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# FORMULATION AND EVALUATION OF MOUTH DISSOLVING TABLETS OF TELMISARTAN BY SOLID DISPERSION TECHNIQUE

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## ABSTRACT

Telmisartan (TLM) is an angiotensin II receptor antagonist used in the treatment of hypertension. The aim of present investigation was to prepare Mouth dissolving tablets of an Anti-hypertensive drug Telmisartan. The solubility of poorly soluble drug was enhanced by preparing solid Dispersions of the drug with Poloxamer 407 and PEG 3350 in various concentrations by Kneading method. The optimized solid Dispersions (Drug: Poloxamer 407, 1:3 ratio) were further kneaded with suitable proportions of superdisintegrants such as; Crosscarmellose, Sodium starch glycolate and Crosspovidone. Mouth dissolving tablets of Telmisartan was prepared by direct compression method. The pre-compressive parameters for the blends and post-compressive parameters for the prepared tablets were evaluated. All formulations showed desired pre and post-compressive characteristics. FTIR study showed no evidence of drug excipient interaction. The optimized formulation was found to be F6. It was concluded that Mouth dissolving tablets of Telmisartan can be prepared by solid Dispersions of drug with Poloxamer 407 and combination of superdisintegrants provide complete and better dissolution within in shorter period of time. Hence effective Hypertensive treatment anywhere, and anytime particularly for geriatric, pediatric, mentally ill, bedridden and patients who do not have easy access to water.

## KEYWORDS

Telmisartan, Poloxamer 407, PEG 3350, Superdisintegrants, Kneading method and Mouth dissolving tablets.

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## INTRODUCTON

Telmisartan is 2-(4-{[4-methyl-6-(1-methyl-1H-1, 3- benzodiazol-2-yl)-2-propyl-1H-1, 3-benzodiazol-1-yl] methyl} phenyl) benzoic acid. It 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 one (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. The bioavailability of poorly water soluble drug is often limited by its dissolution rate, which in turn is controlled by the surface area available for dissolution. Larger the surface area, higher will be the dissolution rate. Since the surface area increases with decreasing particle size, decrease in particle size, which can be accomplished by conventional methods like trituration, grinding, ball milling, fluid energy micronization, salt formation and precipitation. Although these conventional methods have commonly been used to increase dissolution rate of the drug, there are practical limitation with these techniques, the desired bioavailability enhancement may not be achieved. Therefore formulation approaches are being explored to enhance bioavailability of poorly water soluble drugs. The formulation of poorly soluble drugs for oral delivery presents a challenge to the formulation scientists. Formulation approach that has shown to significantly enhance absorption of such a drug is to formulate/prepare solid dispersion. The solid dispersion approach has been widely and successfully applied to improve the solubility, dissolution rate and consequently the bioavailability of poorly soluble drugs

The concept of solid dispersions was originally proposed by Sekiguchi and Obi, in 1961. They developed practical method and achieved success in improving the solubility of poorly water drugs by using the hydrophilic carriers[1]. The term solid dispersion refers to a group of solid products consisting of at least two different components, generally a hydrophilic matrix and a hydrophobic drug. The most commonly used hydrophilic carriers in the preparation of solid dispersions polyvinylpyrrolidone (Povidone, PVP)[2,3], polyethylene glycols (PEG 6000)[4], Surfactants like Tween-80, Poloxamer, and Sodium Lauryl Sulphate (SLS). The main mechanism involved in the solid dispersion are reduction of the particle size, Drug in amorphous state, Particles with high porosity, Particles with improved wettability, solubilization of the drug by the carrier at the diffusion layer. It has been suggested by many authors that the solubility of low aqueous soluble drugs was increased by incorporating surfactants in the dissolution medium like sodium lauryl sulfate, Tween -80, benzalkonium chloride (BKC), cetrimide etc.

## EXPERIMENTAL

## MATERIAL AND METHODS[5-7]

Telmisartan was a gift sample from medoform Pharmaceutical Ltd., Pullulan from Kumar organic products limited, microcrystalline cellulose and Aspartame from Laser chemical Ltd., Strawberry flavor from Emerald Flavors and Fragrances, were gifted for carrying out various experiments. All other chemicals used were of Analytical grade.

Physical mixtures of Telmisartan at three different mass ratios (1:1, 1:2, 1:3 and 1:4) were prepared. The mixtures were passed through a sieve no. 60. The prepared mixtures were then filled in glass bottles, sealed and stored in a dessicator until further use.

**Preparation of Telmisartan Solid Dispersions by physical mixture method**

Physical mixtures were prepared by mixing pre-weighed quantity of Telmisartan and carriers (Poloxamer 407, PEG 3350) in 1:1, 1:2, 1:3 and 1:4, ratios. Four batches of drug: carrier in different ratios was prepared.

**Preparation of Telmisartan Solid Dispersions by kneading method Table No.1**

Solid Dispersions was prepared by kneading method. The different ratio of drug with PXM 407 & PEG 3350 was prepared like 1:1, 1:2, 1:3 and 1:4 respectively in a mortar with methanol and water mixture (1:1, by volume). Then kneaded the wet mixture thoroughly with a pestle to obtain a paste like consistency. The paste was then dried under vacuum at room temperature, pulverized by passing through sieve no. 80 and stored in a dessicator till further use[8].

**Evaluation parameters for Solid Dispersions**[8,9]

**Practical Yield**

Solid Dispersions were collected and weighed to determine practical yield (PY) from the following equation.

Practical mass (Solid Dispersion)

PY (%) = theoretical mass (drug + Carrier)*100

**Drug content**

Equivalent to 10 mg of the drug was weighed accurately, dissolved in methanol and suitably diluted with phosphate buffer solution of pH 6.8. The content of Telmisartan was determined spectrophotometrically at 296 nm against blank using UV-visible spectrophotometer (Shimadzu).

**Solubility study**

The apparent solubility of solid Dispersions of Telmisartan with Poloxamer 404 and PEG 3350 was determined in distilled water and Phosphate buffer pH 6.8 at 37°C. Each solid Dispersions equivalent to 10 mg was added to 10 ml of solvent in glass vials with rubber closures. Then the vials were kept in a Shaking incubator at 37± 0.5°C for 24 hr. After shaking, the vials were kept in an shaking incubator at 37± 0.5°C for equilibrium for 12 hr. The solution was then filtered through 0.45mcm filter paper and the filtrate was assayed Spectrophotometrically at 296 nm.

