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Formulation and evaluation of sustained release tablets by *Tridax procumbens*

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Abstract

The objective of the present study was to formulate sustained release matrix tablets of *Tridax procumbens*, for treatment of bacterial infections. The matrix tablets were prepared by direct compression method using hydroxyl propyl methyl cellulose K4M, sodium alginate in various concentrations. The powder showed satisfactory flow properties and compressibility. All the formulations showed acceptable pharmacopoeia standards. The result of formulation F1. Successful formulation was found stable after evaluation for physicochemical parameters when kept for 90 days at room temperature, 40 ^{0}c and 2-8 ^{0}c. It concluded that sustained release matrix tablets of *Tridax procumbens* containing HPMC K4M and sodium alginate provide a better option for Sustained release of tridax.

Keywords: *Tridax procumbens*, Sustained release matrix tablets, polymers, direct compression technique, *in vitro* drug release studies

Introduction

Traditional medicines has important in India since hundreds of years and it has potential action on various diseases and disorders therefore it is an impactful way of treatment. Herbal drugs are becoming more popular in the modern world not only for their use but also for research because of their application to cure variety of diseases with less toxic effects and widespread availability and lower cost [1]. There are three main reasons for the popularity of herbal medicines. *Tridax procumbens* is a plant belongs to family *Asteraceae* and genus *Tridax*, it is also called as Tridax daisy. This plant is found easily in all parts of country either tropical or subtropical, rural part of Maharashtra has variety of uses of this plant, mainly in farmers, workers and other people related with farming profession [2]. Due its easy availability, its acceptance has grown exponentially. When we focus on uses and acceptance of this plant in the rural parts of the country [3]. Oral sustained (SR) systems continue to be the most popular ones among all the drug delivery systems. The basic goal of sustained release therapy is to achieve a steady state blood level that is therapeutically effective and non-toxic for an extended period of time, in order to reduce administration frequency and increase patient compliance using natural, safe polymers. It a good candidate for formulation into a sustained release tablet, which may improve patient compliance due to reduced frequency of administration [4]. Sustained release matrix tablets prepared by direct compression technique using polymers showed good sustaining drug release concluding that sustained release tablet could be successfully combined with accurate control and prolongation of the drug release patterns [5].

Materials

Tridax procumbens was obtained from Synpharma research Labs, HYD. were procured from Synpharma research Labs, Hyderabad, and other chemicals, and the reagents used were of analytical grade.

Methodology

Preparation of plant extract [6]

The aerial parts of plant (leaves, flowers, and stem) were shade dried for a week. The plant material were cut into fine pieces and dried powder (50 gm) of each part were extracted sequentially using soxhelet extractor with 250ml of hexane, chloroform, methanol and petroleum ether separately in order to extract non- polar and polar compounds [10]. The crude extract then filtered through whatmann filter paper no. 1 and concentrated extract was subsequently dried aseptically at room temperature.

Preparation of *Tridax procumbens* SR tablets

Formulation Table

Table 1: Formulation of *Tridax procumbens* sustained release tablets

S.no	Ingredients	F1	F2	F3	F4
1	*Tridax procumbens*	50	50	50	50
2	Sodium alginate	100	50	-	-
3	HPMC K15	-	-	100	50
5	MCC	45	95	45	95
6	Magnesium stearate	3	3	3	3
7	Talc	2	2	2	2
8	Total Wt	200	200	200	200

Weight variation [7]

Twenty tablets were randomly selected form each batch and individually weighed. The average weight and standard deviation of 20 tablets was calculated. The batch passes the test for weight variation test if not more then two of the individual tablet weight deviate from the average weight by more than the percentage shown in Table No 1 and none deviate by more than twice the percentage shown.

Thickness [8]

Twenty tablets were randomly selected form each batch and there thickness was measured by using vernier caliper. Thickness of three tablets from each batch was measured and mean was calculated.

Hardness [9]

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in kg/cm^2. Three tablets were randomly picked and hardness of the tablets were determined.

Friability [10]

Friability test is performed to assess the effect of friction and shocks, which may often cause tablet to chip, cap or break. Roche friabilator was used for the purpose. This device subjects a number of tablets to the combined effect of abrasion and shock by utilizing a plastic chamber that revolves at 25 rpm dropping the tablets at distance of 6 inches with each revolution. Twenty tablets were weighed and placed in the Roche friabilator, which was then operated for 25 rpm for 4 min. After revolution Tablets were dedusted and reweighed. Compressed tablets should not loose more than 1% of their weight.

The percentage friability was measured using the formula,

$$\% F = \{1-(Wo/W)\} \times 100$$

Where,
% F = friability in percentage
Wo = Initial weight of tablet
W = weight of tablets after revolution

Content Uniformity [11]

Twenty tablets from each batch were powdered and weighed accurately equivalent to 100 mg *Tridax procumbens*. Dissolve the weighed quantity of powder into 100 ml of 0.1 N NaOH solution by stirring it for 15 min. 01 ml of solution was pipette out into 10 ml volumetric flask and make up the volume with distilled water. Immediately analyze the drug by taking absorbance at 260 nm using reagent blank.

