The Pharma Innovation Journal 2019; 8(6): 89-92

www.ThePharmaJournal.com

The Pharma Innovation

ISSN (E): 2277- 7695
ISSN (P): 2349-8242
NAAS Rating: 5.03
TPI 2019; 8(6): 89-92
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www.thepharmajournal.com
Received: 21-04-2019
Accepted: 25-05-2019

Ranjana Dubey
School of Biological and Chemical Sciences, MATS University, Raipur, Chhattisgarh, India

Tripti Pendharkar
School of Pharmacy, Chouksey Engineering College, Chhattisgarh, India

Utpal Jana
School of Pharmacy, Chouksey Engineering College, Chhattisgarh, India

Abhijeet Soni
School of Pharmacy, Chouksey Engineering College, Chhattisgarh, India

Mrutyunjaya Satpathy
BPUT, Raurkela, Odisha, India

Milan Hait
Department of Chemistry, Dr. C. V. Raman University, Kota, Bilaspur Chhattisgarh, India

Sandhya Rani Panda
School of Biological and Chemical Sciences, MATS University, Raipur, Chhattisgarh, India

Correspondence
Sandhya Rani Panda
School of Biological and Chemical Sciences, MATS University, Raipur, Chhattisgarh, India

Formulation and evaluation of fast dissolving tablets containing hydro alcoholic dried leaf extract of *Nyctanthes arbortristis*

Ranjana Dubey, Tripti Pendharkar, Utpal Jana, Abhijeet Soni, Mrutyunjaya Satpathy, Milan Hait and Sandhya Rani Panda

Abstract
Medicinal plants are widely used as a source of life saving drugs over the world. They play an important role in drug discovery process and are exclusively used to develop a meaningful therapeutic agent. These natural medicinal agents have enormous benefits and can be used as an alternative to synthetic one and are being used to develop the drugs. The present study is aimed to develop a fast dissolving tablets containing hydroalcoholic leaf extract of *Nyctanthes arbortristis* to treat inflammation associated with arthritis. *Nyctanthes arbortristis* is commonly known as Night-flower Jasmine, Coral Jasmine and Parijat. Arthritis is a disorder which affect joint and cause joint pain and stiffness. The fast dissolving tablets are prepared by direct compression method using other excipients. The prepared tablets are evaluated for *in vitro*. The results showed good compressibility of the powdered extract with the fast release of constituents from the tablets.

Keywords: Fast dissolving tablet, Medicinal plant, therapeutic agent

1. Introduction

Natural products have been used as a remedies and drugs over the world for various diseases. They have potential to develop a novel therapeutic agent with a great benefit with desirable action. Over the last decades, medicinal plants and their active compounds have been used to treat disease and also found as a source of biologically active compound. These bioactive compounds are used to produce new drugs to provide definite physiological action on the human body. The natural bioactive compounds are the symbol of safety as they contain organic compound which found beneficial in comparison to synthetics [1-3].

Nyctanthes arbortristis Linn belongs to family Nyctantheaceae which is commonly known as Harishringi, Night Jasmine and Parijat. The plant is growing to height of 20-25 ft. and found in India and distributed wild in sub-Himalayan region and also found in Indian garden as ornamental plant (Fig 1) [4-6]. The whole plant is widely used as traditional medicine for household remedies for the treatment of cancer, Fever, sciatica, anorexia, expectorant, fever, diabetes etc. Various extracts of the plant is used to treat arthritis, malaria, and intestinal worm's tonic, and laxative, anti-inflammatory and antioxidant activity [7-9]. Juice of the leaves is used as digestives, antidote to reptile venoms, mild bitter tonic, and laxative, diuretic [10-12].

Fig1: Leaves and flower of *Nyctanthes arbortristis*

Fast dissolving tablets are the solid unit dosages forms that dissolve in saliva without the need of water. Some drugs are absorbed from mouth, pharynx and oesophagus as the saliva passes down in the stomach. FDTs are designed to dissolve in saliva to provide an onset of action and are considered as true fast dissolving tablets. Fast dissolving tablets are the result of advance technologies adopted to serve the product which is widely acceptable and reliable for all populations. Swallowing problems are common in particularly in children and elderly persons. Other group people who found problems using conventional oral dosage form include the mentally ill, developmentally disabled and patients who are uncooperative and suffering from nausea and vomiting. Such kind of formulations provides advantages on taking of convectional oral dosage form (solution, suspension, tablet and capsules). FDTs are prepared by various techniques like direct compression, lyophilization and moldings. Direct compression technique is cost effective and simple technique. Mainly super disintegrants are added to a drug formulation to facilitate the break-up of tablet into small particles that can dissolve more rapidly. This study was an attempt to formulate fast dissolving tablet of hydroalcoholic extract of above mentioned plant. Formulation includes the use of microcrystalline cellulose as diluents and sodium saccharin as sweetening agent for tablet. To achieve fast disintegration and dissolution superdisintegrants like Crospovidone, sodium starch glycolate and mixture of crospovidone and sodium starch glycolate are used [13, 14].

