Archives of Pharmaceutical Sciences and Research E-ISSN 0975-2633 | PRINT ISSN 0975-5284
Vol 13 Issue 4 154-158 December 2023 Research Article

Formulation and Evalution of Poly Herbal Chewable Tablet for Reducing Nicotin Dependence

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ABSTRACT

The goal of the current study was to develop and assess poly herbal chewable tablets to lessen nicotine dependence. Many of the medications that are currently available in the market have either been directly or indirectly produced from plants, which have long been considered an experimental source of medication. Following all data and knowledge of chewable tablet for smoking cessation was prepared using Ginger (Zingiber officinale), Tulsi (Ocimum sanctum), Almond (Prunus amygdalis), Cinnamon (Cinnamomum zeylanicum), Liquorice (Glycyrrhiza glabra), Akarkara (Anacyclus pyrethrum), pippali (Piper longum), Kiwi fruit (Actinidia deliciosa) and Cardamom (Elettaria cardamomum) with PVP as a binding agent, lactose and mannitol as sweetening agent as well as filler. Chewable poly herbal tablets were created using the wet granulation method. The weight variation test, friability, hardness, thickness, and chewing time for the tablets were all assessed. Pre and Post-compression parameters of all the formulations were within the Pharmacopoeial limits.

Keywords: Ginger, Kiwi Fruit, Liquorice, Nicotine dependence, Polyherbal chewable tablet.

INTRODUCTION

The present scenario of global market is in urgent need of standardized and modern herbal dosage forms and their evaluation by modern techniques. Solid oral dosage forms represent the preferred class of product for orally administered drugs[1]. One of the solid oral dosage forms is Chewable tablets which are required to be broken and chewed in between the teeth before ingestion. These tablets are given to the children who have difficulty in swallowing and to the adults who dislike swallowing[2]. Chewable tablet are often employed when the active ingredient is intended to act in a localized manner rather than systemically. Chewable tablet is one that is palatable and may be chewed and ingested with little or no water. Manufacturing of chewable tablet is generally done using either wet granulation process or direct compression[3]. Advantage being's unit dosage forms, easy to handle and transport, convenient and safe. Considering their convenience, ease of administration and ability to mask unpleasant tastes and odor of herbal extracts, this dosage form was selected[4].

Nicotine usage fuels tobacco addiction, which in turn wreaks havoc on the body's organs and poses serious health risks. The majority of smokers in India say they want to stop. Despite the statistics, only around 3% of smokers who try to stop on their own manage to stay smoke-free after six months5, and about 80% relapse during the first month of abstinence. This exemplifies the stronghold of tobacco addiction and the chronic character of disorder. The "supportive attitude" hypothesis of smoking should be used instead of the "will-power" theory, which is practised by the majority of health professionals. Up to 96 percent of them think they can't kick their smoking habit.

The purpose of the formulation is to reduce the nicotine dependence using the herbal drugs which are also act as the neutraceuticals. The chewable tablet formulation include Tulasi (used for respiratory tract disorder), Almond (vitamin E source and antioxidant), Cinnamon (source of vitamin c stops haemorrhage), Liquorice (dental plaque, TB, also gives sour taste to formulation), Akarkara (anti oxidant), Ginger (nausea caused by cancer, relief of cough) and kiwi fruit (source of vitamins and anti oxidant), pippali as active ingredients by wet granulation method.

MATERIALS AND METHODS

Tulsi, Almond, Ginger, Liquorice, Cinnamon, Akarkara, Pippali, Kiwi fruit were purchased from local available source. PVP, Cross cormellose sodium, lactose, mannitol, talc, magnesium sterate

were purchased from S.D. Fine Chem.Ltd., Mumbai, India.

DEVELOPMENT OF FORMULATION

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 sterate milled in a pestle mortar and sieved again through sieve number 80. The material was mixed with the PVP (10%w/w) solution, which was added slowly. After mixing, the powder mass was screened through sieve to get the granules and dried at 35°C in hot air oven After drying, the granules were again screened through sieve to remove bigger granules and stored in desiccators[5].

