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SOLUBILITY ENHANCEMENT OF TELMISARTAN BY USING SOLID DISPERSION TECHNIQUE

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ABSTRACT
The present study investigates the enhancement of Telmisartan solubility through the use of the solid dispersion technique. Telmisartan, an angiotensin II receptor antagonist used for hypertension management, has limited solubility in water, leading to poor bioavailability. To overcome this challenge, solid dispersions of Telmisartan were prepared using water-soluble carriers like Polyvinylpyrrolidone (PVP), Polyethylene glycol 4000 (PEG 4000), and Poloxamer 407 via solvent evaporation method. The solid dispersions were evaluated for drug release, physicochemical properties, and tablet formulation. Dissolution studies revealed a significant increase in the dissolution rate of Telmisartan from solid dispersions compared to the pure drug, following first-order kinetics. Among the carriers tested, PEG 4000 provided the highest dissolution rate enhancement. Tablets formulated with these solid dispersions showed satisfactory hardness, friability, and rapid dissolution. The dissolution of Telmisartan was markedly enhanced with increased carrier concentration, especially in the 1:2 drug-to-carrier ratios. Fourier Transform Infrared Spectroscopy (FTIR) confirmed the absence of significant chemical interaction between the drug and carriers. These results indicate that the solid dispersion technique is an effective strategy for improving the dissolution rate and bioavailability of Telmisartan.

KEYWORDS: Telmisartan, Solubility Enhancement, Solid Dispersion, Bioavailability, Solvent Evaporation Method, Tablet Formulation.

1. INTRODUCTION

Telmisartan, an angiotensin II receptor blocker (ARB), is widely used in the treatment of essential hypertension and certain cardiovascular conditions. Despite its effectiveness in managing hypertension, Telmisartan faces a significant limitation—its poor aqueous solubility, which leads to low bioavailability (42%) when administered orally. This low bioavailability is primarily due to its highly hydrophobic nature, resulting in limited dissolution and absorption in the gastrointestinal tract. As a result, achieving therapeutic plasma concentrations often requires higher doses, which can lead to undesirable side effects.

To overcome this challenge, various formulation strategies have been explored to enhance the solubility and bioavailability of poorly soluble drugs. Among these, the solid dispersion technique has emerged as a promising method. Solid dispersions involve the dispersion of the active pharmaceutical ingredient (API) in a carrier or matrix that enhances its solubility by improving drug wettability, reducing particle size, and increasing the surface area available for dissolution. This technique involves the use of hydrophilic carriers such as polyvinylpyrrolidone (PVP), polyethylene glycol (PEG), and poloxamer, which can significantly improve the dissolution characteristics of poorly soluble drugs.

The solvent evaporation method is one of the most commonly used techniques for preparing solid dispersions. In this method, the drug and the carrier are dissolved in a suitable solvent, and the solvent is

subsequently evaporated, resulting in the formation of a solid dispersion. The resultant product typically exhibits improved drug release profiles and enhanced solubility compared to the pure drug.

The present study aims to evaluate the potential of solid dispersion as a strategy for improving the solubility and dissolution rate of Telmisartan. The effect of different hydrophilic carriers—PVP, PEG 4000, and Poloxamer 407—on the solubility enhancement of Telmisartan was investigated. In addition, the study also explores the preparation of tablets containing these solid dispersions, with the goal of developing a practical and effective dosage form that can improve the bioavailability of Telmisartan. The findings of this study could provide valuable insights into the formulation of improved Telmisartan dosage forms with better therapeutic outcomes.

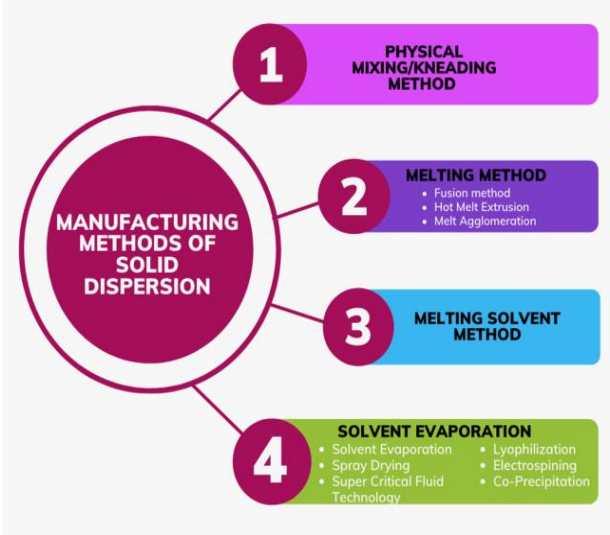

Fig. 1: Solid Dispersion Method.

