

FORMULATION AND IN-VITRO EVALUATION OF CONTROLLED POROSITY OSMOTIC PUMP TABLETS OF TELMISARTAN FOR SUSTAINED RELEASE DRUG DELIVERY

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ABSTRACT

The purpose of the present research was for the development and assessment of controlled porosity osmotic pump (CPOP) tablets for the long-term oral administration of the poorly soluble hypertension medication telmisartan. The objective was to use an osmotic formulation technique that would improve the drug dissolution and bioavailability. FT-IR was used in order to confirm drug-excipient compatibility and validate analytical procedures. SLS was used as a pore-forming agent in a cellulose acetate membrane that was applied to tablets that were made by direct compression. A number of formulations were tested after it had been determined that all quality criteria satisfied requirements. Following zero-order kinetics, the lead formulation, F9C2 with a 5% coating, showed a steady, nearly full drug release (97.93% over 8 hours). Stability studies and SEM imaging confirmed the formulation's prolonged stability and consistent pore distribution, making it an appropriate approach for enhancing Telmisartan's therapeutic efficacy.

KEYWORDS: Osmotic drug delivery system, zero-order kinetics, controlled porosity osmotic pump, sustained release, and Telmisartan.

INTRODUCTION

Hypertension stands as a leading chronic cardiovascular condition globally, contributing substantially to worldwide morbidity and mortality.^[1] Sustained efficacy while minimizing side effects is dependent on maintaining sustained plasma concentrations of antihypertensive medications, which is essential for achieving the most effective therapeutic outcomes in its therapy. One commonly prescribed non-peptide angiotensin II receptor blocker (ARB) that is regularly administered for both hypertension and lowering cardiovascular risk is telmisartan.^[2,3] Despite having a broad application, the drug's intrinsic weak water solubility and resulting fluctuations in oral bioavailability hinder its therapeutic effectiveness, making it challenging for traditional formulations to achieve controlled and predictable release.^[4]

Oral controlled-release devices are establishing themselves as an important component of pharmaceutical development to address the drawbacks of conventional medication administration.^[5] By sustaining steady-state drug levels in the circulation, these sophisticated instruments are intended to improve therapeutic performance by reducing the frequency of dose and significantly enhancing patient adherence. The Osmotic Pump Drug Delivery System (OPDDS) stands out among the other technical alternatives as a very reliable and consistent platform.^[6] Its key benefit is that it may provide continuous medication delivery by offering a constant, zero-order release profile that is mainly unaffected by biological parameters like stomach pH and motility.

An advanced development in osmotic drug delivery technology is the Controlled Porosity Osmotic Pump (CPOP). Its primary innovation is the replacement of the establishment that must be physically drilled in traditional systems.^[7] Rather, water-soluble pore-forming chemicals are used to design the semi-permeable membrane. These chemical compounds disintegrate when they come into touch with gastrointestinal fluids, creating an in-situ network of microporous channels that control the drug's osmotic outflow. This method of manufacturing is especially well-suited for difficult, poorly soluble medications like Telmisartan because it has several benefits, including as simpler, more cost-effective production and highly stable release kinetics.

MATERIALS AND METHODS

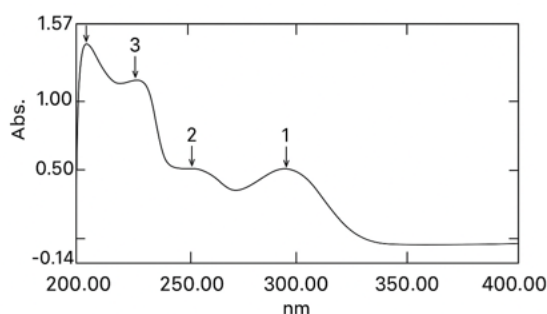
Materials Sai Mirra Innopharm Pvt. Ltd. supplied the active pharmaceutical ingredient (API), Telmisartan, as well as a number of essential excipients, including as lactose, mannitol, sodium chloride, hydroxypropyl methylcellulose (HPMC K15M and K100M), and sodium lauryl sulphate.

Methods

Establishing the linearity of the pure Telmisartan medicine along with determining its absorption maxima were the first steps in the pre-formulation research. Fourier Transform Infrared (FTIR) spectroscopy was used to examine drug-excipient compatibility in order to make sure formulation stability.^[8] Direct compression was used in the manufacturing of the osmotic medication delivery device. Both at every stage development and during final preparation, the resultant formulations were meticulously assessed to figure out their key quality aspects.