***In Vitro* Dissolution Studies of Solid Dispersions**

The quantity of solid Dispersions equivalent to 40 mg of Telmisartan was placed in dissolution medium. The dissolution study of solid Dispersions was conducted using dissolution testing apparatus II (paddle method) in 900 ml of phosphate buffer solution of pH 6.8 at 37ºC and at a speed of 50 rpm. Aliquots of 5 ml was withdrawn at predetermined time interval and equivalent amount of fresh medium was replaced to maintain a constant volume after each sampling and analyzed spectrophotometrically at 296 nm against suitable blank using UV visible spectrophotometer.

**Drug carrier compatibility study**

**Fourier Transform infrared spectroscopy (FTIR)**

The drug-carrier mixtures of Telmisartan were prepared in the form of KBr pellets and subjected for scanning from 4000 cm-1 to 400 cm-1 using FTIR spectrophotometer.

**Differential scanning calorimetry (DSC)**

Approximately 2 mg of telmisartan or drug-carrier mixture was taken in aluminium pan, sealed with aluminium cap and kept under nitrogen purging (atmosphere). Both the samples were scanned from 50-400°C with the scanning rate of 10°C rise/min using differential scanning calorimeter.

**Preparation of Tablet Blend of Mouth Dissolving Tablets**

The composition of preliminary trial batches of mouth dissolving tablets of Telmisartan were shown in table 04. Solid Dispersions of Telmisartan, Crospovidone, crosscarmellose sodium, Sodium starch glycolate, Pearlitol SD 200, MCC PH 102 and Aspartame were passed through sieve #22, while talc and magnesium stearate were passed through sieve #60. Firstly, all the ingredients were mixed with the help of mortar and pestle. Magnesium stearate and Talc were finally added as lubricants. The blend was compressed into 250 mg weight of hardness 2.0 - 2.5kg/cm2 using 9 mm flat-faced punch on a tablet punching machine.

**Evaluation Parameters for Mouth Dissolving Tablets of Telmisartan**

**Precompression parameters**

The prepared powder mixtures were evaluated for the blend property like bulk density, tapped density, Carr's index, angle of repose and Hausner's ratio.

**Post-compression parameters**

The tablets after punching of every batch were evaluated for in-process and finished product quality control tests i.e. thickness, weight uniformity test, hardness, friability, *in vitro* dissolution time, water absorption ratio, wetting time and in vitro drug release studies

**Hardness Test**[10]

The hardness was tested using Monsantotester.

"Hardness factor", the average of the six determinations, was determined and reported. The force was measured in kilograms per centimeter square.

**Weight Uniformity Test**[11]

Twenty tablets were weighed individually and all together. Average weight was calculated from the

total weight of all tablets. The individual weights were compared with the average weight. The percentage difference in the weight variation should be within the permissible limits (±7.5%).

**Friability**[12]

Friabillator consist of a plastic-chamber that revolves at 25 rpm, dropping those tablets at a distance of 6 inches with each revolution. The tablets were rotated in the friabillator for at least 4 minutes. At the end of test tablets were dusted and reweighed, the loss in the weight of tablet is the measure of friability and is expressed in percentage as:

%Friability = initial weight- final weight/initial weight x 10

**Water absorption ratio**[9]

It was tested by using double folded tissue paper and the Petri dish contains 6ml of Saliva buffer pH 6.8. Firstly randomly taken tablets form the all formulations weight was calculated it was denoted as Wb and then the tablets were allowed to place on the tissue paper. After completely wet of the tablet weight was calculated and it was denoted as Wa. And by using the following formula water absorption ratio (R) was measured.

$R = 100 \{(Wa – Wb) / Wb\}$

Where,

Wb = Weight of tablet before absorption Wa = Weight of tablet after absorption.

**Wetting time**[12]

Simple tissue paper (12 cm X 10.75 cm) folded twice was placed in a small Petri dish (Internal Diameter = 6.5 cm) containing 6 ml of Phosphate buffer pH 6.8. A tablet was put on the paper, and the time for complete wetting was measured.

**Uniformity of Drug Content**[13]

Five tablets of each type of formulation were weighed and crushed in mortar and powder equivalent to 40 mg of Telmisartan was weighed and dissolved in 100 ml of Phosphate buffer (pH 6.8) This was the stock solution from which 1 ml sample was withdrawn and diluted to 10 ml with Phosphate buffer (pH 6.8). The absorbance was measured at wavelength 296 nm using UV-Visible spectrophotometer.

Content uniformity was calculated using formula: % Purity = 10 C (Au /As)

Where,

C - Concentration

Au and As = Absorbance of unknown and standard respectively.

**Disintegration Time**[13]

**Solubility**

The solubility of TEL in water was reported as 4.69µg/ml, therefore, TEL can be considered as a practically insoluble drug. According to observations obtained from the solubility analysis of physical mixture of drug and carrier, there were significant changes in the solubility of drug as compared to that of pure drug in distilled water. The solubility values of physical mixtures for drug and carrier Poloxamer 407 in ratios 1:1, 1:2, 1:3 and 1: 4 were found to be 20.10, 20.00, 21.60, and 21.01µg/ml, respectively in distilled water. Similarly, the solubility values of physical mixtures for drug and carrier PEG 3350 in ratios 1:1, 1:2, 1:3 and 1:4 were found to be 19.09, 19.60, 18.62 and 19.14µg/ml, respectively in Distilled water. The increase in Solubility rate is in the order of PLX 407 > PEG 3350.

**Drug content and % Yield of solid Dispersions**

The percent drug content was found to be 92±2% for all the solid Dispersions formulations. The % Yield was found to be 87.50±4% for all the solid Dispersions formulations.

Initially the disintegration time for Orodispersible tablets was measured using the conventional test for tablets as described in the Pharmacopoeia. Tablets required for complete disintegration that is without leaving any residues on the screen was recorded as disintegration time.

