www.ThePharmaJournal.com

The Pharma Innovation

ISSN: 2277- 7695
TPI 2014; 3(6): 01-03

www.thepharmajournal.com
Received: 02-07-2014
Accepted: 14-07-2014

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Formulation development and evaluation of antidiabetic polyherbal tablet

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ABSTRACT
In the present study a solid pharmaceutical dosage form (Tablet) was prepared using hydro-alcoholic extracts of *Cassia fistula* (Stem Bark), *Tamarindus indica* (Stem Bark) and *Tectona grandis* (Heart Wood) by the direct compression method. Various combinations of dried granules of powdered extracts were prepared and characterized on the basis of pre-formulation parameters like angle of repose, loose bulk density, tapped bulk density, loss on drying, compressibility index and Hausner ratio etc. Pre-formulation study of the granules showed that all the evaluated parameters were within the acceptable limits. The tablets were evaluated for various parameters like Hardness, Friability, Disintegration time etc. Among six formulations prepared (F1 to F6), F3 showed appreciable results.

Keywords: Hydro-alcoholic extract, Heart Wood, Tablet, *Cassia fistula, Tectona grandis, Tamarindus indica*

1. Introduction
Plants have formed the basis of sophisticated traditional medicine systems that have been in existence for thousands of years [1]. In the early development of modern medicine, biologically active compounds from higher plants have played a vital role in providing medicines to combat various diseases. Plant-derived medicines continue to occupy an important niche in the treatment of diseases in developing countries worldwide. Around 75-80% of the world population depends on crude plant drug preparations to treat their health problems. Economic considerations, safety, adherence to the traditional practices can be the reason behind using the plant based medicines [2].
Pharmaceutical manufactures all over the word are also focusing on plant based medicines. A number of plants have been evaluated for their pharmacological activities and quite many active constituents have been isolated. Previous study was such an attempt to evaluate the pharmacological potential of *Cassia fistula* (Stem Bark), *Tamarindus indica* (Stem Bark) and *Tectona grandis* (Heart Wood) [3, 4]. To make the study more worth, an attempt was made to prepare a pharmaceutically acceptable dosage form of the above mentioned extracts.

2. Materials and Methods
Stem barks of *Cassia fistula* and *Tamarindus indica* were collected around the area near Greater Noida U.P. India. *Tectona grandis* heart wood was collected from the area around Noida, U.P. (India). Herbariums of the collected herbs were submitted at the National Bureau of Plant and Genomic Research (NBPGR), Pusa Campus, New Delhi, India for authentication and voucher no. NHCP/NBPGR/2009/1 was provided. The hydro-alcoholic extraction of course powdered drugs were carried out in Soxhlet extractor and dried under vacuum followed by lyophilization. The antidiabetic activity by using alloxan induced diabetic model was carried out [5].

2.1 Preparation of Tablets
The dried plant extracts were mixed with the excipients and compressed into tablets. The details of the composition are given in Table 1.

2.2 Evaluation of Formulated Tablets
2.2.1 Pre-formulation studies [6, 7]
a. Angle of repose
Angle of repose was determined by using funnel method. The accurately weighed blend was taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel

just touches the apex of the heap or head of blend. The drug excipient blend was allowed to flow through the funnel freely on to the surface. The diameter of the powder cone was measured and angle of repose was calculated using the following equation:

$$\tan \theta = h/r$$

Where, h = height of powde
r cone formed
r = radius of the powder cone formed

Table 1: Composition of formulation ingredients

Ingredients	Batch No.					
	Quantity per tablet (mg)					
	F1	F2	F3	F4	F5	F6
***Cassia fistula* extract**	100	100	100	100	100	100
***Tamarindus indica* extract**	100	100	100	100	100	100
***Tectona grandis* extract**	100	100	100	100	100	100
Ethyl cellulose	-	-	-	20	30	40
Microcrystalline cellulose	40	40	40	40	40	40
Dibasic calcium phosphate	30	20	10	30	20	10
PEG 400	10	10	10	10	10	10
Methyl paraben	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Weight per tablet	380	380	380	400	400	400

Table 2: Relationship between angle of repose (θ) and powder flow

Angle of Repose (θ)	Type of flow
<25	Excellent
25-30	Good
*30-40	Passable
>40	Very poor

*Adding the glidant e.g. 0.2% aerosol, may improve flow

b. Loose bulk density
Apparent bulk density was determined by pouring a weighed quantity of blend into graduated cylinder and measuring the volume and weight.
LBD = Weight of the powder / volume of the packing

c. Tapped bulk density
It was determined by placing a graduated cylinder, containing a known mass of drug excipient blend. The cylinder was allowed to fall under its own weight on to a hard surface from the height of 10 cm at two second intervals. The tapping was continued until no further change in volume was noted.
TBD = Weight of the powder/vol of the tapped packing

d. Compressibility index
The Compressibility index of the blends was determined by Carr's compressibility index.
Compressibility index (%) = (TBD-LBD) x 100/TBD