Determination of Absorption Maxima for Telmisartan

Using UV-visible spectrophotometry, the absorption maximum (λ_{max}) for Telmisartan was ascertained. Using a 1 cm quartz cell, a standard solution of the drug, containing 10–20 $\mu\text{g/mL}$, was prepared in methanol and scanned in the 200–400 nm wavelength range.^[9] A clear peak with highest absorbance at 295 nm was observed in the resulting spectra, which is shown in Figure 1. In the UV spectrophotometric approach, the specific wavelength was hereafter selected for all quantitative analyses.



[Peak Pick Table]

Threshold: 0:001000

Number of Points: 2

No.	P/V	Wavelength nm.	Abs.	Description
1	↑	295.5	0.561	
2	↓	254.0	0.561	
3	↑	228.0	1.176	
4	↑	206.0	1.430	

Fig. 1: λ_{max} Scan of Telmisartan.

Calibration curve for Telmisartan

Chromatographic analysis was used to create a calibration curve for Telmisartan, and the HPLC technique was used for quantitative analysis.

Table 1: Calibration Data Table for Telmisartan.

S.No	Concentration (mcg/ml)	Peak Area
1	55	1266720
2	88	1974260
3	110	2538486
4	132	2983258
5	165	3839232

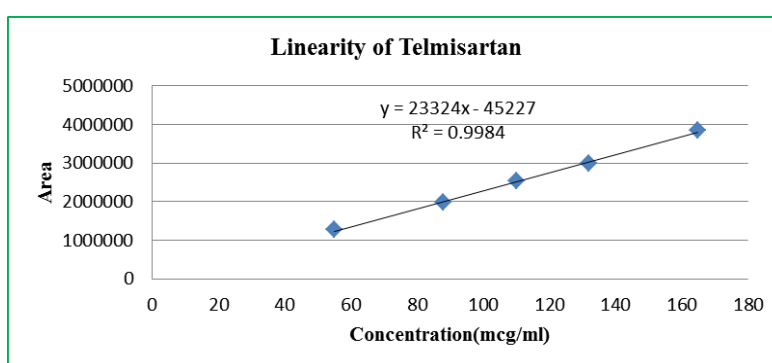


Fig. 2: Standard curve for Telmisartan.

Drug-excipient interaction studies

When developing a formulation, drug-excipient compatibility is a crucial need that is evaluated using Fourier-Transform Infrared (FT-IR) spectroscopy. To ensure consistent blending and assess any interactions, the process starts with a separate evaluation of the chosen excipients and the active pharmaceutical ingredient (API), then moves on to their physical blends. A hydraulic press is then used to compress each sample into a pellet after it was properly mixed with potassium bromide (KBr). An FTIR spectrometer, which operates at room temperature and scans a wavelength range of 400–4000 cm^{-1} , is used to investigate these pellets.

The produced spectra are processed utilizing baseline correction and smoothing methods to improve their apparent clarity after data capture. The spectra of the pure components and their mixes undergo comparison as part of the critical analysis. Finding any notable spectrum changes—like the shifting, attenuation, or removal of characteristic peaks—that might be

signs of a possible physicochemical incompatibility between the medicine and the excipients is the goal.

This study details the formulation of controlled porosity osmotic pump tablets for Telmisartan, employing the direct compression technique

Preparation of core tablets

Direct compression was used for manufacturing the core tablets for the telmisartan osmotic pump technology. The active pharmaceutical ingredient (telmisartan), swellable polymers (HPMC K15M and HPMC K100M), osmotic agents (mannitol, lactose, sodium chloride), the diluent Vivapur 102, and the glidant colloidal anhydrous silica were just some of the necessary formulation components that were first sieved through a #24 mesh sieve. To maintain the consistency and stop moisture absorption, the sieved components were then kept in an HDPE container coated with polybags. To guarantee its ideal dispersion, magnesium stearate, which served as the lubricant, was sieved by itself through a finer #60 mesh.

All of the sieved components with the exception from magnesium stearate were transferred into a Rapid Mixer Granulator (RMG) for a preliminary dry mixing step in the blending process. In order to create an evenly distributed powder mix without causing premature agglomeration, this was done for five minutes at a low impeller speed without the chopper. In order to ensure even more homogeneity, this pre-lubricated substance was then moved to a Double Cone Blender and mixed slowly for ten more minutes. To ensure suitable lubrication for the ensuing compression, the sieved magnesium stearate was added as an intra-granular lubricant and mixed for an additional five minutes. A punch set in the shape of a capsule was then used to compress the prepared blend into core tablets.

Table 2: Different formulations for controlled porosity osmotic pump core tablet.

