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Original Article

DESIGN, DEVELOPMENT AND FABRICATION OF MOUTH-DISSOLVING TABLETS CONTAINING EXTRACT OF *TRIBULUS TERRESTRIS* FOR THE TREATMENT OF HYPERTENSION

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ABSTRACT

Objective: The present work is aim to design, development and fabrication of mouth dissolving tablets containing extract of *Tribulus terrestris* for the treatment of hypertension.

Methods: The extract of fruits of *Tribulus terrestris* was formulated as mouth dissolving tablets (MDTs) by full factorial design at 3^2 levels and prepared by direct compression method using super integrants like sodium starch glycolate and cross povidone. Furthermore, the tablet was evaluated for thickness, hardness, weight variation, wetting time, disintegration time, and *in vitro* drug release study.

Results: The tablets were analyzed for a variety of characteristics, such as hardness (2.4-2.9 kg/cm2), friability (0.33-1.7%), disintegration time (20-34 s), drug content (95.32-99.09%), water uptake ratio (26-48%), wetting time (29-69 s), and *in vitro* drug release illustrated in 5 min (99.04-68.21%). There was no interaction between both the drug and the polymer, according to FTIR and DSC studies.

Conclusion: The research revealed that *Tribulus terrestris* fruits extract can be designed, developed and fabricated into mouth dissolving tablet for the treatment of hypertension with improved bioavailability and expected patient compliance.

Keywords: *Tribulus terrestris,* Mouth dissolving tablet, Hypertension, Full factorial design

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INTRODUCTION

Except for water, Mouth Dissolving Tablets (MDTs) dissolve in saliva or break down and are ingested. Because of their self-administration, self-convenience, and compactness, MDTs have had an advantage over regular tablets. As a result, it accelerates the onset of action, improves bioavailability, and improves stability, which all contribute to increasing demand for dosage forms in the current economy [1]. It also applies to people who are ill and in bed, those who are travelling, as well as those who are busy, particularly those without access to water, it dissolves inside the oral cavity in 15–3 min. Oral disintegrating tablets (MDTs) are becoming in demand as a result of patients' increased acceptance of them [2]. A considerable portion of people prefer tablets that dissolve in the mouth, especially those who have trouble swallowing [2, 3]. Dysphasia (difficulty swallowing) has been reported to affect people of all ages, but it is most common in children and elderly people, as well as institutionalised patients, psychiatric patients, and people who have nausea, vomiting, and motion sickness symptoms. Good-tasting and fragrant MDTs increase the adoption of bitter medicines among particular population groups. Orally dissolving tablets can satisfy all of these requirements, which include the ability to change the course of the disease, cost effectiveness, and drug safety [4, 5].

An herb known as *Tribulus terrestris L.* (Zygophyllaceae) is widely distributed in India, China, Japan, Korea, western Asia, southern Europe, and Africa. The fruit of *T. terrestris* has been used to treat coronary artery disease and high blood pressure in conventional Chinese medicine. Additionally, it has been used as an impotence treatment [5, 6]. This plant is quite abundant in compounds with potential biological significance, including as saponins, flavonoids, alkaloids, and several minerals [4]. On the specific plant components employed, it matters how much of these essential metabolites are present. *Tribulus terrestris* (caltrop fruit) contains pharmacologically important compounds like phytosteroids, flavonoids, alkaloids, and glycosides in both the fruit and the root. With some substantial adverse effects, *Tribulus terrestris* has been used as a natural therapy for high blood pressure for years [7]. The most recent findings revealed that *Tribulus terrestris* significantly lowered blood pressure in rats with renovascular hypertension. Although this plant has antihypertensive effects, its precise antihypertensive mechanism is unknown. Evidence from the existing research indicates to *Tribulus terrestris* ' ability to reduce blood pressure in 2K1C hypertensive rats by inhibiting ACE activity in their serum and numerous tissues [8]. The current project aims to create a mouth-dissolving tablet containing *Tribulus terrestris* extract for the treatment of hypertension.

MATERIALS AND METHODS

Materials

Fruits of the plant *Tribulus terrestris* were collected directly from the plant in and around Rahuri Krishi Vidyapeeth, Ahmednagar, Maharashtra, India, from January to February. The plant was authenticated as *Tribulus terrestris* by the Botanical survey of India, Pune. Cross povidone, Magnesium stearate, lactose was procured from Merck Labs, Mumbai. propylene glycol, sodium starch glycolate and talc was from Pure chem Scientific, Mumbai. All ingredients were of pure and analytical grade.

