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# Development and Assessment of Sustained Release Matrix Tablet of Telmisartan

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## ABSTRACT

Development and Assessment of Sustained Release Matrix Tablet of Telmisartan the UV-Visible spectra analysis of Telmisartan in methanol and water solvents discovered a consistent absorption peak at approximately 234 nm, indicating its characteristic absorbance wavelength. The FT-IR spectrum highlighted functional groups such as hydroxyl, carbonyl, and aromatic rings present in Telmisartan, essential for identifying molecular characteristics. Formulation F8 emerged as the most promising option for sustained-release matrix tablets of Telmisartan, demonstrating superior flow properties, compressibility, and tablet characteristics. Compatibility studies with various excipients indicated stable conditions at lower temperatures, but interaction challenges arose at elevated temperatures and humidity levels. Differential Scanning Calorimetry (DSC) analysis provided insights into the thermal behavior of Telmisartan and excipients, aiding in formulation optimization. Furthermore, formulation F8 exhibited prolonged floating time and sustained drug release in dissolution profiles, suggesting its suitability for once-daily dosing regimens. Stability studies confirmed F8's robustness and reliability over a one month period, indicating its potential for clinical use. Further investigations may be required to assess long-term stability under different environmental conditions.

***KEYWORDS:*** *Telmisartan Sustained Release Matrix Tablet, DSC, FT-IR etc*

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## INTRODUCTION

The majority of oral sustained release systems rely on dissolution, diffusion or a combination of both mechanisms, to generate slow release of drug to the gastrointestinal tract. Sustained release constitutes any dosage form that provides medication over an extended time or denotes that the system is able to provide some actual therapeutic control whether this is of a temporal nature, spatial nature or both. Sustained release system generally do not attain zero order type release and usually try to mimic zero order release by providing drug in a slow first order.[1]

Repeat action tablet are an alternative method of sustained release in which multiple doses of drug are an alternative method of sustained release, in which, multiple doses are contained within a dosage form and each dose is released at a periodic interval. A sustained release dosage form will provide a therapeutic concentration of the drug in the blood that is maintained throughout the dosing interval with a reduction in a peak concentration ratio.[2]

Telmisartan stands out as a favored choice in the management of hypertension due to its efficacy and tolerability. It is frequently recommended as a first-line treatment and can be administered either alone or in conjunction with other antihypertensive medications, depending on the specific requirements and severity of the patient's condition.[3] Hypertension, characterized by persistently elevated blood pressure levels, is a prevalent medical condition affecting a substantial portion of the global population. Left untreated or poorly managed, hypertension poses a significant risk factor for various cardiovascular complications, including coronary artery disease, stroke, heart failure, and renal impairment. Consequently, effective management strategies, such as pharmacological interventions with agents like

Telmisartan, are essential for mitigating these risks and improving patient outcomes.[4]

## MATERIALS AND METHODS

**Materials:** Telmisartan was obtained as gift sample from Nivedita Chem Pvt. Ltd, Mumbai. HPMC E15 and Microcrystalline cellulose was procured from powder pack chem laboratory. Citric acid procured from Acme chemicals, Mumbai. Sodium bicarbonate was procured from Suvchem Laboratory Chemicals. Talc and magnesium stearate was procured from Loba Chemie Pvt. Ltd., Mumbai. All chemicals were of analytical grade.

**Tabel No.1: The composition of all formulations**

| Ingredients (mgs) | Formulation Code (in mg) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
| Telmisartan | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 |
| HPMC(E15) | 50 | 75 | 100 | 125 | 150 | 175 | 190 | 180 | 200 |
| HPMC K( 15) | 200 | 200 | 175 | 150 | 125 | 100 | 50 | 50 | 35 |
| Sodium bicarbonate | 10 | 10 | 10 | 10 | 10 | 10 | 5 | 5 | 5 |
| Microcrystalline cellulose | 35 | 10 | 10 | 10 | 10 | 10 | 50 | 60 | 70 |
| Talc | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Citric acid | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Magnesium Stearate | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| **Total** | **350** | **350** | **350** | **350** | **350** | **350** | **350** | **350** | **350** |

**Methods:** Formulation of sustained release matrix tablet of Telmisartan by Direct Compression Method.

1. All material were accurately weighed and passed through 60 mesh sieve accordingly and (Talc and magnesium stearate were added last).
2. Mixing and transferred to glass mortar and triturated until mixed uniformly.
3. The mixture was then compressed by direct compression using punching machine.

## PREFORMULATION PARAMETER

### 1. Organoleptic Properties: [5]

Description of the drug is the first line indication for purity for its identification. 1.0 gm. of Telmisartan was weighed and transferred into a clean, dry petri dish and physical appearance, color ,odor, taste were observed carefully.

### 2. Melting point determination:

Melting point of Telmisartan was carried out by capillary method using digital melting point apparatus.

### 3. Solubility

Telmisartan is soluble in ethanol, Methanol, 0.1 N HCL, and dimethyl formamide (DMF), among other organic solvents. The solubility of Telmisartan in these solvents is approximately 0.2, 10, and 20 mg/ml, respectively.

