Research Article Journal of Pharmacy and Pharmaceutical Research 2021
Vol.5 No.6

FORMULATION AND EVALUATION OF ORO-DISPERSIBLE TABLETS OF Tridax Procumbens HERBAL DRUG

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Introduction:
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 better therapeutic effects, widespread availability and lower cost. There are three main reasons for the popularity of herbal medicines:
1)There is a growing concern and doubts over the reliance and safety of modern drugs and surgery.
2)Many modern medicines are failing to treat the most common health conditions effectively. On the other side, many natural products and procedures are proving better than drugs or surgery without the side effects. [1]
3)Also there are increasing evidences which suggest that many current drug therapies simply suppress symptoms and ignore the underlying disease causes. In contrast, natural products appear to address the cause of many diseases and yield superior clinical results [2].
Our country has a vast knowledge base of Ayurveda whose potential is only being realized in the recent years. Unfortunately, most physicians and patients are not aware that these natural alternatives exist. However, the drug delivery system used for administering the herbal medicine to the patient is traditional and out-of-date, resulting in reduced efficacy and acceptance of the drug. Novel drug delivery system is a novel approach to drug delivery that addresses the limitations of the traditional drug delivery systems. Drug delivery system is the method by which an optimum amount of the concerned drug is administered to the patient in such a way that it reaches exactly the 'site of action' and starts working then and there. Novel drug delivery system attempts to eliminate all the disadvantages associated with conventional drug delivery systems. There are various approaches by which novel drug delivery can be achieved.[3,4]. Modern medicine cures a particular disease by targeting exactly the affected zone inside a patient's body and transporting the drug to that area.The method by which a drug is delivered can have a significant effect on its efficacy. Some drugs have an optimum concentration range within which maximum benefit is derived, and concentrations above or below this range can be toxic or produce no therapeutic benefit at all. On the other hand, the very slow progress in the efficacy of the treatment of severe diseases has suggested a growing need for a multidisciplinary approach to the delivery of therapeutics to targets in tissues. From this, new ideas on controlling the pharmacokinetics, pharmacodynamics, non-specific toxicity, immunogenicity, bio-recognition and efficacy of drugs were generated. These new strategies, often called drug delivery systems (DDS), are based on interdisciplinary approaches that combine polymer science, pharmaceutics, bio-conjugate chemistry and molecular biology.

PREPARATION: Tridax Procumbens leaves were collected in Palamuru University campus and authenticated by department of botany, authenticated leaves were separated, washed and dried under shade.
Tridax procumbens belongs to family Asteraceae, and commonly known as Gaddi chamanthi (in telugu), Vettukaaya – thalai (in tamil).
Tridax procumbens leaves have vast benefits like wound healing,
antidiabetic,antibacterial,antiplasmodial,antihepatotoxic , anti oxidant, anti microbial, immuno- modulatory and anti cancer.
The plant was collected from surrounding area of Palamuru University and authenticated by Department of Botany Palamuru University.Based on literature and traditional knowledge The leaves were selected for wound healing study.

EXTRACTION: The extracts of Tridax using a soxhlet extractor from Juice of fresh leaves, dried leaves powder, air dried whole plant is pulverized and extracts are prepared for 72 hours and the yield found to be 6% W/V at room temperature . Standard solutions were prepared in methanol for alkaloids and tannins,and methylene chloride for phytosterols.Extraction was carried out using Ethanolic Water mixture in the ratio of 7:3. To extract all the components by percolation for 48 hrs. The Extract was dried at 40ºc and stored in a desiccators . It is used for phyto-chemical screening and standardization

s.no	Concentration (µg/ml)	Mean absorbance 469 nm
1.	0	0
2.	10	0.603
3.	20	1.202
4.	30	1.813
5.	40	2.36
6.	50	2.903
7.	60	3.4
8.	70	3.884

TABLE: 1 standard calibration data

PREPARATION OF STANDARD CALIBRATION CURVE
The extracts are subjected to phyto-chemical screening using following standard procedures for determining chemical constituents.

- Test for Alkaloids
- Test for Tannins
- Test for Phenol
- Test for Falvonoids
- Test for Saponins

The extract is tested for organoleptic studies and physicochemical analysis like moisture content, loss on drying, ash value, acid insoluble value and water soluble value.

TABLE 2: PHYTOCHEMICAL ANALYSIS OF EXTRACT

Sr. No.	Parameters	Observation
1.	Colour	Dark Green
2.	Odour	Intense
3.	Taste	Bitter
4.	Moisture Content	0.42
5.	Loss on drying	9.5
6.	Ash Value	11.02%
7.	Acid insoluble value	2.0
8.	Water soluble value	4.5

COMPATIBILITY STUDIES OF DRUG AND FORMULATION COMPONENTS

The compatibility of drug and polymers under experimental conditions is important prerequisite before formulation.