Methods

Preparation of extract

Tribulus terrestris fruit powder weighing 100g was added to the Soxhlet extractor's thimble. A graduated cylinder was used to measure 300 ml of the solvent (ethanol) and pour it into the Soxhlet extractor's distillation pot [9]. The apparatus was then coupled once, and the condenser unit once was connected to an above-water tank

to cool rising solvent vapours. The heat source was a Bunsen burner set to a temperature of 68 °C. The Soxhlet extractor's condenser unit is where the solvent condensed after evaporating through the distillation path, sleeve, and growth adapter [10]. The vapour that had condensed at this point re-entered the thimble as liquid droplets and contacted the sample there. Earlier, the whole contents of the thimble and syphon were discharged back into the still of the Soxhlet extractor when the solvent in the thimble reached the level of the top of the syphon. Previously, the method was repeated numerous times for nine refluxes totalling around three hours, followed by one extraction. Previously, a thermometer was used to control the temperature [11].

Experimental design

The ratio of plasticizer to polymer was optimised using a 3^2 complete factorial design. In this design, two components were taken through three variables of evaluation, and nine different possible combinations were tested experimentally [12]. The amount of the plasticizer SSG (X2) and the amount of the polymer Crosspovidone (X1) were selected as independent variables, and each one was looked at the-1, 0 and+1 levels. The levels of the independent variables utilised, or the whole factorial design structure of the variables, are provided in table 1. Table 2 lists the ingredients of some orally disintegrating tablets [13].

Table 1: Independent variables design

Factor	Level used, actual (coded)			References
Independent variables	Low (-1)	Medium (0)	High (+1)	[14]
X1 = Concentration of polymer (mg)	20	30	40	
X2 = Concentration of plasticizer (mg)	5	10	15	

Table 2: Design layout of 3^2 factorial design

Formulation batches	X_1	X_2	References
F1	−1	−1	[12]
F2	0	−1	
F3	+1	−1	
F4	−1	0	
F5	0	0	
F6	+1	0	
F7	−1	+1	
F8	0	+1	
F9	+1	+1	

Where 1 is the high value, −1 is the low value, and 0 is the center value for the factors X1 and X2 and X1 is amount of Crosspovidone, X2 is amount of SSG.

Table 3: Composition of 3^2 factorial design batches of mouth-dissolving tablets

S. No.	Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	*Tribulus terrestris* (mg)	150	150	150	150	150	150	150	150	150
2	SSG(mg)	5	5	5	10	10	10	15	15	15
3	Cross povidone (mg)	20	30	40	20	30	40	20	30	40
4	Mag. Stearate(mg)	1	1	1	1	1	1	1	1	1
5	Talc(mg)	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
6	Lactose(mg)	q. s.	q. s.	q. s.	q. s.	q. s.	q. s.	q. s.	q. s.	q. s.

Procedure for preparation of mouth-dissolving tablet

Tribulus terrestris MDT tablets were made by way of a direct compression process the use of wonderful disintegrants such as cross-povidone [15]. The drug, superb disintegrant, diluent and sweetener were sieved via 40 mesh and correct combined together [16]. SSG and talc were sieved via 80 mesh and combined with the initial mixture. Thus, the powder acquired was compressed into tablets on an 8-station punch-rotary tablet compression machine. A biconvex punch with a diameter of 6 mm was used for tabletting. Tablets have been made via direct compression and the disintegration time of all batches produced was checked and the greatest polymer concentration required to achieve a shorter disintegration time was determined [17].

Drug-excipients compatibility study

Fourier transform infrared (FTIR) spectroscopy

In order to determine the structural composition of the drug and excipients in the form of deliberate group frequencies and their repeatability in excipient combinations and formulations, FT-IR analyses have been conducted on the following samples, such as Pure extract and Pure Extract+Excipient. Using an FTIR spectrophotometer, the FTIR spectra of pure drugs and physical mixture have been evaluated (Shimadzu IRxross). The samples were scanned from 400 to 500 cm-1 in space [18].

Differential scanning calorimetry (DSC) studies

To determine whether there was a difference in enthalpy of fusion, glass transition temperature, or drug component interactions, *Tribulus terrestris* (pure extract) and excipients were evaluated using DSC. A MicroCal PEAQ DSC analyzer served as the platform for the evaluation. The sample, which was placed in common aluminium pans, was scanned at temperatures ranging from 5 °C to above its melting point at a rate of 10 °C/min with dry nitrogen (flow rate 50 ml/min) acting as the exhaust [19].

