

Formulation and Evaluation of Nutraceutical Tablets Using Herbal Drugs by Direct Compression Methods

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ABSTRACT

To formulate and evaluate the nutraceutical tablets with different combination of herbal drugs. Material and Method: The nutraceutical tablet containing lactose and mannitol as diluent and containing natural drugs like clove and cinnamon which was prepared by direct compression method. Pre-compression studies of nutraceutical tablet shows satisfactory results. The thickness, hardness, weight variation, and friability of nutraceutical tablet were found to unacceptable range. The in-vitro drug release of eugenol from optimised nutraceutical formulation was found to be 90.23%. Significant results were obtained from present study. Discussion: The finding of current investigation clearly found that the health promotion of the body could be done by nutraceuticals.

Keywords: Direct compression, Nutraceutical, Eugenol, In-vitro drug release.

INTRODUCTION

Oral route has been one of the most popular routes of medicine delivery due to its ease of administration, forbearance compliance, least sterility constraints and flexible design of capsule forms. Tablets are defined as unit cure, temper apparent solid specifics containing one or further active ingredients. Conventional drug delivery systems like tablets and capsules constantly dissolve swiftly in the gastrointestinal tract for absorption into the bloodstream give rise to exorbitantly high drug attention in tube (1). The generality of making avail of food as health promoting factor beyond its nutritional value is gaining acceptance with in public arena and among scientific community. Nutraceuticals contain health- supporting ingredients or natural factors that have a capability health benefit for the body (2). A 'nutraceutical' is a product isolated or purified from foods that is generally sold in medicinal forms not generally connected with food. A nutraceutical is bearing to have a physiological benefit or give protection against habitual complaint. Term chased by Dr. Stephen L De Felice, Author and chairman of the Foundation for Innovation in Medicine, New Jersey, USA. Nutraceuticals sometimes appertained as "functional foods", have caused heated debate because they change the traditional dividing line between food, and medicine (3). A nutraceutical is "any non- poisonous food element that has scientifically proven health benefits, including complaint treatment or prevention." The functional element of the food must be homogenized in the nutraceutical product and induce under good manufacturing practices (GMPs) (4). Increased public demand, trends in demography, socio-profitable script further inquiries and studies, nearly two thirds of the world's 6.1 billion people calculate on the mending power of plant predicated paraphernalia for multitudinous reasons vacuity, affordability, safety or their belief in traditional affordability, safety or their belief untraditional cures medical benefits of food have been excavated for thousands of times. modern nutraceutical sedulity began to develop in Japan during the 1980s. various benefits of nutraceuticals are may help us live longer, may increase the health asses of our diet, help us to vacillate particular medical condition, it have a cerebral advantage from doing commodity for oneself, and may be tasted to be more "natural" than traditional medicine and less likely to produce unpleasant side- effect (5, 6).

The nutraceuticals generally contain demanded amount of lipids, protein, carbohydrates, vitamins, minerals and other necessary nutrients depending upon their stresses. Nutraceuticals in the request contains both traditional foods and non-traditional. When a supplement tablet is ingested, the body must digest and absorb the nutrients. Nutraceutical may include a whole area of products like insulated nutrients, salutary supplements, herbal products and other reused foods.(7) The growing deprecation among the cases about the synthetic remedial agents and affect about their toxicological profile gave

birth to the “Dietary Supplements Health and Education Act”(DSHEA) in USA in 1994.(8,9) The generality behind the mode of action of nutraceutical capsule form is to give functional benefits by enhancing the force of natural structure blocks. It works in to two ways that is to minimize conditions subscribe or to meliorate body performance (10, 11).

MATERIALS AND METHOD

Materials

All materials were collected from Rungta Institute of Pharmaceutical Sciences and Research.

Method

Nutraceutical tablets containing clove and cinnamon were prepared by direct contraction system. Other constituents like lactose were used as diluent, magnesium stearate as lubricant and talc as glidant. All the excipients along with API counted as shown in Table 1 and passed through sieve no. 20. also, all constituents were mixed following geometric mixing banning glidant and lubricant completely for 15min. The grease paint mix was completely mixed with talc and magnesium stearate and compressed into a 400 mg tablet using single rotatory punching machine (Rungta Institute of Pharmaceutical Science and Research Kohka, CG, India).