Preparation of poly herbal tablets: The tablet granules were prepared by different compositions of herbal drugs, cross cormellose as disintegrator, talc as lubricant magnesium sterate as glidant, PVP as a binder and lactose was used as filler. The formulations were coded as F1, F2, F3, F4 Table no.1.

EVALUATION OF CHEWABLE TABLET

Precompressional parameters

Bulk Density: Bulk density was calculated using the formula mentioned below. It is expressed in g/ml [6].

$$\mathbf{Db} = \frac{\boldsymbol{M}}{\boldsymbol{V}}$$

Where, M=Mass of powder

V = Bulk volume of the powder

Tapped Density: The tapped density was calculated using the formula given below. It is expressed in g/ml.

$$\mathbf{DT} = \frac{\mathbf{M}}{\mathbf{Vt}}$$

Where, M= Mass of powder

Vt= Tapped volume of powder

Car's compressibility index: The tapped density was calculated using the formula given below. Car's compressibility index was expressed in percentage.

$$\boldsymbol{I} = \frac{\boldsymbol{Db-Dt}}{\boldsymbol{Dt}} \times \mathbf{100}$$

Where, D_b =Bulk density of powder

D_t =Tapped density of powder

Angle of Repose: Tan and angle of repose was calculated using the formula.

$$\mathbf{Tan\ \theta = h/r\ (or)\ \theta = tan\text{-}1\ (h/r)}$$

Where, θ =Angle of repose

h = height in cm

r = radius in cm

Post compressional parameter

Friability

The friability of the prepared tablets were measured using Roche friabilator (TAR 200 Eureka, Germany), and the percentage loss in weights were calculated and taken as a measure of friability[7].

$$\mathbf{F = W\ initial - W\ final / W\ initial \times 100}$$

Hardness

The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in kg/cm^2. Six tablets from each formulation were tested for hardness.

Weight variation

10 tablets were randomly selected and individual weight was measured using electronic weighing balance and the average weight and % weight variation was calculated.

$$\mathbf{\%\ Deviation = (Individual\ weight - Average\ weight\ /\ Average\ weight) \times 100}$$

In-Vitro Disintegration Time

The disintegration time of the tablets was measured in 7.4PH phosphate buffer (37 ± 2°C) using disintegration test apparatus (Electro lab, India) with disk. Five tablets from each formulation were tested for the disintegration time calculations.

RESULT AND DISCUSSION

In the experimental section, attempts were made to prepare poly herbal chewable tablet using different excipients ratios. The chewable tablets were formulated and were evaluated for various quality control parameters.

PRECOMPRESSIONAL PARAMETERS

Bulk density and tapped density

Both bulk density and tapped density results are shown in table no.2. The untapped bulk density and tapped density for all the formulation varied from 0.480±0.005 to 0.490±0.005 and 0.556±0.0040 to 0.568±0.0058 respectively. The value obtained lies within the acceptable range and no large differences found between bulk density and tapped density. These results help in calculating the % compressibility of powder.

Carr's consolidation index

The results of the Carr's consolidation index of all the formulations were in the range from 10.2±0.25 to 12.9±0.36. Results of Carr's consolidation index of all the formulations were shown in the table no.2 results clearly showed that the flow ability of all the formulations was good and also had good compressibility.

Angle of repose (θ)

The data obtained for angle of repose for all the formulations were tabulated in the table no.2. The values were founded to be in the range of 21.1±1.99 to 29.1±1.542. All the formulation showed the angle of repose below 30°, which indicates good flow with least standard deviation.