S.No	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Telmisartan	80	80	80	80	80	80	80	80	80
2	Microcrystalline Cellulose PH 102	138	142	176	202	202	182	156	182	102
3	Mannitol	100	80	-	-	-	-	80	-	100
4	Sodium chloride	-	-	-	-	60	80	60	100	80
5	Lactose Monohydrate	40	60	100	80	-	-	-	-	-
6	HPMC K15M	20	28	20	-	20	28	-	28	28
7	HPMC K100M	12	-	14	28	28	20	14	-	-
8	Colloidal	4	4	4	4	4	4	4	4	4

	anhydrous silica									
9	Magnesium stearate	6	6	6	6	6	6	6	6	6
Weight of Tablet (mg)		400	400	400	400	400	400	400	400	400

Preparation of the coating solution

For the purpose of tablet coating, three separate formulations were developed, varying in total solid content at 4%, 5%, and 6%. In conjunction with PEG 6000 as a plasticizer and Ferric oxide yellow as a colorant, the coating compositions contained the polymers Cellulose Acetate, Ethyl Cellulose, and Hydroxypropyl Methylcellulose (HPMC 5 cps). These ingredients were carefully weighed and dissolved in a 60:40 acetone and isopropyl alcohol co-solvent solution. To ensure a uniform, blue dispersion, the solutions were continuously agitated for a further half hour after they were combined until total dissolution was reached.

Table 3: Composition of Coating Solutions for Telmisartan Osmotic Tablets.

S.No	Ingredients	C1	C2	C3
		4%	5%	6%
1	Cellulose acetate	7	7	11
3	HPMC 5 cps	4	4	4
4	PEG 6000	2	-	8
5	Sodium lauryl sulphate	2	8	-
6	Acetone	60	60	60
7	Isopropyl Alcohol	40	40	40
9	Ferric oxide yellow	1	1	1
Total weight of core tablet (mg/T)		16	20	24

Optimization Studies for Telmisartan Osmotic Core Tablet Formulations

Powder characterization: Before compression, an extensive investigation of the powder's flow properties was carried out. Significant parameters were measured, such as mass, tapped, compressibility, Hausner's ratio, and the angle of repose. Table 4 provides an overview of these results.

Evaluation Test Of Telmisartan Osmotic Tablet

Assay Procedure for Telmisartan

UV spectrophotometry was used to further investigate the Telmisartan tablets. Twenty tablets have been crushed into a fine powder after getting weighed. A 100 mL volumetric flask was filled with an aliquot of 10 mg of Telmisartan, which was then dissolved in methanol. To ensure total dissolution, the solution was sonicated for 15 to 20 minutes, methanol was added

to bring it up to volume, and then it was filtered. A final working standard concentration of 10 µg/mL was manufactured by dilution of the filtered solution.

Preparation of Standard Solution

To perform the assay, a standard solution was made by specifically dissolving 10 mg of the reference Telmisartan standard in solvent and then diluting it to a final concentration of 10 µg/mL, which matched the concentration of the sample. The absorbance at 295 nm (λ_{max}) of both solutions was measured using UV-Vis spectrophotometry according to a solvent blank. The following formula, which compares the absorbance characteristics of the sample and standard solutions, was then used to figure out the percentage of label claim.

$$\text{Assay (\% of label claim)} = \left(\frac{\text{Absorbance of sample}}{\text{Absorbance of standard}} \right) \times \left(\frac{\text{Weight of standard}}{\text{Weight of sample}} \right) \times 100$$

Swelling index

In advance of the tablets were individually placed in the Petri dishes with 10 mL of phosphate buffer (pH 6.8), their initial weight (W_1) was measured in order to calculate the swelling index. The tablets were taken out of the medium every hour for eight hours. The hydrated weight (W_2) was determined after the extra surface fluid was wiped using filter paper. After that, the swelling index was calculated using the given formula.^[10]

$$\text{Swelling index} = \frac{W_s - W_d}{W_d}$$

In-vitro Dissolution study

A USP Type II (paddle) dissolving equipment^[11] functioning at 50 rpm was used to perform a dissolution examination on Telmisartan tablets. The study was using a 1000 mL volume, with the medium mimicking the stomach pH (1.2) for the first two hours and an intestinal pH phosphate buffer (6.8) for the next six. A stabilized temperature of $37 \pm 0.5^\circ\text{C}$ was maintained during the whole testing process. Hourly withdrawals of aliquots were made, filtered, and measured at 295 nm using UV spectrophotometric analysis. Concentrations were computed using a calibration curve that was originally verified. Each batch's ensuing dissolution data has been organized into tables and displayed interactively.

Scanning electron microscopy

The surface morphology of the tablet coating layer was examined using scanning electron microscopy (SEM) before and after the disintegration process.^[12]

RESULTS AND DISSCUSION

Pre-Compression parameters

Table 4: Powder characterization.

