powder mixture was lubricated with talc.
- 4) The tablets were prepared by using direct compression method.

Table 1: Formulation composition for tablets.

Ingredients	Formulation Code											
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Telmisartan	20	20	20	20	20	20	20	20	20	20	20	20
Eudragit RSPO	10	20	30	40	50	60	-	-	-	-	-	-
Eudragit RLPO	-	-	-	-	-	-	10	20	30	40	50	60
Lactose	153	143	133	123	113	103	153	143	133	123	113	103
Mg.stearate	4	4	4	4	4	4	4	4	4	4	4	4
Talc	3	3	3	3	3	3	3	3	3	3	3	3
Polaxomer	10	10	10	10	10	10	10	10	10	10	10	10
Total weight	200	200	200	200	200	200	200	200	200	200	200	200

All the quantities were in mg

Preformulation parameters

The quality of tablet, once formulated by rule, is generally dictated by the quality of physicochemical properties of blends. There are many formulations and process variables involved in mixing and all these can affect the characteristics of blends produced. The various characteristics of blends tested as per Pharmacopoeia.

Angle of repose

The frictional force in a loose powder can be measured by the angle of repose. It is defined as, the maximum angle possible between the surface of the pile of the powder and the horizontal plane. If more powder is added to the pile, it slides down the sides of the pile until the mutual friction of the particles producing a surface angle, is in equilibrium with the gravitational force. The fixed funnel method was employed to measure the angle of repose. A funnel was secured with its tip at a given height (h), above a graph paper that is placed on a flat horizontal

surface. The blend was carefully pored through the funnel until the apex of the conical pile just touches the tip of the funnel. The radius (r) of the base of the conical pile was measured. The angle of repose was calculated using the following formula:

$$\tan \theta = h / r \quad \tan \theta = \text{Angle of repose}$$

h = Height of the cone, r = Radius of the cone base

Table 2: Angle of Repose values (as per USP).

Angle of Repose	Nature of Flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

Bulk density

Density is defined as weight per unit volume. Bulk density, is defined as the mass of the powder divided by

the bulk volume and is expressed as gm/cm³. The bulk density of a powder primarily depends on particle size distribution, particle shape and the tendency of particles to adhere together. Bulk density is very important in the size of containers needed for handling, shipping, and storage of raw material and blend. It is also important in size blending equipment. 10 gm powder blend was sieved and introduced into a dry 20 ml cylinder, without compacting. The powder was carefully leveled without compacting and the unsettled apparent volume, V_o, was read. The bulk density was calculated using the formula:

$$\text{Bulk Density} = M / V_o$$

Where, M = weight of sample

V_o = apparent volume of powder

Tapped density

After carrying out the procedure as given in the measurement of bulk density the cylinder containing the sample was tapped using a suitable mechanical tapped density tester that provides 100 drops per minute and this was repeated until difference between succeeding measurement is less than 2 % and then tapped volume, V measured, to the nearest graduated unit. The tapped density was calculated, in gm per L, using the formula:

$$\text{Tap} = M / V$$

Where, Tap= Tapped Density

M = Weight of sample

V= Tapped volume of powder

Measures of powder compressibility

The Compressibility Index (Carr's Index) is a measure of the propensity of a powder to be compressed. It is determined from the bulk and tapped densities. In theory, the less compressible a material the more flowable it is. As such, it is measures of the relative importance of interparticulate interactions. In a free- flowing powder, such interactions are generally less significant, and the bulk and tapped densities will be closer in value.

Table 4: Pharmacopoeial specifications for tablet weight variation.

Average weight of tablet (mg) (I.P)	Average weight of tablet (mg) (U.S.P)	Maximum percentage difference allowed
Less than 80	Less than 130	10
80-250	130-324	7.5
More than	More than 324	5

Hardness

Hardness of tablet is defined as the force applied across the diameter of the tablet in order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its hardness. For each formulation, the hardness of three tablets was determined using Monsanto hardness tester and the average is calculated and presented with deviation.