### 4. Analysis of API by UV Visible spectrophotometer [6]

100 mg of Telmisartan was accurately weighed and transferred into 100 ml ethanol in volumetric flask (to get 1000 µg/ml). In volumetric flask from above stock solution 10 ml was pipette out and diluted up to 100 ml with ethanol (to get 100 µg/ml solution). Then from above stock solution 1 ml was pipette out and diluted up to 10 ml with ethanol (to get 10 µg/ml solution). From II$^{nd}$ stock solution 0.2, 0.4, 0.6, 0.8 and 1.0 ml were transferred into 10 ml volumetric flask and diluted with ethanol up to the mark to obtain Telmisartan concentration of 2, 4, 6, 8 and 10 µg/ml respectively. The prepared solution i.e. 10 µg/ml concentration was scanned for λ max from 200-400 nm in UV visible spectrophotometer.

### 5. FTIR Analysis [12]

The infrared spectra of pure drugs and all formulations were recorded by using a Fourier transform infrared spectrophotometer. A base line correction was made using dried potassium bromide and then the spectrum of the pure drug. Weighed amount of drug (3 mg) was mixed with 100 mg of potassium bromide (dried at 40 - 50 $^{o}$ C). The mixture was taken and compressed under 10-ton pressure in a hydraulic press to form a transparent pellet. The mixture was compressed into transparent disks in a moisture free atmosphere and IR spectra were obtained. The scanning range was selected between 4000 and 400 cm$^{1}$.

**6. DSC Analysis**

DSC measures the heat loss or gain resulting from physical or chemical changes within a sample as a function of temperature. The sample was hermetically sealed in an aluminium and heated with continuous purge of argon and compared with the reference sample. Thermal behavior of the samples was investigated and scanned from 10 to 200 °C at rate of 10 °C/min.

**PRECOMPRESSION PARAMETER [13, 14]**

Precompression involves the application of biopharmaceutical principles to the physicochemical parameters of drug substance and is characterized with the goal of designing optimum drug delivery system. Precompression parameters of powder were bulk density, tapped density, carr's index, hausner's ratio, angle of repose determined for each formulation.

**CHARACTERIZATION OF RAFT FORMING TABLET**

**1. Thickness and diameter: [15]**

For the determination of diameter and thickness, vernier caliper was used. The dimensions were calculated in millimeters.

**2. Hardness: [16]**

The hardness of each batch of tablet was checked by using Monsanto hardness tester. The hardness was measured in terms of $kg/cm^2$. 5 tablets were chosen randomly and tested for hardness.

**3. Weight variation: [17]**

The weight of the tablet being made was routinely determined to ensure that a tablet contains the proper amount of drug. According to Indian Pharmacopoeia, 20 tablets were selected at random, weighed together and then individually, to calculate the average weight. The mean and standard deviation were determined.

**4. Friability test: [18]**

Twenty tablets were initially weighed (W1) and transferred into the Friabilator. The Friabilator was operated at 25 rpm for 4 minutes in which tablets are subjected to combined effect of shock and abrasion in a plastic chamber dropping the tablets at a height of 6 inch in each revolution. The tablets were de dusted and weighed again (W2).

$$\% \text{ friability} = (W1 - W2 / W1) \times 100$$

**5. Drug content uniformity: [19]**

Tablets from formulation was taken and dropped in 100ml 0.1N HCl in a beaker. After 24 hrs. or when the drug is released completely the same sample was withdrawn (about 1ml) and diluted to 10ml with 0.1N HCL and absorbance was taken at 278 nm using UV spectrometer. From the standard graph % drug release was calculated.

**6. Floating lag time: [20]**

The floating lag time the tablet constantly floats on the dissolution medium (i.e. duration of floating) in the dissolution medium. The tablets were placed in a 100 ml beaker containing 0.1N HCL. The time required for the tablet to rise to the surface and float was determined as floating lag time.

**7. In-Vitro Dissolution test: [21]**

Using a USP type II paddle type dissolution apparatus, the drug release for different batches of the produced Telmisartan raft forming tablets was studied. The method of dissolving 900 ml of 0.1 N HCl buffer were used. The temperature was maintained at 37°C ± 0.5°C with continuous stirring at a rate of 50 rpm. To maintain the sink condition, a sample of 5 mL volume was withdrawn at pre-determined time intervals of 10, 20, 30, 45, 60 and 75 min and replaced with the same volume of fresh medium maintained at 37±0.5°C so as to maintain constant volume. Samples were filtered through 0.45 µm Millipore membrane filter and analyzed by UV-Visible spectrophotometer.

**8. Stability studies: [22]**

The selected formulations were subjected for three month stability study as per ICH guidelines. The selected formulations were placed in a wide mouth glass bottles, mouth of the bottle was tightly closed and packed in aluminum foils. In the present study, stability studies were carried out at 25°C/60% and 40°C/75% RH for a specific period of 3 months for the selected formulations.

## RESULTS AND DISCUSSION:

## PREFORMULATION STUDTY:

### 1. Organoleptic Properties:

**Table No. 2: Organoleptic characteristics of API**

| Sr. No. | Organoleptic Analysis | Result |
|---|---|---|
| 1 | Color /Appearance | White, Light yellowish |
| 2 | Odor | Characteristic |
| 3 | Taste | Bitter |

### 2. Melting point determination:

The melting point was carried out by using capillary tube method. Melting point of Telmisartan was found to be in the range of 262° C.

**Table No. 3: Determination of melting point of Telmisartan**

| Sr. No. | Telmisartan Melting Point | |
|---|---|---|
| | Observed value | Standard value |
| 1. | 125 °C | 261-263 °C |

### 3. Solubility:

Studies of different commonly used solvents i.e. water, 0.1 N HCL (pH1.2) , pH 7.4 Phosphate buffer, methanol ,ethanol, dimethyl formamide were used to carry out solubility studies of Telmisartan. Saturated solutions of Telmisartan were prepared by adding excess drug to vehicles and shaking on shaker for specific period of time under constant vibration.