Code	Bulk density (g/ml)	Tapped density (g/ml)	Compressi on index (%)	Hausner's ratio	Angle of repose (θ)	Flow property
F1	0.422	0.581	1.377	27.37	31° 92'	GOOD
F2	0.433	0.632	1.460	31.49	32° 75'	GOOD
F3	0.452	0.645	1.427	29.92	33° 28'	GOOD
F4	0.572	0.671	1.173	14.75	31° 45'	GOOD
F5	0.551	0.654	1.187	15.75	31° 45'	GOOD
F6	0.55	0.676	1.229	18.64	33° 75'	GOOD
F7	0.571	0.686	1.201	16.76	30° 47'	GOOD
F8	0.548	0.671	1.224	18.33	30° 21'	GOOD
F9	0.554	0.673	1.215	17.68	31° 35'	GOOD

FTIR compatibility tests between drugs and excipients

The investigation verified that there was no chemical interaction between the excipients and the drug at hand. This was demonstrated by the fact that, as seen in Figures 4 and 5, the distinctive peak of the pure drug remained mostly unaltered in the physical combination of drugs.

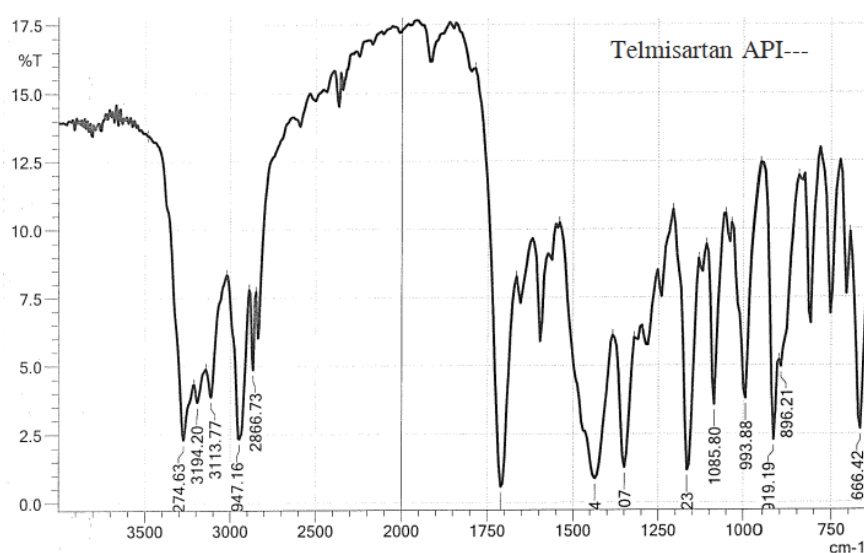


Fig. 4: FTIR Spectra of pure Telmisartan.

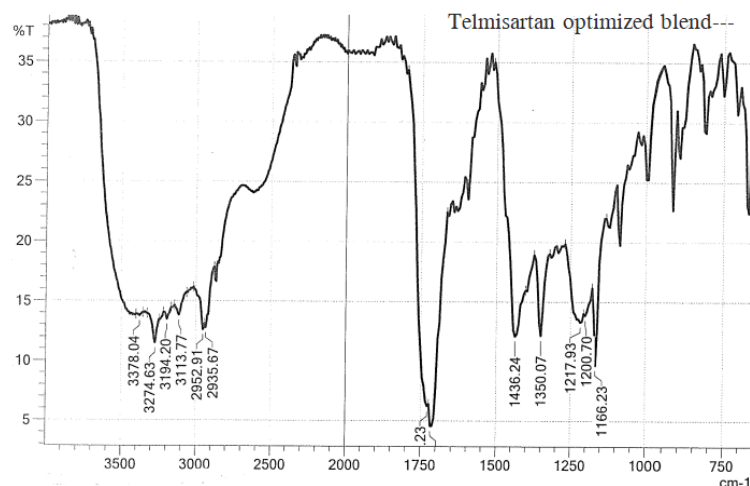


Fig. 5: FTIR Spectra of optimized formula blend.

Telmisartan osmotic core tablet evaluation test

A selection of standard tests were used to comprehensively assess the manufactured telmisartan osmotic core tablets' quality. To figure out their structural integrity, important physical properties such as thickness, hardness, friability, and weight fluctuation were assessed. To confirm dose consistency and the core's ability to provide control over substance release, measurements were performed in addition of the swelling index and drug content uniformity.

Table 5: Evaluation of Osmotic core tablet of Telmisartan (F1 to F9).