***In vitro* drug release study of tablets**[13]

*In vitro* release of the tablets was conducted using USP dissolution apparatus II (Electrolab, Mumbai) at 75rpm, using Phosphate buffer pH 6.8 as a dissolution media maintained at 37±0.5°. Samples were withdrawn at various time intervals, filtered through a 0.45 micron membrane filter, diluted and assayed at 296 nm, using an UV/VIS spectrophotometer.

## RESULTS AND DISCUSSION

### Preparation of Solid Dispersions

In the present investigation the solubility of poorly water soluble Telmisartan was enhanced by preparing solid Dispersions with Poloxamer 407 (Kneading method). The drug and carrier ratio of 1:1, 1:2, 1:3 and 1:4 were used for preparation of solid Dispersions by Kneading method to enhance the solubility of TEL.

### *In-Vitro* Dissolution Study

In vitro release studies reveal that there is marked increase in the dissolution rate of Telmisartan from all the solid Dispersions when compared to pure Telmisartan itself. The increase in dissolution rate is in the order of PLX 407 > PEG 3350. From the in vitro drug release profile, it can be seen that formulation A3 containing PLX 407 (1:3 ratio of drug: PLX 407) shows higher dissolution rates. This may be attributed to the increase in the wettability, conversion to amorphous form and solubilisation of the drug due to hydrophilic carrier. But as the amount of PLX 407 is increased (1:4 ratio of drug: PLX 407) in formulation, the dissolution rate was decreased. This might be due to formation of viscous layer around the drug particles leading to decrease in the dissolution rate. So, formulation ratio 1:3 (A3) was selected for further studies and tablets were formulated.

### Fourier Transform Infra-Red Studies

FT-IR spectroscopic studies conducted for possible drug: carrier interactions. FT-IR spectra of pure drug Telmisartan, Poloxamer 407 and Solid Dispersions which are as shown in figure 02 & 03 indicating no significant evidence of chemical interaction between drug and carrier, which confirms the stability of drug with its Solid Dispersions.

### DSC Thermogram

DSC was used to assess the thermal behavior of the drug (TLM) and its solid Dispersions prepared. In figure, DSC thermogram of telmisartan shows a single sharp characteristic endothermic peak (Tpeak = 269.06°C) corresponding to its melting, indicating its crystalline nature and a single peak indicates that the drug sample is free from impurities. However, the characteristic endothermic peak corresponding to drug melting was broadened and shifted toward lower temperature with reduced intensity in the solid Dispersions prepared by kneading method (Figures No.4 and 5). This could be attributed to higher polymer concentration and uniform distribution of drug in the crust of carrier, resulting in complete miscibility of drug in the carrier.

### Preparation and Evaluation of Mouth Dissolving Tablets

Appropriate quantity of solid Dispersions was blended with superdisintegrants. After adding filler, sweetener, glident and lubricating agent; Mouth dissolving tablets were prepared by direct compression method. The super-disintegrants i.e., Crospovidone, Croscarmellose sodium and Sodium starch glycolate were taken in various ratios to find the optimum concentration of the super-disintegrants required to yield formulation having least wetting time and disintegration time.

### Pre-compressive parameters

- The values for angle of repose were found in the range of 25.74 to 27.59°.
- Loose bulk and tapped densities of the blend was found as 0.68 to 0.74 and 0.74 to 0.80 (g/ml) respectively.
- Carr's index of the prepared blends falls in the range of 7.14 to 9.85% and this is also supported by Hausner's factor values which were in the range of 1.07 - 1.09**.** Hence the prepared blends possessed good flow properties and can be used for manufacturing of tablets by Direction compression method.

### Post-compressive parameters

The hardness of tablets was found to be 2.0 to 2.6 kg/cm2. All the tablets shows % friability in the range of 0.66-0.85 % which is within the limit. All the formulations passes the weight variation test as all tablets within the range limit for weight variation. The disintegration time is very important and it is desired to be less than 1 minute. The quick disintegration may assist quick swallowing and drug absorption in buccal cavity, thus greater bioavailability of the drug. The disintegration time

was found 37 to 53 sec. The Wetting time is the indicator for the ease of disintegration of the tablet in buccal cavity. It was observed that wetting time of tablets was in the range of 30 to 47 seconds. Assay for the prepared formulations was performed to determine drug content uniformity and it was found between 97.10 to 99.50 %.

***In-vitro* drug release study**

Finally, the tablets were evaluated for *in vitro* dissolution studies in phosphate buffer solution pH 6.8. Among all the formulations F1 to F3 prepared with different concentration of superdisintegrant (Crosscarmellose sodium) showed 89.39% to 97.84% drug release within 30 min and F4 to F6 prepared with different concentration of superdisintegrant (Sodium starch glycolate) showed 92.69% to 98.78% drug release within 30 min and formulations F7 to F9 prepared with different concentration of superdisintegrant (Crosspovidone) showed 89.56% to 95.26% drug release within 30 min respectively.

This result suggests a direct relationship of concentration of superdisintegrants with drug release. As the amount of superdisintegrant increases in the acceptable range, the drug release also increases. Among all the formulations F6 showed maximum Drug Release 98.78%, Prepared by using SSG as a superdisintegrant.

**Table No.1: Solid Dispersions of Telmisartan with Poloxamer 407 and PEG 3350 prepared by kneading method**

| S.No | Formulation code | Method of preparation | Content (mg) | | |
|---|---|---|---|---|---|
| | | | Drug | Poloxamer 407 | PEG 3350 |
| 1 | A1 | Kneading method | 100 | 100 | - |
| 2 | A2 | Kneading method | 100 | 200 | - |
| 3 | A3 | Kneading method | 100 | 300 | - |
| 4 | A4 | Kneading method | 100 | 400 | - |
| 5 | B1 | Kneading method | 100 | - | 100 |
| 6 | B2 | Kneading method | 100 | - | 200 |
| 7 | B3 | Kneading method | 100 | - | 300 |
| 8 | B4 | Kneading method | 100 | - | 400 |

**Table No.2: Characterization of Solid Dispersions prepared by kneading method**

| S.No | Formulation code | % Yield | %Drug content | Solubility µg/ml |
|---|---|---|---|---|
| 1 | A1 | 85.00 | 92.01 | 20.10 |
| 2 | A2 | 87.50 | 91.56 | 20.00 |
| 3 | A3 | 90.12 | 94.40 | 21.60 |
| 4 | A4 | 89.00 | 93.90 | 21.01 |
| 5 | B1 | 84.37 | 91.60 | 19.09 |
| 6 | B2 | 82.11 | 92.90 | 19.60 |
| 7 | B3 | 89.18 | 92.60 | 18.62 |
| 8 | B4 | 91.11 | 93.11 | 19.14 |