Table1: Formulation tableofnutraceuticaltablet400mg

Ingredients(mg)	G1	G2	G3	G4
Clove	100	-	100	-
Cinnamon	-	100	-	100
Lactose	290	290	-	-
Mannitol	-	-	290	290
Sodium Sachrine	2	2	2	2
Talc	4	4	4	4
Magnesium Stearate	4	4	4	4

EVALUATION OF NUTRACEUTICAL TABLETS

Pre-compressional studies of greasepaint mix

In development of rearmost lozenge form pre formulation study is that the previous step in the implicit medicine development. it's the top disquisition in the medicine development to attained information on the known parcels of emulsion and the proposed development schedule. So, this pre formulation disquisition may simply confirm that there are not any significant walls to emulsion development. Following pre-compressional parameters were studied like angle of repose, bulk viscosity, tapped viscosity, compressibility indicators etc. (13,14)

Angle of repose

It's the maximum angle that can be attained between the freestanding face of greasepaint mound and the vertical aeroplane it had been determined by using fixed channel system. Specified quantum of greasepaint medicine was transfer to the channel keeping the perforation of the channel blocked by thumb. When greasepaint was cleared from channel also measured its angle of repose and measured in θ (15).

$$\text{Angle of repose}(\theta) = \tan^{-1} h/r$$

Bulk density

It's the rate of bulk mass of greasepaint to the bulk volume. It is denoted by pb. Bulk density is used to find out homogeneity.

$$\text{Bulk density}(pb) = M/Vb$$

Where, M is that the mass of the sample, Vb bulk volume

Tapped density

It's the rate of the weight of greasepaint to the minimal volume enthrallled in measuring cylinder. Tapped viscosity is set by placing a graduated cylinder containing a known mass of medicine or expression on a mechanical stop cock outfit which is operated at fixed no. of taps (1000) until the greasepaint bed reached a minimal volume. (16)

$$\text{Tapped density (pt)} = \text{weight of greasepaint mix} / \text{minimal volume enthrallled by cylinder}$$

Compressibility Indices

a. Carr's index

Supported the apparent bulk density and thus the tapped viscosity, the share compressibility of the grease paint admixture decided by the following formula.

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

b. Hausner's rate

Lower Hausner's ratio (<1.25). indicates better flow properties than higher ones (1.25). (17)

$$\text{Hausner's rate} = \frac{\text{Tapped density}}{\text{Bulk viscosity}} \quad (11,12)$$

Post-compressional studies of set nutraceutical tablets

The nutraceutical tablets were estimated for various parameters after consideration of pre formulation. These are such like appearance, consistence, weight variation, hardness and frangibility.

Physical Properties analysis

The general appearance of tablet was studies visually in shape, color, texture and odour.

Thickness

The tablet consistence was calculated by Vernier calipers. 6 tablets were used for this test and expressed in mm. (18)

Weight variation

Weight variation test is pass by importing 20 tablets collectively, calculating the standard weight and comparing individual tablet weight to the normal.

Hardness

Hardness also nominated as tablet crushing strength. The tablet hardness decided by Monsanto hardness tester. The tablet was placed lengthwise between upper and lower plunger and force applied by turning a threaded bolt until the tablet fractures and measured hardness of tablet in Kg/cm^2 (19,20)

Frangibility

Friability has tested by using Roche friabilator, subjects sort of tablets to combined goods of bruise and shock by utilising a plastic chamber that revolves at 25 rpm, dropping tablet from elevation distance operated for 100 revolutions. Pre-weighed tablets were dusted and re-weighed and according to standard limit frangibility should be lower than 1%. (21) It is calculated by formula;

$$\% \text{ Frangibility} = \frac{\text{original weight} - \text{Final weight}}{\text{original weight}} \times 100$$

In- vitro medicine release- Dissolution profile of eugenol decided at $37 \pm 0.5^\circ\text{C}$ at a shifting rate of 100 rpm using the USP dissolution outfit II in 900 ml of dissembled gastric fluid (0.1 N HCl). Simulated aliquot samples were withdrawn with relief dissembled fluid of same quantum at 5,10,15,20,25 and 60 min independently. Samples were filtered using Whatmann paper and brought absorbance at wavelength of 366 nm by UV spectrophotometer (22,23).

RESULTS AND DISCUSSION

The nutraceutical tablet of clove and cinnamon was formulated by direct contraction system. This fashion was used for conventional from nutraceutical tablet which minimize processing way and excluded wetting down and drying process (24).