Pre-Compression evaluation

Bulk density

Weigh 2 g of granules precisely, then transfer to a 10 ml graduated cylinder after passing through a 20# sieve. Level the powder gently without compacting it, then gauge the apparent volume (V0). Using the following formula, determine the apparent bulk density in g/ml [20].

$$Bulk\ Density\ = \frac{Weight\ of\ powder}{Bulk\ volume} \ldots\ldots\ldots (1)$$

Tapped density

Exact 2g of granules were previously put into a 10 ml graduated cylinder after passing through a 20# sieve. Then, using a mechanically tapped density tester, mechanically tap the cylinder

containing the sample while lifting it and allowing it to fall under its own weight at a nominal rate of 100 drops, and measure the tapped volume to the nearest graded units. Use the following calculation to determine the tapped bulk density in g/ml [21].

$$\text{Tapped density} = \frac{Weight\ of\ powder}{Tapped\ volume} \ldots\ldots\ldots (2)$$

Carr's index

The Carrs compressibility index was used to calculate the compressibility index of the powder mixture. It was an easy test to determine a powder's BD, TD, and agglomeration rate. The following equation is used to calculate the Carrs Index [22].

$$Carr's\ index = \frac{Tapped\ Density - Bulk\ Density}{Tapped\ volume} \times 100 \ldots\ldots\ldots (3)$$

Hausner's ratio

Hausner's ratio is a number that correlates to the flowability of a powder or granule [23].

$$Hausner's\ Ratio = \frac{Tapped\ Density}{Bulk\ Density} \ldots\ldots\ldots (4)$$

Angle of repose

The funnel method was used to calculate the powder's angle of repose. The hopper was filled with the powder mixture and weighted down. The funnel's height was adjusted such that its tip barely touched the surface of the powder mixture. The hopper was left open, allowing the powder mixture to pour freely onto the ground. The powder cone's diameter was measured, and the following equation was used to determine the angle of repose [24].

$$\boldsymbol{\theta} = \text{Tan}^{-1}\frac{h}{r} \ldots\ldots\ldots (1)$$

Where h and r are the height and radius of the powder cone, respectively.

Post-compression evaluation

Thickness and diameter

Using a micrometer, the thickness of each tablet was measured, allowing for precise measurement and revealing the variation between tablets [25].

Hardness

The breaking strength of a tablet is another name for the hardness of the tablet. This may be brought on by the powder's poor flow characteristics or moisture content. The hardness of the tablets was examined using a Monsanto hardness tester [26].

Friability

Twenty tablets have been randomly selected from each batch and weighed. These tablets were tested for friability using a friabilator (of the Roche type) for 100 rotations (25 rpm for four min.) The tablets have been taken out. Dusting off and reweighing. SD was calculated using average triplicate readings that were recorded.

$$\%\ F = \frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}} \times 100 \ldots\ldots\ldots (2)$$

Weight variation

20 tablets were chosen at random, and they were weighed on a digital scale. From the overall weight, the average of the three weights was determined. Calculations were made of the percentage deviations from the mean [26].

$$Weight\ Variation = \frac{W1 - W2}{W2} \times 100\% \ldots\ldots\ldots (3)$$

Where W1 is the initial weight of the tablet and W2 is the average weight of the tablet.

Wetting time

6.8 phosphate buffer at a volume of 6 ml was formerly used in a petri dish. The dish once held a tissue paper that had been folded twice and was set on top of that. The higher surface of the tablet was painted with a modest amount of amaranth red hue. The amount of time needed for the tablet's higher surface to turn red was recorded as the tablet's wetting time. Previously, the average of three readings was recorded, and the standard deviation was calculated [27].

Determination of drug content

Each formulation's 10 tablets were powdered. In 100 ml standard flasks, 5 mg of *Tribulus terrestris* powder was weighed and dissolved in an acidic buffer with a pH of 1.2. Using phosphate buffer pH 6.8 as a blank, an adequate dilution was created from this, and the solution was then examined at 327 using a UV double-beam spectrophotometer [28].

Disintegration test

Each of the six tubes of the disintegrating tablet was filled with one tablet, and a disc was placed on top of each tablet. The device was maintained and operated (30 cycles/min) at 370.5 °C with a pH of 6.8 at 30 cycles/min (stimulated saliva). The time necessary for total disintegration with no remaining sensible mass was recorded. The mean disintegration time and standard deviation have been determined. Dissolution Examines using a modified dissolve apparatus; all F1-F9 formulations were subjected to *in vitro* dissolution testing [29].

Statistical analysis

The results are presented as mean (±SD) and were analyzed by using GraphPad Prism 5.0 (GraphPad Software, Inc., San Diego, CA, USA). Optimization of the formulation was done by using Design expert software Ver. 13.0, A difference below the probability level of P-value = 0.05 was calculated using ANOVA [30].

