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STUDIES ON APPLICABILITY OF PEANUT SHELL POWDER AS SUPER DISINTEGRANT IN TELMISARTAN MOUTH DISSOLVING TABLETS

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ABSTRACT

Telmisartan, a BCS class II antihypertensive drug has been indicated for treatment of Hypertension. To enhance the onset of action and solubility characteristics of Telmisartan, an effort was made to formulate mouth dissolving tablets (MDT) using natural super disintegrant. The main objective of the current investigation is to study the applicability of peanut shell powder (PSP) as super disintegrant. MDT of Telmisartan were prepared using various concentration of PSP using direct compression technique and evaluated for the physical tableting properties post compression, in vitro drug release, FTIR and stability studies. The results of the investigation indicate that the incorporation of PSP as a super disintegrant significantly reduces the disintegration time of Telmisartan MDTs compared to conventional formulations. Moreover, dissolution studies reveal improved drug release profiles, suggesting enhanced bioavailability and potentially better therapeutic outcomes due to swelling and water absorption properties of PSP. FTIR studies showed absence of significant drug excipient interaction. Accelerated stability studies on optimized formulation indicated stability of formulation.

**Keywords: Peanut Shell Powder, Super disintegrant, Telmisartan, Mouth Dissolving
Tablets, Pharmaceutical Formulation**

INTRODUCTION

The application of mouth dissolving tablets (MDTs) is a growing interest in formulation research and development in recent times not only due to their advantages in enhancing patient compliance in individuals with dysphagia, also it is potential in rapid drug therapy for various disease conditions like hypertension, diabetes, migraine, peptic ulcers etc. MDTs disintegrate rapidly in the oral cavity, facilitating ease of administration without the need of water, thereby offering convenience and improved drug bioavailability for poorly soluble drugs. However, the effectiveness of MDTs heavily relies on the choice of super disintegrants, which play a crucial role in accelerating disintegration and dissolution rates [1-3].

Super disintegrants are substances that facilitate the rapid breakup or disintegration of tablets upon contact with water or saliva. They enhance drug dissolution and bioavailability by increasing the surface area available for dissolution. Commonly used super disintegrants include cross-linked polymers, modified starches etc. [4, 5]. This research article delves into the utilization of peanut shell powder (PSP) as a super disintegrant in the formulation of Telmisartan mouth dissolving tablets

(MDTs). It has garnered attention due to its fibrous nature and potential as a natural super disintegrant in pharmaceutical formulations. PSP exhibits low toxicity and is readily available at low cost, making it an attractive candidate for pharmaceutical applications.

MATERIAL AND METHODS

Materials

Telmisartan was obtained as a gift sample from Dr. Reddy's Labs, Hyderabad. Lactose, Magnesium stearate, talc procured from SD Fine Chemicals. Peanuts were collected, washed, dried, finely powdered and passed through # 60 mesh. Marketed formulation Telmicum-40 used for comparative studies obtained from local outlets.

Methods

Calibration curve of Telmisartan in 0.1 N HCl

The maximum absorbance (λ_{max}) of telmisartan (10 $\mu\text{g/ml}$) was recorded over the UV range of 200-400 nm. The calibration curve of telmisartan drug was performed by measuring the absorbance of drug concentration (5-25 $\mu\text{g/ml}$) in 0.1 N HCl using UV Spectrophotometer at 296 nm as represented in **Figure 1**.

