



Formulation and Evaluation of Nutraceutical tablets

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Aim: The objective of present work was to formulate and evaluate the nutraceutical tablets of Ginger and Malabar nut. **Material and Method:** The nutraceutical tablet containing excipients such as lactose, mannitol, sodium saccharine, talc, magnesium stearate and natural drugs like Ginger and Malabar nut was prepared by direct compression method. The Pre-compressional studies of powder blend was evaluated by Angle of repose, Bulk density Tapped density and Compressibility Indices. The compressed nutraceutical tablets formulations were subject to several evaluation parameters like appearance, thickness, weight variation, hardness and friability. The In-vitro drug release of gingerol determined by USP dissolution apparatus II. **Results:** The results of all evaluation parameters of nutraceutical tablet were within the acceptable limit. Pre-compression studies of nutraceutical tablet show satisfactory results. The thickness, hardness, weight variation, and friability of nutraceutical tablet were found to in acceptable range. The in-vitro drug release of gingerol from optimised nutraceutical formulation was found to be 89.22%. 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:- Ginger, Malabar Nut, Tablets, Evaluation.

Introduction:-

The oral route has been one of the most popular routes of drug delivery due to its ease of administration, patient compliance, least sterility constraints and flexible design of dosage forms. Tablets are defined as unit dose, temper evident solid preparations containing one or more active ingredients. Conventional drug delivery systems like tablets and capsules often dissolve rapidly in the gastrointestinal tract for absorption into the bloodstream give rise to inordinately high drug concentrations in plasma (1). The concept of making utility 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 components that have an ability health benefit for the body. (2) The concept behind the mode of action of nutraceutical dosage form is to provide functional benefits by enhancing the supply of natural building blocks. It works in to two ways that is to minimize diseases sign or to improve body performance. (2, 3) A “nutraceutical” is a product isolated or purified from foods that is generally sold in medicinal forms not usually connected with food. A nutraceutical is bearing to have a physiological benefit or give protection against chronic disease. Term coined by Dr. Stephen L De Felice, Founder and Chairman of the Foundation for Innovation in Medicine, New Jersey, USA. Nutraceuticals sometimes referred as “functional foods”, have caused heated debate because they change the traditional dividing line between food, and medicine. (3) A nutraceutical is “any non-toxic food component that has scientifically proven health benefits, including disease treatment or prevention.” The functional component of the food must be standardized in the nutraceutical product and generate under good manufacturing practices (GMPs). (4) Increased public demand, trends in demography, socio-economic scenario. More researches and studies, nearly two thirds of the world’s 6.1 billion people rely on the healing power of plant-based materials for many reasons-availability, affordability, safety or their belief in traditional affordability, safety or their belief in traditional cures medical benefits of food have been investigated for thousands of years. Modern nutraceutical industry 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 abstain particular medical condition, it have a psychological advantage from doing something for oneself, and maybe sensed to be more “natural” than traditional medicine and less likely to produce unpleasant side-effects. (3, 5) The nutraceuticals normally contain required amount of lipids, protein, carbohydrates, vitamins, minerals and other necessary nutrients depending upon their emphases. Nutraceuticals in the market 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 isolated nutrients, dietary supplements, herbal products and other processed foods. (5) The growing disapproval among the patients about the synthetic therapeutic agents and affect about their toxicological profile gave birth to the “Dietary Supplements Health and Education Act” (DSHEA) in USA in 1994. (5, 6)

Ginger (*Zingiber officinale*) is a flowering plant whose rhizome, ginger root or ginger, is widely used as a spice and a folk medicine.[7] It is herbaceous perennial which grows annual pseudo stems (false stems made of the rolled bases of leaves) about one-meter-tall bearing narrow leaf blades. The inflorescences bear flowers having pale yellow petals with purple edges, and arise directly from the rhizome on separate shoots. (8)

Usticia adhatoda commonly known in English as Malabar nut, adulsa, adhatoda, vasa, vasaka,(9)(10) is a medicinal plant native to Asia, widely used in traditional medicine.(11)

The plant's native range is the Indian subcontinent (Assam, Bangladesh, India, Nepal and Sri Lanka), Laos and Myanmar. It has been introduced elsewhere.(12)

Materials and method:

Materials:

Collection of Materials:-

Dried Rhizomes of ginger were collected from the nearby area of Nashik and dried leaves of malabar nut had been bought from the local marketplace of Nashik and were checked for quality and were used without purification. The procedure for the mixing of ingredients is carried out followed by the grinding of the dried rhizomes and leaves to get powder.

Method:-

Nutraceutical tablets containing ginger and Malabar nut were prepared by direct compression method. Other ingredients like lactose were used as diluent, magnesium stearate as lubricant and talc as glidant. All the excipients along with API weighed as shown in Table 1 and passed through sieve no. 20. Then, all ingredients were mixed following geometric mixing excluding glidant and lubricant thoroughly for 15min. (4) The powder blend was thoroughly mixed with talc and magnesium stearate and compressed into a 300mg tablet using single rotatory punching machine.