**Table No. 4: Solubility of Telmisartan**

| Sr. No. | Solvents | Interpretation |
|---|---|---|
| 1. | Water | Soluble |
| 2. | 0.1 N HCL | Soluble |
| 3. | pH 7.4 Phosphate buffer | Soluble |
| 4. | Ethanol | Soluble |
| 5. | Methanol | Freely soluble |

### 4. UV Visible Spectrophotometer analysis:

- **Determination of λ max (maximum wavelength):**

The weight amount of Telmisartan drug was dissolved in ethanol in a 100 ml volumetric flask to frame a stock arrangement of 100 µg/ml. The stock arrangement was then pipetted into a 10 ml volumetric flask, and the volume was raised of 10 µg/ml.

The subsequent solution was then examined in the range of 200 and 400 nm with an UV-spectrophotometer. Determination of wavelength (λ max) of Telmisartan was obtained by scanning the ethanolic stock solution.The maximum absorbance has occurred at 234 nm which is near to standard.

**Table No. 5: Maximum wavelength (λ max) of Telmisartan**

| Drug | λ max | |
|---|---|---|
| | Actual λ max | Observed λ max |
| Telmisartan | 230-240 nm | 234 nm |

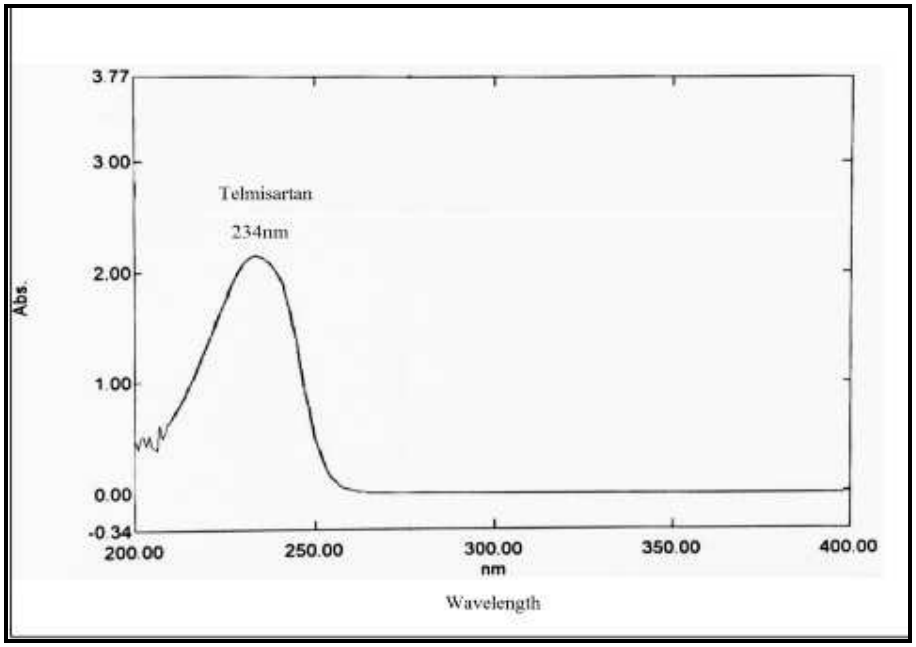


**Fig No. 1: UV Spectrum of Telmisartan**

➢ **Plot of calibration curve:**

The absorbance obtained was tabulated in below and graph was obtained by plotting absorbance Vs concentration.

**Table No. 6: Absorbance of Telmisartan in Ethanolic stock solution**

| Concentration (ug/ml) | Absorbance |
|---|---|
| 00 | 00 |
| 10 | 0.21 |
| 20 | 0.42 |
| 30 | 0.63 |
| 40 | 0.84 |
| 50 | 1.01 |
| 60 | 1.21 |

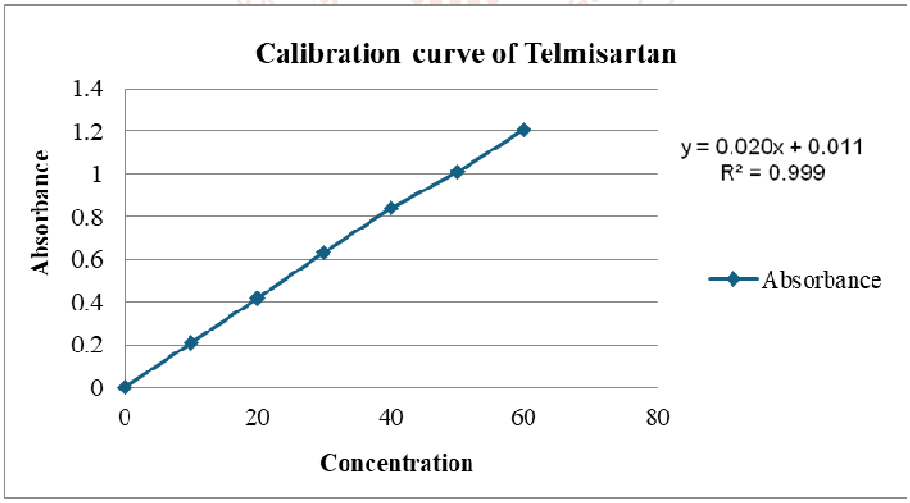


**Fig No. 2: Calibration curve of Telmisartan**

**5. Drug study by FTIR Spectroscopy:**

The drug was identified by the FTIR spectrum of the sample which shows characteristic absorption of the various functional group of Telmisartan. Potassium bromide IR disc was prepared using 1mg of Telmisartan on Hydraulic Pellet press which was scanned of 4000- 400 $cm^{-1}$ re in FTIR and obtained IR Spectrum was compare with reference spectrum of Telmisartan. Ths spectrum of Telmisartan were found to be drug is pure.