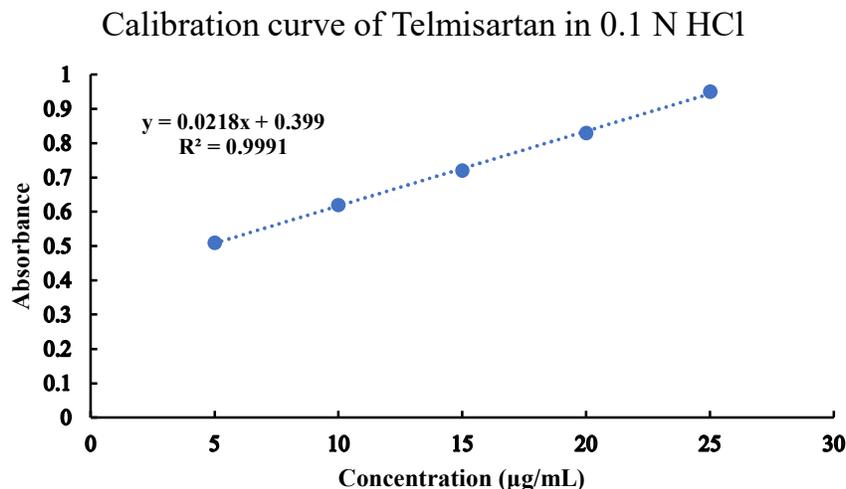


Figure 1: Calibration curve of telmisartan in 0.1 N HCl

Formulation of Telmisartan MDTs:

Experimental studies were conducted to formulate Telmisartan MDTs using varying concentrations of PSP as a superdisintegrant. Specified quantities of Telmisartan, lactose, peanut shell powder, saccharin, talc and magnesium stearate were weighed accurately after passed through 60 # screen and then triturated in a mortar for

uniform blending. Further the powder blend was evaluated for angle of repose, bulk density, tap density and compressibility index and compressed into tablets of 100mg weight using single punch tablet machine [6]. Composition of tablets prepared using direct compression method was given in **Table 1**.

Table 1: Formulation of Telmisartan MDT

Ingredients (mg)	F1	F2	F3	F4	F5
Telmisartan	40	40	40	40	40
Lactose	45	43	41	39	37
PSP	2	4	6	8	10
PVP K30	4	4	4	4	4
Sodium Saccharin	5	5	5	5	5
Magnesium stearate	2	2	2	2	2
Talc	2	2	2	2	2

Evaluation of Telmisartan MDT

The formulations were evaluated for various parameters including weight variation, thickness, hardness, friability, drug content as per pharmacopeial procedures and specifications. Disintegration time, wetting time and in vitro dispersion are critical parameters for mouth dissolving tablets.

Disintegration test was performed in 1000 mL water maintained at $37 \pm 2^\circ \text{C}$ [7-9]. Wetting time was determined by placing tablet on tissue paper folded twice kept in a petridish containing 6 ml of purified water. The time required for complete wetting of the tablet was then recorded. The in vitro dispersion time was measured by dropping

tablet in a beaker containing 100ml of water and stirring gently. The time for the tablet to completely disperse into fine particles was noted [10]. The results of post compression parameters were clearly mentioned and discussed in further sections.

Invitro dissolution profile of Telmisartan MDT

All the batches were subjected to dissolution studies in 0.1 N HCl as per the FDA guidance for dissolution testing of Telmisartan tablets at temperature of medium 37 ± 0.5 °C. Cumulative % drug released was calculated by spectrophotometric analysis of dissolution samples at 296 nm [11, 12]. The dissolution performance of all formulations were compared with commercial formulation to select the optimized formulation as shown in **Figure 2**.

RESULTS AND DISCUSSION:

The tablet blends of all batches subjected to precompression tests proved to exhibit excellent flow properties with the following results, angle of repose (< 25), Carr's Index (< 17), Hausners ratio (< 1.11). The results indicate that incorporation of PSP does not show any negative effect on flow property of blend due to its fibrous nature and fine particle size. The post compression parameters of all batches also found to be within the Pharmacopoeial standards as represented in **Table 2**.

Among all the formulations, F4 and F5 batches exhibited less disintegration and wetting time compared to other formulated and marketed batches. Comparative dissolution profile of all batches also reveals that F4 and F5 exhibit dissolution within 9 min and 6 min respectively. But the formulation F5 has minimum hardness with high friability may be due to high fibrous content which attributed to brittleness of the formulation, hence F4 with 8% of PSP as super disintegrant optimized as best formulation and further subjected to drug-excipient interaction and stability studies.