Thickness

Tablet thickness is an important characteristic in reproducing appearance. Tablet thickness is an important characteristic in reproducing appearance. Average

For poorer flowing materials, there are frequently greater interparticle interactions, and a greater difference between the bulk and tapped densities will be observed. These differences are reflected in the Compressibility Index which is calculated using the following formulas:

$$\text{Carr's Index} = [(\text{tap} - b) / \text{tap}] \times 100$$

Where, b = Bulk Density, Tap = Tapped Density

Table 3: Carr's index value (as per USP).

Carr's index	Properties
5 – 15	Excellent
12 – 16	Good
18 – 21	Fair to Passable
2 – 35	Poor
33 – 38	Very Poor
>40	Very Very Poor

Evaluation of post compression parameters for prepared Tablets

The designed formulation tablets were studied for their physicochemical properties like weight variation, hardness, thickness, friability and drug content.

Weight variation test

To study the weight variation, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of determining the drug content uniformity. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the following table and none deviate by more than twice the percentage. The mean and deviation were determined. The percent deviation was calculated using the following formula:

$$\% \text{ Deviation} = (\text{Individual weight} - \text{Average weight} / \text{Average weight}) \times 100$$

thickness for core and coated tablets is calculated and presented with deviation.

Friability

It is measured of mechanical strength of tablets. Roche friabilator was used to determine the friability by following procedure. Pre weighed tablets were placed in the friabilator. The tablets were rotated at 25 rpm for 4 minutes (100 rotations). At the end of test, the tablets were re weighed, loss in the weight of tablet is the measure of friability and is expressed in percentage as,

$$\% \text{ Friability} = [(W1 - W2) / W] \times 100$$

Where, W1 = Initial weight of three tablets, W2 = Weight of the three tablets after testing

Determination of drug content

Tablets were tested for their drug content. Ten tablets were finely powdered quantities of the powder equivalent to one tablet weight of drug were accurately weighed, transferred to a 100 ml volumetric flask containing 50 ml water and were allowed to stand to ensure complete solubility of the drug. The mixture was made up to volume with media. The solution was suitably diluted and the absorption was determined by UV-Visible spectrophotometer. The drug concentration was calculated from the calibration curve.

In vitro drug release studies

Procedure

900ml Of 0.1 HCl was placed in vessel and the USP apparatus -II (Paddle Method) was assembled. The medium was allowed to equilibrate to temp of $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$. Tablet was placed in the vessel and apparatus was operated for 2 hours and then the media 0.1 N HCl were removed and pH 6.8 phosphate buffer was added process was continued up to 12 hrs at 50 rpm. At definite time intervals withdrawn 5 ml of sample, filtered and again 5ml media was replaced. Suitable dilutions were done with media and analyzed by spectrophotometrically at required wavelength using UV-spectrophotometer.

Drug – Excipient compatibility studies

Fourier Transform Infrared (FTIR) spectroscopy

The compatibility between the pure drug and excipients was detected by FTIR spectra obtained on Bruker FTIR Germany(Alpha T).The solid powder sample directly place on yellow crystal which was made up of ZnSe. The spectra were recorded over the wave number of 4000 cm^{-1} to 400 cm^{-1} .

RESULTS AND DISCUSSION

Analytical Method

Table 5: Observations for graph of Telmisartan in 0.1N HCl (234 nm).

Conc[$\mu\text{g/ml}$]	Absorbance
0	0
2	0.134
4	0.241
6	0.349
8	0.458
10	0.567

Preformulation parameters of powder blend

Table 7: Pre-formulation parameters of Core blend.

Formulation Code	Angle of Repose	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's Ratio
F1	26.90 ± 1.2	0.410 ± 0.01	0.480 ± 0.02	14.58	1.17
F2	29.89 ± 1.4	0.390 ± 0.04	0.462 ± 0.01	15.58	1.18
F3	28.97 ± 1.5	0.355 ± 0.05	0.409 ± 0.07	13.20	1.15
F4	23.2 ± 0.2	0.555 ± 0.1	0.714 ± 0.1	22.22	1.285
F5	25.2 ± 0.1	0.384 ± 0.4	0.434 ± 0.3	11.53	1.130
F6	27.1 ± 0.1	0.416 ± 0.2	0.476 ± 0.3	12.50	1.142
F7	24.4 ± 0.4	0.476 ± 0.3	0.526 ± 0.2	9.52	1.105