Pre- contraction studies of greasepaint mix

The greasepaint mix was estimated for various parameters and their results are shown in Table 2. The evaluation parameters similar as angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio were set up to be 21.12±0.11 to 27.46 ±0.12 (Θ), 0.4071±0.21 to 0.4741 ±0.32 g/ml, 0.4132±0.17 to 0.4965±0.028 g/ml, 11.00±0.12 to 14.17±0.39, 1.11±0.012 to 1.17±0.13 independently. After evaluation of pre-formulation parameters, it showed that there's no presence of humidity in power and showed uniformity of greasepaint mix 11. After study of inflow rate, it concludes that greasepaint mix live optimum proportion that leads to outside inflow rate. So, the result showed that the greasepaint has good flowing property which doesn't beget affect the process of tablet punching (25,26).

Table 2: Pre contraction studies of nutraceutical tablet containing clove and cinnamon

Pre-Compression Parameters	G1	G2	G3	G4
Angle of repose(θ)	21.12±0.11	24.32±0.12	27.46±0.12	22.14±0.17
Bulk Density(g/ml)	0.4649±0.12	0.4741±0.32	0.4541±0.21	0.4071±0.21
Tapped Density (g/ml)	0.4262±0.08	0.4132±0.17	0.4587±0.023	0.4965±0.028
Carr's Index	12.19±0.14	13.04±0.16	11.00±0.12	14.17±0.39
Hausner's Ratio	1.14±0.16	1.16±0.021	1.11±0.012	1.17±0.13

Table 3: Post- contraction studies of nutraceutical tablet containing clove and cinnamon

Post-Compression Parameters	G1	G2	G3	G4
Thickness(mm)	1.2±0.1	1.2±0.21	1.2±0.21	1.2±0.21
Hardness(kg/cm ²)	5.5±0.2	4.8±0.11	4.31±0.21	5.21±0.033
% Weight Variation	0.399±0.021	0.399±0.034	0.397±0.012	0.398±0.019
% Friability	0.23±0.023	0.31±0.0.12	0.14±0.045	0.22±0.011
% <i>In-vitro</i> drug release	90.23	86.88	88.64	85.34

Table 4: Angle of repose as a suggestion of greasepaint inflow property (9)

Angle of repose	Type of flow
<20	Excellent
20-30	Good
30-40	Passable
>40	Very passable

Table 5: Carr's indicator as a suggestion of greasepaint inflow (15)

Carr's index (%)	Flow ability
5-15	Excellent
12-16	Good
18-21	Fair to passable
23-35	Poor
33-38	Very poor
>40	Extremely poor

Table 6: Hausner's rate (15)

Hausner's ratio	Flow ability
<1.25	Good
>1.25	Poor

Post-compression study

The result from different physical parameters like consistence, thickness, hardness, weight variation, and frangibility of tablets was shown in table 3. The presence of active pharmaceutical constituents, padding, glidant and lubricant is sufficient for handed bulk to the tablet which drop threat during punching. The consistence, hardness, weight variation, and frangibility of nutraceutical tablet were innovated to be in respectable limit. It shows that the herbal medicines containing nutraceutical tablets have satisfactory decomposition profile due to their hardness within range of standard limit (27).

Physical appearance

The general appearance of tablet was set up to be round in shape, brown in colour, smooth texture, and odourless.

Thickness

The thickness of clove and cinnamon containing nutraceutical tablet was set up to be 1.2 ± 0.1 cm. It's based upon the size of bones and a function of bones filler and contraction force. (28)

Weight variation

The weight of 20 tablets was measured and it was set up to be 0.397 ± 0.012 to 0.399 ± 0.034 for all phrasings independently. Weight variation was within the USP limits of ± 5 .

Hardness

The hardness of the tablet was set up to be 4.31 ± 0.21 kg/cm² to 5.21 ± 0.033 for clove and cinnamon containing phrasings. Mannitol containing expression law showed more brickle and lower hardness than lactose as diluent. It's depended upon the contraction force of punching machine and showed that it's sufficient for permitting mechanical strength. Tablets showed sufficiently hard to repel breaking during packaging, payload, and normal running. (29, 30).

Frangibility- Frangibility of all phrasings was set up to be 0.14 ± 0.045 to 0.31 ± 0.012 . The frangibility of clove and cinnamon containing tablet was set up to be in respectable limit i.e. lower than 1%.