Tests	Specifications	F1	F2	F3	F4	F5	F6	F7	F8	F9
Description	White colored Capsule shaped uncoated Tablet	Meet	Meet	Meet	Meet	Meet	Meet	Meet	Meet	Meet
Average weight (mg)	400 mg \pm 5%	406	402	409	404	408	410	405	407	402
Thickness (mm)	4.60 \pm 0.2	4.66	4.67	4.61	4.63	4.64	4.62	4.64	4.65	4.62
Hardness (kg/cm ²)	NLT 3.0	7.5	8.35	7.75	8.25	7.95	8.5	8.35	8.75	8.85
Friability (% w/w)	NMT 1%	0.09	0.12	0.11	0.11	0.12	0.09	0.1	0.1	0.1
Weight variation (n=20)	\pm 5% from the average weight	-2.1 to +2.16	-1.7 to +1.9	-1.7 to +1.5	-1.0 to +1.7	-1.3 to +1.9	-1.4 to +1.7	-2.1 to +1.9	-2.15 to +2.25	-1.1 to +2.5
Assay										
Telmisartan	90 – 110%	98.90%	99.20%	99.10%	98.75%	98.18%	97.80%	98.19%	98.60%	99.10%

Swelling study

Following pre-formulation studies (Table 6), uncoated tablets from formulations F7, F8, and F9, which met all coating prerequisites and showed suitable swelling, were coated with a semipermeable membrane at 4%, 5%, and 6% weight development, respectively, according to with pre-formulation tests (Table 6). To find the ideal coating thickness for regulated porosity and drug release, these coated tablets will go through in-vitro release testing.

Table 6: Results of swelling index.

S.No	Formulation code	Swelling index (%)
1	F1	165
2	F2	181
3	F3	187
4	F4	192
5	F5	245
6	F6	252
7	F7	288
8	F8	291
9	F9	297

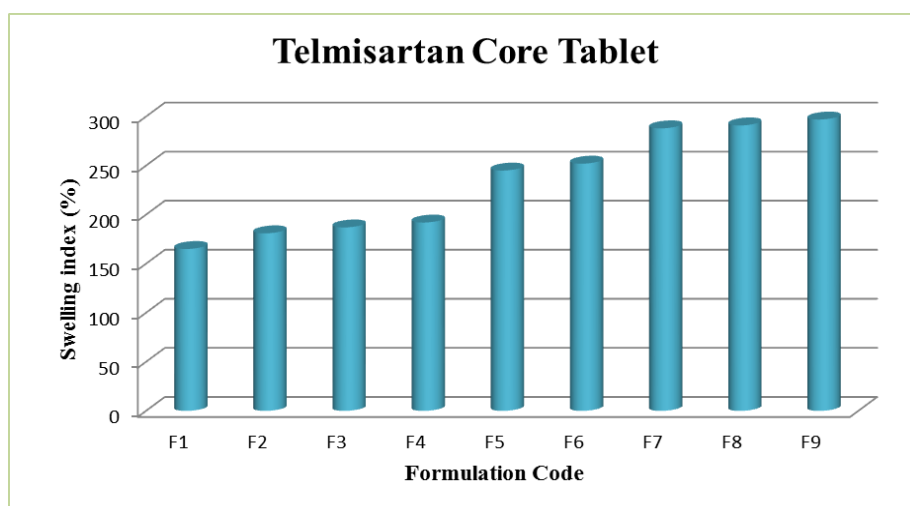


Fig. 6: % of swelling index in Telmisartan core tablet.

Evaluation parameters of Telmisartan controlled porosity osmotic pump coated tablets

The prepared telmisartan osmotic coated tablets performed a number of quality control procedures to evaluate their physical properties. Thickness, hardness, weight fluctuations, uniformity of drug content, in-vitro release profile, and surface porosity morphology were the factors that were analyzed.

Table 7: Post formulation study results for coated tablets.

Formulation code	Weight variation test (mg)	Thickness(mm)	Hardness test(kg/cm ²)	Drug content %
Coating 4 % (w/w)				
F7C1	420±1.85	4.6±0.03	7.2±0.52	97.24±1.85
F8C1	421±1.35	4.6±0.03	7.4±0.75	97.32±1.45
F9C1	421±1.64	4.6±0.04	7.2±0.46	97.45±1.9
Coating 5 % (w/w)				
F7C2	425±1.28	4.6±0.09	8.6±0.54	96.74±1.36
F8C2	424±1.45	4.6±0.07	8.5±0.66	96.36±1.74
F9C2	425±1.68	4.6±0.06	9.3±0.89	99.20±1.48
Coating 6 % (w/w)				
F7C3	428±1.39	4.6±0.03	7.1±0.73	96.22±1.97
F8C3	428±1.78	4.6±0.02	8.3±0.36	96.87±1.56
F9C3	428±1.25	4.6±0.01	8.5±0.87	96.17±1.42

Drug content

Excellent content uniformity was shown by analysis of the Telmisartan osmotic core tablets, with values ranging from 96.36% ± 3.85 to 99.21% ± 2.74. The results presented here confirm that the manufacturing method provides a constant and uniform dispersion of the therapeutic drug in every tablet, since they meet the strict USP criteria (90–110%).

In-vitro release study of the tablets

The percentage of drug release from osmotic tablet were shown in table,

Table 8: *In-vitro* study results of coated tablet F7C1 to F9C3.