RESULTS AND DISCUSSION

Fourier transform infrared (FTIR) spectroscopy

To determine the compatibility of *Tribulus terrestris* with its polymers and formulation, FTIR spectroscopy was applied to the pure drug extract *Tribulus terrestris* and the solid mixture of drug and various excipients with the formulation. The IR transmission spectra of the drug, the polymer, and the formulation are provided in (fig. 1 and 2) [31, 32]. All peaks were present in their original positions, indicating that there is no interaction between the drug and the excipients. The characteristic peak of *Tribulus terrestris* is 3391.21 cm^{-1} due to its amino group i.e. N-H stretching. Another characteristic peaks present were 3746.05 cm^{-1} (-OHStretch), 2959.23 cm^{-1} (C-H bending), 2258.23 cm^{-1} (C=Cstretching), 1725.98 cm^{-1} (C=O) stretching), 1200.15 cm^{-1}(C-OH stretching). Similarly, the polymer utilised in the formulation displayed characteristic peaks that were unique from the drug, indicating that the drug is compatible with the polymer and leads to good stability.

Table 4: Results of pre-compression parameters

F. Code	Bulk density	Tapped density	% Carr's index	Hausner's ratio	Angle of repose
F1	0.61±0.025	0.64±0.78	7.82±3.22	1.085±0.96	22.43±3.45
F2	0.56±0.041	0.59±0.64	7.56±2.34	1.094±0.78	21.53±3.14
F3	0.65±0.025	0.68±0.34	7.94±2.14	1.078±0.89	22.42±2.45
F4	0.52±0.024	0.54±0.96	7.84±1.47	1.08±0.96	22.54±3.66
F5	0.62±0.078	0.69±0.79	8.16±1.98	1.104±0.94	22.76±3.47
F6	0.68±0.096	0.58±0.93	9.32±1.46	1.124±0.91	22.58±2.14
F7	0.57±0.063	0.61±0.88	6.06±2.45	1.061±0.90	22.63±2.36
F8	0.58±0.015	0.63±0.36	7.34±1.23	1.076±0.88	23.15±2.45
F9	0.54±0.014	0.58±0.78	7.36±2.34	1.073±0.87	23.16±2.96

Values are expressed in mean±SD (n=3)

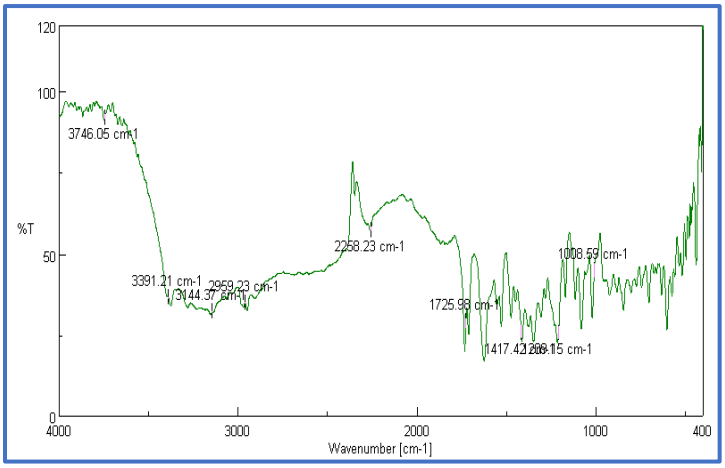

Fig. 1: IR spectra of pure drug (*Tribulus terrestris)*

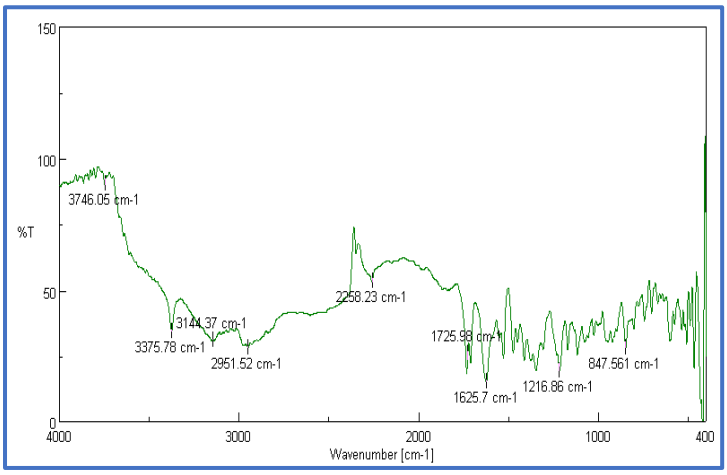

Fig. 2: FT-IR spectra of pure drug+excipients

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DSC thermogram of *Tribulus terrestris* and physical mixture of the formulation is shown is fig. 3 and 4. The thermogram of the extract showed an endothermic peak at 182.87 °C corresponding to its melting point. DSC thermogram for extract added a physical mixture of formulation show peak around at 101.35 °C and 181.87 °C. he thermograms of SSG indicated their melting points at 101.35 °C were according to their melting range. Indicated that there is no interaction between drug and the excipients.

