ISSN 0976 – 3333

Available Online at www.ijpba.info

International Journal of Pharmaceutical & Biological Archives 2017; 8(3): 28-32

RESEARCH ARTICLE

Formulation and Development of Fast Dissolving Tablet of Methanolic Extract of Some Traditionally Used Medicinal Plants for Arthritis

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Received 19 Mar 2017; Revised 07 Jun 2017; Accepted 20 Jun 2017

ABSTRACT

Aim: The aim of the study is to formulate fast dissolving tablet of Methanolic Extract of Some Traditionally Used Medicinal Plants for Arthritis. **Material & Methods:** Fast dissolving tablet of methanolic extract of selected medicinal plants were prepared by using Crospovidone & β-cyclodextrin by kneading methods. Various physicochemical parameter i.e. angle of repose, bulk density, tapped density; drug content, disintegration time etc were studied. **Results** Hardness of tablets was between 3.2-3.7kg/cm2 for all the formulations. Friability was found in between 0.62-0.69%. The friability value below 1% was an indication of good mechanical resistance of the tablet. The drug: content was found to be 98.18- 102.50% which was within the acceptable limits. Formulations F1, F4 and F7 which contains 3% super disintegrates releases 97.43%, 91.00% and 93.75% drug respectively at the end of 60 min. **Conclusion:** The prepared herbal fast dissolving tablets shows good disintegration property and dissolution rate. The comparative study of several superdisintegrants yielded a conclusion that Crospovidone at 3% concentration are suitable for the preparation of Herbal fast dissolving tablets which will satisfy all the criteria and official limits.

Key words: Fast Dissolving Tablet, Methanolic Extract, Crospovidone, Disintegration, *Nyctanthes arbor-tristis*

INTRODUCTION

Fast dissolving Tablets are disintegrating or dissolve rapidly in the saliva without the need for water. Some tablets are designed to dissolve in saliva extremely fast, within a few seconds, and are true fast-dissolving tablets. Such formulations provide an opportunity for product line expansion in the many elderly persons will have difficulties in taking conventional oral dosage forms (viz., solutions, suspensions, tablets, and capsules) because of hand tremors. Swallowing problems also are common in young individuals because of their underdeveloped muscular and nervous systems. Other groups that may experience problems using conventional oral dosage forms include the mentally ill, the developmentally disabled, and patients who are uncooperative, are nauseated (Vaidya & Devasagayam, 2007). In our previous study, it has been observed that *Nyctanthes arbor-tristis* (leaf), *Alstonia scholaris* (leak and bark), *Butea monosperma* (flower) showed potent anti-arthritic activity in FCA induced arthritis model (Kirtikar & Basu, 2006; Nadkarni, 2002). Hence an attempt was made to formulate fast dissolving tablet of methanolic extract of above mentioned plants. To achieve this goal, MCC is used as diluents and sodium saccharin as sweetening agent for the formulation of tablets. Attempts were made to enhance dissolution rate along with faster disintegration using superdisintegrants like Crospovidone, Sodium starch glycolate (SSG)and mixture of crospovidone and sodium starch glycolatein the formulation of tablets.

MATERIAL & METHODS

Collection and authentication of the plant materials

The leaves of *Nyctanthes arbor-tristis* and *Alstonia scholaris* and roots of *Boerhaavia diffusa* and flowers of *Butea monosperma* were collected from outfield and also purchased from local markets. Plant was identified by the Botanist, Research Officer; Botany (Scientist C) at Central Council for Research in Ayurveda, Govt. of India.

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Preparation of Total Crude Extract

Accurately weighed quantity of leaf powder of *Nyctanthes arbor-tristis* and *Alstonia scholaris*, dried flowers of *Butea monosperma* were defatted by using petroleum ether. The mark were dried, weighed and then again extracted by using methanol by soxhlet apparatus for 72 h. The extract of all plants were dried completely under reduced pressure and finally converted into powder. After drying, the respective extracts were weighed and percentage yield was determined (Mukherjee, 2002).