Disintegration time [12]

The disintegration time of tablets was determined by using Disintegration test apparatus (scientific). Tablets were placed in disintegration test assembly and disc was placed on tablets in each glass tube of assembly. The assembly was dipped in a vessel containing 900 ml distilled water at 37 °C. The time for disappearance of tablet residue above mesh was noted as disintegration time.

In- Vitro Release study [13]

In-Vitro drug release studies were carried out using Tablet dissolution test apparatus USP II at 100 rpm. The dissolution medium consisted of 900 ml of Standard buffer pH 1.2 for the first 2 hrs, followed by pH 6.8 for remaining period of time. Temperature maintained at 37±5. The sample of 5ml was withdrawn at predetermined time intervals and an equivalent amount of fresh dissolution fluid equilibrated at the same temperature was replaced. From that 5 ml sample, 1 ml sample was withdrawn and placed in a 10 ml volumetric flask and make the volume with distilled water. The diluted samples were assayed at 260 nm against reagent blank.

Stability studies [14]

The success of an effective formulation can be evaluated only through stability studies. The purpose of stability testing is to obtain a stable product which assures its safety and efficacy up to the end of shelf life at defined storage conditions and peak profile. The prepared Matrix tablets of *Tridax procumbens* were placed on plastic tubes containing desiccant and stored at ambient conditions, such as at room temperature, 40±2 °C and refrigerator 2-8 °C for a period of 90 days.

Results and Discussion

FT-IR Spectrum of *Tridax procumbens*

The compatibility between the drug and the selected Drug and other excipients was evaluated using FTIR peak matching method. There was no appearance or disappearance of peaks in the drug-excipients mixture, which confirmed the absence of any chemical interaction between the drug, polymers and other chemicals.

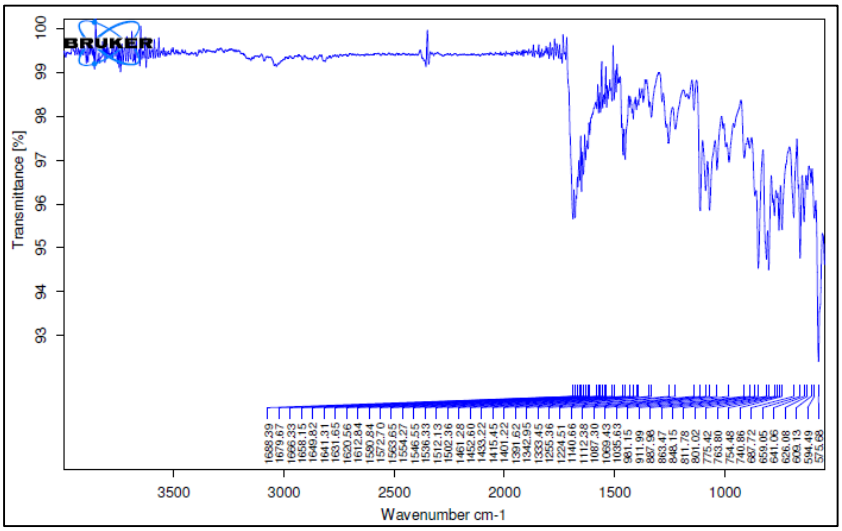

Fig 1: FTIR Studies of *Tridax procumbens* extract

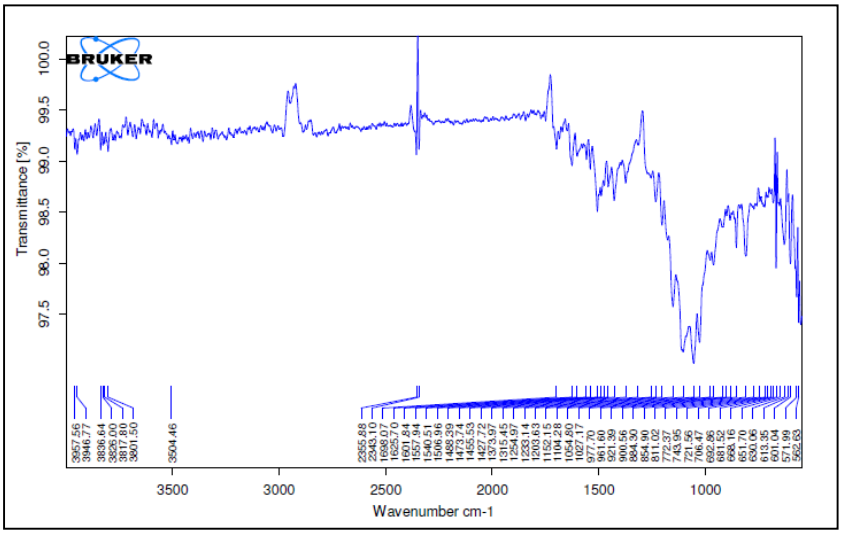

Fig 2: FTIR Studies of physical mixture of extract and excipients

Weight variation

All the formulated (F1 to F4) tablets passed weight variation test as the % weight variation was within the pharmacopoeial limits of ±7.5% of the weight. The weights of all the tablets were found to be uniform with low standard deviation values.