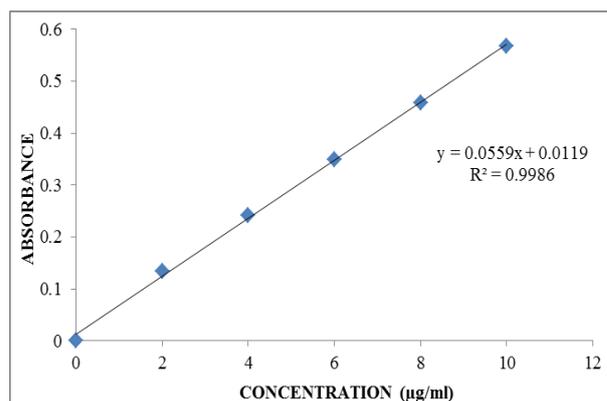


Figure 2: Standard graph of Telmisartan in 0.1N HCl.

Table 6: Observations for graph of Telmisartan in pH 6.8 phosphate buffer (237nm).

Concentration[$\mu\text{g/ml}$]	Absorbance
0	0
2	0.116
4	0.224
6	0.347
8	0.449
10	0.571

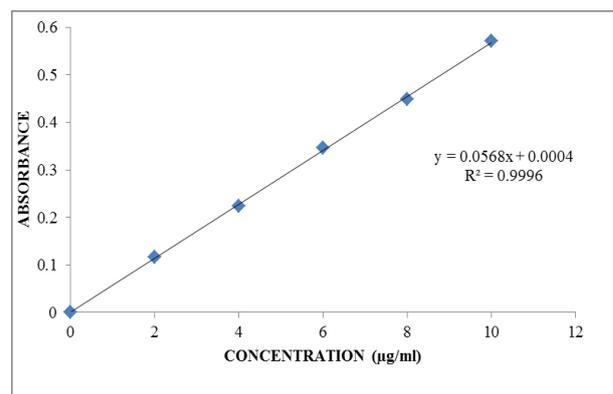


Figure 3: Standard graph of Telmisartan pH 6.8 phosphate buffer (237nm).

F8	28.3 ±0.4	0.625 ±0.1	0.833 ±0.1	25.00	1.333
F9	25.1 ±0.1	0.521 ±0.3	0.631 ±0.3	17.39	1.121
F10	26.7 ±0.4	0.588 ±0.3	0.666 ±0.4	11.76	1.333
F11	26.0 ±0.3	0.277 ±0.2	0.312 ±0.2	11.11	1.133
F12	26.6 ±0.2	0.434 ±0.2	0.476 ±0.3	8.695	1.095

The bulk density of all the formulations was found to be in the range of 0.277 ±0.2 to 0.625 ±0.1 (gm/cm³) showing that the powder has good flow properties. The tapped density of all the formulations was found to be in the range of 0.312 ±0.2 to 0.833 ±0.1 showing the powder has good flow properties. The compressibility index of all the formulations was found to be below 25 which show that the powder has good flow properties.

All the formulations has shown the hausner ratio below 1.333 indicating the powder has good flow properties.

Quality Control Parameters For tablets

Tablet quality control tests such as weight variation, hardness, and friability, thickness, and drug release studies in different media were performed on the compression coated tablet.

Table 8: In vitro quality control parameters for tablets.

Formulation codes	Average weight(mg)	Hardness (kg/cm ²)	Friability (%loss)	Thickness (mm)	Drug content (%)
F1	197.21	5.1	0.19	2.91	98.15
F2	199.36	5.8	0.26	2.45	99.78
F3	200.1	5.0	0.54	2.36	98.61
F4	196.48	5.9	0.61	2.45	99.36
F5	199.79	5.2	0.33	2.48	97.81
F6	198.56	5.7	0.45	2.61	99.28
F7	199.43	5.3	0.36	2.15	100.2
F8	198.68	5.8	0.57	2.61	99.20
F9	199.21	5.9	0.62	2.19	98.37
F10	197.41	5.3	0.55	2.38	98.54
F11	199.67	5.7	0.62	2.56	99.78
F12	199.89	5.2	0.35	2.61	99.91

Weight variation test

Tablets of each batch were subjected to weight variation test, difference in weight and percent deviation was calculated for each tablet and was shown in the Table 8.4. The average weight of the tablet is approximately in range of 197.21 to 200.1mg, so the permissible limit is ±7.5% (>250 mg). The results of the test showed that, the tablet weights were within the pharmacopoeia limit.