**Table No.3: *In - vitro* dissolution profile of TEL, TEL: PLX 407 and TEL: PEG 3350 Solid Dispersions prepared by Kneading method in Phosphate buffer (pH 6.8)**

| % Drug dissolved | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **S.No** | **Time (min)** | **Pure drug** | **A1** | **A2** | **A3** | **A4** | **B1** | **B2** | **B3** | **B4** |
| 1. | 05 | 38.88 | 40.05 | 55.14 | 60.70 | 59.60 | 50.15 | 58.87 | 59.33 | 58.17 |
| 2. | 15 | 45.60 | 48.55 | 60.14 | 68.30 | 65.96 | 54.55 | 64.14 | 64.05 | 60.41 |
| 3. | 30 | 55.84 | 58.15 | 64.34 | 75.65 | 74.63 | 59.15 | 73.38 | 72.15 | 68.49 |
| 4. | 60 | 60.20 | 61.54 | 69.24 | 80.18 | 75.56 | 63.25 | 76.16 | 74.07 | 71.69 |
| 5. | 120 | 68.73 | 70.11 | 76.46 | 86.76 | 82.36 | 69.99 | 81.49 | 78.38 | 72.79 |

*A1-A4 = *In vitro* Drug release of TEL: PLX 407 Solid Dispersions

*B1-B4 = *In vitro* Drug release of TEL: PEG 3350 Solid Dispersions

**Table No.4: Formula for Mouth dissolving tablets of Telmisartan**

| **S.No** | **Ingredients** | | **Batches** | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | **F1** | **F2** | **F3** | **F4** | **F5** | **F6** | **F7** | **F8** | **F9** |
| | SD eq. to 40mg TEL | 160 | 160 | 160 | 160 | 160 | 160 | 160 | 160 | 160 |
| 2 | Pearlitol SD 200 | 36.5 | 30.5 | 40 | 36.5 | 30.5 | 40 | 36.5 | 30.5 | 40 |
| 3 | MCC PH-102 | 36.5 | 40 | 28 | 36.5 | 40 | 28 | 36.5 | 40 | 28 |
| 4 | Crosscarmellose sod | 7.5 | 10 | 12.5 | - | - | - | - | - | - |
| 5 | Sodium Starch Gly | - | - | - | 7.5 | 10 | 12.5 | - | - | - |
| 6 | Crosspovidone | - | - | - | - | - | - | 7.5 | 10 | 12.5 |
| 7 | Aspartame | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| 8 | Magnesium Stearate | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |
| 9 | Talc | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 |
| 10 | Aerosil | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| 11 | Average weight | 250 | 250 | 250 | 250 | 250 | 250 | 250 | 250 | 250 |

*All quantities are in mg

**Table No.5: Precompression parameters of priminary trial batches of Mouth dissolving tablet of Telmisartan**

| **S.No** | **Parameters** | **F1** | **F2** | **F3** | **F4** | **F5** | **F6** | **F7** | **F8** | **F9** |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Bulk Density (mg/ml) | 0.68 | 0.71 | 0.74 | 0.70 | 0.73 | 0.74 | 0.73 | 0.71 | 0.72 |
| 2 | Tapped Density (mg/ml) | 0.74 | 0.78 | 0.80 | 0.75 | 0.79 | 0.80 | 0.79 | 0.77 | 0.79 |
| 3 | Hausner's ratio | 1.08 | 1.09 | 1.08 | 1.07 | 1.08 | 1.08 | 1.08 | 1.08 | 1.09 |
| 4 | Carr's Index (%) | 8.82 | 9.85 | 8.10 | 7.14 | 8.21 | 8.10 | 8.21 | 8.45 | 9.72 |
| 5 | Angle of repose (degree) | 27.59 | 25.74 | 26.31 | 25.85 | 27.59 | 26.71 | 26.31 | 25.74 | 25.93 |

**Table No.6: Physical parameters of Telmisartan Mouth dissolving tablets**

| **S.No** | **Evaluation parameters** | **F1** | **F2** | **F3** | **F4** | **F5** | **F6** | **F7** | **F8** | **F9** |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | wt. variation (mg) | 249 | 250 | 251 | 249 | 248.5 | 250 | 249.5 | 248 | 250 |
| 2 | Thickness (mm) | 2.62 | 2.63 | 2.54 | 2.37 | 2.43 | 2.64 | 2.52 | 2.31 | 2.63 |
| 3 | Hardness (kg/cm2) | 2.1 | 2.0 | 2.2 | 2.4 | 2.3 | 2.0 | 2.2 | 2.6 | 2.2 |
| 4 | % Friability (%) | 0.80 | 0.85 | 0.72 | 0.65 | 0.79 | 0.66 | 0.72 | 0.69 | 0.83 |
| 5 | Content uniformity (%) | 98.72 | 98.99 | 99.21 | 99.09 | 98.23 | 99.34 | 98.72 | 98.21 | 98.90 |
| 6 | Wetting time (sec) | 47±1.00 | 38±1.15 | 32±2.00 | 45±1.00 | 40±1.15 | 30±1.00 | 39±1.15 | 35±2.00 | 36±1.00 |
| 7 | Water absorption Ratio (%) | 81.08 | 85.02 | 87.63 | 63.08 | 65.33 | 90.01 | 86.63 | 83.02 | 82.10 |
| 8 | Disintegration time(sec) | 53 | 43 | 40 | 51 | 46 | 37 | 43 | 41 | 42 |
| 9 | % Drug content | 97.10 | 98.30 | 98.75 | 98.00 | 95.80 | 99.50 | 97.50 | 97.90 | 98.75 |