Preliminary Phytochemical Tests

Qualitative chemical tests of Methanolic extracts were subjected to various chemical tests to detect various phytoconstituents (Kokate, 2003; Khandelwal, 2006).

Preformulation Study of for the Preparation of Tablets

Powder Characteristics

Herbal powders are of wide range with varied physical properties and micromeritic properties. Powdered solids are heterogeneous because they are composed of individual particles of widely differing sizes and shapes randomly interspersed with air spaces. (Lai, 2004)

Angle of repose

Flow properties of the physical mixtures of all the formulations were determined by calculating angle of repose by fixed height method. A funnel with 10 mm inner diameter of stem was fixed at a height of 2 cm. over the platform. About 10 gm of sample was slowly passed along the wall of the funnel till the tip of the pile formed and touches the steam of the funnel. A rough circle was drawn around the pile base and the radius of the powder cone was measured. (Lai, 2004)

Angle of repose was calculated from the average radius using the following formula.

$\Theta = \tan^{-1} (h/r)$

Where; Θ= Angle of repose

h = Height of the pile

r = Average radius of the powder cone

Bulk density

Bulk densities of all types of granules were determined by pouring gently 25 gm of sample through a glass funnel into a 100 ml graduated cylinder. The volumes occupied by the sample were recorded. Bulk density was calculated. (Lai, 2004)

$$\text{Bulk density (g/m)} = \frac{\text{weight of sample in gms}}{\text{volume occupied by the sample}}$$

Tapped density

Tapped densities of all types of granules were determined by pouring gently 25 gm of sample through a glass funnel into a 100 ml graduated cylinder. The cylinder was tapped from height of 2 inches until a constant volume was obtained. Volume occupied by the sample after tapping were recorded and tapped density was calculated. (Lai, 2004)

$$\text{Tapped density (g/ml)} = \frac{\text{weight of sample in gms}}{\text{volume occupied by the sample}}$$

Compressibility

It is also one of the simple methods to evaluate flow property of powder by comparing the bulk density and tapped density. A useful empirical guide is given by the Carr's compressibility. (Lai, 2004)

$$\text{Carr's index} = \frac{\text{Tapped density} - \text{bulk density}}{\text{Tapped density}} \times 100$$

Preparation of fast dissolving tablet

Herbal Fast dissolving tablets were prepared by direct compression method using various formulation additives in varying concentrations. All the ingredients were powdered separately in a clean and dry porcelain mortar and then they were passed through # 60 mesh sieve. The extract and β-cyclodextrin were complexed (kneading method) and then all the additives were mixed thoroughly in an inflated polyethylene pouch in a geometric ratio of their weight. Then the powder mixture was compressed in to the tablets of 500 mg weight. (Patil *et al*., 2011).

Table 1: Formulation of fast dissolving tablets of methanolic extracts (Formula as per 500 mg)

Ingredients (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Extract of *Nyctanthes arbor-tristis*	100	100	100	100	100	100	100	100	100
Extract of *Alstonia scholaris*	100	100	100	100	100	100	100	100	100

Extract of *Butea monosperma*	100	100	100	100	100	100	100	100	100
β-cyclo dextrin	100	100	100	100	100	100	100	100	100
Crospovidone	15	-------	-------	15	-------	-------	15	-------	-------
Sodium starch glycolate	-------	20	-------	-------	20	-------	-------	20	-------
Mixture of CP + SSG	-------	-------	25	-------	-------	25	-------	-------	25
MCC	65	60	55	65	60	55	65	60	55
Sodium saccharin	10	10	10	10	10	10	10	10	10
Mg.sterate	5	5	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5	5	5
Total	500	500	500	500	500	500	500	500	500

Evaluation of tablets

The tablets from all the batches were evaluated for different parameters as follows:

Appearance

Tablets were evaluated for organoleptic properties (Patil *et al*., 2011).

Weight Variation

Ten tablets were selected and average weight was determined. Then individual tablets were weighed and the individual weight was compared with an average weight (Patil *et al*., 2011; Mehta, 2002).