Hardness test

Hardness of the three tablets of each batch was checked by using Pfizer hardness tester and the data's were shown in Table 8.4. The results showed that the hardness of the tablets is in range of 2.15 to 5.9 kg/cm², which was within IP limits.

Thickness

Thickness of three tablets of each batch was checked by using Micrometer and data shown in Table-8.4. The

result showed that thickness of the tablet is raging from 2.15 to 2.91mm.

Friability

Tablets of each batch were evaluated for percentage friability and the data were shown in the Table 8.4. The average friability of all the formulations was less than 1% as per official requirement of IP indicating a good mechanical resistance of tablets.

Drug content

Drug content studies were performed for the prepared formulations. From the drug content studies it was concluded that all the formulations were showing the % drug content values within 97.81- 100.2%.

All the parameters such as weight variation, friability, hardness, thickness and drug content were found to be within limits.

In-Vitro Drug Release Studies

Table 9: Dissolution Data of Telmisartan Tablets Prepared with Eudragit RSPO.

Time (hr)	Cumulative Percent Drug Dissolved					
	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
0.5	15.78	17.25	18.4	21.58	8.2	3.2
1	25.79	23.93	22.3	26.94	13.2	8.9
2	36.84	31.68	29.5	30.62	16.3	12.3

3	48.92	39.77	32.3	34.86	22.4	17.4
4	57.41	44.51	41.3	40.35	26.3	19.3
5	63.72	52.97	52.6	48.45	29.5	22.4
6	68.27	59.84	59.4	54.80	32.8	25.6
7	75.48	65.81	65.2	59.25	38.4	32.3
8	82.68	70.91	72.3	65.24	42.5	37.6
9	89.12	78.29	79.5	70.73	48.15	42.8
10	95.75	83.94	82.5	78.34	56.36	52.6
11		89.88	89.1	85.52	73.46	62.3
12		93.82	91.2	95.48	89.67	72.3

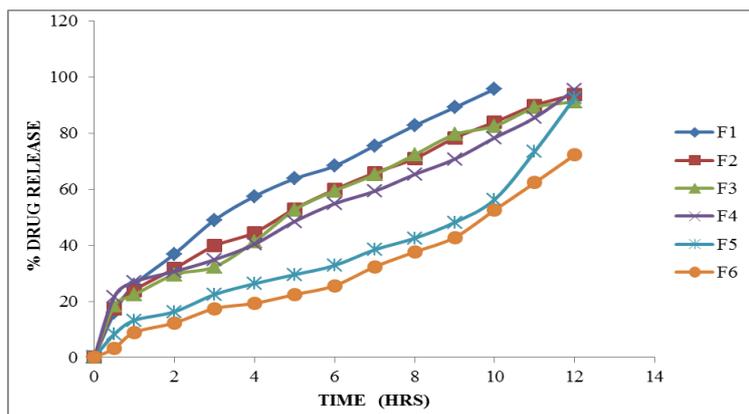


Fig 4: Dissolution profile of Telmisartan (F1-F6 formulations).

Table 10: Dissolution Data of Telmisartan Tablets Prepared With Eudragit RLPO.