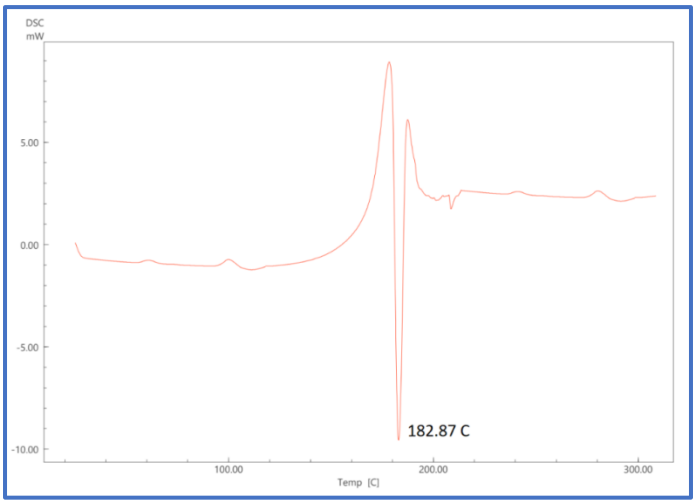

Fig. 3: DSC of extract (*Tribulus terrestris*)

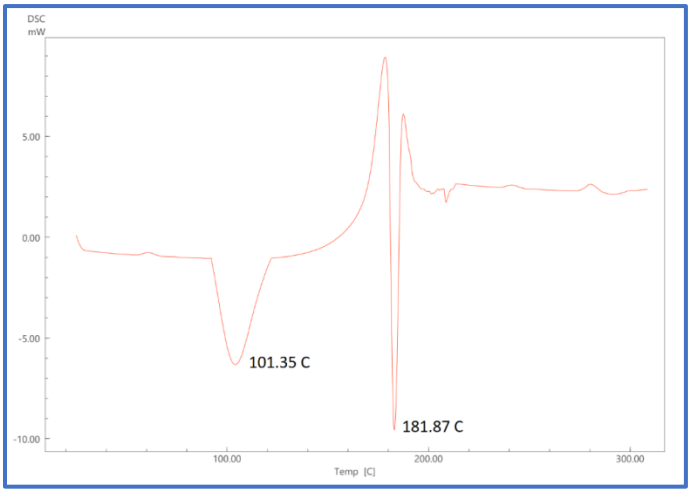

Fig. 4: DSC of extract+excipients

Table 5: Physical and mechanical properties of formulations

F. code	Hardness (kg/cm2)	Friability (%)	Weight variation (%)	Disintegration time (sec)	Wetting time (sec)	Drug content (%)	Water absorption ratio
F1	2.99±0.016	0.55±0.016	7.467±0.024	23.26±0.030	69.8±1.04	93.438±0.020	26±1.12
F2	2.94±0.075	0.33±0.017	3.447±0.096	28.89±0.067	39.0±0.95	97.527±0.094	28±1.34
F3	2.96±0.016	0.54±0.240	3.396±0.022	31.11±0.098	42.4±1.15	97.875±0.097	29±1.40
F4	3.13±0.18	0.91±0.019	3.416±0.098	32.91±0.065	89.0±0.85	97.489±0.098	30±1.20
F5	2.98±0.05	0.95±0.026	3.499±0.064	27.78±0.239	66.0±1.35	97.451±0.065	32±1.09
F6	2.98±0.024	1.08±0.098	3.319±0.067	20.05±0.027	36.4±1.48	97.587±0.027	36±1.59
F7	3.14±0.18	1.38±0.022	0.974±0.243	34.72±0.101	67.8±0.35	99.353±0.019	43±2.01
F8	3.06±0.06	0.55±0.066	2.431±0.023	30.09±0.249	41.7±1.45	97.905±0.249	45±2.06
F9	2.96±0.004	1.07±0.242	6.001±0.236	26.23±0.096	29.1±1.05	96.394±0.032	48±2.46

Data are represented as mean±SD (n=3)

Regression analysis

Analysis of variance revealed that all polynomial equations were statistically significant (P≤0.005) [33]. (ANOVA). The results of an ANOVA are shown in table 6 for each of the three replies. Table 5's multiple linear regression analysis findings show that all responses—weight variation, disintegration time, dispersion time, and content uniformity-were negatively impacted by the concentration of SSG (X2), but crospovidone (X1) had a negative impact on just some of these variables. This indicates a beneficial effect because as the concentration of crospovidone grows, the dispersion time increases along with the disintegration time, but when the concentration of SSG increases, both the dispersion time and the disintegration time increase. Therefore, high crospovidone and medium SSG dosage should be used to ensure that the tablets disintegrate quickly.