Thickness

Tablets mean thickness were uniform in F1 to F4 formulations and were found to be in the range of 2.07 mm to 2.15 mm.

Hardness

The measured hardness of tablets of each batch ranged between 2.6 to 2.10 kg/cm^2. This ensures good handling characteristics of all batches.

Friability

The % friability was less than 1% in all the formulations ensuring that the tablets were mechanically stable.

Content Uniformity

The percentage of drug content for F1 to F4 was found to be between 90.28 % to 95.86 % of *Tridax procumbens*, it complies with official specifications.

Disintegration Time

In the presented studies, three different types of *in vitro* methods of tablet disintegration were used: those where the only factor leading to the disintegration was water wicking into the matrix of the tablet, the tests with water agitation or stirring, and the methods where direct destructive forces were put on the tested tablet, such as grinding or pressing with additional weight. Therefore, disintegration tests showed great variability in the data measured with different methods.

Table 2: Evaluation parameters of *Tridax procumbens* tablets

F. No.	Weight variation (mg)	Thickness (mm)	Hardness (kg/cm^2)	Friability (%)	Drug content (%)	Disintegration time
F1	200	2.15	2.6	0.30	95.86	12
F2	201	2.13	2.8	0.32	94.24	10
F3	199	2.07	2.9	0.34	93.67	13
F4	200	2.10	2.10	0.32	90.28	17

Dissolution studies

All the 4 formulation of *Tridax procumbens* tablets were subjected to *in vitro* release studies these studies were carried out using dissolution apparatus. The dissolution medium consisted of 900 ml of Standard buffer pH 6.8 for period of time.

Table 3: Drug release studies of all formulations

Time	F1	F2	F3	F4
0	0	0	0	0
1	22.95	23.50	20.18	21.25
2	44.25	46.52	34.85	35.45
3	51.30	54.63	49.70	48.53
4	60.22	59.75	59.85	50.43
5	68.29	65.23	64.36	63.28
6	75.63	73.26	78.32	77.15
7	89.56	85.29	82.96	85.69
8	93.51	90.15	91.50	89.68

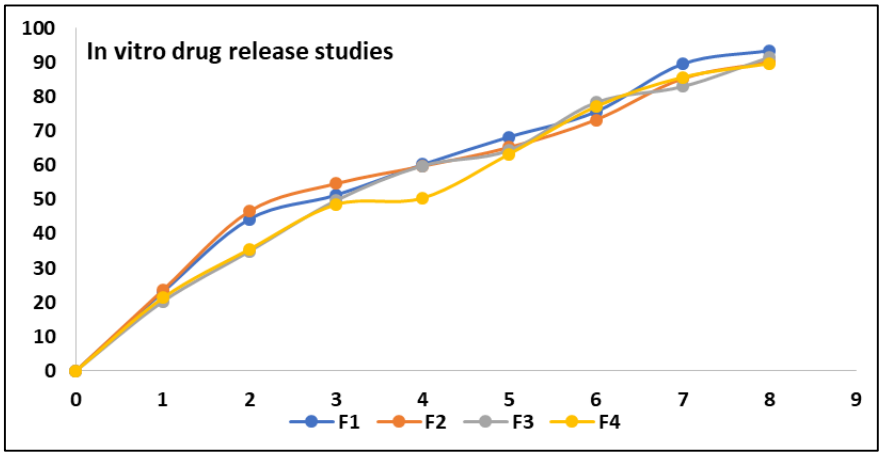

Fig 3: Dissolution Profile of F1 to F4 formulations

Stability Study

There was no significant change in physical and chemical properties of the tablets of formulation F-1 after 90 days. Parameters quantified at various time intervals were shown.

Table 4: Stability studies of all formulations

Formulation Code	Parameters	Initial	1st Month	2nd Month	3rd Month	Limits as per Specifications
F-1	25^0C/60%RH % Release	93.51	93.10	92.89	91.48	Not less than 85 %
F-1	30^0C/75% RH % Release	93.51	93.09	92.85	91.42	Not less than 85 %
F-1	40^0C/75% RH % Release	93.51	93.02	92.75	91.30	Not less than 85 %

Conclusion

Various formulations of sustained release tablets of *Tridax procumbens* were prepared by using different polymers *viz*, HPMC K15M and Sodium alginate in different proportions and combinations by direct compression technique. The tablets were evaluated for physical parameters, *in vitro* release study and stability studies. All formulations were found to be with in the specifications of official pharmacopoeias and/or standard references. In-vitro release indicated that the formulation F1 had better dissolution profile along with sustained action as compare to other formulations. Stability study was conducted on tablets of Batch F1 stored at room temperature, 40^0C, and 2-8^0C for one month. Tablets were evaluated for hardness, friability, in-vitro release profile and drug content. No significant changes were observed in any of the studied parameters during the study period (3 months), thus it could be concluded that formulation was stable.

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