Table.1: Formulation of Polyherbal Tablets

Material (mg)	F_1	F_2	F_3	F_4
Tulsi	20	20	20	20
Almond	10	10	10	10
Cinnamon	15	15	20	15
Ginger	15	10	10	15
Liquorice	10	20	15	10
Akarkara	20	10	10	15
Pippali	10	15	10	15
Kiwi fruit	10	15	15	10
Lactose	365	360	355	350
PVP	10	10	10	10
Cross cormellose	5	10	15	20
Magnesium sterate	5	5	5	5
Talc	5	5	5	5

Table: 2 Precompressional parameters of all the formulations

Formulation code	Bulk density (gm/ml)	Tapped density(gm/ml)	Carr's index (%)	Angle of repose(°)
F1	0.482±.0036	0.556±0.0040	10.23±0.25	22.7±0.25
F2	0.490±0.005	0.568±0.0058	12.9±0.36	29.1±1.542
F3	0.484±0.006	0.564±0.0040	12.88±0.28	26.5.9±0.59
F4	0.480±0.0051	0.558±0.0068	12.35±0.45	21.1±1.997

Table:3 Post compressional parameters of all the formulations

Formulation code	Hardness (kg/cm^2)	Thickness (mm)	Friability (%)	Weight variation (mg)	Disintegration time (min)
F1	3.33±0.2	4.51±0.05	0.42±0.023	294±3.64	38±2.88
F2	3.7±0.17	4.8±0.05	0.25±0.05	296±2.88	32±1.54
F3	3.6±0.17	4.86±0.11	0.283±0.02	298±1.34	30±1.58
F4	3.5±0.01	4.34±0.07	0.247±0.02	298±2.16	25±1.45

POST COMPRESSIONAL PARAMETERS

Organoleptic studies

Appearance: All the batches of tablets were evaluated for their appearance. Macroscopic examination of tablet from each formulation showed circular shape with no cracks or pinholes.

Colour: Blackish green

Odour: characteristic

Taste: sour

Hardness

The hardness value ranges from 3.3 to 3.86 kg/cm^2 with lower standard deviation values that the hardness of all formulations was almost uniform in specific method and possesses good mechanical strength. Result was tabulated in the table no 3.

Friability

Another measure of tablet strength is friability. The values of friability test were given in the table no 3. The % friability for all the formulations was below 1% indicating that the friability was within the prescribed limits and the results of friability test indicates that the tablet possesses good mechanical strength.

Weight variation

The weight variations for all the formulations were shown in table no 3. All the tablets were passed weight variation test as the average weight variation was within the limit ±5%. The weight of all the tablets was found to be uniform with low standard deviation value.

Thickness

The thickness of the tablets was reported in the micrometer (mm). The thickness of tablet indicates that, die fill was uniform. The thickness depends on the size of the punches and the weight of one tablet (500 mg). The value of thickness ranges between 4.34-4.8 mm. all the formulations were shown in table no 3.

Disintegration time

The disintegration time of the tablets was measured in 7.4 pH phosphate buffer (37 ± 2°C) using disintegration test apparatus. The value of disintegration time between 25±2.88 min to 38±2.88 min. all the formulations were shown in table no 3.

CONCLUSION

The evaluation of granules and tablets indicate successful formulation of poly herbal chewable tablet. From the disintegration studies, it was observed that the formulation containing 20mg of cross cormellose shows minimum disintegration time (25±2.88 min.) whereas formulation having no or less concentration of cross cormellose shows increase in disintegration time. It was observed that the formulation containing lactose shows less disintegration time. The tablet containing lactose and cross cormellose (5mg) is the best herbal chewable tablet with maximum disintegration time (it will be remains long term in the month), sufficient hardness, pleasant taste and meeting all USP limits. 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 consumer compliance and acceptability

CONFLICT OF INTEREST

The authors declare that this article content has no conflict of interest.

ACKNOWLEDGMENT

We express our gratitude to Sha. Bra. Sri Varasadyojatha Shivacharya Swamiji. T.M.A.E. Society President and T.M. Chandrashekaraiah T.M.A.E. Society Secretary for their support, as well as Principal, S.C.S. College of Pharmacy, Harapanahalli, Karnataka, for providing the essential facilities and assistance in carrying out this work.

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