Table 6 summarises the results of the ANOVA for each of the three answers. The results of the multiple linear regression analysis, shown in table 5, indicate that the concentration of SSG (X2) had a negative effect, while the amount of crospovidone (X1) had a negative effect for all responses, i. H. Weight variation, disintegration time, dispersion time, and content uniformity. This means that the amount of crospovidone has a positive impact when the dispersion time, disintegration time, and dispersion time all increase. In comparison, the amount of SSG has a negative effect when both the dispersion time and the disintegration time rise. So, for the tablets to dissolve quickly, high crospovidone and medium SSG dosage should be used. Using surface response plots, the relationship between the dependent and independent variables was further clarified [25, 29]. The data from the response surface plots [fig. 5-7] showed that both X1 and X2 have an impact on the drug's disintegration, dispersion, and uniformity of content.

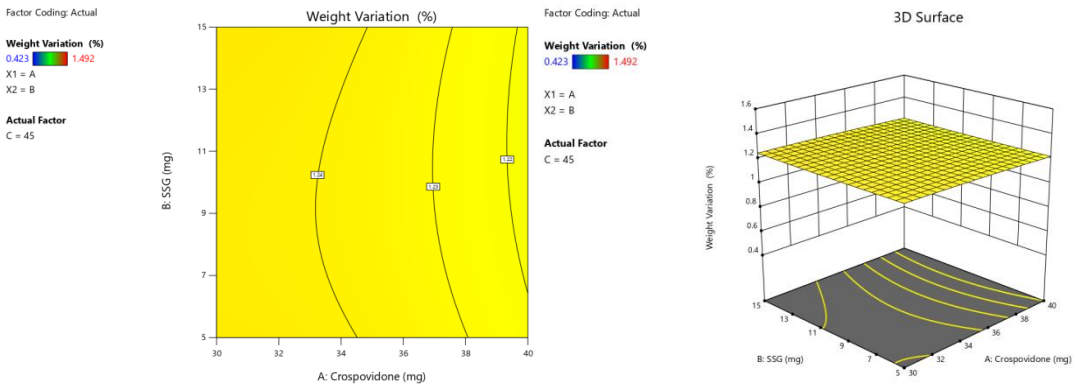

Fig. 5: Responses surface plots showing the effect of concentration of cross povidone and SSG on measured responses of weight variations

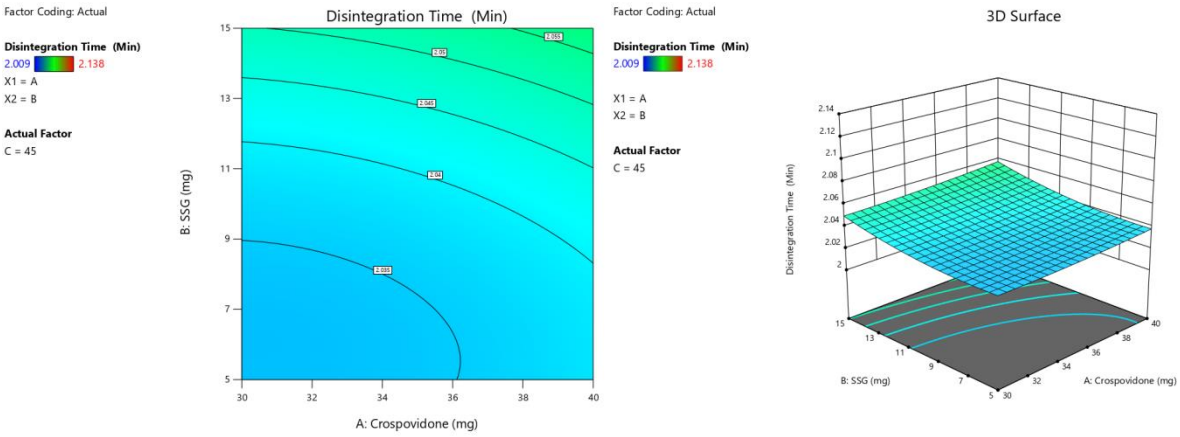

Fig. 6: Responses surface plots showing effect of concentration of cross povidone and SSG on measured responses of disintegration time (min)