Compatibility studies of drug and excipient

To determine the compatibility of drug and excipients, FTIR studies were carried out for pure drug and powdered tablet of optimized formulation and the corresponding spectra was represented in **Figure 3**. The FTIR spectrum of F4 formulation showed characteristic peaks at 3061 cm^{-1} (O-H stretch), 1687 cm^{-1} (C=O stretch), 1608 cm^{-1} (C=N & C=C stretch), 2959 cm^{-1} (C-H stretch), 1008 cm^{-1} (C-N) corresponding to the retention of active functional groups of Telmisartan indicating that there is significant drug excipient interaction after compression of tablets.

Stability studies of optimized formulation

Freshly prepared batch of 50 tablets of optimized formulations were subjected to accelerated stability studies upto 6 months,

then characterized for the tableting properties of MDT after 3 months and 6 months, the results were mentioned [13] in

Table 3. Maximum % drug release was observed in less than 10 mins.

Table 2: Tableting properties of Telmisartan MDT

Batch	Hardness (kg/cm ²)	Friability (%)	Uniformity of weight (mg)	Drug content (%)	Dispersion time (sec)	Disintegration time (sec)	Wetting time (sec)s
F1	4.5±0.5	0.42±0.02	100.5±0.2	99.64±0.8	81±0.2	75±0.5	52±0.9
F2	4.3±0.2	0.45±0.01	100.2±0.4	99.87±0.36	69±0.1	63±0.3	47±0.7
F3	4.2±0.3	0.46±0.03	100.3±0.5	100.2±0.31	60±0.2	52±0.6	42±0.2
F4	4.1±0.1	0.52±0.02	99.8±0.6	99.61±0.42	55±0.3	48±0.8	39±0.3
F5	3.3±0.2	0.85±0.02	100.3±0.6	99.74±0.61	53±0.3	45±0.5	35±0.4
M	4.6±0.2	0.48±0.01	99.86±0.5	99.65±0.5	69±0.5	58±0.3	48±0.3

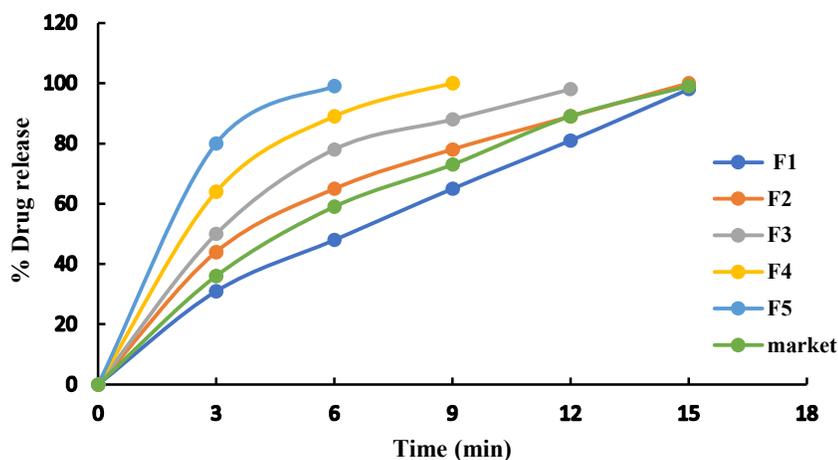
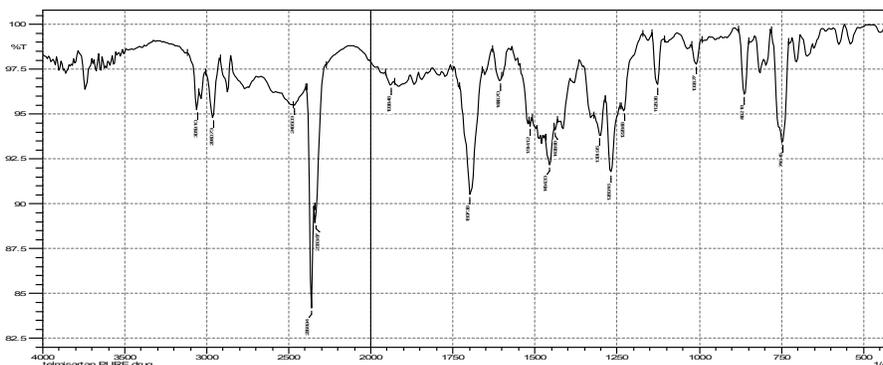