Friability

Pre-weighed sample of tablets was placed in the Roche Friabilator tester, which was then operated for 100 revolutions. Tablets were deducted and reweighed; tablets should not lose more than 1% of their initial weight (Patil *et al*., 2011; Mehta, 2002).

Dispersion time

Two tablets were placed in 100 ml of water and stirred gently until completely dispersed. A smooth dispersion was obtained which passes through a sieve screen with a nominal mesh aperture of 710 μm (Patil *et al*., 2011; Mehta, 2002).

Wetting Time

A piece of tissue paper (12cmx10.75cm) folded twice was placed in a Petri dish containing 10 ml of water. Containing Eosin, a water soluble dye, was added to Petri dish. A tablet was carefully placed on the surface of the tissue paper and allowed to wet completely. The time required for water to reach upper surface of the tablet was noted as a wetting time (Patil *et al*., 2011; Mehta, 2002).

Disintegration Time

The disintegration time of tablet was measured in water (37 0C) according to USP Disintegration test apparatus (Patil *et al*., 2011; Mehta, 2002).

Hardness

Tablets were selected at random from each formulation and hardness was checked using Monsanto Hardness Tester (Majumdar and Nikam 2009).

Drug content

Drug content of all the batches was determined. Six tablets were weighed and crushed with pestle in a small glass mortar. The fine powder was weighed to get 500 mg, and transferred to 250 ml conical flask containing 100 ml of Distilled water stirred for 45 min in ultra sonicator. Solution was filtered and the filtrates obtained were analyzed UV spectrophotometrically and drug content was determined (Jadhav *et al*., 2011).

In-vitro Dissolution

The in vitro dissolution study was performed in the USP apparatus type II Aliquot equal to 5 ml of dissolution medium was withdrawn at specific interval and replaced with fresh medium for maintaining sink condition. Sample was filtered and absorbance of filtered solutions determined by UV spectroscopy. Dissolution rate was studied for all formulations (Jadhav *et al*., 2011).

RESULTS

Physicochemical evaluation of tablets

The results of physicochemical evaluation of tablets are given in Table 2 & 3. As the material was free flowing, tablets were obtained of uniform weight due to uniform die filling. Hardness of tablets was between 3.2-3.7kg/cm2 for all the formulations. Friability was found in between 0.62-0.69%. The friability value below 1% was an indication of good mechanical resistance of the tablet. The drug content was found to be 98.18-102.50% which was within the acceptable limits. The disintegration time is shorter with quick wetting properties at the core of the tablets. The wetting time/dispersion time decreases with increase in the concentration of super disintegrates.

Table 2: Micromeritic parameters of physical mixtures containing methanolic extract

Formulation	Angle of Repose (gm/ml)	Bulk Density (gm/ml)	Tapped Density	Compressibility
F1	31.12	0.48	0.52	24.41
F2	25.22	0.44	0.56	15.36
F3	27.22	0.45	0.57	17.63
F4	25.27	0.48	0.55	14.75
F5	24.23	0.44	0.58	15.78
F6	28.24	0.42	0.53	16.22
F7	22.22	0.43	0.51	18.44
F8	28.27	0.44	0.58	16.71
F9	21.23	0.46	0.52	12.74

Table 3: Evaluation of polyherbal tablet by different parameters

Formulation	Hardness (kg/cm2)	% Weight variation	% Friability	Disintegration time	Wetting Time	Drug Content
F1	**3.2±0.09**	**1.11±0.16**	**0.58±0.05**	**20 sec**	**43 sec**	**101.12**
F2	3.5±0.01	2.23±0.18	0.64±0.18	47 sec	2min 12sec	82.65
F3	3.1±0.08	2.34±0.19	0.66±0.15	1 min 15 sec	3min 34sec	94.27
F4	3.7±0.04	2.22±0.18	0.67±0.17	1 min 32 sec	1 min 31sec	97.34
F5	3.2±0.02	2.21±0.16	0.61±0.16	1 min 48 sec	2min 42 sec	91.89
F6	3.5±0.06	2.45±0.13	0.67±0.15	1 min 55 sec	2 min 43 sec	99.52
F7	3.3±0.05	2.16±0.22	0.64±0.14	59 sec	1 min 57 sec	98.44
F8	3.1±0.03	2.26±0.16	0.63±0.13	1 min 10 sec	3min 22sec	97.17
F9	3.7±0.01	2.44±0.19	0.61±0.33	1 min 45 sec	2 min 50 sec	99.13