2. Material and methods

2.1 Collection of plant

The leaves of *Nyctanthes arbortristis* were collected from the outfield and bioactive compound is extracted using a suitable method and identified from the Department of Botany, Guru Ghasidas University, Bilaspur (C.G)

2.2 Extraction of plant

Fresh leaves of *Nyctanthes arbortristis* were washed thoroughly with water and shade dried and powdered. The extraction (maceration) was carried out with powdered leaves (200 g) using the mixture of water and ethanol (1:1). Hydro-alcoholic extract of *Nyctanthes arbortristis* evaporated in water bath at 60 ^{o}C temperature. The residue thus obtained was stored in a container until further use [15, 16].

2.3 Pre-compression evaluation

2.3.1. Bulk density and tapped density

The bulk density of a powder is the ratio of the mass of an untapped powder sample to the volume (including the interparticulate void volume). Hence, the bulk density of a powder depends on both the density of powder particles and the spatial arrangement of particles in the powder bed. The bulk density is expressed in grams per ml (g/ml) although the international unit is kilograms per cubic meter (1 g/ml = 1000 kg/m3). It is determined by gently pouring sample powder extract through a glass funnel into a cylinder the volume occupied is recorded [13, 17-19].

Bulk density = Weight of sample in gm /Volume occupied by sample

The tapped density is an increased bulk density attained after mechanically tapping a container containing the powder sample. Tapped density of powdered extract is obtained by mechanically tapping a graduated measuring cylinder or vessel. After observing the initial powder volume, the measuring cylinder or vessel is mechanically tapped, and volume is measured until little further volume change is observed [13, 17, 19].

Tapped density = Weight of sample in gm / Volume occupied by sample

2.3.2. Compressibility index (Carr's Index) and Hausner's ratio

The inter-particulate interactions influencing the bulking properties of a powder are also the interactions that interfere with powder flow, a comparison of the bulk and tapped densities can give a measure of the relative importance of these interactions. Such a comparison is often used as an index of the ability of the powder to flow, for example the Compressibility Index or the Hausner Ratio [13, 18-20]. The Hausner Ratio of the dried powdered extract sample is measured using the following equation:

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

2.3.3. Angle of repose

Angle of repose is the maximum possible angle between the surface of the pile of powder and the horizontal plane. A funnel with 10 mm diameter is fixed at a height of 2 cm over the plane. Sample powder is slowly allowed to pass through it till the pile touches the funnel stem then a rough circle was drawn around the pile base and the radius was measured of the circle [13, 18, 19]. The angle of repose is calculated using below mentioned formula:

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

Where,
Θ = Angle of repose
h = Height of the pile
r = Radius of the circle

2.4. Preparation of fast dissolving tablets

The fast dissolving tablets are prepared by direct compression method using dried powdered hydro-alcoholic leaf extract of *Nyctanthes arbortristis* and other excipients. The addition of super disintegrants in fast dissolving tablets is to disintegrate or dissolve the tablets in oral cavity within 15-60 seconds, without the need of water providing a pleasant feel. All the ingredients are powered in a clean pestle and mortar and passed through 60 mesh size sieve. The extracted dry leaf powder and all the additives are mixed thoroughly in a sufficient ratio. The powdered mixture is then compressed using a hand operated single punch tablet punching machine. The tablets are prepared and stored in closed container for further evaluation [13, 14].

2.5. Post compression evaluation

2.5.1. Weight variation

10 tablets are weighed individually and the average weight is determined using digital balance. The test requirements are met; if not more than two of the individual tablets weights deviate from the average weight of the tablet [17, 19, 21].

2.5.2. Hardness test

The prepared tablets are tested individually for the hardness.

It is carried out by using Pfizer hardness tester and the result is expressed in kg/cm^2. [17, 22, 23].

2.5.3. Friability test

The friability test is carried out using Roche Friabilator apparatus and expressed in percentage (%). Ten tablets were weighed separately and placed in the friabilator, which was then operated for 100 revolutions at 25 rpm. The tablets are weighed and the percentage weight loss is calculated [13, 17, 22].

2.5.4. Disintegration test

The disintegration time of the prepared tablets is determined using disintegration test apparatus. Each tablet is placed in each of the 6 tubes of the basket. The experiment is carried out by using water and temperature maintained at 37 ± 2 °C. The time at which the tablet gets disintegrated is noted [13, 17, 22].

2.5.5. Stability study

The stability study for the tablets is carried out in three different temperature and humidity condition (25 ºC and 40% RH, 40 ºC and 70% RH and 8 ºC) as per ICH guidelines. The study is conducted for six months and the tablets are evaluated for disintegration time and physical appearance.

2.5.6. Wetting time

A tissue paper was folded and placed on a petri dish containing 10 ml of water and eosin dye was added to the water and tablet was gently placed on a petri dish and tablet is allowed to wet completely and the wetting time was noted [13, 14].