Figure 2: Comparative dissolution profile of formulated and marketed tablets



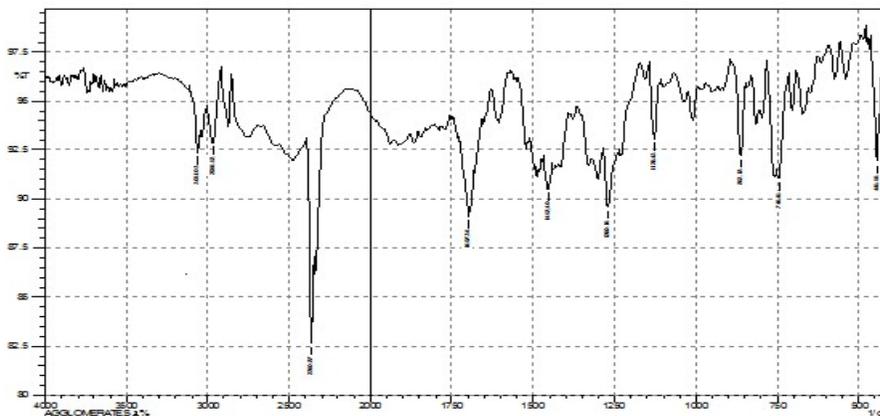


Figure 3: FTIR spectra (a) Pure drug (b) F4 formulation

Table 3: Tableting characteristics of Telmisartan MDT after 3 months

Test	Initial	Storage condition			
		30±2° C/65±5% RH		40±2° C/75±5% RH	
		3 months	6 months	3 months	6 months
Friability (mm)	0.52±0.02	0.50±0.03	0.53±0.04	0.52±0.03	0.52±0.05
Hardness (Kg/cm ²)	4.2±0.58	4.1±0.55	4.2±0.45	4.2±0.36	4.2±0.52
Uniformity in weight (mg)	100±0.48	100±0.33	100±0.49	100±0.54	100±0.51
Drug content ^c (%)	99.96±0.13	99.95±0.14	99.95±0.17	99.95±0.23	99.95±0.12
Dispersion time (sec)	55±0.3	54±0.3	57±0.3	53±0.3	55±0.6
Disintegration time (sec)	48±0.8	49±0.7	48±0.6	45±0.8	49±0.7
Wetting time (sec)	39±0.3	37±0.5	39±0.6	38±0.32	41±0.3

CONCLUSION

This research highlights the potential of peanut shell powder as a natural superdisintegrant in the formulation of Telmisartan mouth dissolving tablets. Moreover, dissolution studies reveal improved drug release profiles, suggesting enhanced bioavailability and potentially better therapeutic outcomes. The observed effects correlate with the swelling and water absorption properties of PSP, which promote rapid disintegration and dissolution of the tablets. The promising results encourage further optimization of formulations and extensive pharmacokinetic and pharmacodynamic studies to validate the efficacy and safety of PSP-enhanced

MDTs. Future research may also explore the application of PSP in other pharmaceutical formulations, contributing to sustainable and cost-effective drug development.

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Conflict of interest: The authors declare no conflict of interest.

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