International Journal of Pharmacy and Biological Sciences
ISSN: 2321-3272 (Print), ISSN: 2230-7605 (Online)
IJPBS | Volume 7 | Issue 1 | JAN-MAR | 2017 | 115-120
Original Research Article – Pharmaceutical Sciences

FORMULATION AND EVALUATION OF POLYHERBAL CHEWABLE TABLETS FOR REDUCING NICOTINE DEPENDENCE

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ABSTRACT

The present study aimed at the formulation and evaluation of polyherbal chewable tablets for reducing nicotine dependence. Plants have always been an experimental source of drugs and many of the currently available drugs have been derived directly or indirectly from them. Following all data and knowledge chewable tablet for smoking cessation was prepared using Ginger (Zingiber officinale), Tulsi (Ocimum sanctum), Almond (Prunus amygdalis), Fennel (Foeniculum vulgare), Cinnamon (Cinnamomum zeylanicum), Clove (Eugenia caryophyllus), cardamom (Elettaria cardamomum) with acacia gum 5% w/v) as a binding agent, sorbitol as sweetening agent. Development of chewable herbal tablets for reducing nicotine dependence is important to quit smoking & chewing tobacco. Poly herbal chewable tablets were prepared by wet granulation technique by using acacia gum 5% w/v) as a binding agent. Tablets were evaluated for weight variation test, friability, hardness; time required for complete chewing and is found to be in acceptable limits. In conclusion, our data confirm that the selected formulation of poly herbal chewable tablets has acceptable physicochemical features and may be considered as herbal medication for reducing nicotine dependence. As our formulation contains a non-sugar sweetening agent i.e. sorbitol, so it can also take by diabetic patients. By this formulation we can reduce the nicotine dependency in normal people.

KEY WORDS

Herbal chewable Tablets, nicotine dependence.

INTRODUCTION

The present scenario of global market is in urgent need of standardized and reproducible herbal preparations, which can be achieved by the formulation of modern herbal dosage forms and their evaluation by modern techniques. Solid oral dosage forms represent the preferred class of product for orally administered drugs. Advantage being's unit dosage forms, easy to handle and transport, convenient and safe[1]. Considering their convenience, ease of administration and ability to mask unpleasant tastes and odor of herbal extracts, this dosage form was selected. As we use the poly herbal chewable tablets it can helpful for acceptance old age people. It contains herbal products like edible parts of the plant[2]. They are crude drugs of clove, ginger, almond, cinnamon, tulsi, cardamom. In our formulation for sweetening of the drug a non-sugar substance i.e., sorbitol is incorporated. So, it can also take by diabetic patients [3-5].

Use of nicotine sustains tobacco addiction, which in turn causes severe health problems & harms almost every organ of the body. Majority of smokers in India indicate in quitting. Despite of facts, however approximately 80% of smokers who attempt to quit on their own relapse within the first month of abstinence and only approximately 3% remain abstinence at 6 months[6]. This illustrates the powerful force of tobacco addiction and the chronic nature of disorder. Most health professionals are adepts of the "will-power" theory of smoking which should be replace by a "supportive attitude". Most of them (up to 96%) believe that they cannot change the smoking habit.

The present study aimed at the formulation and evaluation of polyherbal chewable tablets for reducing nicotine dependence [7]

MATERIAL & METHODS

Material

Fresh tulsi leaves were collected from the botanical garden, shade dried and powdered. Ginger, Almond, Fennel, Cinnamon, Clove, cardamom powder were prepared using a mixer grinder.

Development of formulations

The wet granulation technique was selected due to its convenience for small scale preparations. The standardized extracts and other ingredients in each formula were weighed, ground and screened through sieve number 80 separately. All the ingredients were mixed together except talc and magnesium stearate milled in a pestle mortar and sieved again through sieve number 80. The material was mixed with the acacia gum (5%w/w) solution, which was added slowly. After mixing, the powder mass was screened through sieve number 18 to get the granules and dried at 35°C in vacuum dryer After drying, the granules were again screened through sieve no. 18 to remove bigger granules and stored in desiccators[8]

Preparation of polyherbal tablets:

The tablet granules were prepared by using isopropyl alcohol with different compositions of herbal drugs, starch as disintegrator, talc as lubricant magnesium stearate as glidant, acacia gum as a binder and lactose was used as filler. The formulations were coded as F1, F2, F3, F4 and F5 (Table 1).

