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Telmisartan Matrix Tablets Using Trigonella foenum-*graecum* Seed Mucilage: Fabrication and Description

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Abstract

The authors aimed to create Telmisartan (TSN) tablets with a long half-life by combining herbal and synthetic polymers. TSN matrix tablets were made with Trigonella foenum-graecum seed mucilage (TFGSM) and ethyl cellulose. The proposed tablets were tested for official and non-official tests, including TSN discharge, and the flow properties of the blend were evaluated. TSN matrix tablets have a high TSN and meet the pre-and post-formulation requirements. There were no chemical interactions between TSN and the polymers used in the study. When coupled with other polymers, TFGSM was proven to be a useful polymer for managing medicine release.

Keywords: Matrix; Mucilage; Tablets; Telmisartan; *Trigonella foenum-graecum*

Abbreviations: TSN: Telmisartan; TFGSM*: Trigonella foenum-graecum* seed mucilage; DSC: Differential Scanning Calorimetry; FTMT: Fenugreeks Telmisartan matrix tablets.

Introduction

Oral drug delivery systems are safe and effective and gained attraction by all age range patients as it is convenient, easy to manage, and carry [1]. The antihypertensive medication Telmisartan (TSN) was chosen as the medicine of choice for the current trial [2]. It belongs to the class of angiotensin receptor blockers, which work by blocking the angiotensin-II receptor [3]. This decreases blood pressure by preventing vasoconstriction [4]. TSN's absolute bioavailability is determined by the dosage. The medication has a high affinity for plasma proteins (>99.5%). It has a terminal elimination half-life of about 24h [5]. Prolonged drug delivery systems with zero-order drug release can be achieved by various techniques among them matrix system is simple, economical, and effective [6,7]. The use of costly polymers can be released by economical and easily available herbal seed mucilage from *Trigonella foenum-graecum* seed mucilage (TFGSM) (commonly known as Fenugreeks) [8].

Materials and Methods

Material

Telmisartan was gifted from Dr. Reddy's labs, Hyderabad, Telangana, Ethyl Cellulose, Lactose, Magnesium stearate and silica powder were from Fischer Chemic Ltd, Hyderabad. Distilled water was used whenever it is required.

Methods

Identification of Telmisartan: TSN was identified based on its physical appearance, melting point, and solubility.
Method to Estimate Telmisartan: To make 10g/ml solutions,

TSN was dissolved in phosphate buffer pH 2.0.λmax was found to be 234nm after further diluting with the same buffer and scanning in a double beam UV-VIS Spectrophotometer from 200 to 400nm [9,10].

Telmisartan Calibration Curve: The procedure for plotting the TSN calibration curve (Chart 1) [11].

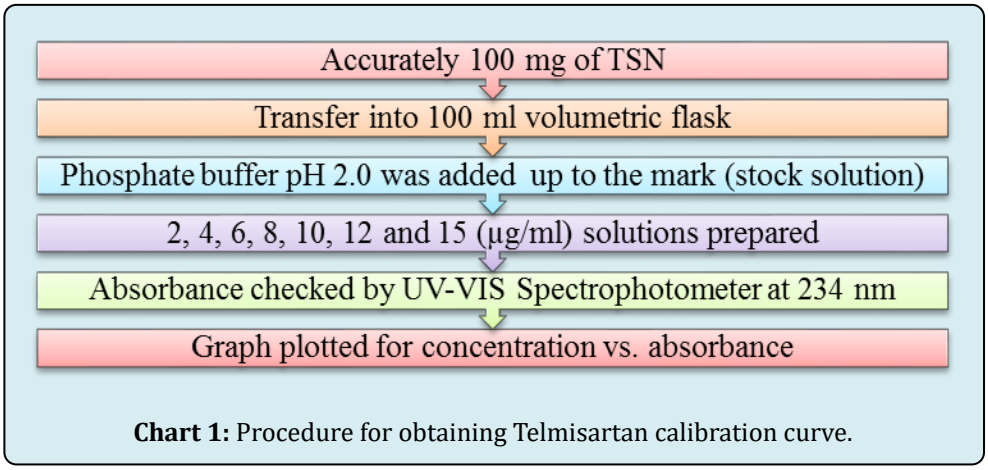

Chart 1: Procedure for obtaining Telmisartan calibration curve.

Extraction of Mucilage: The extraction and purification were done according to Ahad et al studies [12,13]. Fresh *Trigonella foenum-graecum* seeds were soaked in water overnight, ground, and treated with acetone to precipitate the mucilage, then dried, sieved with # 80, and stored in an airtight container until use.

Drug Excipient Compatibility

Differential Scanning Calorimetry (DSC): To rule out any drug-excipient interactions, DSC studies of TSN and formulation blend were performed using a Perkin Elmer FTIR spectrophotometer. Each sample was heated independently in an aluminium pan at 10°C/min from 50 to 300°C under nitrogen at 50ml/min.

FTIR Study: Bruker IR spectrophotometer was used to create FTIR spectra and distinctive peaks of TSN and TSN with an excipient blend.