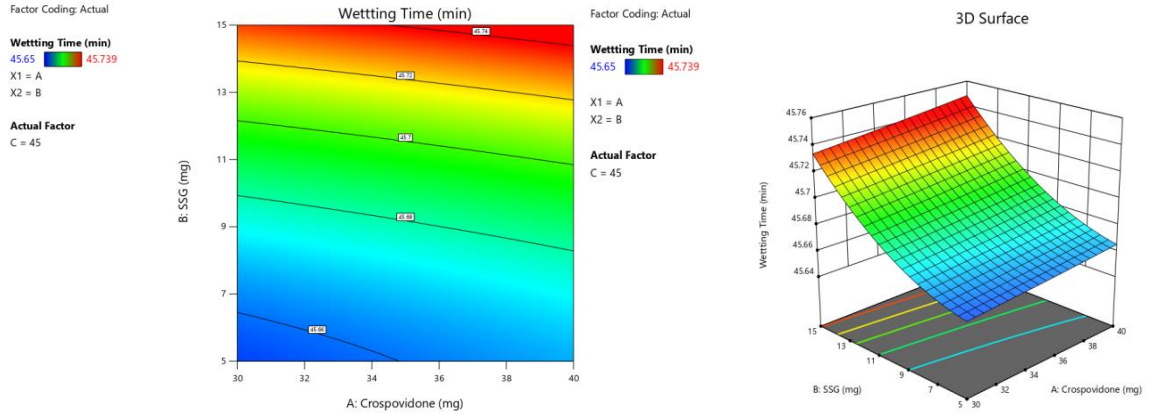

Fig. 7: Responses surface plots showing the effect of concentration of crosspovidone and SSG on measured responses of wetting time (sec)

Response surface analysis

The response surface models fit between the factors and measured responses is shown in the equations given below:

Weight Variation =+0.1.24+0.0132*A++0.0003*B+0.2606*C–0.0022*AB-00058A^{z}-0.7947B^{z}.

Disintegration Time =+2.04+0.0031*A+0.0090*B-0.0256*C+0.0009* AB+0.0013A^2+0.0052 B^2.

Wetting time=+45.69-0.0060*A+0.0403*B+0.0025*C+0.0013*AB+ 0.0003A^2+0.0142 B^2.

In vitro drug release study of formulation (F1-F9)

To determine the effect of cross povidone and SSG on the release pattern of *Tribulus terrestris*, the *in vitro* drug release tests of the manufactured MDTs were carried out (fig. 8). In 5 min, the drug release increased to 94.27% (F6). According to the findings, MDTs with 40 mg of Crospovidone and 10 mg of SSG are the formulation that maximizes *Tribulus terrestris* release [34].

Table 6: Summary of results of regression analysis and ANOVA for a measured response.

Response	Result value
Weight variation (%)	
F Value	118.84
P value	0.0084
R^2	0.9972
	Significant
Disintegration time (min)	
F Value	25.74
P value	0.0379
R^2	0.9872
	Significant
Wetting time (s)	
F Value	44.90
P value	0.0219
R^2	0.9926
	Significant

Table 7: *In vitro* drug release data of formulation F1-F9

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	10.52±0.65	15.89±0.59	9.79±0.38	8.24±0.84	12.57±0.57	39.89±0.78	12.04±0.68	10.52±0.35	8.02±0.48
2	22.85±0.45	33.21±0.87	21.38±0.98	18.18±0.62	26.91±0.09	68.21±0.39	25.88±0.82	22.85±0.86	17.73±0.47
3	30.96±0.56	43.82±0.98	29.08±0.52	24.92±0.87	36.1±0.76	80.82±0.73	34.8±0.53	30.96±0.28	24.32±0.98
4	52.34±0.36	68.44±0.67	49.7±0.94	43.64±0.87	59.17±0.27	91.44±0.38	57.5±0.42	52.34±0.92	42.73±0.67
5	67.13±0.38	82.27±0.39	64.32±0.84	57.68±0.34	73.91±0.84	94.27±0.91	72.29±0.75	67.1±0.53	56.66±0.39
6	81.29±0.59	90.04±0.38	78.7±0.62	86.23±0.57	93.33±0.33	98.04±0.47	94.93±0.29	79.29±0.25	91.2±0.38

*Data represent mean±SD, (n=3)