In vitro release study

In table no 4, Formulations F1, F4 and F7 which contains 3% super disintegrates releases 97.43%, 91.00% and 93.75% drug respectively at the end of 60 min. An increase in the drug release was observed when 3% super disintegrants used in formulations. The rapid drug dissolution might be due to easy breakdown of particles and rapid absorption of drug into the dissolution medium.

Table 4: Drug Release Profile from Formulation

Time (min)	F1 %	F2 %	F3 %	F4 %	F5 %	F6 %	F7 %	F8 %	F9 %
2	0.97	1.33	1.98	2.45	1.22	1.10	2.14	1.93	11.44
4	11.15	22.31	13.04	12.32	12.24	11.13	11.15	11.20	11.22
6	33.42	31.33	35.04	37.21	31.62	32.14	33.23	30.94	32.52
8	45.55	46.25	42.57	42.12	42.33	43.12	41.20	40.22	41.28
10	55.01	54.22	64.07	60.10	63.22	53.31	58.11	53.60	45.54
15	68.74	62.76	71.46	72.12	71.51	64.34	62.14	65.98	63.42
20	77.92	73.11	73.58	74.92	72.00	72.21	74.15	72.62	77.41
25	86.67	75.87	85.12	81.24	81.22	81.23	78.12	79.92	82.15
30	83.25	84.31	83.28	85.22	82.64	82.22	82.35	83.04	81.64
45	90.96	86.15	90.94	91.42	90.83	91.21	89.32	90.01	89.55
60	96.01	91.43	92.19	93.14	92.82	93.22	91.12	91.43	90.51

DISCUSSION

Fast dissolving Tablets are disintegrating or dissolve rapidly in the saliva without the need for water. Some tablets are designed to dissolve in saliva extremely fast, within a few seconds, and are true fast-dissolving tablets. Others contain agents to increase the rate of tablet disintegration in the oral cavity, and are more appropriately termed fast-disintegrating tablets. Fast or mouth dissolving tablets have been formulated for pediatric, geriatric, patients and for active patients who are busy and traveling and may not have access to water. Such formulations provide an opportunity for product line expansion in the many elderly persons will have difficulties in taking conventional oral dosage forms (viz., solutions, suspensions, tablets, and capsules) because of hand tremors (Vaidya & Devasagayam, 2007).The micromeritic properties were determined for all the physical mixtures of *Nyctanthes arbor-tristis*, *Alstonia scholaris* and *Butea monosperma*. The results of angle of repose, bulk density, tapped density and compressibility indicated that the powder mixtures possess good flow properties and good packing ability. The physical property of tablet was determined and the results of the uniformity of weight, hardness, drug content and friability of the tablets. All the samples of the test product complied with the official requirements of uniformity of weight. The drug content was found to be close to 100% in F1 formulations. The low friability indicates that the herbal tablets are compact and hard. F1 formulation which contains 3% super disintegrates releases 96.01%, drug respectively at the end of 60 min. An increase in the drug release was observed when 3% super disintegrates used in formulations. The rapid drug dissolution might be due to easy breakdown of particles and rapid absorption of drug into the dissolution medium.

CONCLUSION

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The prepared herbal fast dissolving tablets shows good disintegration property and dissolution rate. The comparative study of several super disintegrants yielded a conclusion that Crospovidone at 3% concentration are suitable for the preparation of Herbal fast dissolving tablets which will satisfy all the criteria and official limits.

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