Table 3: Grading of powders for their flow properties

Consolidation index (Carr's index)	Flow
5-15	Excellent
12-16	Good
*18-21	Fair to Passable
*23-35	Poor
33-38	Very poor
<40	Very Very poor

e. Hausner ratio
It is the measurement of frictional resistance of the drug. The ideal range should be 1.2-1.5. It is determined by using the following formula: Hausner ratio= TBD / LBD

f. Loss on drying
A well-mixed granules (1g) was transferred into a dried, glass stoppered shallow weighing bottle. The contents were distributed evenly and placed in the drying chamber. The stopper was removed from the bottle and the contents were dried for a specified time to achieve a constant weight.
Loss on drying (%) = [(Initial weight – Final weight)/ (Initial weight)] x 100

2.3 Physical evaluation of tablets [6, 7]
All the formulated tablets were subjected to following evaluation parameters:

a. Color and appearance
The compressed tablets were examined for their color and appearance.

b. Weight variation test
The average weight was determined by randomly selecting and weighing 20 tablets. Each tablet was also weighed individually. The deviation from the average weight in each case was calculated and expressed as a percentage. Not more than two of the tablets from the sample size deviate from the average weight by a greater percentage and none of the tablets deviate by more than double that percentage.

c. Hardness and Friability test
The hardness and friability were tested for the tablets by using calibrated hardness tester (Monsanto) and Roche friabilitor (4 minute at 25 rpm) tests respectively.

d. Disintegration test for tablets
A glass of plastic tube 80-100 mm long with an internal diameter of about 28 mm and external diameter 30-31 mm fitted at the lower end with a disc of rust proof wire gauge. Six tablets were placed in the tube, raise and lower the tube in such a

manner that the complete up and down movement is repeated 28 to 32 per minute. The tablets are disintegrated when no particles remains above the gauge, which readily pass through mesh (10 mesh screen).

e. Thickness and Diameter

The thicknesses and Diameter of the tablets were evaluated by using Vernier calipers.

3. Results and Discussion

The various combinations of dried granules of powdered extracts of *C. fistula, T. indica* and *T. grandis* were prepared and characterized on the basis of pre-formulation studies including parameters like angle of repose, loose bulk density, tapped bulk density, loss on drying, compressibility index and Hausner ratio etc. Preformulation study of the granules showed that all the evaluated parameters were within the acceptable limit.

All the six formulations were evaluated for their hardness, thickness, friability, weight variation, moisture content and *in-vitro* disintegration time. The hardness of formulation was measured in kg/cm^2 with the help of Monsanto tester. Amongst all the formulations prepared, F3 has been found to be the most acceptable one in terms of weight variation and *in vitro* disintegration time. This formulation showed appreciable hardness characteristics (4.1), which facilitated its fast disintegration. The friability (0.73) of formulation indicated that the tablets were mechanically stable. As the average weight of tablets was 380 mg, the acceptable weight variation range is ±5%. Hence the entire formulated tablet passed the weight variation test. The disintegration time of formulation was not more than 20 Minute.

Table 4: Pre-formulation studies of dried granules

Batch	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's ratio	Angle of repose (^{0})
F1	0.48	0.54	12.50	1.13	29.1
F2	0.45	0.52	15.56	1.16	32.0
F3	0.46	0.51	10.87	1.11	23.6
F4	0.44	0.5	13.64	1.14	31.2
F5	0.51	0.57	11.76	1.12	27.47
F6	0.43	0.55	27.91	1.28	30.96

Table 5: Standardization of formulated tablets

Batch	%Weight variation (±5%)	Hardness (Kg/cm^2)	Thickness (mm)	Diameter (mm)	% Friability (NMT 1%)	Disintegration time
F1	±2.51	4.2±0.02	4.5±0.02	11.1±0.03	0.69±0.01	19 min 50 sec
F2	±2.48	4.0±0.02	4.6±0.02	11.2±0.02	0.79±0.01	18 min 15 sec
F3	±1.99	4.1±0.01	4.6±0.02	11.1±0.02	0.73±0.01	15 min 15 sec
F4	±2.60	4.1±0.03	4.7±0.02	11.1±0.02	0.79±0.01	20 min 25 sec
F5	±2.21	4.0±0.03	4.6±0.02	11.2±0.03	0.76±0.02	17 min 30 sec
F6	±2.71	4.0±0.9	4.5±0.02	11.1±0.03	0.87±0.02	18 min 35 sec

The results expressed as mean ± standard error (SEM).

Results of pre-formulation study of granules and standardization parameter of formulated tablet showed that all the parameters evaluated were ±within the acceptable limits. Results of physical evaluation concluded that formulation had acceptable hardness, friability and disintegration time.

4. Conclusion

It can be concluded that formulated tablets of hydro-alcoholic extracts of *C. fistula, T. indica* and *T. grandis* qualify the parameters under study. However, further investigations are required to evaluate the other qualitative, quantitative parameters and stability etc.

5. Acknowledgement

The authors are duly thankful to R.V. Northland Institute for providing necessary facilities to successfully carry out the present study.

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