Time (hr)	Cumulative Percent Drug Dissolved					
	F7	F8	F9	F10	F11	F12
0	0	0	0	0	0	0
0.5	15.74	17.52	30.62	14.44	27.98	17.29
1	26.21	21.65	34.86	23.18	36.72	25.87
2	34.48	39.27	40.35	29.39	43.14	36.58
3	45.69	41.27	48.45	37.58	49.61	42.19
4	57.35	47.93	54.80	44.94	55.49	49.67
5	63.61	58.75	59.25	56.85	57.31	58.91
6	78.89	66.14	65.24	58.12	63.90	67.49
7	85.36	72.85	73.49	62.24	68.49	74.20
8	88.25	78.46	78.34	69.20	75.89	81.91
9	94.52	86.93	85.52	74.66	89.19	86.80
10	97.49	93.54	96.98	82.96	95.41	89.78
11		98.75		88.28		93.11
12				98.96		96.76

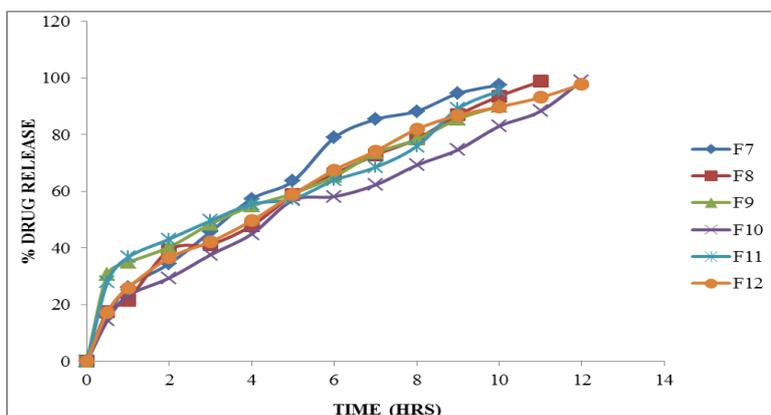


Fig. 5: Dissolution profile of Telmisartan (F7- F12 formulations).

From the dissolution data it was evident that the formulations prepared with Eudragit RSPO as polymer were retard the drug release up to desired time period i.e., 12 hours and showed maximum of (F4) 95.48 % in 12 hours with good retardation.

Formulations prepared with Eudragit RLPO retarded the drug release in the concentration of 40 mg (F10 Formulation) showed required release pattern i.e., retarded the drug release up to 12 hours and showed maximum of 98.96% in 12 hours with good retardation but increase the concentration of polymer the release pattern is not uniform.

Among all 12 formulations F10 formulation showed good drug permeation from the patch. Among all *in vitro* evaluation parameters F10 formulation passed all evaluation parameter.

Application of Release Rate Kinetics to Dissolution Data

Various models were tested for explaining the kinetics of drug release. To analyze the mechanism of the drug release rate kinetics of the dosage form, the obtained data were fitted into zero-order, first order, Higuchi, and Korsmeyer-Peppas release model.

Table 11: Release Rate Kinetics to Dissolution Data.

Cumulative (%) Release Q	Time (T)	Root (T)	Log (%) Release	Log (T)	Log (%) Remain	Release rate (Cumulative % Release / t)	1/Cum% Release	PEPPAS log Q/100	% Drug Remaining	Q01/3	Qt1/3	Q01/3-Qt1/3
0	0	0			2.000				100	4.642	4.642	0.000
14.44	0.5	0.707	1.160	-0.301	1.932	28.880	0.0693	-0.840	85.56	4.642	4.406	0.235
23.18	1	1.000	1.365	0.000	1.885	23.180	0.0431	-0.635	76.82	4.642	4.251	0.391
29.39	2	1.414	1.468	0.301	1.849	14.695	0.0340	-0.532	70.61	4.642	4.133	0.508
37.58	3	1.732	1.575	0.477	1.795	12.527	0.0266	-0.425	62.42	4.642	3.967	0.675
44.94	4	2.000	1.653	0.602	1.741	11.235	0.0223	-0.347	55.06	4.642	3.804	0.837
56.85	5	2.236	1.755	0.699	1.635	11.370	0.0176	-0.245	43.15	4.642	3.507	1.134
58.12	6	2.449	1.764	0.778	1.622	9.687	0.0172	-0.236	41.88	4.642	3.473	1.169
62.24	7	2.646	1.794	0.845	1.577	8.891	0.0161	-0.206	37.76	4.642	3.355	1.287
69.2	8	2.828	1.840	0.903	1.489	8.650	0.0145	-0.160	30.8	4.642	3.135	1.507
74.66	9	3.000	1.873	0.954	1.404	8.296	0.0134	-0.127	25.34	4.642	2.937	1.704
82.96	10	3.162	1.919	1.000	1.231	8.296	0.0121	-0.081	17.04	4.642	2.573	2.068
88.28	11	3.317	1.946	1.041	1.069	8.025	0.0113	-0.054	11.72	4.642	2.271	2.370
98.96	12	3.464	1.995	1.079	0.017	8.247	0.0101	-0.005	1.04	4.642	1.013	3.628