**Table No.7: *In-vitro* release study of Mouth dissolving tablets of Telmisartan**

| S.No | % Drug Release | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Time (sec) | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
| 1 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 | 00 |
| 2 | 05 | 50.92 | 58.71 | 59.43 | 51.48 | 57.62 | 62.25 | 54.87 | 56.03 | 57.07 |
| 3 | 10 | 63.04 | 69.75 | 70.57 | 65.09 | 70.29 | 70.95 | 68.10 | 68.92 | 70.24 |
| 4 | 15 | 77.81 | 82.37 | 85.55 | 80.45 | 84.62 | 85.77 | 81.71 | 82.31 | 85.06 |
| 5 | 20 | 87.14 | 93.18 | 95.65 | 90.88 | 95.03 | 97.02 | 87.42 | 88.84 | 92.74 |
| 6 | 25 | 88.78 | 96.58 | 96.58 | 92.58 | 96.18 | 98.17 | 88.90 | 89.89 | 93.45 |
| 7 | 30 | 89.39 | 97.02 | 97.84 | 92.69 | 96.68 | 98.78 | 89.56 | 90.00 | 95.26 |

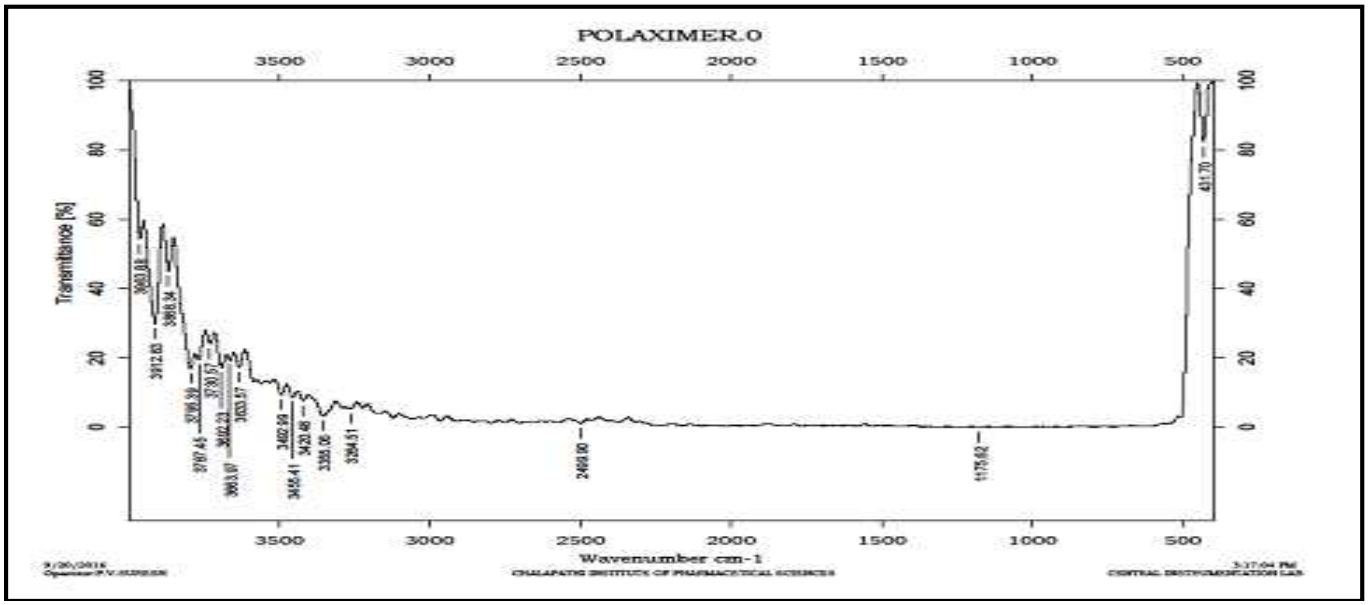