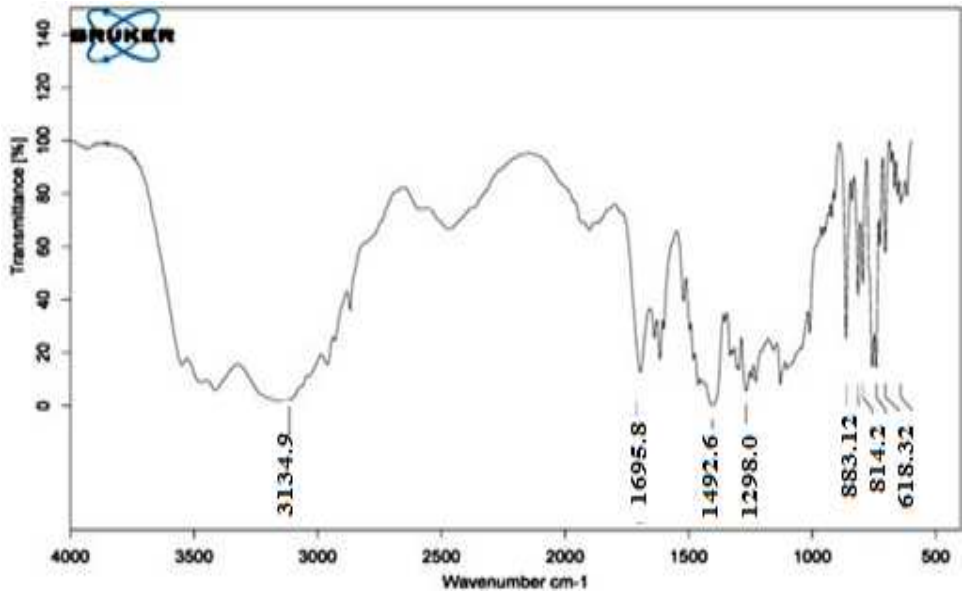


**Fig No. 3: FTIR of Telmisartan drug**

- **Drug Excipients Compatibility Studies by FTIR spectroscopy:**

The IR spectrum indicates that there was no interaction between drugs and studied excipients. Results of the drug interaction studies suggest that all the studied excipients are compatible with Telmisartan. All the characteristic peaks of Telmisartan were present in the spectrum of drug and polymer mixture, indicating compatibility between drug and polymer. The spectrum confirmed that there is no significant change in the chemical integrity of the drug.

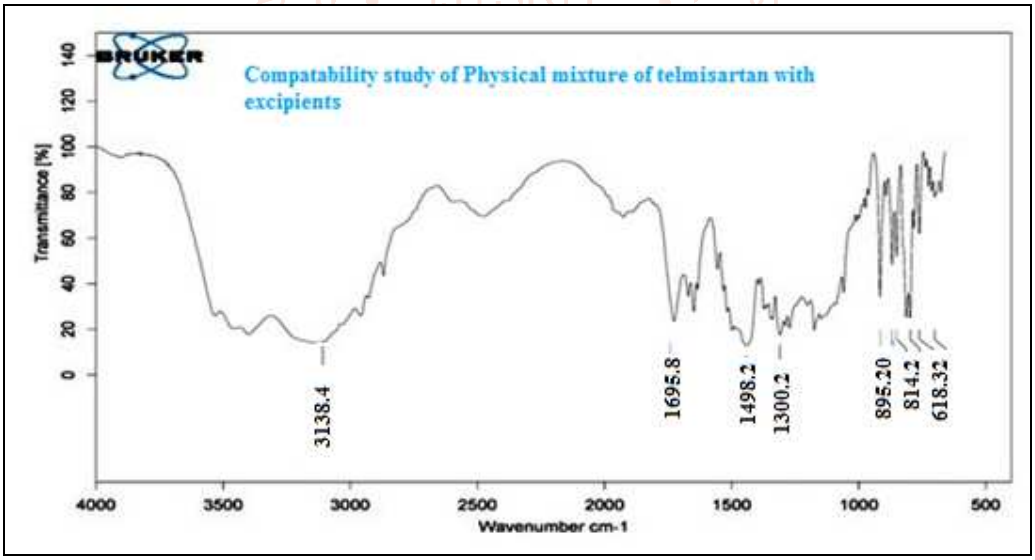


**Fig No. 4: FTIR of Telmisartan with Physical mixture**

## 6. DSC Analysis:

Telmisartan typically shows a sharp endothermic peak around 264°C. Sodium Bicarbonate exhibits a peak around 90.2°C. MCC displays a peak near 280°C, while Magnesium Stearate peaks around 115°C. These peaks correspond to melting points or thermal transitions in the materials.