Formulation of Tablets by Wet Granulation Technique: Steps involved in the preparation of Fenugreeks Telmisartan matrix tablets (FTMT) (Chart 2) [14-17].

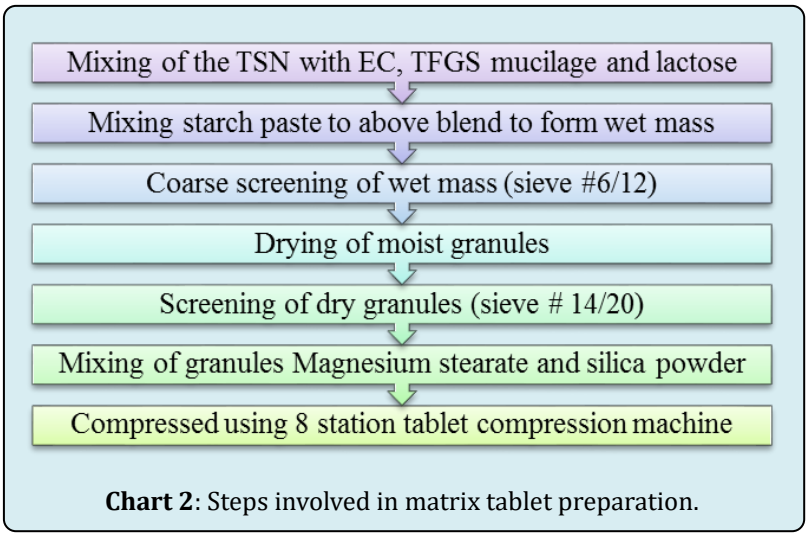

Chart 2: Steps involved in matrix tablet preparation.

Pre Formulation Studies: To guarantee that the dried wet granules went readily from the hopper to the tablet dyes for compression, flow patterns were applied to them [18,19].

Post Formulation Studies: On the manufactured tablets, the following parameters were measured.

Thickness of Tablets: A sliding calliper was used to control the thickness of five tablets from each batch [20].

Uniformity of Weight: Each batch had 20 tablets weighed disjointedly, with [21] the mean weight resolute. Individual weights' unorthodoxy was afterwards projected.

Tablet Hardness and Friability: A Pfizer tester was used to evaluate the hardness of 5 pills from each batch at random.

Following de-dusting, 10 pre-weighed tablets from each batch were subjected to 100 falls (4 minutes) from a height of 6 inches before being weighed [22].

Assessing Drug Content: The technique outlined in Chart 3 hampered TSN content in the FTMT [23,24].

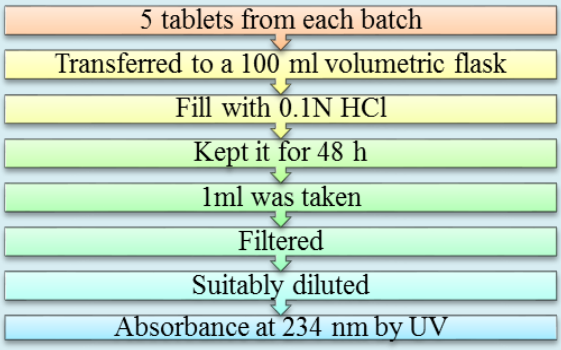

Chart 3: Procedure for determining the drug content in prepared tablets.

In Vitro Dissolution Studies: The dissolution conditions utilized for pharmaceutical dissolution are summarized in Table 1 [25,26].

Parameter	Description
USP Apparatus	II
Rotation (rpm)	100
Medium	0.1MHCl for the first 2h than in pH 6.8
	phosphate buffer solution for 10 h
Volume	900ml
Temperature	37±0.5°C
Sampling at	1, 4, 6, 8, 10 and 12h
Wavelength	234nm

Table 1: In vitro dissolution conditions.

Results and Discussion

Results TSN Description

In Chart 4, the appearance, melting point, and solubility of TSN were listed.

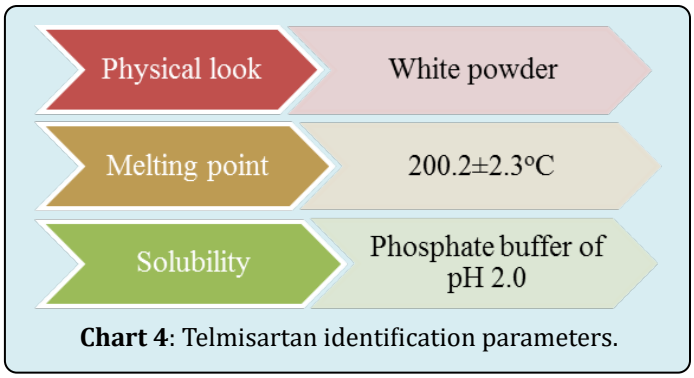

Chart 4: Telmisartan identification parameters.

Compatibility Studies

There was no loss of specific peaks or emissions of new peaks when comparing the DSC of the TSN thermogram to pure TSN, demonstrating that TSN is not incompatible with the polymers used (Table 2).