2. DRUG PROFILE

- **Chemical Formula:** 2-(4-{[4-methyl-6-(1-methyl-1H-1,3-benzodiazol-2-yl)-2-prpoyl-1H-1,3-
- **Molecular Formula:** $C_{33}H_{30}N_4O_2$
- **Molecular Weight:** 514.617g/mol
- **Solubility:** slightly soluble in chloroform and 0.1mol/ml NaOH liquor and very lightly soluble in methanol and acetonitrile and hardly soluble in water.
- **Bioavailability:** 42%
- **Protein Binding:** 99.5%
- **Half Life:** 24 Hours
- **Therapeutic Category:** Telmisartan is an angiotensin II receptor antagonist (angiotensin receptor blocker, ARB) used in the management of hypertension.
- **Indication:** Telmisartan is indicted in the treatment if essential hypertension.

Chemical Structure

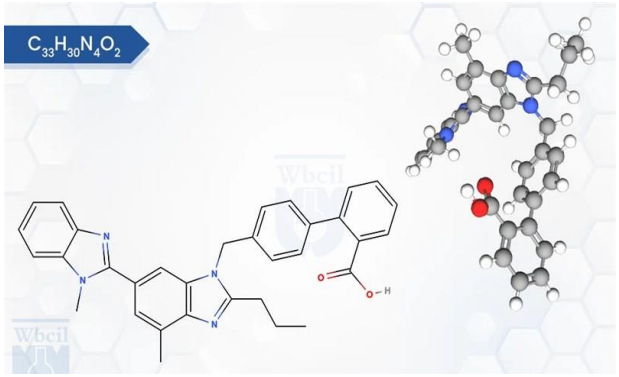

Fig. 2: Chemical Structure of Telmisartan.

Contraindication

Telmisartan is contraindicated during pregnancy. Like other drugs affecting the renin-angiotensin system (RAS), Telmisartan can causes birth defects, stillbirths and neonatal deaths. It should not be taken by breastfeeding women since il is not known whether the drug passes into the breast milk

Adverse effect

Side effects are similar to other angiotensin II receptor antagonists and include tachycardia and bradycardia (fast or slow heartbeat), hypotension (low blood pressure), edema (swelling of arms, legs, lips, tongue, or throat, the later leading to breathing problems), and allergic reactions.

3. MATERLAL AND METHODS

3.1 Analytical Method for Calibration Curve of Telmisartan

Maximum wavelength of telmisartan was found 1o be 296 nm using UV-visible spectroscopy. Standard solution (100ug/ml) was prepared from stock solution (1mg/ml) in a 0.IN hydrochloric acid. A standard drug solution ranging from 0.2 to 1.8ml were transferred into1Oml volumetric flask and were diluted up to the mark with 0.IN hydrochloric acid. The absorbance of each solution was measured at 2% nm against 0.IN hydrochloric acid. A plot of concentration of drug versus absorbance was plotted.

3.2 Fourier transform infrared spectroscopy (FT-IR)

FTIR spectroscopy was used to study the structural changes and possible interactions between drug and carrier in the solid dispersion. Infrared spectra of pure drug, solid dispersions were scanner over the frequency range 40000-400 cm^1. The resultant spectra were compared for any changes.

3.3 Preparation of Telmisartan Solid Dispersions by Solvent Evaporation Method

Telmisartan solid dispersion were prepared by solvent evaporation method using carries (PVP PEG 4000 and poloxomer 407) in proportion viz 1:1 and 1:2 (drug: carrier). The drug and carrier were dissolved in methanol in a china dish and the mixture was heated until the

solvent evaporated. The resultant solid dispersion was collected, pulverized and passed through sieve no.60, store in a desiccators for further use.