In-vitro medicine release- The in-vitro medicine release of eugenol from all nutraceutical tablets in 0.1 HCL was set up to be 85.34 to 90.23% independently in 1 h. Basically, eugenol is main chemical element of clove so, it gives more salutary effect to the cinnamon containing tablets. The release profile of nutraceutical tablet was given in Fig. 1 and Fig.2 (33, 34).

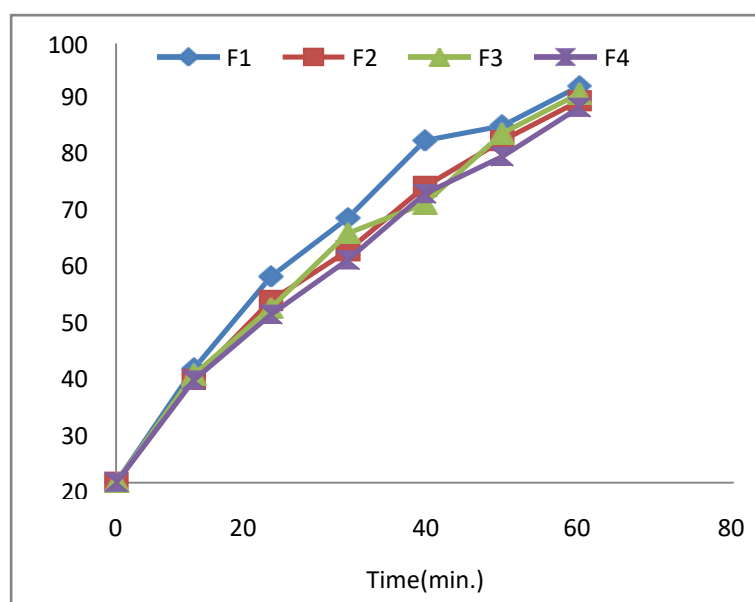


Fig. 1: In vitro medicine release profile of all phrasings of nutraceutical tablets

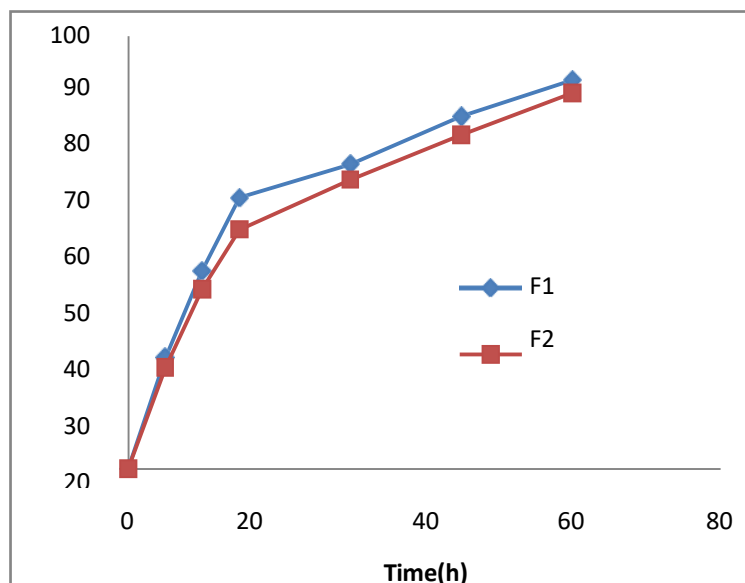


Fig. 2: The in-vitro medicine release profile of clove and cinnamon containing nutraceutical tablet

CONCLUSION

Nutraceutical tablets are dietary supplements that are intended to provide health benefits beyond basic nutrition. They typically contain concentrated doses of bioactive compounds such as vitamins, minerals, herbs, or other substances that are believed to have physiological benefits or provide protection against chronic diseases. These tablets are often marketed as supporting functions such as immune health, joint health, cardiovascular health, skin rejuvenation, or cognitive function. They are not drugs and do not undergo the rigorous testing and approval processes that pharmaceutical drugs do. Instead, their efficacy and safety are often supported by studies and research, though not always to the same extent as pharmaceuticals. It's important for consumers to consult with healthcare professionals before starting any nutraceutical tablets, especially if they have existing health conditions or are taking other medications, to ensure there are no potential interactions or contraindications.

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