It is therefore necessary to confirm that the drug does not react with the polymers and excipients under experimental conditions and not affecting the shelf life of product or any other unwanted effects on the formulation.

The physical mixture of drug & polymers was used for compatibility study.

Mixtures of extract and excipients were kept in sealed vials and observed for any change in physical properties.

TABLE 3: COMPATIBILITY STUDIES

Sample	Room temp	0
40 C in oven	30°C±2°C/	
65% ± 5%	40°C±2°C/	
75% ± 5%		
Extract +Lactose	No Change	No Change No Change No Change No Change
Extract +Mannitol	No Change	No Change No Change No Change No Change
Extract +PVP K 30	No Change	No Change No Change No Change No Change
Extract +Starch	No Change	No Change No Change No Change No Change
Extract +SSG	No Change	No Change No Change No Change No Change
Crosspovidone	No Change	No Change No Change No Change No Change
Extract+Crosscarmellose sodium	No Change	No Change No Change No Change No Change
Extract +Magnesium stearate	No Change	No Change No Change No Change No Change
Extract +Sod.Sacharine	No Change	No Change No Change No Change No Change
Extract +Citric acid	No Change	No Change No Change No Change No Change

FORMULATION AND EVALUATION OF ORO-DISPERSIBLE TABLETS OF HERBAL DRUG

Oro-dispersible tablets are defined as uncoated tablets intended to be placed in the mouth where they disperse readily within 3 min before swallowing.

Oro-dispersible tablets are also called as orally disintegrating tablets, mouth-dissolving tablets, rapid-dissolving tablets, fast-disintegrating tablets, fast-dissolving tablets.

Like all other solid dosage forms, they are also evaluated for hardness, friability, wetting time, moisture uptake, disintegration test, and dissolution test.

Formulation of ODT is done by using super disintegrants, binders, taste enhancers, glidants, diluents, anti oxidants.

Lactose,polyvinylpyrollidinek30,sodium starch glycolate,

crosspovidone,crascarmellosesodium,mannitol,magnesium stearate,starch, sodium saccharin, citric acid are used in formulating ODT.

ODTs are formulated by using direct compression method.

The accurately weighed materials were mixed with required quantities of superdisintegrants, lubricant and blended for 5 minutes in polybag to form a homogenous powder mix and pre formulation studies have been performed for this blends and compressed using 6mm round concave punch set on an instrumented 16-station rotary tablet press (Cadmach model CMD4, Ahmedabad, India).

TABLE 4: FORMULATION CHART FOR ORO-DISPERSIBLE TABLE

Ingredients	FORMULATIONS						
	F1	F2	F3	F4	F5	F6	F7 F8
Extract	30%	30%	30%	30%	30%	30%	30% 30%
Lactose	30%	30%	30%	30%	30%	30%	30% 30%
Mannitol	25.8	20.8	32.8	31.8	30.8	32.8	31.8 30.8
PVP K 30	2%	2%	2%	2%	2%	2%	2% 2% 2%
Starch	10%	15%	-	-	-	-	- -
SSG	-	-	3	4	5	-	- -
Crosspovidone	-	-	-	-	-	3	4 5
Crosscarmellose sodium	-	-	-	-	-	-	- - -

Magnesium stearate		1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Sod.Sacharine	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Citric acid	1%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%

TABLE 5: FORMULATION CHART FOR ORO-DISPERSIBLE TABLE

Ingredients	FORMULATIONS										
	F9	F10	F11	F12	F13	F14	F15	F16			
Extract	30%	30%	30%	30%	30%	30%	30%	30%			
Lactose	30%	30%	30%	30%	30%	30%	30%	30%			
Mannitol	32.8	31.8	30.8	32.8	31.8	30.8	31.8	31.8			
PVP K 30	2%	2%	2%	2%	2%	2%	2%	2%			
Starch	-	-	-	-	-	-	-	-			
SSG	-	-	-	-	-	-	2%	-			
Crosspovidone	-	-	-	--	-	-	2%	2%			
Crosscarmellose sodium	3	4	5	-	-	-	-	2%			
Magnesium stearate	1%	1%	1%	1%	1%	1%	1%	1%			
Sod.Sacharine	1%	1%	1%	1%	1%	1%	1%	1%			
Citric acid	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%			