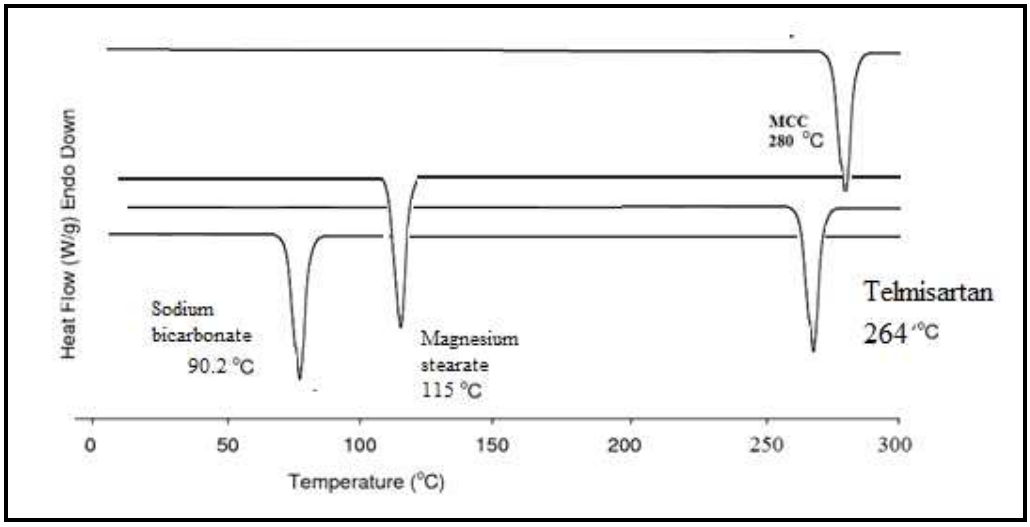


**Fig No. 5: Thermal Spectra of Physical mixture**

**PRECOMPRESSION EVALUATION:**

**Table No. 7: Pre-compression parameters for Telmisartan sustained release matrix tablets**

| Formulation Code | Angle of Repose (θ) | Bulk Density (gm/cm$^3$) | Tapped Density (gm/cm$^3$) | % Compressibility | Carr's index (%) | Hausner's ratio |
|---|---|---|---|---|---|---|
| F1 | 26.44±0.02 | 0.38±0.01 | 0.48±0.01 | 35.28±0.04 | 12.65±0.03 | 1.13±0.02 |
| F2 | 27.36±0.02 | 0.38±0.02 | 0.48±0.02 | 34.42±0.03 | 12.34±0.04 | 1.20±0.03 |
| F3 | 28.77±0.01 | 0.39±0.01 | 0.47±0.01 | 30.38±0.05 | 13.89±0.02 | 1.10±0.03 |
| F4 | 27.99±0.01 | 0.39±0.01 | 0.44±0.01 | 31.21±0.02 | 14.56±0.01 | 1.23±0.01 |
| F5 | 25.13±0.03 | 0.38±0.03 | 0.45±0.02 | 30.42±0.03 | 15.67±0.03 | 1.16±0.01 |
| F6 | 24.55±0.04 | 0.38±0.03 | 0.53±0.02 | 31.93±0.02 | 14.58±0.01 | 1.24±0.01 |
| F7 | 25.65±0.02 | 0.38±0.02 | 0.48±0.03 | 30.83±0.01 | 12.44±0.02 | 1.24±0.03 |
| **F8** | **24.22±0.04** | **0.36±0.01** | **0.47±0.03** | **25.23±0.04** | **12.44±0.02** | **1.24±0.03** |
| F9 | 29.62±0.03 | 0.38±0.02 | 0.49±0.01 | 30.78±0.03 | 12.34±0.02 | 1.14±0.01 |

**CHARACTERIZATION OF RAFT FORMING TABLET:**

**1. Physico-chemical Evaluation**

The physicochemical evaluation of tablet include the tablet thickness, tablet hardness, weight variation, percentage friability and % drug content and disintegration time.

**Table No. 8: Evaluation parameters for Telmisartan raft forming tablets**

| Formulation code | Parameters | | | | | |
|---|---|---|---|---|---|---|
| | Average weight (mg) | Thickness (mm) | Hardness | % Friability | % drug content | DT (Min) |
| F1 | 349.0±0.81 | 3.67±0.2 | 3.4±0.1 | 0.76±0.01 | 96.82±0.53 | 26±2.03 |
| F2 | 347.1±0.26 | 3.75±0.2 | 3.3±0.1 | 0.79±0.01 | 94.36±0.44 | 34±1.75 |
| F3 | 348.1±0.39 | 3.65±0.2 | 3.2±0.15 | 0.85±0.02 | 95.67±1.24 | 49±1.5 |
| F4 | 348.4±0.89 | 3.85±0.02 | 3.2±0.15 | 0.79±0.01 | 94.76±1.34 | 29±1.23 |
| F5 | 348.6±0.93 | 3.86±0.02 | 3.6±0.1 | 0.66±0.02 | 96.50±0.65 | 24±1.89 |
| F6 | 345.1±0.32 | 3.76±0.02 | 3.8±0.15 | 0.78±0.01 | 98.62±0.61 | 20±1.13 |
| F7 | 349.1±0.29 | 3.79±0.2 | 3.8±0.1 | 0.78±0.02 | 99.23±0.40 | 19±1.73 |
| **F8** | **349.6±0.28** | **3.85±0.2** | **3.5±0.05** | **0.61±0.01** | **99.77±0.26** | **18±0.97** |
| F9 | 355.4±0.43 | 3.73±0.2 | 3.1±0.05 | 0.74±0.01 | 99.41±0.56 | 19±1.25 |

**2. Floating lag time**

Floating lag time for all the formulations was determined in 0.1N HCl buffer, and the values were within the range from 70 to 160 sec. The results are clearly indicating that floating time increases by increasing polymer concentration.