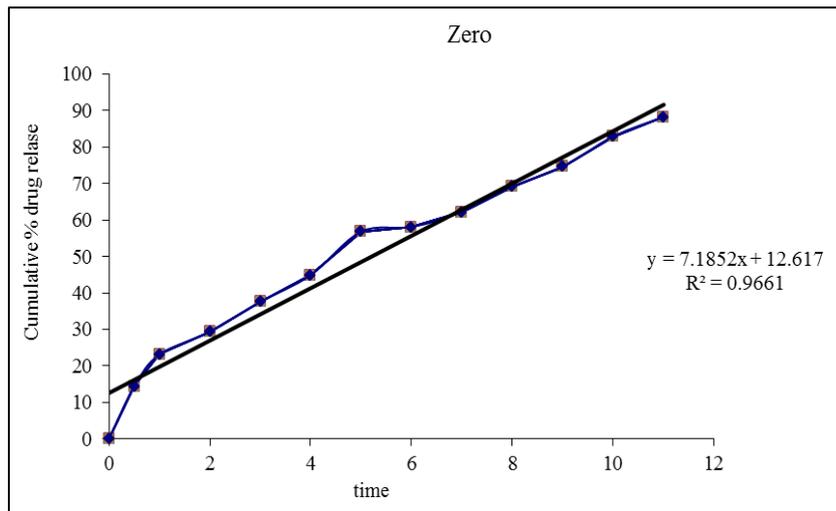


Fig 6: Zero order release kinetics graph.

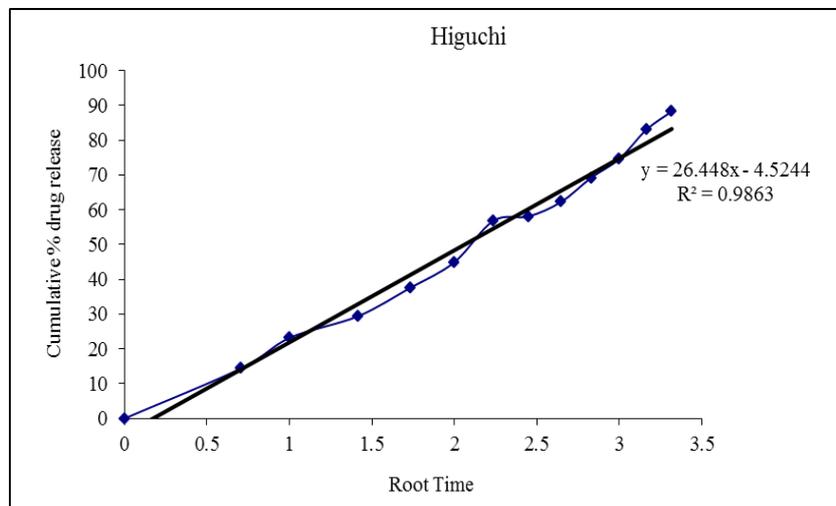


Fig 7: Higuchi release kinetics graph.