TABLE 6 : PRE-FORMULATION STUDIES FOR POWDERED DRUG BLEND

Parameter	FORMULATIONS							
	F1	F2	F3	F4	F5	F6	F7	F8
Angle of repose	32±1.2							
%	33±1.4							
%	31±3.2							
%	32±2.1%		32±3.3					
%	32±1.4							
%	33±1.0							
%	30±1.2							
%								
Tapped Density								
3								
(g/cm)Vf	0.552	0.544	0.435	0.437	0.440	0.437	0.439	0.441
3								
Bulk Density (g/cm)								
V0	0.621	0.618	0.532	0.541	0.542	0.539	0.542	0.551
Cars index								
100× (vo-vf/ vo)	11.1	11.9	18.2	18.8	18.8	18.9	19	19.9
Hausners ratio vo/vf	1.125	1.136	1.222	1.237	1.231	1.233	1.234	1.249

TABLE 7 : PRE-FORMULATION STUDIES FOR POWDERED DRUG BLEND

Parameter	FORMULATIONS							
	F9	F10	F11	F12	F13	F14	F15	F16
Angle of repose	30±1.2							
%	31±1.2							
%	29±1.2							
%	30±1.2							
%	29±1.2							
%	31±1.4							
%	30±0.5							
%	29±1.7							
%								
Tapped Density	0.438	0.439	0.441	0.431	0.437	0.438	0.439	0.441
Bulk Density	0.536	0.530	0.544	0.561	0.549	0.531	0.531	0.537
Cars index	18.2	17.1	18.9	23.1	20.4	17.5	17.3	17.8
Hausners ratio	1.223	1.207	1.233	1.301	1.256	1.212	1.209	1.217

POST COMPRESSION EVALUATION PARAMETERS

TABLE 8: POST COMPRESSION EVALUATION PARAMETER

Parameters	FORMULATIONS							
	F1	F2	F3	F4	F5	F6	F7	F8

Weight variation	250±1.1	250±0.8	250±1.3	250±0.7	250±2.0	250±0.6
	250±0.7	250±1.0				
Hardness		3.2±0.2				
2	3.1±0.4					
2	3.0±0.8					
5	3.2±0.3					
2	3.3±0.0					
1	3.2±0.6					
4	3.1±0.2					
1	3.2±0.4					
2						
Friability		0.82	0.92	0.86±	0.82	0.86
	0.88	0.75	0.81			
Wetting time						
(Sec)	39±0.8	37±18	23±1.0	22±0.7	21±0.8	22±0.8
	22±1.8	22±2.8				
Absorption						
ratio (%)	92.07	97.06	98.05	97.06	97.01	98.09
	96.03	97.45				
Disintegratio						
n time (Sec)		258±1.3	209±0.8	30±0.12	26±0.18	25±0.7
	31±0.9	26±0.18	25±0.6			

TABLE 9: POST COMPRESSION EVALUATION PARAMETER

Parameters	FORMULATIONS					
	F9	F10	F11	F12	F13	F14
	F15	F16				
Weight variation	250±0.					
5	250±0.					
7	250±0.					
6	250±0.2					
3	250±0.8					
0	250±0.3					
2	250±0.1					
4	250±0.5					
3						
Hardness		3.3±0.3				
1	3.2±0.9					
1	3.2±0.0					
1	3.0±0.2					
1	3.2±0.4					
4	3.2±0.3					
2	3.2±0.6					
1	3.3±0.4					
6						
Friability		0.82	0.83	0.84	0.86	0.88
	0.89	0.80	0.81			
Wetting time (Sec)		22±3.1	22±0.5	24±0.8	23±0.7	22±0.9
	28±0.8	21±0.8	21±0.1			
Absorption ratio (%)	96.35	98.06	97.97	94.28	96.19	97.36
	98.22	98.76				
Disintegrati on time (Sec)	25±0.8	32±1.3	29±2.8	25±2.2	33±2.9	27±0.6
	25±2.1	22±1.3				

Results and Discussion: According to the evaluation parameters the formulation F16 was selected as optimized as the superdisintegrants crosspovidone and crasscarmellose sodium has shown a good and fast disintegration.carbopol 934, Xanthan gum, carbopol 940 and carbopol 71G NF polymers, glycerin, propylene glycol, ethanol, Transcutol P and triethanolamine were prepared desirable gel characteristics good efficacy of the topical delivery of herbal drugs. The prepared formulations were evaluating for their physical appearance, pH, viscosity, Spreadability, grittiness, homogeneity, swelling index and drug content. In our study we find that formulation F2, F4, F7 and F10 show good gelling properties with concern to the above evaluation parameters. By comparing the all formulations of herbal gel they are further evaluated for in vitro drug release study, in which the formulation F2 and F10 showed highest release in 8 hr's. The kinetics of invitro drug release showed that, the F2, F4, F7 and F10 formulations had good release kinetics and showed non fickian drug release as the n value was between 0.8 to 0.9. From these release parameters, formulations F2 and F4 showed highest release of herbal drugs in 8 hr's. These results suggest the improvement of efficacy of topical gel for the treatment of psoriasis. The enhanced efficacy of herbal gel is due to increased penetration of drugs from hydrogel than conventional formulations