

FORMULATION AND EVALUATION OF NUTRACEUTICAL CINNAMON TABLET BY WET GRANULATION METHOD

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ABSTRACT

The objective of study was to formulate and evaluate the nutraceutical tablets by the wet granulation methods and to study the effect of it on the various parameters such as dissolution studies. The nutraceutical tablet was formed by mixing the lactose and cinnamon and sodium saccharine by geometric mixing and the 5% starch paste was added as binder. The granules were prepared and dried in air. Tablet was compressed. The compressed formulation were subjected to all studies such as appearance, thickness, weight variation, hardness and friability. The friability, weight variation, hardness, thickness, dissolution of tablet was found in acceptable range. The in-vitro release of eugenol

from optimized nutraceutical tablet was found to be 88.1%. Significant result was obtained from the studies. Tablet was found to be stable during handling and shows more promising results than direct compression methods. The current investigation clearly found that the wet granulation do not affects the in-vitro release of eugenol from the cinnamon. So wet granulation method has scope in the nutraceutical cinnamon tablet formulations.

KEYWORDS: Wet granulation, Eugenol, Nutraceutical, In-Vitro release.

INTRODUCTION

The most popular route of administration is oral because its ease of administration, patient compliance, least sterility constraints and flexible design of dosage form. Tablet is defined as

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unit dosage, tamper proof solid preparations containing one or more active ingredients. Conventional drug delivery systems like tablets and capsules frequently dissolve rapidly in the gastrointestinal track for absorption into blood stream give rise to high drug concentration in plasma.^[1] The concept of making utility of food as health promoting factor beyond its nutritional value is gaining acceptance with in public and scientific community. Nutraceuticals contain.^[1] health promoting ingredients or natural components that have health benefits for the body.^[2] A ‘nutraceutical’ is a food or part of a food that allegedly provides medicinal or health benefits, including the prevention and treatment of disease. A nutraceutical may be a naturally nutrient-rich or medicinally active food. A nutraceutical have a physiological benefit or give protection against chronic disease. The term invented by Dr. Stephen L De Felice, Founder and Chairman of the Foundation for Innovation in Medicine, New Jersey, USA.

Nutraceutical sometime also called as “Functional Food”, have caused heated discussion because they change the traditional dividing line between food and medicine.^[3] A nutraceutical is “any non-toxic food component that has health benefits, including disease treatment.” The functional component of the nutraceutical product must be standardized and generate under good manufacturing practices (GMPs).^[4] Increased public demands, trends in demography, socio-economic scenario, more researchers and studies, nearly two thirds of the world rely on the healing of the plant based materials for many purposes –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. In Japan during the 1980s modern nutraceutical industry began to develop. Various benefits of nutraceuticals are may help us live longer, may increase the health asses of our diet, help us to increase particular medical condition, and may be sensed to be more “natural” than traditional medicine and less likely to produce unpleasant side-effects.^[3,5]

The nutraceuticals contains normally required amount of lipids, protein, carbohydrates, vitamins, minerals and other necessary nutrients depending upon their value. In market nutraceuticals contain both traditional and non-traditional foods. When a nutraceutical supplement tablet is ingested, the body must digest and absorb the nutrients. Nutraceutical include 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 their toxicological profile gave birth to the “Dietary Supplements

Health and Education Act” (DSHEA) in USA in 1994.^[5,6] The concept behind the mode of action of nutraceutical dosage form is by enhancing the supply of natural building blocks to provide functional benefits. It is effective in two ways that is to minimize disease sign or to improve body performance.^[2,3]

Cinnamon(Sy:Kalmi-Dalchini) consist of the dried inner bark of the shoots of coppiced trees of *Cinnamomum zeylanicum* Nees, belonging to the family Lauraceae. It should not contain less than 1.0% of volatile oil. Bark is used as a carminative, stomachic, expectorant, demulcent, mild astringent and stimulant. It is also used as a flavouring agent, an aromatic, antispasmodic and antiseptic. The major diseases for prevention or treatment of which, nutraceuticals have been used are cancer, heart diseases, diabetes, Hypertension.^[6]

MATERIAL AND METHODS

Material

Cinnamon powder was purchased from local market. All other ingredients like lactose, magnesium stearate, starch and talc were also purchased from local market. All ingredients used were of analytical grade.

Table No1: Formulation of nutraceutical tablet having total weight 400mg.

Ingredients(mg.)	F1	F2
Cinnamon	100	100
Lactose	290	270
Sodium Saccharine	2	2
Talc	4	4
Magnesium Stearate	4	4
Starch	-	120

Method

Nutraceutical tablet containing the cinnamon were prepared by wet granulation method. Other ingredients such as lactose was used as diluent, Magnesium Stearate as lubricant and talc as glidant. API along with excipients weighed as shown in table no.1 and passed through sieve number 20 all the ingredients such as lactose, sodium saccharine were added and mixed. Starch paste (5%) was prepared by using warm water. Dump Mass was formed and sieved through sieve no.80. Granules were dried in air. Talc and magnesium Stearate was added at last. Tablet was formed of weight 400 mg.