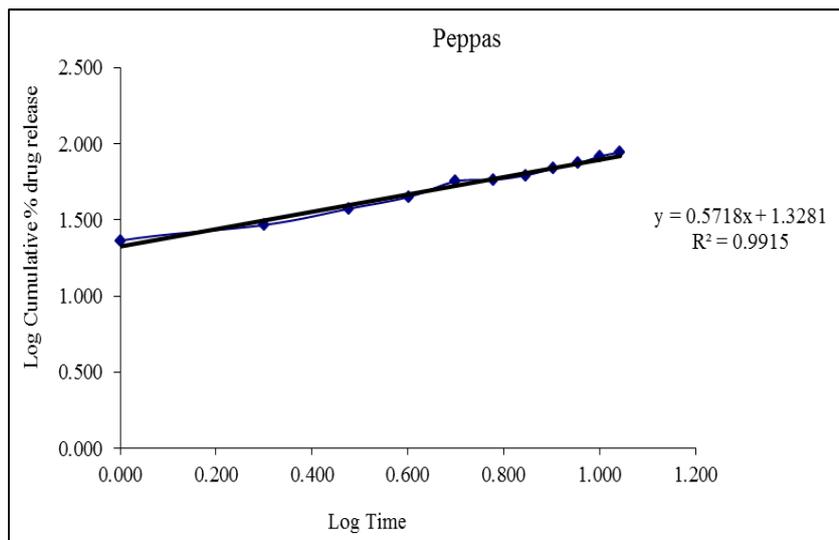


Fig 8: Kars mayer peppas graph.

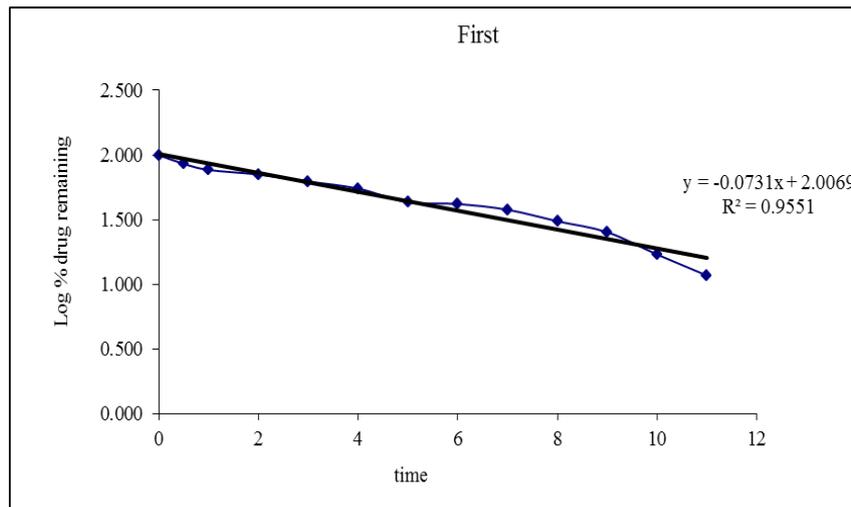


Fig 9: First order release kinetics graph.

Drug – Excipient compatibility studies

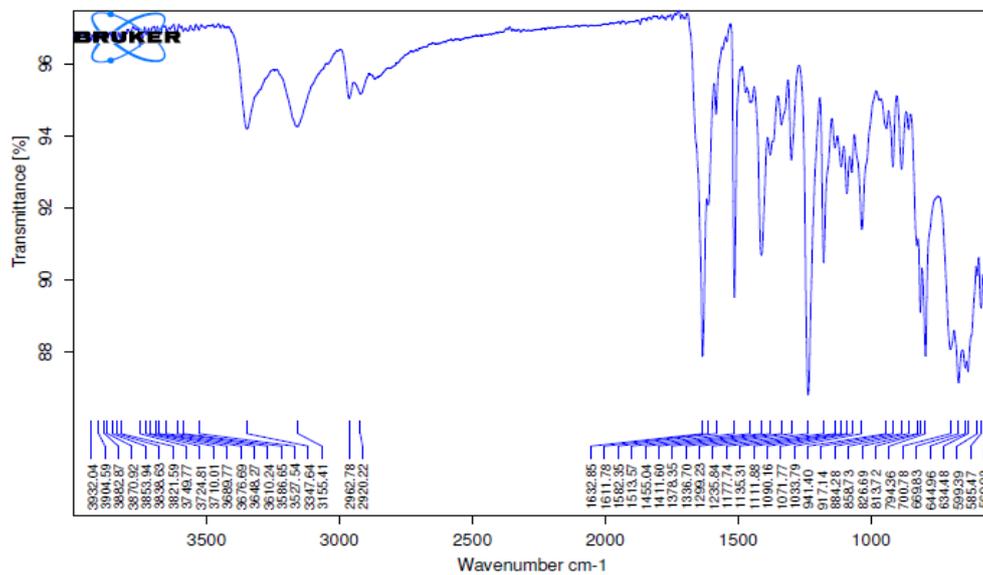


Figure 10: FT-TR Spectrum of Telmisartan pure drug.