Table-1: Formulation of polyherbal tablets

Dry powder (mg)	F1	F2	F3	F4	F5
TULASI	20	15	15	10	20
ALMOND	10	15	20	15	10
CINNAMON	15	15	10	20	15
CARDAMOM	15	10	15	10	15
FENNEL	10	20	10	15	10
Clove	20	10	15	10	15
Cardamom	10	15	20	15	10
Starch	20	20	20	20	20
Talc	5	5	5	5	5
Magnesium stearate	5	5	5	5	5
Lactose	370	370	365	375	375

Power blends were compressed to 500 mg tablet on hand rotating single punch tablet presses using 11 X 8 mm punch set with appropriate compression pressure. The granules were mixed with talc and magnesium stearate before punching and the die cavity was adjusted for required weight and the granules were punched to tablets.

Preformulation studies:

The following pre-compression parameters were tested[9- 10]

Angle of repose:

Determined by using the funnel method. Accurately weighed granules were taken in a funnel and the height of the funnel was adjusted in such a way that the tip of the funnel just touches the apex of the heap. The granules were allowed to flow through the funnel freely onto the surface. The diameter of the powder cone was measured, and angle of repose was calculated from the following formula:

$\tan \theta = h/r$

Where, θ = angle of repose, h = height of powder cone formed, r = radius of powder cone formed

Loose bulk density (LBD):

Determined by pouring a weighed quantity of granules into a graduated cylinder and measuring the volume and weight.

LBD = Weight of the powder / volume of the packing

Tapped bulk density (TBD):

Determined by placing a graduated cylinder, containing a known mass of granules. The cylinder was allowed to fall under its own weight onto 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 / volume of the tapped packing

Hausner ratio:

It is the measurement of frictional resistance to the drug. The ideal range should be 1.2-1.5. It is determined by using the following formula:

Hausner ratio= TBD / LBD

Compressibility index:

The Compressibility index of the blends was determined by the Carr's compressibility index.

Compressibility index (%) = (TBD-LBD) X 100 /TBD

Loss on drying:

One gram of granules 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

Evaluation of Polyherbal Tablets

The following post-compression parameters were employed for evaluation of tablets[11, 12, 13]

Uniformity of Weight:

Randomly selected 20 tablets of each formulation were individually weighed.

The average value was calculated and compared to individual tablet weights.

General appearance:

While considering the general appearance, the color, odor and texture of the tablet were observed.

Hardness test:

Tablet requires a certain amount of strength or hardness and resistance friability to withstand mechanical shocks of handling in all processes. The hardness of randomly selected 20.0 tablets of each formulation was determined by the Monsanto hardness tester.

Percentage friability test:

The friability of tablets was determined by Roche friabilator. Percentage of weight loss of 20 tablets randomly selected from each batch tumbled in friability apparatus. After 4 minutes of rotating at 25 rpm, the dust of tablets was removed, and the percentage of weight loss was calculated.

Disintegration test:

The disintegration time of tablets was determined using the digital microprocessor based disintegration test apparatus (basket rack assembly, Lab India). One tablet was introduced into each tube and added a disc. The assembly was suspended in a 1000mL beaker filled in with water. The volume of water was such that the wires mesh at its highest point (at least 25 mm) below the surface of the water, and at its lower point (at least 25 mm) above the bottom of the beaker. The apparatus was operated and maintained at 37±2°C. The time requires to all tablets to disintegrate and pass through wire mesh was noted.

Accelerated Stability Studies

The stability parameters of a drug dosage form can be influenced by environmental conditions of storage, i.e. Temperature, light, air and humidity, as well as the package components[14]. All the formulations were subjected for accelerated stability for the period of 3months at accelerated temperature conditions, i.e. room temperature (25±.2°C)/60% RH, 5C/Ambient and40°C /75% RH. The different parameters such as color, odor and the texture of the tablets, average weight, hardness, friability and disintegration time were studied at accelerated temperature conditions[15]

RESULTS AND DISCUSSION

The present investigation was undertaken to design, formulate and evaluate polyherbal tablets. The granule was evaluated for angle of repose, characterizes the flow properties and is a characteristic related to interparticle friction resistance to movement between particles. The granules indicated good flowability with 25-29°. The compressibility index has been proposed as an indirect measure of bulk density, size and shape, surface area, moisture content

and cohesiveness of materials because all of these can influence the observed compressibility index. The results of LBD, TBD, Hausner ratio, and compressibility index lies between 22.42±1.24 and32.95±1.07 % shows good flow properties (Table 2).