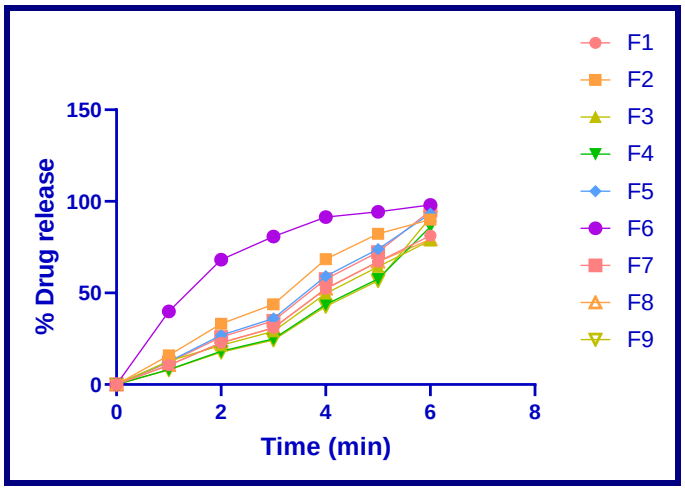

Fig. 8: Drug release (%) of formulations versus time (min)

DISCUSSION

The various MDT batches were created using the direct compression method, Crosspovidone, SSG, and various excipient concentrations. All formulations were then tested.[35,36] Ten distinct formulations with various excipient and pure drug concentrations were examined. All formulations showed weight differences of 3 to 5%, which USP considered to be within accepted limits for uncoated tablets. *In vitro* drug release ranged from 56.67 to 82.85% within 5 min, while MDTs (batch F1 to F10) displayed weight variation, a thickness of 2 to 3 mm, a drug content of 89.57 to 97%, a water absorption ratio of 26 to 48%, and a wetting time of 29.89 s. Of all the formulations, the best outcomes were produced by the most optimised formulas (F9 and F10). F6 is the most optimal formulation in both circumstances, with a disintegration time of 20 seconds. Different evaluation parameters were used to evaluate each formulation. Weight variation was the initial evaluation criterion, and it was applied to all 10 formulations [35].

According to the USP, weight variations were seen within MDT-acceptable limits. Steady decline is the main requirement for MDTs. The internal friction and cohesiveness of particles are determined by the angle of repose (h). A higher angle of repose value indicates stronger cohesion of the powder, whereas a lower value indicates non-cohesion of the powder [36]. Angle of repose values for all formulations indicated good to acceptable flow characteristics (30.31 to 39.28). The Carrs index displayed values up to 20, which denotes a flowability that is satisfactory to good. The values of Hausner's ratio in every formulation were within the predetermined range. Higher breaking strength (hardness) MDTs require more time to break apart. Therefore, the mechanical integrity of MDTs is crucial in their formulation. The tablets' hardness was determined to be between 2.1 to 2.9 kg/cm2 and their friability was found to be between 0.33 and 1.07%, which was likewise within accepted limits. The disintegration time was measured at 20 to 34 seconds. The disintegration test revealed rapid degradation in formulations with optimised concentrations of Crosspovidone and SSG. However, a formulation with more than 10 mg of SSG added had slower disintegration. This is because water from the medium is absorbed quickly. The swelling reduces the time required for disintegration [37]. As a result, the formulation with the highest level of optimization, 40 mg crossed povidone and 10 mg SSG, demonstrated quick disintegration. Wetting time and drug content percentage was also measured, and both parameters were confirmed to be within permissible ranges. In the instance of a prepared formulations, it was discovered that 98.04% of the active ingredient was released within the first 6 min. However, 68.21% of the medication was discharged in 5 min. As a result, the direct compression technique was crucial in improving drug release [38]. As a result, Formulation 6 was regarded as the ideal formulation. There is presently no interaction between *Tribulus terrestris* and other excipients, as indicated by the FT-IR spectra and DSC. This resulted in the conclusion that *Tribulus terrestris* MDTs had quick drug release, quick degradation, and quick onset of action.

CONCLUSION

The oral *Tribulus terrestris* disintegrating tablets created in this experiment had a successful drug release profile. The amount of super disintegrants reduces tablet disintegration time, shortens wetting time, increases cumulative drug release percentage, and improves absorption, according to the study's findings. These developments are anticipated to trigger additional major developments that will enhance patient outcomes and quality of life. An orally disintegrating tablet containing an extract of *Tribulus terrestris* was successfully designed and produced for the treatment of high blood pressure in the current work because of the use of Crosspovidone and SSG at the 40 mg and 10 mg conc. will give the good formulation a drug release with better mechanical strength.

ABBREVIATION

FTIR-Fourier transform infrared spectroscopy, DSC-Differential scanning calorimetry, MDT-Mouth dissolving tablet, SSG-sodium starch glycolate.

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AUTHORS CONTRIBUTIONS

SA performed the experiments, LB and PS supervised the study, RK guided and provided the facilities to conduct experiments, revisions and editing was done by HT.

CONFLICT OF INTERESTS

The authors declared that the No conflict of interest for the given article.

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