**Figure No.1: FTIR Spectrum of Telmisatran**

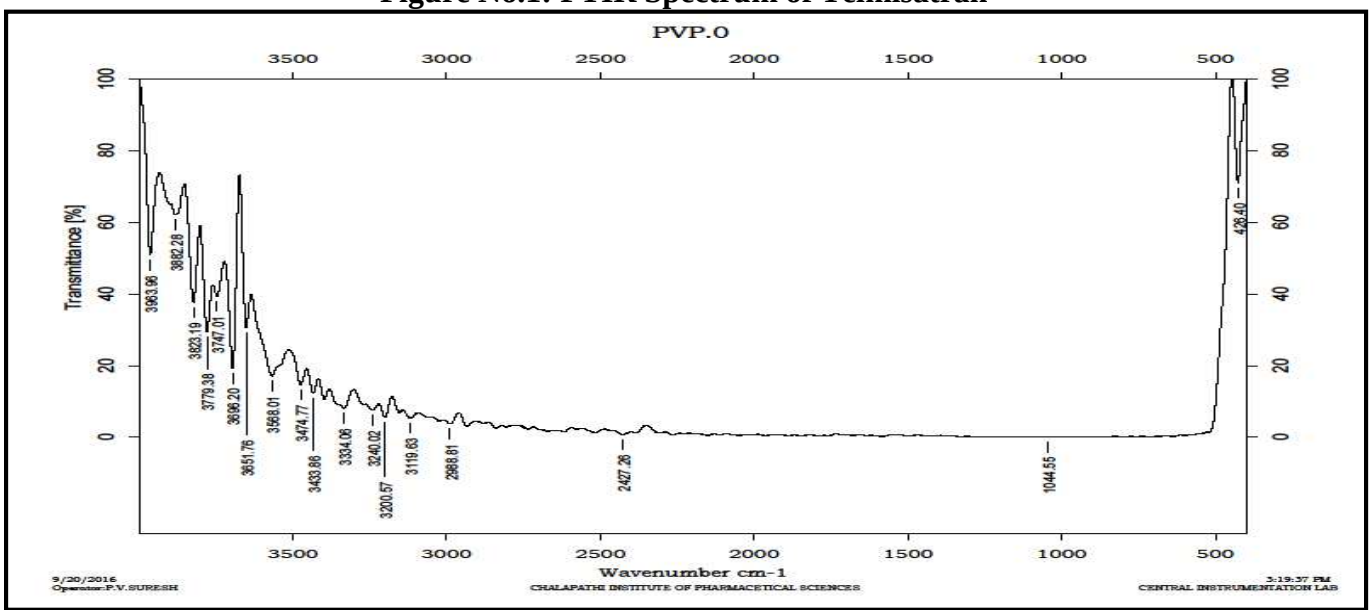


**Figure No.2: FTIR Spectrum of physical mixture of Telmisatran and polaximar**

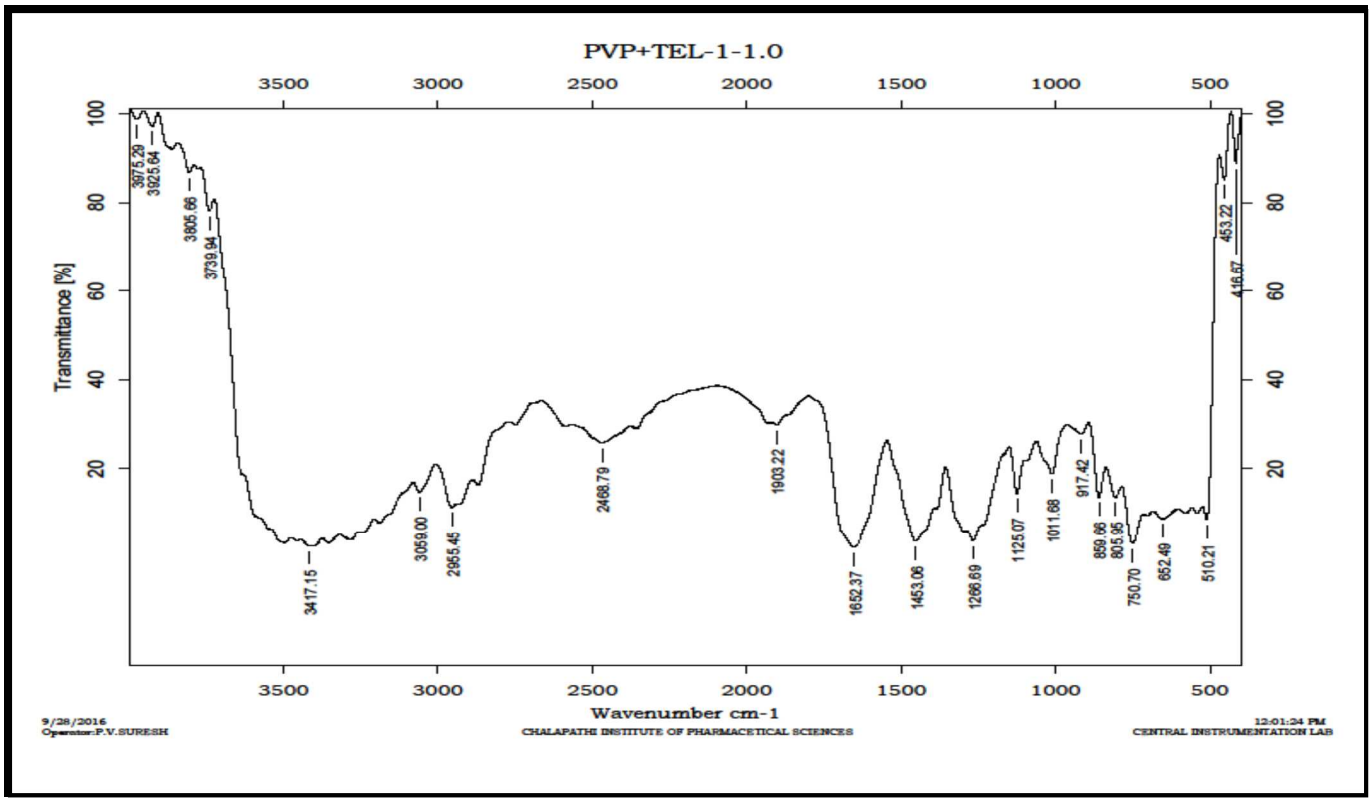


**Figure No.3: FTIR Spectrum of physical mixture of Telmisatran and PVP 1-1.0**

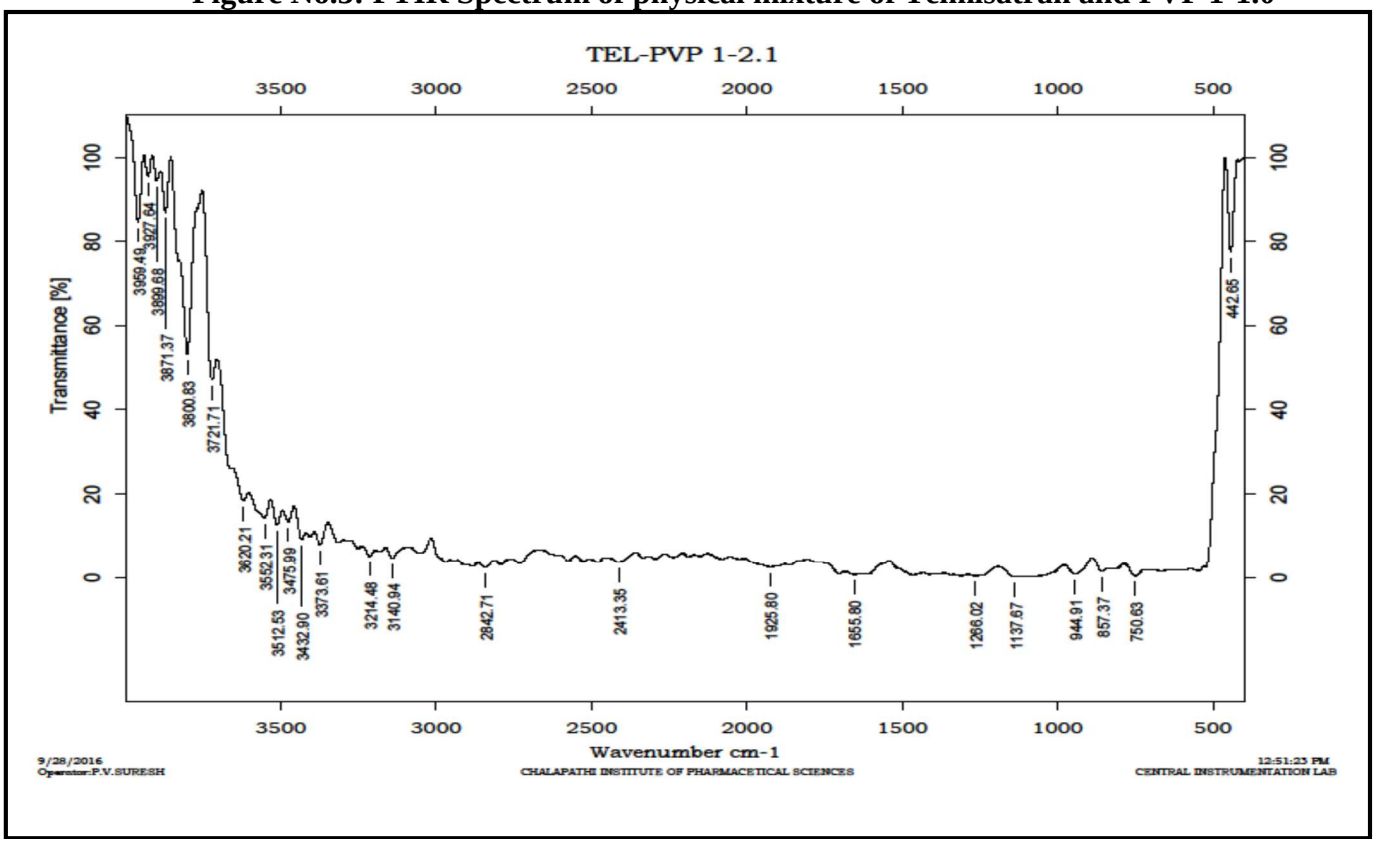


**Figure No.4: Figure No.4: FTIR Spectrum of physical mixture of Telmisatran and PVP 1-2.0**

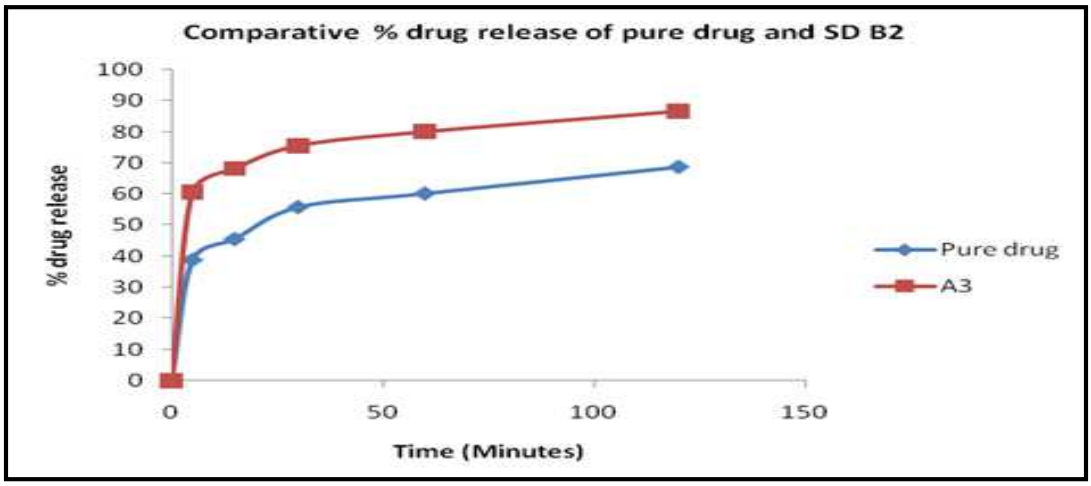


**Figure No.5: a. Comparative % drug release of pure drug and SD B2**

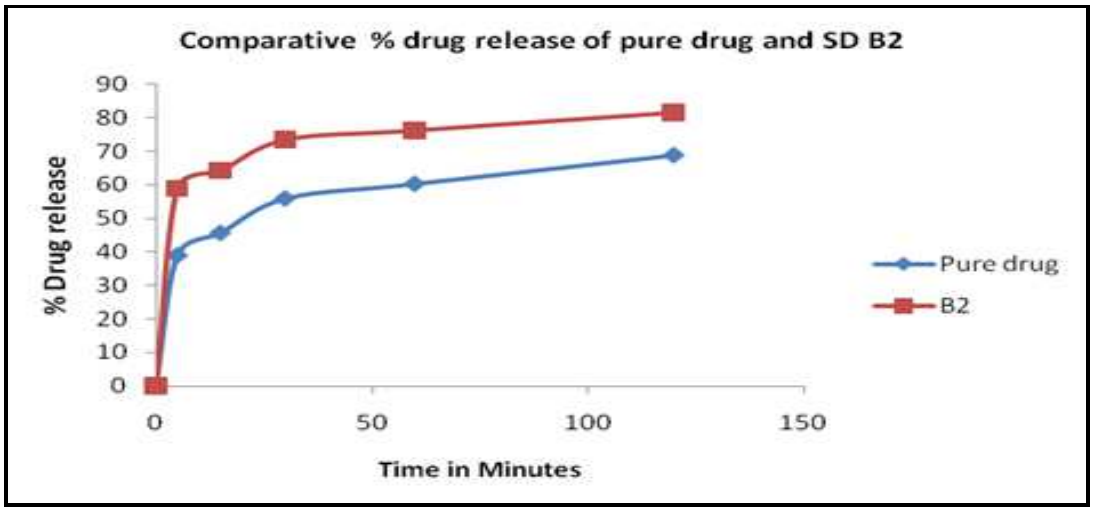


**Figure No.6: b. Comparative % drug release of pure drug and SD B2**

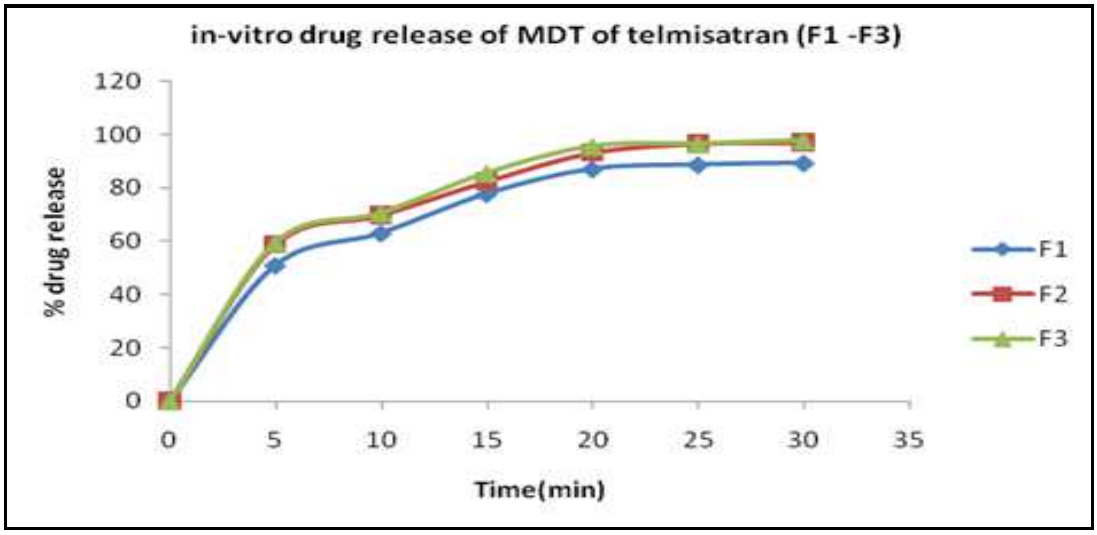


**Figure No.7: *In-vitro* drug release of MDT of Telmisatran (F1-F3)**

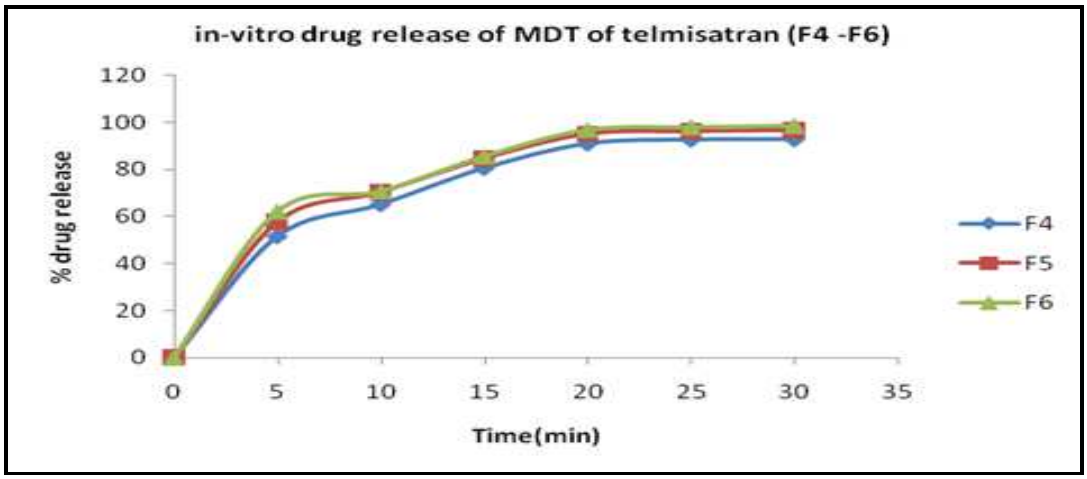


**Figure No.8: *In-vitro* drug release of MDT of Telmisatran (F4-F6)**

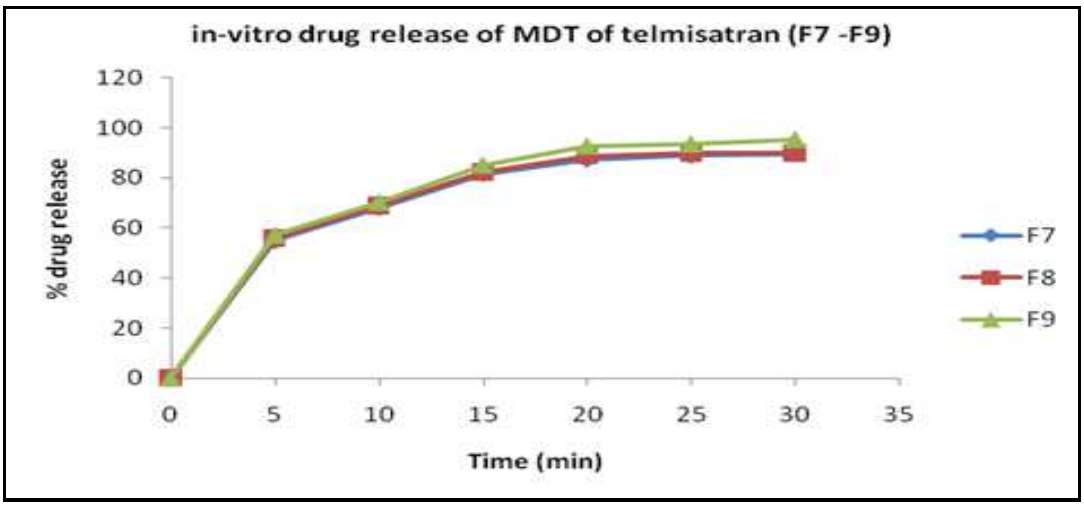