Preparation of Telmisartan Tablets: Compressed tablets each containing equivalent of 20 mg of telmisartan was prepared employing selection solid dispersions by direct compression methods. For direct compression microcrystalline cellulose was used as directly compressible vehicle. Solid dispersion containing the medicament, microcrystalline cellulose and other excipients were blended thoroughly in a closed polyethene bag and were directly compressed into tablets on a rotary 12-station tablet punching machine using 9 mm round and flat punches.

Table 1: Formulation Table.

Ingredients (mg/tab)	Formulation					
	SDF1	SDF2	SDF3	SDF4	SDF5	SDF6
Telmisartan	20	20	20	20	20	20
Microcrystalline Cellulose	68	70	67	68	66	70
Mannitol	56	54	56	55	56	55
Magnesium Stearate	4	4	5	4	4	2
Talc	1	1	2	2	2	2
Sodium Lauryl Sulphate	1	1	1	1	2	1
Total Weight	**150**	**150**	**150**	**150**	**150**	**150**

4. RESULTS AND DISCUSSION

4.1 Analytical Method for Calibration Curve of Telmisartan

Maximum wavelength of telmisartan was found to be 296mm using UV visible spectroscopy. The standard regression equation for telmisartan obtained was y =0.054x+0.002 with a coefficient of regression (R^2) of 0.999.

4.2 FT-IR Spectrum

Drug and carrier interactions in the solid dispersions prepared were evaluated by FTIR special study. The FTIR spectra of pure telmisartan, which gave highest enhancement in the dissolution rate of telmisartan containing PEG 4000 (1:2). Telmisartan exhibits characteristic peaks at indicated characteristic peaks at 3,433 cm^{-1} (N-H stretch), 3059 cm^{-1} (aromatic C-H stretch) 2956cm^{-1} (aliphatic C-H stretch), 1691 cm^{-1} (carbonyl group) and the peak at 1454 cm^{-1}indicated the presence of C=C aromatic group. All the above characteristic peaks appear in the spectra of best formulation at same wave number indicating no significant evidence of chemical interaction between drug, carrier and other excipients.

4.3 Evaluation of Tablets

Table: 2 Physical Evaluation.

Formulation Code	Hardness (kg/cm^2)	Friability	Disintegration Time (Min & Sec)	In-vitro Dissolution
SDF1	3.2±0.10	0.87	19.5±1.39	9.25
SDF2	3.7±0.15	0.54	14.41±0.59	57.86
SDF3	3.7±0.06	0.57	12.25±0.94	48.63
SDF4	3.9±0.10	0.62	11.50±0.45	62.66
SDF5	3.9±0.10	0.64	12.03±0.39	85.45
SDF6	3.3±0.11	0.86	6.7±0.28	90.90

4.4 Dissolution Study

Table: 3 Dissolution Study.

Solid Dispersion	Drugs: Polymer Ratio	% Of Drug Dissolved In 10 Min	K1 (Min^1)	Increase In K1 No. Of Folds
Telmisartan	-	9.25	0.0092	-
SDF1	1:1	38.40	0.030	3.33
SDF2	1:2	57.86	0.046	5.12
SDF3	1:1	48.63	0.039	4.35
SDF4	1:2	62.66	0.055	6.14
SDF5	1:1	85.45	0.111	12.28
SDF6	1:2	90.94	0.159	17.66

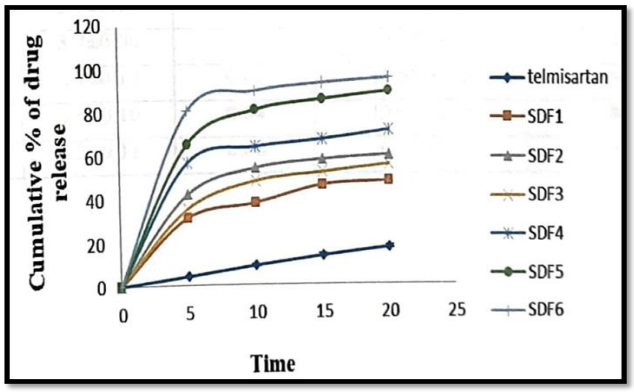

Fig. 3: Dissolution Study.