3. Result and Discussion

3.1 Plant Materials Extraction

The hydro alcoholic extracts were obtained by extracting the leaf of *Nyctanthes arbortristis* using mixture of water and ethanol (1:1) (Figure 2). The extracted materials were further used for the formulation of fast dissolving tablet.

Fig 2: Hydro alcoholic extract of *Nyctanthes arbortristis*

3.2. Pre-compression evaluation

The pre-compression evaluation of the dried powdered extract was carried out for ascertaining the compressibility of the powder into tablet dosage forms. The results of pre-compression parameters were in the acceptable range as per the specifications. The value of bulk density, tapped density, compressibility index, Hausner's ratio and angle of repose was found to be 0.45, 0.24, 20, 1.25 & 27 which shows the pre-compression parameters are ranges between excellent to fair and further studies was carried out. (Table 2)

3.3. Preparation of fast dissolving tablet

The fast dissolving tablets of four formulations were prepared by direct compression method using different composition of extract and super disintegrant (Table1). The tablets surface was smooth and no visible colour changes were observed after physical verification (Fig. 3).

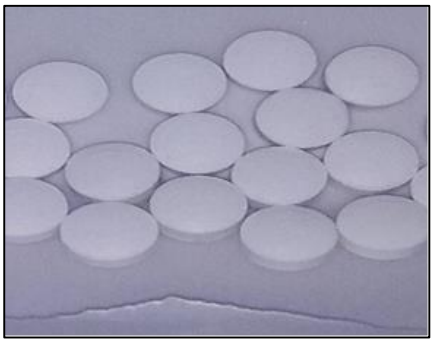

Fig 3: Fast dissolving tablet of extract of *Nyctanthes arbortristis*

3.4. Post compression evaluation

3.4.1. Weight variation test

The weight variation study will assure the uniformity of the weight of the individual tablets. The weight variation also suggests the preliminary information of the uniformity of the drugs inside the tablet. The weights of individual tablets were not differing from each other. The weight variation data is shown in table 3.

3.4.2. Hardness test

Hardness test is done to determine the tensile strength of the tablet and insured the pressure needed to break the tablet. The hardness test for present formulation is done with the help of Pfizer hardness tester and the hardness of the tablet was found to be 3.1 kg/cm^3 (Table 3).

3.4.3. Friability

It is carried out to access the ability of tablet to withstand abrasion during the time of packing, handling and transportation. The test was carried out with the help of apparatus Roche friabilator. The result showed that only 0.5% weight loss was found after agitation (table 3). This suggests the good adhering properties between the granules which is also evident from the tablet hardness.

3.4.4. Disintegration time

This test is done to determine the time of burstness of tablet when it comes in the contact with water and get swell and get disintegrated. This test was completed with 6 tablets and when needed another 6 tablets are added. The prepared formulation takes average 43 seconds to get disintegrated completely. The data is shown in table 3.

3.4.5. Stability study

The stability studies were carried out in three different climatic conditions. After six months the tablets were weighed and evaluated. The outer surface become grayish and become sticky after six months in high temperature and humid condition. It may be the hygroscopic nature of the extract and oxidation of plant composition in presence of moisture. But the tablets kept in cold temperature were in good condition and there were no change in colour and

appearance.

3.4.6 Wetting time
The wetting time is measured to ensure the disintegration of the tablets constituents in the oral cavity very quickly. The melting of tablets depends on the rate and time of water absorbed. The water absorb by the tablet was found to be in 3minute 30 seconds.

Table 1: Different formulations of tablets containing dried plant extract

S. No	Ingredients	F1	F2	F3	F4
1	Plant extract	300 mg	300 mg	500 mg	500 mg
2	B-cyclo dextrin	100 mg	100 mg	100 mg	100 mg
3	Crospovidone	15 mg	15 mg	15 mg	15 mg
4	Microcrystalline cellulose	50 mg	60 mg	50 mg	60 mg
5	Sodium saccharin	10 mg	10 mg	10 mg	10 mg
6	Magnesium stearate	5 mg	5 mg	5 mg	5 mg
7	Talc	5 mg	5 mg	5 mg	5 mg

Table 2: Pre compression parameters of the prepared formulation

Bulk Density	Tapped density	Compressibility Index	Hausner's ratio	Angle of repose
0.45 ± 0.066	0.24 ± 0.049	20 ± 3.51	1.25 ± 0.053	27.1 ± 0.01

Table 3: Post compression parameters of the prepared formulation F3

Thickness (mm)	Weight variation (mg)	Hardness (kg/cm^3)	Friability (%)	Disintegration Time (sec)
2.5 ± 0.001	0.191 ± 0.16	3.1 ± 0.09	0.52 ± 0.001	43 sec

4. Conclusion
The fast dissolving tablets of dried leaf extract of *Nyctanthes arbortristis* is prepared by direct compression method and evaluated. The tablets show good disintegration time suitable for quick absorption in the mouth cavity. The stability study results suggest the storage of the tablets in cold condition. The results further suggest *in vivo* experimentation of the tablets for further exploration.

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