Table 2: Peformulation studies of powder blends

Parameters	Power blend of F1	Power blend of F2	Power blend of F3	Power blend of F4	Power blend of F5
Angle of repose	25±1.23	28±0.25	23±036	26±0.36	28±1.65
Loose bulk density (g/cm3)	0.375±0.012	0.398±0.005	0.348±0.015	0.387±0.013	0.393±0.009
Tapped bulk density (g/cm3)	0.526±0.023	0.513±0.008	0.519±0.016	0.546±0.011	0.578±0.004
Hausner ratio	1.40±0.03	1.30±0.019	1.49±0.014	1.41±0.005	1.47±0.029
Compressibility index (%)	28.71±1.19	22.42±1.24	32.95±1.07	29.12±1.31	32.01±1.08
Loss on drying (%)	0.96±0.007	0.99±0.012	0.980±0.002	0.95±0.019	0.950±0.009

All tablet formulations were subjected to various evaluation parameters and the results obtained were within the Pharmacopoeia limit. No marked change was observed in the general appearance of the tablets. The test for uniform weight indicates that all the tablets were uniform with low standard deviation values (1.06 to 2.02 %). It was observed that the hardness and friability were remarkably related i.e. tablets presenting lower hardness values also had higher friability values. The hardness of tablets was in a range of 6.5 to 7.2 kg/cm^2 showed appreciable hardness characteristics which facilitated its fast disintegration. The weight loss of tablets in percentage friability was in a range of 0.38 to 0.50 indicated that the tablets are mechanically stable. Disintegration testing is most appropriate when a relationship to dissolution has been established or when disintegration is shown to be more discriminating than dissolution. The time required to disintegrate the tablets was in the range of 11 to 14 minutes and the range was within the pharmacopoeia limit, thus all the formulations passed the disintegration test (Table 3).

Table 3: Characteristics of prepared herbal Tablets

Parameters	F1	F2	F3	F4	F5
Colour	Blackish green	Blackish green	Blackish green	Blackish green	Blackish green
Odour	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic
Texture	Smooth	Smooth	Smooth	Smooth	Smooth
Weight variation (%)	1.08±0.003	1.06±0.012	2.02±0.008	2.01±0.017	1.81±0.006
Hardness (kg/cm^2)	7.2±0.15	7.0±0.50	6.7±0.76	6.5±0.41	7.1±0.22
Friability (%)	0.47±0.002	0.38±0.013	0.45±0.0034	0.50±0.0026	0.46±0.007
Disintegration time minutes)	14±1.12	12±1.74	11±1.46	12±1.13	12±1.32

The term stability with respect to herbal dosage form, refer to the chemical and physical integrity of the dosage unit, and when appropriates, the ability of the dosage unit to maintain protection against contamination. No marked changes in color, odor, texture, average weight, hardness, friability and disintegration time were observed in all the formulations (Table 4).

Table 4: Accelerated stability studies of tablets

Parameters	Initial	Observations								
		30 days			60 days			90 days		
		RT/ 60%RH	5°C/ Ambient	40°C/ 75%RH	RT/ 60%RH	5°C/ Ambient	40°C/ 75%RH	RT/ 60%RH	5°C/ Ambient	40°C/ 75%RH
Colour	Blackish green	NC	NC	NC	NC	NC	NC	NC	NC	NC
Odour	Characteristic	NC	NC	NC	NC	NC	NC	NC	NC	NC
Texture	Smooth	NC	NC	NC	NC	NC	NC	NC	NC	NC
Weight Variation (%)	1.65	1.60	1.62	1.61	1.62	1.59	1.60	1.61	1.62	1.59
Hardness (kg/cm^2)	6.54	6.55	6.54	6.56	6.66	6.62	6.55	6.40	6.45	6.42
Friability (%)	0.45	0.42	0.45	0.46	0.42	0.44	0.45	0.44	0.45	0.47
Disintegration time (minutes)	12.0	12.11	12.9	11.5	11.5	12.0	12.0	11.5	11.9	11.5

CONCLUSION

This laboratory scale preparation of polyherbal tablet may be used as a stable, solid dosage form and the work done in stability testing may help in the progress of shelf-life determination. The present study revealed that the composition ratio of ingredients of polyherbal tablets, not affect the stability parameters. From this study it is concluded that using traditional knowledge and the recent technologies, the medicinal plants can be prepared in the form of cost effective tablet formulations to improve their stability, consumer compliance and acceptability

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