**Table No. 9: Floating lag time and Total floating time (hrs)**

| Formulation code | Floating lag time(sec) | Total floating time(hrs) |
|---|---|---|
| **F1** | 70 | 04 |
| **F2** | 75 | 04 |
| **F3** | 80 | 08 |
| **F4** | 81 | 08 |
| **F5** | 72 | 08 |
| **F6** | 90 | 08 |
| **F7** | 100 | 16 |
| **F8** | **110** | **16** |
| **F9** | 160 | 20 |

### 3. In-vitro dissolution study:

In vitro dissolution of Telmisartan, raft forming tablets were carried out in 0.1 N HCl buffer solution under sink condition up to 20 hr. The result which are got in vitro drug release for F1 to F9. The formulation formulated by direct compression technique was obtained in the range of 77.66 ± 2.30 to 94.32 ± 1.79 %. Here in all batch of F1 to F9 the dissolution rate was found to be increase linearly with increasing sodium alginate concentration. The batch F8 showed 99.20 % drug release respectively. This was highest drug release compared to all formulations. By the dissolution data of formulation F1 to F9 it was concluded that the formulation of F8 was showed the highest drug release. The values are shown in the table.

**Table No. 10: In-vitro drug release for all formulations of Telmisartan raft forming tablets**

| Times hrs. | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
|---|---|---|---|---|---|---|---|---|---|
| **0** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | **0** | 0 |
| **1** | 56.58 | 47.65 | 38.08 | 39.65 | 41.32 | 41.66 | 46.33 | **25.20** | 30.00 |
| **4** | 99.99 | 99.99 | 56.44 | 74.78 | 82.33 | 55.33 | 67.99 | **45.80** | 40.56 |
| **8** | 00 | 00 | 99.99 | 99.99 | 99.99 | 86.88 | 82.77 | **65.56** | 55.05 |
| **16** | 00 | 00 | 00 | 00 | 00 | 99.99 | 99.99 | **85.50** | 65.05 |
| **20** | 00 | 00 | 00 | 00 | 00 | 00 | 00 | **99.20** | 75.50 |