Time (Hr)	F7C1	F7C2	F7C3	F8C1	F8C2	F8C3	F9C1	F9C2	F9C3
0	0	0	0	0	0	0	0	0	0
1	14.75	13.62	12.54	14.91	14.17	15.12	15.65	13.14	16.07
2	26.53	25.25	24.82	24.28	25.96	23.06	28.06	27.97	27.81
3	37.12	34.63	29.17	28.09	27.83	38.26	43.21	39.83	45.17
4	43.12	44.25	52.72	39.47	40.96	42.19	51.17	56.96	56.26
5	62.15	54.38	61.72	59.13	69.56	51.32	70.01	72.56	62.67
6	73.75	72.17	83.21	65.17	76.96	68.21	75.54	86.96	72.78
7	81.94	77.18	85.17	72.09	81.51	74.05	83.29	93.51	82.95
8	89.61	87.35	87.46	91.15	94.91	92.45	92.16	97.93	89.52

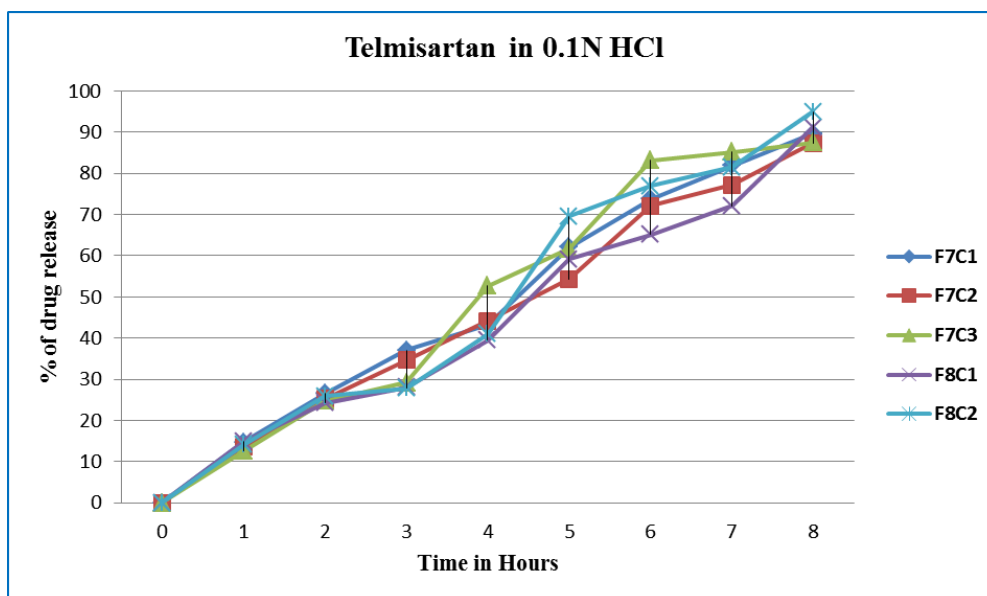


Fig. 7: *In-vitro* drug release of coated tablet F7C1 to F8C2.

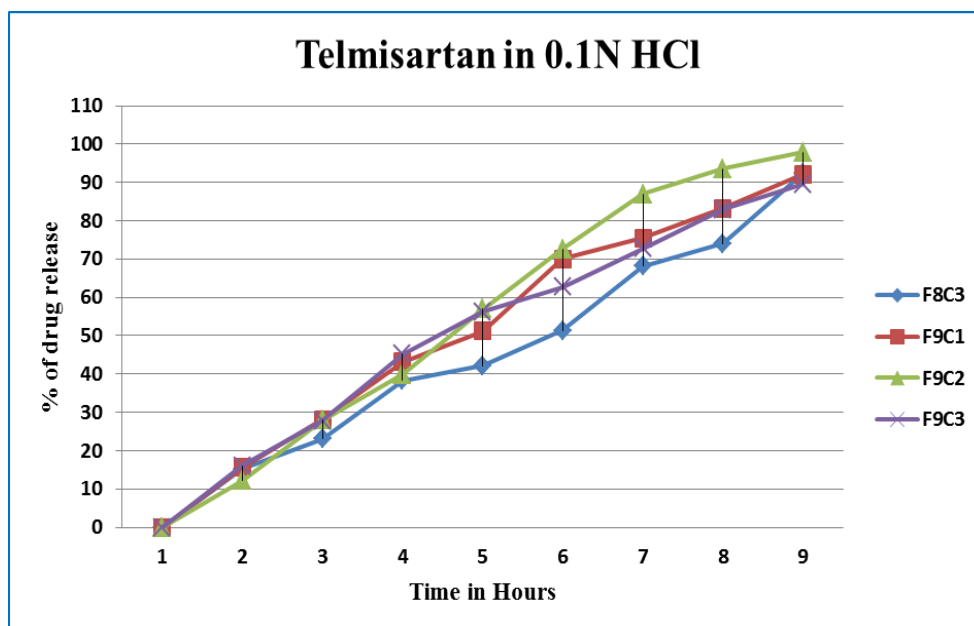


Fig. 8: *In-vitro* drug release of coated tablet F8C3 to F9C3.