**Figure No.9: *In-vitro* drug release of MDT of Telmisatran (F7-F9)**

## CONCLUSION

From the above studies, it was concluded that the solid Dispersions of the drug (Telmisartan) formulated with the use of various water soluble carriers like (PEG 3350 and Poloxamer 407) in their different ratios prepared with different techniques like Physical mixing and Kneading method showed enhanced solubility and dissolution characteristics in one or many factors. Solubility studies showed increase in solubility of drug in the various carriers used in the study. All the solid Dispersions showed enhanced dissolution as compared to the pure drug, however, Poloxamer 407 came out as the most promising carrier. Fasted drug release was obtained from the solid Dispersions containing TEL: PXM 407 of 1:3 wt/wt ratios prepared by Kneading method. Various compatibility tests like FTIR studies showed no evidence of any chemical interactions between drug and the carrier and DSC studies further provided useful information about the drug and carrier compatibility studies. Formulation of MDT by using Solid Dispersions of TEL is unique technique by which solubility of the drug can be enhanced which is most challenging aspects of the drug delivery. The technique adopted was found to be economical and industrially feasible. Thus, it can be concluded that combination of Solid Dispersions and Superdisintegrants is a promising approach to prepare efficient Mouth Dissolving Tablets of Poorly water soluble drug i.e. Telmisartan.

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**CONFLICT OF INTEREST**

We declare that we have no conflict of interest.

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