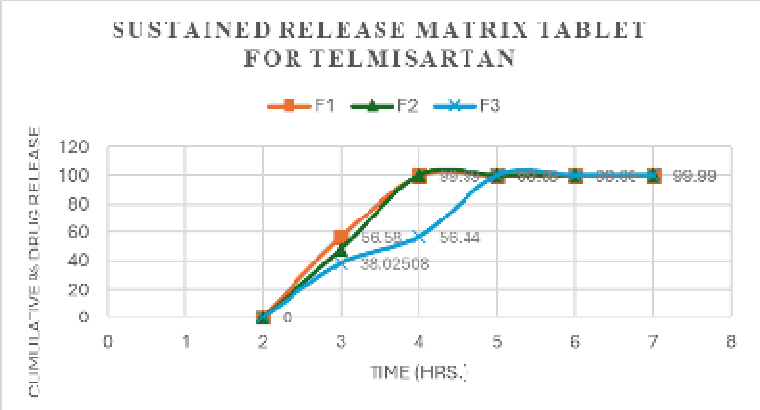


**Fig No. 6: In-vitro drug release of F1-F3**

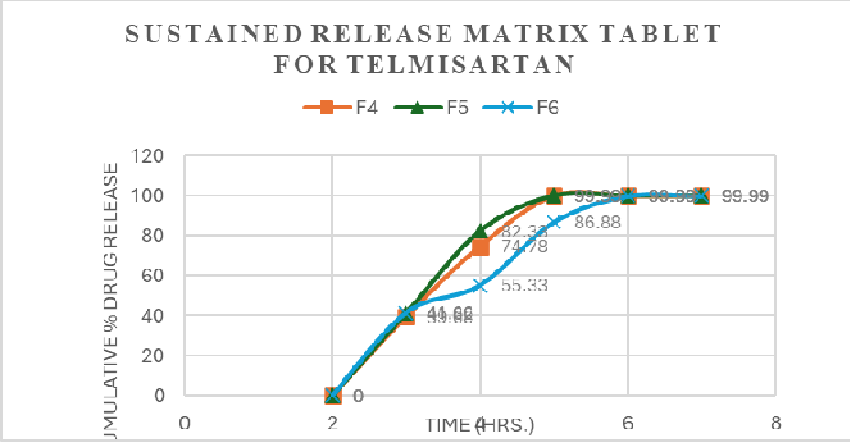


**Fig No. 7: In-vitro drug release of F4-F6**

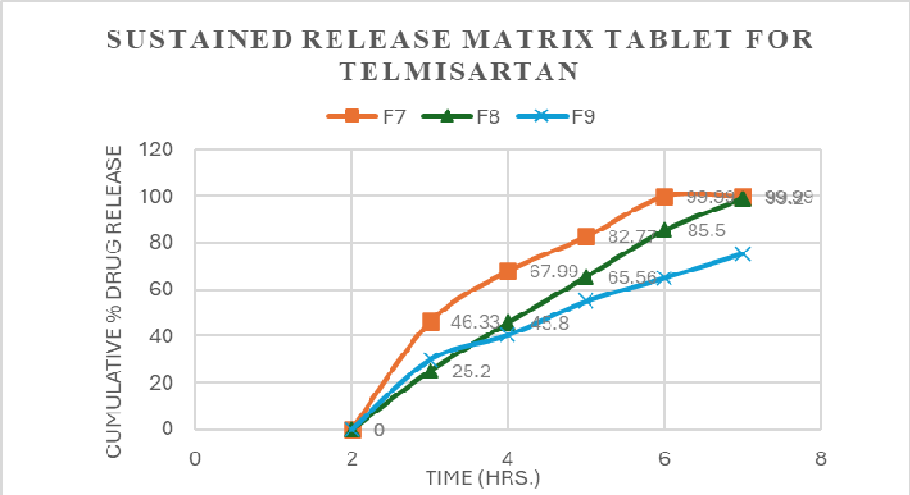


**Fig No. 8: In-vitro drug release of F7-F9**

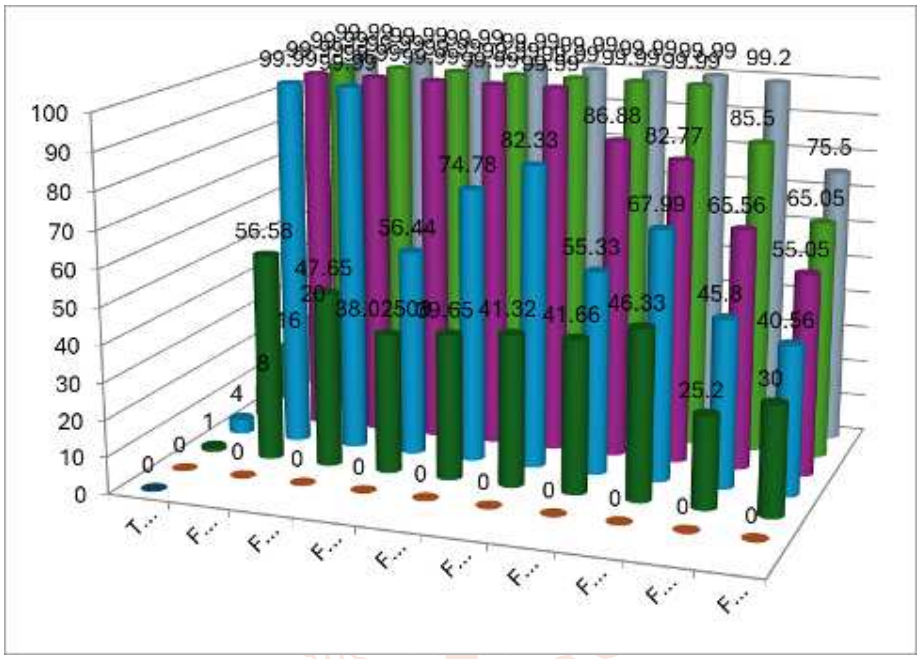


**Fig no. 9: *In-Vitro* release Dissolution study of Sustained Release Matrix Tablet for Telmisartan tablet formulation F1 to F9.**

## 4. Stability studies:

The batch F6 has shown best results among the all formulations hence, it has selected forS stability study. The optimized sustained release formulation was subjected to stability studies at 40 ºC ±2 ºC / 75% RH ± 5% for 3 months.

**Storage condition -**at 40°C±2°C/75%RH±5%

**Table No. 11: Stability data**

| Time | Parameters | | | | |
|---|---|---|---|---|---|
| | Hardness ($Kg/cm^2$) | Uniformity of weight | Friability (%) | Disintegration time(sec) | Drug content (%) |
| **0 Days** | 3.3±0.57 | 350.2±0.32 | 0.64±0.02 | 18±1.02 | 99.57±0.09 |
| **30 days** | 3.4±0.15 | 3480.3±0.28 | 0.68±0.01 | 17±1.59 | 98.83±0.11 |
| **60 days** | 3.3±0.10 | 351.6±0.34 | 0.69±0.01 | 17±0.83 | 97.49±0.12 |
| **90 days** | 3.3±0.15 | 350.8±0.33 | 0.71±0.01 | 16±0.93 | 96.71±0.15 |

The stability studies for optimized formulation F8 was carried out based accelerated stability conditions and study of various parameters carried out at 0, 30, 60, 90 days of intervals and the results found satisfactorily and that reveals that the optimized formulation was stable under accelerated condition.

**Table No. 12: Dissolution data of % cumulative drug release for formulation F8**

| Time (hrs) | 0 days | 30 days | 60 days | 90 days |
|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 |
| 1 | 25.20 | 25.10 | 24.90 | 24.91 |
| 4 | 45.80 | 45.20 | 45.10 | 44.00 |
| 8 | 65.56 | 64.56 | 65.46 | 65.16 |
| 16 | 85.50 | 85.56 | 85.59 | 84.50 |
| 20 | 99.20 | 99.40 | 99.10 | 99.10 |

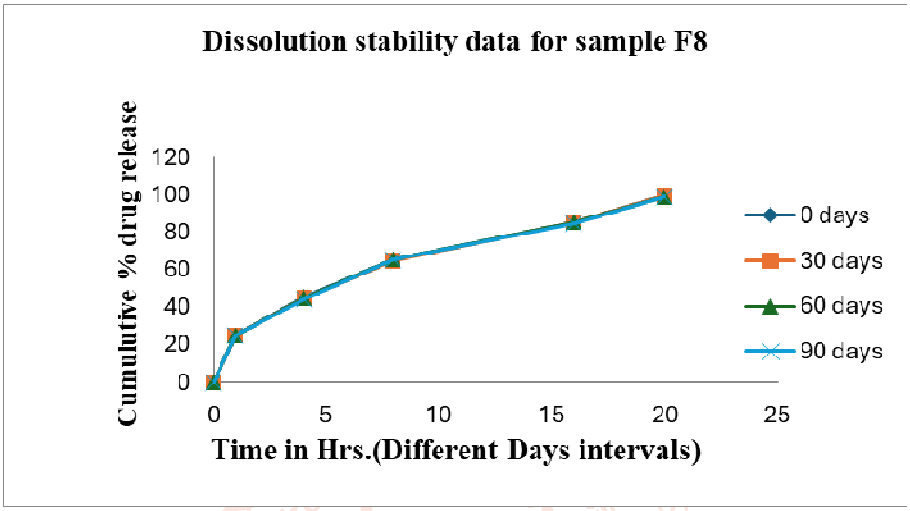


**Fig No. 10: Dissolution stability data for sample F8**

The stability studies for optimized formulation F8 was carried out based accelerated stability conditions and study of various parameters carried out at 0, 30, 60, 90 days of intervals and the results found satisfactorily and that reveals that the optimized formulation was stable under accelerated condition.