DSC sample	Endothermic events (°C)			ΔH Fusion	Inference
	T onset	T peak	T end	Enthalpy (J)	
Telmisartan	195.54	200.25	211.28	-298.08	An endothermic peak
Telmisartan+ Polymers	190.51	195.84	199.69	-258.32	A shift in peak to left due to positive blending of Telmisartan with polymers

Table 2: DSC thermograms of drug and polymers used.

The FTIR spectra revealed that the usual TSN bands were not recovered in the physical combinations, indicating that TSN and EC and TFGSM polymers have no unfavorable interactions.

Calibration Curve: TSN calibration curve shows a slope of 0.0155x +0.06 with a regression (R2) value of 0.9909 (Figure 1).

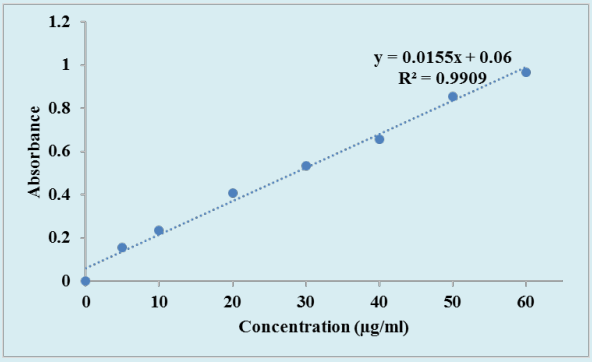

Figure 1: Calibration curve of Telmisartan.

Pre Formulation Studies: The flow parameters of the granules were illustrated in Table 3.

Flow properties					
Formulation	**Angle of repose (°)**	**Bulk Density**	**Tapped Density**	**Carr's Index**	**Hausner's Ratio**
FTMT-1	24.51±0.09	0.451±0.02	0.496±0.02	9.973±0.02	1.099±0.02
FTMT-2	27.67±0.15	0.526±0.01	0.541±0.01	2.773±0.04	1.028±0.01
FTMT-3	26.28±0.08	0.355±0.02	0.381±0.02	6.824±0.02	1.073±0.02
FTMT-4	25.29±0.26	0.402±0.03	0.446±0.01	9.865±0.05	1.109±0.03
FTMT-5	25.65±0.85	0.523±0.01	0.557±0.03	6.104±0.03	1.065±0.02
FTMT-6	29.68±1.05	0.502±0.04	0.533±0.02	5.816±0.02	1.061±0.03

Table 3: Flow parameters of prepared granules.
Readings in mean ±SD; The number of trials (n=3)

Post Formulation Studies

The thickness (5mm) and weight of the FTMT were determined to be uniform, indicating that the medicine and excipients were added and blended systematically. The fact that the hardness was > 4Kg/cm2 and the friability loss was minor (1%) shows that the FTMT is robust. The TSN content in FTMT was deemed to be sufficient according to the criterion (Table 4). In vitro, TSN is released from the formulation in a controlled manner. One of the formulations that demonstrated regulated release over time was FTMT-5 (Figure 2).

Formulation	Uniformity of weight (mg)	Hardness (cm^2)	Thickness (mm)	Friability (%)	Assay (%)
FTMT-1	298.8±1.74	4.8±0.04	4.52±0.04	0.61±0.01	98.8±1.49
FTMT-2	298.4±1.95	5.6±0.02	4.56±0.05	0.29±0.01	97.8±2.68
FTMT-3	299.1±1.84	4.9±0.07	4.59±0.09	0.57±0.05	96.9±1.85
FTMT-4	297.7±3.28	5.1±0.03	4.58±0.07	0.36±0.02	99.7±2.05
FTMT-5	299.3±2.26	5.8±0.09	4.52±0.09	0.59±0.02	98.9±2.35
FTMT-6	297.9±1.25	6.2±0.01	4.59±0.03	0.55±0.01	97.2±1.65

Table 4: Physical description of the prepared matrix table.
Values in mean ±SD; the number of trials (n=3)

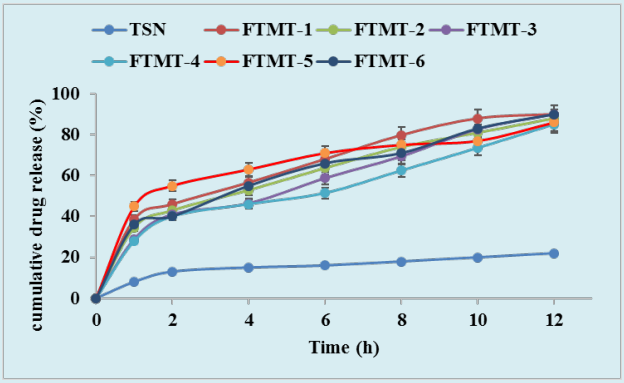

Figure 2: Zero-order plots of prepared matrix tablets.

Conclusion

In this study, the authors discovered that the Telmisartan matrix tablet extends the emission rate for more than 12 hours with enhanced bioavailability and no need for repetitive dosing and dose. It was also shown that *Trigonella foenum-graecum* seed mucilage when combined with Ethylcellulose, can be a good polymer for controlling drug release with fewer side effects and costs, as well as increased patient satisfaction and effectiveness.

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