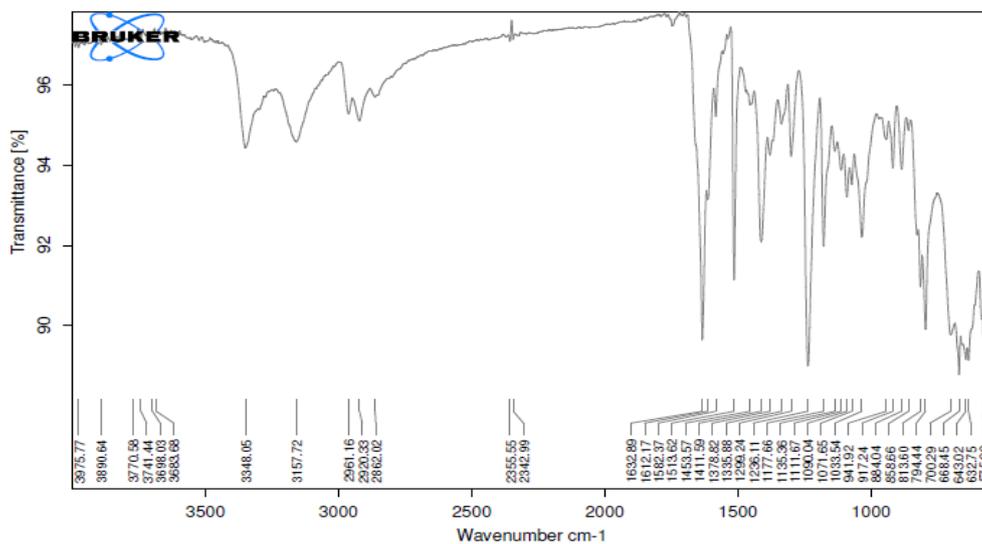


Figure 11: FT-IR Spectrum of Optimised Formulation.

From the FTIR data it was evident that the drug and excipients doses not have any interactions. Hence they were compatible.

CONCLUSION

The present study was carried out on Telmisartan. The main aim of this study is to extend the drug release up to 12 hrs. Drug wavelength and calibration curve was developed in 0.1N HCL and pH 6.8 Phosphate buffer.

The drug and excipient compatibility studies were shown good compatibility between drug and excipients. Tablet powder blend was subjected to various pre-formulation parameters. The angle of repose values indicates that the powder blend has good flow properties. The bulk density of all the formulations was found to be in the range of 0.277 ± 0.2 to 0.625 ± 0.1 (gm/cm³) showing that the powder has good flow properties. The tapped density of all the formulations was found to be in the range of 0.312 ± 0.2 to 0.833 ± 0.1 showing the powder has good flow properties. The compressibility index of all the formulations was found to be below 25 which show that the powder has good flow properties. All the formulations has shown the hausner ratio below 1.333 indicating the powder has good flow properties.

Post compression studies like Weight variation, Hardness, thickness, friability, drug content was determined. The average weight of the tablet is approximately in range of 197.21 to 200.1 mg, so the permissible limit is $\pm 7.5\%$ (>250 mg). The results showed that the hardness of the tablets is in range of 2.15 to 5.9 kg/cm², which was within IP limits. The result showed that thickness of the tablet is ranging from 2.15 to 2.91mm. The average friability of all the formulations was less than 1% as per official requirement of IP indicating a good mechanical resistance of tablets. From the drug content studies it was concluded that all the formulations were showing the % drug content values within 97.81- 100.2 %.

From the dissolution data it was evident that the formulations prepared with Eudragit RSPO as polymer were retard the drug release up to desired time period i.e., 12 hours. Formulations prepared with Eudragit RLPO retarded the drug release in the concentration of 40 mg (F10 Formulation) showed required release pattern i.e., retarded the drug release up to 12 hours and showed maximum of 98.96 % in 12 hours with good retardation.

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