EVALUATION OF NUTRACEUTICAL TABLETS

Pre-compressional studies of granules

In development of new dosage form, preformulation study is the most important step in the potential drug development. It is investigation step in the drug development to obtain information on the known properties of compound and the proposed development schedule. So, this preformulation investigation confirms that there are no significant barriers to compound development. Pre-compressional parameters were studied like angle of repose, bulk density, tapped density, compressibility indices etc.

Angle of repose

Angle of repose is the maximum angle that can be obtained between the freestanding surface of powder heap and the horizontal plane. Fixed funnel method was used for determination of angle of repose. Specified amount of granules were placed in the funnel keeping the orifice of the funnel blocked by thumb. When powder was cleared from funnel then angle of repose is measured.

$$\text{Angle of repose} = \tan^{-1} h/r^{[7]}$$

Bulk density

The ratio of mass of granules to the bulk volume of granules is called bulk density. It is used to find out homogeneity.

$$\text{Bulk density} = M/V_b$$

Where, M is mass of granules, V_b is bulk volume.^[7]

Tapped density

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

$$\text{Tapped density} = M/V_t$$

Where, M is mass of granules, V_t minimum volume occupied by cylinder.

Compressibility indices

a. Carr's index

The percentage compressibility of the granules was determined based on the apparent bulk density and the tapped density, by following formula.

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

b. Hausner's ratio

Hausner's ratio is an indirect index of ease of measuring of granules flow. If the hausner's ratio is lower than 1.25 (<1.25) then indicates better flow properties than higher ones (>1.25).

Hausner's ratio = $\frac{\text{Tapped density}}{\text{Bulk density}}$.^[10]

Table No.4: Angle of repose as an indication of granules flow property.^[9]

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

Table No. 5: Carr's index as an indication of granules flow.^[13]

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 No.6: Hausner's ratio.^[13]

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

RESULT

Table No.2: Pre-compressional study of nutraceutical tablet.

Pre-compression parameters	F1	F2
Angle of Repose	24.32	25.4
Bulk Density(g/ml)	0.4741	0.4071
Tapped Density(g/ml)	0.4132	0.4965
Carr's Index	13.04	17.39
Hausner's Ratio	1.16	1.210

Thickness

The thickness of cinnamon containing nutraceutical tablet was found to be 3mm +/- .2mm. It depends upon the size of die and size of punches or a function of die fill and compression force.^[3,13]

Weight variation

The weight of 20 tablets was measured and it was found that the weight of tablet was 0.432 gm. Hardness is depend upon the compression force of punching machine and showed that it is sufficient for tolerating mechanical strength. Tablets should sufficiently hard to resist breaking during packaging, shipment and normal handling.^[12]

Friability

Friability of all formulations was found to be 1.8%. The friability of nutraceutical tablet was found above limit (standard less that 1%). There is no capping problem occurs in the tablets so that it can be use commercially. It produced no loss during shipping, packaging.^[11,12]

In-vitro drug release

The *in-vitro* drug release from nutraceutical tablets in 0.1N HCL was found to be 88.1% in 1hr. The release of eugenol as a therapeutic agent from nutraceutical tablet is produces maximum release in F2. Eugenol is main chemical constituent of of clove so, it provide more beneficial effects to the cinnamon containing tablets.^[12]

Table No.3: Post-compression studies of nutraceutical tablet.

Post- compression parameters	F1	F2
Thickness (mm)	1.2	3
Hardness (Kg/cm ²)	4.8	5.21
% Weight variation	0.399	0.432
% Friability	0.31	0.25
% <i>In-vitro</i> drug release	86.88	88.1

The nutraceutical tablet of cinnamon was formulated by wet granulation method. The physicochemical property show satisfactory result by nutraceutical tablet which are in range prescribed standards required for investigation of present study.^[7]

CONCLUSION

From the above study, we conclude that the nutraceutical tablet were prepared by wet granulation method and gave satisfactory and acceptable results. Conventional tablet of nutraceutical shows immediate drug release due to wet granulation method. From the above research work it was concluded that prepared herbal nutraceutical tablet is cost effective tablet which will increase patient compliance in regarding ease of administration and enhancing positive effects on the body. There is no significant difference between *in-vitro* drug release by direct compression method and wet granulation method.

FUTURE SCOPE

- The content of cinnamon tablet can be find out by various electrochemical instruments.
- The formulation can be designed by factorial design.

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