Effect of amount of osmogen on drug release

The development of formulations with different concentrations of mannitol, lactose, and NaCl confirmed the important role that osmogen concentration performs in controlling drug release. It was discovered that higher osmogen concentrations increased osmotic pressure, a crucial factor that greatly accelerated the drug's release rate. Mannitol and NaCl were the most successful osmogens among those tested. Figure 9 illustrates the combination's higher effectiveness, since formulation F9C2, which encountered the most effective doses of both, showed the best release profile.

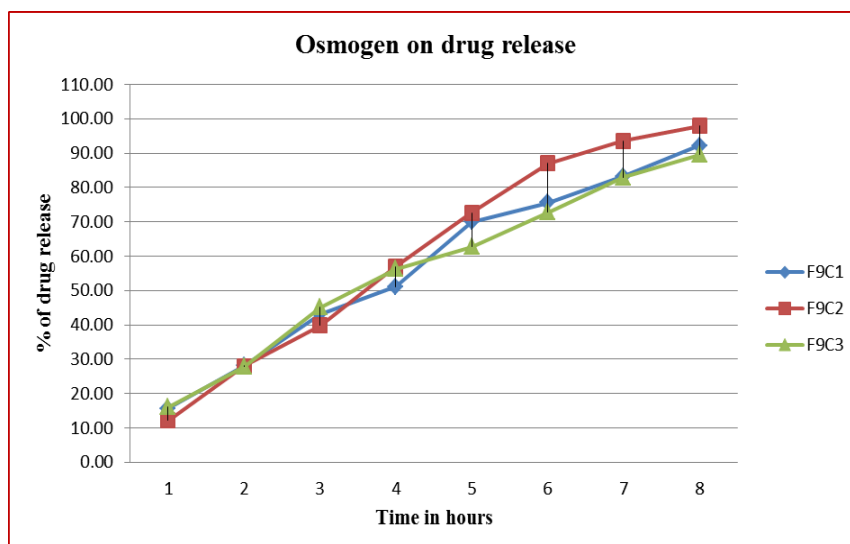


Fig. 9: Variation of effect of amount of osmogen.

Membrane morphology of porous Telmisartan osmotic tablet

The C2-coated tablet (Formulation F9, which incorporated 2% SLS) formed a more porous structure than its C3 counterpart (coated with 2% PEG 6000), as determined by a comparative analysis of coating formulations. Higher membrane permeability was directly connected with this greater porosity. Based on the results, SLS functions as a more potent pore-forming agent than PEG 6000, which significantly improves drug diffusion through the creation of the membrane more permeable.

Drug release kinetic study

The enhanced formulation, identified as F9C2, closely followed zero-order kinetics ($R^2 = 0.980$) and showed a very constant and time-independent drug release profile in vitro. The strong fit with the mathematical models of Hixson-Crowell ($R^2 = 0.972$) and Korsmeyer-Peppas ($R^2 = 0.964$) further supported this releasing mechanism. The combined evidence suggests that the drug dispersion and tablet erosion exhibited not much effects. As a result, osmotic pressure was the main force behind the release mechanism, with surface erosion and diffusion functioning as supportive features.

Table 9: R^2 values for various kinetics model coefficient of determination.

Time (Hr)	cumulative % drug released	% drug remaining	Square root time	log Cumu % drug remaining	log time	log Cumu % drug released	% Drug released	Cube Root of % drug Remaining(Wt)	Wo-Wt
0	0	100	0.000	2.000	0.000	0.000	100	4.642	0.000
1	13.14	86.86	1.000	1.939	0.000	1.119	13.14	4.429	0.213
2	27.97	72.03	1.414	1.858	0.301	1.447	14.83	4.161	0.481

3	39.83	60.17	1.732	1.779	0.477	1.600	11.86	3.919	0.723
4	56.96	43.04	2.000	1.634	0.602	1.756	17.13	3.504	1.138
5	72.56	27.44	2.236	1.438	0.699	1.861	15.6	3.016	1.626
6	86.96	13.04	2.449	1.115	0.778	1.939	14.4	2.354	2.288
7	93.51	6.49	2.646	0.812	0.845	1.971	6.55	1.865	2.777
8	97.93	2.07	2.828	0.316	0.903	1.991	4.42	1.274	3.368