DISCUSSION

Solid dispersions of telmisartan in three water soluble polymers namely PVP, PEG 4000 and poloxomer 407 were prepared by common solvent evaporation method employing methanol as solvent. In each case solid dispersions were prepared all two different ratios of drug, carries namely 1:1 and 1:2. All (he solid dispersions prepared were found to be fine and free flowing powders.

All the tablets prepared contained telmisartan 98.12 to 99.35%. Hardness of the tablets was in the range 3.21 - 3.46kg²sq.cm and was satisfactory. The percentage weight loss in the friability test was less than 0.86 in all the tablet formulations prepared tablets formulated disintegrated rapidly within 6 min. Thus all the tablets formulated employing solid dispersions were found to be of good quality, fulfilling all official (L.P) and other requirements of compressed tablets.

The dissolution rate of telmisartan as pure drug and from various solid dispersions was studied in 0.IN hydrochloric acid. The dissolution of telmisartan from all solid dispersions was rapid and several times higher than the dissolution of telmisartan as such. The dissolution data were fitted into zero order and first order kinetic models to assess the kinetics of dissolution. The dissolution of telmisartan as such and from all solid dispersions followed first order kinetics. Plots of log percent remaining versus lime were found to be linear with all the products. First order rate constant (kg min¹) was calculated in each case from the slope of first order linear plots.

All the dissolution parameters (percent dissolved in 10 min and KI values) indicated rapid and higher dissolution of telmisartan from solid dispersions than that of telmisartan as such. Among the three carries tested (PVP, PEG 4000 and poloxomer 407), poloxomer 407 solid dispersions gave higher dissolution rates than the other (w/o solid dispersions. The dissolution rate of Telmisartan in solid dispersion was strongly dependent. On there live concentrations of the carrier. As the concentration of carrier in the solid dispersion increased, The dissolution talc also increased. AL I12 ratio of drug carrier, PVP, PEG 4000 and poloxomer 407 solid dispersions gave 5.12-, 6.41-and 17.66- (old increases in the dissolution rate of telmisartan respectively. With all the free soluble carriers the dissolution rate was increased as the carrier concentration was increased. The order of increasing dissolution rate observed with various polymers was PEG 4000 > poloxomer 407 >PVP.

Thus the dissolution rate and dissolution deficiency of telmisartan were markedly enhanced by solid dispersion of telmisartan in water soluble carriers. The observed increased in the dissolution rate of telmisartan from its solid dispersions is due to the possible reduction in particle size increased wettability of drug particles when they are dispersed in the hydrophilic water soluble polymers. Solid dispersions in PVP (12) SDF2, PEG 4000 (1:2) SDF4 and Poloxomer 407 (1:2) SDFG exhibited a marked enhancement in the dissolution rate and efficiency of telmisartan. The feasibility of formulating these solid dispersions into compressed tablets with enhanced dissolution rate was evaluated. These solid dispersions were formulated into tablets with usual tablet additives by direct compression methods as per the formulae.

All the tablets formulated employing solid dispersing gave rapid and higher dissolution of telmisartan. Telmisartan dissolution from all the tablets prepared by direct compression method followed first order kinetics with correlation coefficient "R" above 0.910.

5. CONCLUSION

The study shows that the dissolution rate of telmisartan can be enhanced to a greater extent by solid dispersion technique. The dissolution of telmisartan from all the solid dispersions was several times higher than the pure telmisartan. Among the three water soluble carriers PEG 4000 solid dispersions gavehighest enhancement in the dissolution rate of telmisartan. This may be due to the increases in drugwettability, conversion to amorphous form in the solid dispersion. The order of increasing dissolution rate was PEG 4000> poloxormer 407> PVP. Higher dissolution rate of telmisartan was found in formulations containing I:2 ratios of water soluble carriers. The selected solid dispersions could be formulated into tablets by direct compression method. Telmisartan tablets formulated employing solid.

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