Table no 1: Formulation table for nutraceutical tablets

Ingredients(mg)	F1	F2	F3	F4
Ginger	100	-	100	-
Malabar nut	-	100	-	100
Lactose	190	190	-	-
Mannitol	-	-	190	190
Sodium saccharine	2	2	2	2
Talc	4	4	4	4
Magnesium stearate	4	4	4	4

Evaluation of Nutraceutical Tablets:-

Pre-compressional studies:-

Pre-compressional parameters were studied like angle of repose, bulk density, tapped density, compressibility indices etc. the results of pre compressional studies are shown in table no.2.

Angle of repose

It is the maximum angle that can be obtained between the freestanding surface of powder heap and the horizontal plane. It was determined by using fixed funnel method. Specified amount of powder drug was transfer to the funnel keeping the orifice of the funnel blocked by thumb. When powder was cleared from funnel then measured its angle of repose and measured in θ .

Angle of repose (θ) = $\tan^{-1} h/r$

Bulk density

It is the ratio of bulk mass of powder to the bulk volume. It is denoted by ρ_b . Bulk density is used to find outhomogeneity.

Bulk density (ρ_b) = M/V_b

Where,

M is the mass of the sample,

V_b bulk volume

Tapped density

It is the ratio of the weight of powder to the minimum volume occupied in measuring cylinder. Tapped density is determined by placing a graduated cylinder containing a known mass of drug or formulation on a mechanical tapper apparatus which is operated at fixed no. of taps (1000) until the powder bed reached a minimum volume. (13)

Tapped density (ρ_t) = weight of powder blend/Minimum volume occupied by cylinder.

Compressibility Indices

1. Carr's index

Based on the apparent bulk density and the tapped density, the percentage compressibility of the powder mixture was determined by the following formula.

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

2. Hausner's ratio

It is an indirect index of ease of measuring of powder flow. Lower Hausner's ratio (<1.25) indicates better flow properties than higher ones (>1.25).

Hausner's ratio = $\frac{\text{Tapped density}}{\text{Bulk density}}$ (13, 14)

Post-compressional studies of prepared nutraceutical tablets

The nutraceutical tablets were evaluated for various parameters like appearance, thickness, weight variation, hardness and friability. All the evaluation parameters of all formulations are given in Table 4.

Physical Evaluation

The physical evaluation like shape, colour, texture and odour of tablet was studied visually.

Thickness

The tablet thickness was calculated by Vernier callipers. Tablet was put in between two jaws vertically and measured thickness and 5 tablets were used for this test and expressed in mm.

Weight variation

Weight variation test is run by weighing 20 tablets individually, calculating the average weight and comparing individual tablet weight to the average. The weight variation test would be a satisfactory method of determining the drug content uniformity of tablets.

Hardness

Hardness also termed as tablet crushing strength. The tablet hardness was determined 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/cm².

Friability

It is determined by Roche friolator, subjects a number of tablets to combined effects of abrasion and shock by utilising a plastic chamber that revolves at 25 rpm, dropping tablet from inches distance operated for 100 revolutions. Reweighed tablets were dusted and re-weighed and according to standard limit friability should be less than 1%.

It is calculated by formula:-

$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}}$$

In-vitro drug release

Dissolution profile of eugenol was determined at $37 \pm 0.5^\circ\text{C}$ at a stirring rate of 100 rpm using the USP dissolution apparatus II in 900 ml of simulated gastric fluid (0.1 N HCl). Various aliquot samples were withdrawn with replacement simulated fluid of same amount at 5, 10, 15, 30, 45, and 60 min respectively.

RESULTS AND DISCUSSION

The nutraceutical tablet of ginger and Malabar nut was formulated by direct compression method. This technique was used for conventional from nutraceutical tablet which minimize processing steps and eliminated wetting and drying process. The physiochemical property shows satisfactory results by nutraceutical tablet which are within the range of prescribed standards required for investigation of present study.

Table no. 2: - Pre compression studies of nutraceutical tablets

Pre compression parameters	F1	F2	F3	F4
Angle of repose	22.16	25.25	26.44	21.12
Bulk density	0.4548	0.4642	0.4438	0.4050
Tapped density	0.4161	0.4131	0.4386	0.4864
Carr's index	12.16	12.02	12.00	13.16
Hausner's index	1.12	1.14	1.12	1.15

Table no. 3 :- Physical evaluation of nutraceutical tablets

Physical Evaluation	F1	F2	F3	F4
Shape	Flat round	Flat round	Flat round	Flat round
Colour	Brown	Brown	Brown	Brown
Texture	Smooth	Smooth	Smooth	Smooth
Odour	Characteristic	Characteristic	Characteristic	Characteristic

Table no. 4: -post-compression studies of nutraceutical tablets

Post compression parameters	F1	F2	F3	F4
Thickness	1.2	1.2	1.2	1.2
hardness	5.4	4.6	4.28	5.3
Weight variation	0.393	0.395	0.394	0.396
Friability	0.22	0.30	0.16	0.21
In vitro drug release	89.22	84.80	86.55	84.24

CONCLUSION

From the above study, we conclude that the nutraceutical tablets were prepared by direct compression method and gave satisfactory and acceptable result. Conventional tablet of nutraceutical shows immediate drug release due to direct compressed tablet. From the above research work it was concluded that herbal nutraceutical tablet prepared in the form of cost-effective tablet to minimize patients' compliance in regarding suppressing side effects and enhancing positive effects on the body.

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