## CONCLUSION:

The stability study conducted on the optimized batch of F8 sustained-release matrix tablets containing Telmisartan over a 90-day period at 40°C ± 2°C / 75% RH ± 5% revealed several key findings. Firstly, the mechanical strength of the tablets, as indicated by hardness, remained consistent within the range of 3.3 to 3.4 Kg/cm² throughout the study. Secondly, the weight uniformity of the tablets was maintained within acceptable limits, demonstrating consistency in the manufacturing process. Thirdly, the low friability of the tablets (0.64% to 0.71%) suggested minimal abrasion or breakage during handling.

Moreover, the disintegration time of the tablets remained stable between 16 and 18 seconds, ensuring rapid dissolution and drug release. Although there was a gradual decrease in drug content from 99.57% to 96.71% over the study period, the sustained-release profile of Telmisartan remained consistent, indicating the formulation's ability to maintain therapeutic efficacy. Additionally, dissolution testing confirmed that the drug release profile remained unchanged over the 90-day period, further supporting the formulation's stability under the specified storage conditions. Overall, these results suggest that the optimized F8 formulation of sustained-release matrix tablets for Telmisartan exhibits satisfactory stability over a 90-day period under the specified storage conditions. However, continued monitoring is recommended to assess long-term stability and ensure product quality over extended storage durations.

## REFERENCES:

[1] Chugh I, Seth N and Rana A.C. Oral sustained release drug delivery system. Int Res J Pharmacy 2012; 3 (5):57-62.

[2] Vinay K, S K Prajapati, Girish C, Mahendra S and Neeraj k. Sustained release matrix type drug delivery system. IRJP 2012; 1(3):934-60.

[3] Battershill AJ, Scott LJ. Telmisartan: a review of its use in the management of hypertension. Drugs. 2006 Jan; 66:51-83.

[4] Sharpe M, Jarvis B, Goa KL. Telmisartan: a review of its use in hypertension. Drugs. 2001 Aug; 61(10):1501-29.

[5] Hwang SJ, Park H, Park K. Gastric retentive drug-delivery systems. Critical Reviews in Therapeutic Drug Carrier Systems. 1998;

15(3).

[6] M. Harris Shoaib et al., "Evaluation of drug release kinetics from ibuprofen matrix tablets using HPMC". Pak. J. Pharm. Sci. 2006; Vol.19 (2), 119-124.

[7] Y.R Sharma. Elementary organic spectroscopy, principles and chemical application. 1st ed. S. chand publication; 2001. 81-82.

[8] Martin A, Micromeretics. In: Martin A, ed. Physical Pharmacy. Baltimores, MD: Lippincott Williams and Wilkins; 2001. p. 423-454.

[9] Alfred Martin, Physical Pharmacy-physiochemical principles in the pharmaceutical sciences. 4th edition. New Delhi. B.I Waverly Pvt. Ltd; 1996. p. 313-316.

[10] Pannala S and Rathnanand M. Preparation and in vitro Evaluation of Nizatidine immediate release tablets. International Journal of Pharm Tech Research. 2011; 3(3):1688-1692.

[11] Banker G and Anderson N. Tablets. In: Lachman L, Lieberman H. (Eds.), The theory and practice of industrial pharmacy. New Delhi: CBS publishers and distributors Pvt. Ltd., 2009; 293-345.

[12] Latha K, Uhumwangho M, A Sunil, Srikanth M V, Ramana Murthy K V Preparation and In -Vitro Evaluation of Compression Coated Tablet of Losartan Potassium Using Admixture of Hydrophilic Polymer and Excipients. Int J Novel Drug Delivery Tech., 201; 1, 1 29-39.

[13] Indian Pharmacopoeia, 6th ed. Friability of uncoated tablets. The Indian Pharmacopoeia Commission. Ghaziabad, India. 2010; 1:193.

[14] Indian Pharmacopoeia, 6th ed. Disintegration test. The Indian PharmacopoeiaCommission. Ghaziabad, India. 2010; 1:187-189.

[15] Hansiya Sultana H, G B Kiran Kumar, Acharya A, Ahmed MG. Development and evaluation of chitosan based oral controlled release matrix tablets of Pregabalin. World J Pharm Pharma Sci. 2015; 4(6):1306-19.

[16] Yuvraj G. Jadhav, Upendra C. Galgatte, Pravin D. Chaudhari. Estimation of dimenhydrinate in bulk and pharmaceutical dosage form: method development and validation. Indo American Journal of Pharmaceutical Research. 2013; 3(8):7001-7007.

[17] ICH Q1A (R2) Stability testing guidelines: Stability Testing of new drug substances and products. [Online]. [Cited 2008 Nov 10]; Available from: URL:http://www.tga.health.gov.au/docs/pdf/euguide/inch/273699r2en.pdf.