KINETIC MODEL	COEFFICIENT OF DETERMINATION (R^2)
Zero order kinetics	0.998
First order kinetics	0.910
Higuchi kinetics	0.895
Korsmeyer and Peppas Kinetics	0.947
Hixson – Crowell kinetics	0.957

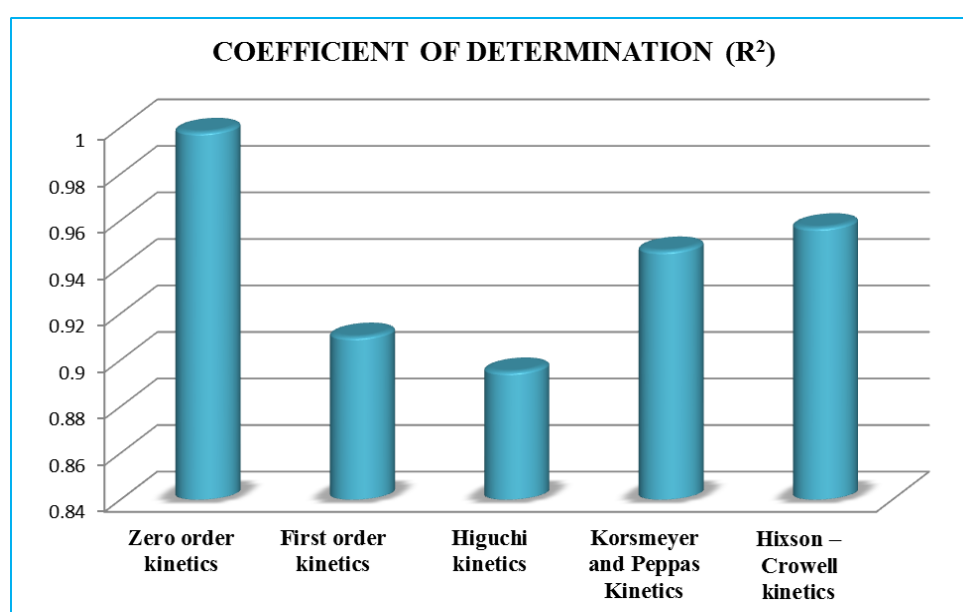


Fig. 10: R^2 values for various kinetics model coefficient of determination.

SUMMARY AND CONCLUSION

This study successfully developed and evaluated a Controlled Porosity Osmotic Pump (CPOP) for the sustained delivery of Telmisartan, with the objective of enhancing its bioavailability. To maximize significant components such as osmotic agents, pore formers, and polymer concentrations, a scientific formulation approach was used. The final batch of tablets, which were produced by direct compression, were covered with a cellulose acetate semi-permeable membrane incorporating sodium lauryl sulfate (SLS) as a pore-forming agent. Excellent linearity has been established by the rigorous verification of analytical methodologies for drug quantification. Additionally, formulation stability was ensured by FT-IR spectroscopy, which verified the physicochemical compatibility between Telmisartan and the excipients.

The produced tablets satisfied pharmacopeial standards regarding uniformity of distribution, flow, and compressibility and maintained outstanding pre- and post-compression characteristics. Higher polymer concentrations and membrane thickness directly improved tablet swelling, which in response modified the drug release rate, according to swelling index studies. The best option among the tested formulas was batch F9C2, which had a 5% coating level with SLS. Over the course of eight hours, it showed a nearly complete cumulative medication release of almost 98%. This formulation's release profile performed best in 0.1N HCl while remaining steady throughout a range of agitation speeds and dissolving medium. This demonstrates the system's resilience and predictability by proving that osmosis is primarily responsible for the release mechanism.

The establishment of a uniform porous membrane, the fundamental structural component in charge of regulating drug diffusion, was successfully verified by scanning electron microscopy (SEM) examination. Both the Zero-order and Hixson-Crowell kinetic models have been confirmed by the drug release profile, indicating a dual release mechanism regulated by diffusion driven by osmotic pressure and the controlled erosion of the semipermeable covering. Furthermore, accelerated stability testing carried out over a three-month period confirmed that the improved formulation maintained its chemical and physical integrity.

In conclusion, this study successfully establishes Controlled Porosity Osmotic Pump (CPOP) technology as a viable and effective strategy for achieving sustained release of poorly water-soluble drugs such as Telmisartan. The essential objectives for design of an osmotic drug delivery system were met by the improved formulation, F9C2, which provided predictable, regulated, and steady release characteristics. The most significant discovery was the finding that sodium lauryl sulfate (SLS) performed better than PEG-6000 as a pore-forming agent. This led to improved membrane porosity and permeability, which improved drug diffusion as well as produced a steady release profile. A strong and promising foundation for creating cutting-edge oral antihypertensive therapies with enhanced pharmacokinetic performance is provided by this formulation technology.

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