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Formulation And Evaluation Of Neutraceutical Tablet Of *Nigella Sativa* By Using Direct Compression Method

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ABSTRACT

Aim: The objective of present study was to formulate and evaluate the neutraceutical tablets herbal drugs. **Material and Method:** The nutraceutical tablet containing lactose and mannitol as diluent and containing natural drugs like Nigella sativa, which was prepared by direct compression method. The compressed formulations were subject to several evaluation parameters like appearance, thickness, weight variation, hardness and friability. **Results:** The results of all evaluation parameters of nutraceutical tablet were within the acceptable limit. Pre-compression studies of nutraceutical tablet show the thickness, hardess, weight variation, and friability of nutraceutical tablet were found to in acceptable range. The *in-vitro* drug release of nutraceutical formulation was found to be 90.23%. **Discussion:** The finding of current investigation clearly found that the health promotion of the body could be done by nutraceuticals.

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

INTRODUCTION

Plants have long been used as a basis of traditional remedies in the history of mankind and also act as sources of modern medicines. A nutraceutical is a product isolated or purified from foods that is generally sold in medicinal forms not usually connected with food. More researches and studies, 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 [(1)]. 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 may be sensed to be more "natural" than traditional medicine and less likely to produce unpleasant side-effects [(2,3)]. The concept behind the mode of action of nutraceutical dosage form is to provide functional benefits by enhancing the supply of natural building blocks [(4)].

Nigella sativa has been traditionally used for the treatment of a variety of disorders, diseases and conditions pertaining to respiratory system, digestive tract, kidney and liver function, cardio vascular system and immune system support, as well as for general well-being [(5)].

MATERIALS AND METHOD

Formulation of tablet

Nutraceutical tablets containing Nigella sativa was prepared by direct compression method. Other ingredients like lactose were used as diluent, magnesium stearate as lubricant and talc as glidant. All the excipients 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. The powder blend was thoroughly mixed with talc and magnesium stearate and compressed into a 400mg tablet using single rotatory punching machine (KI-150, Khera Instruments Ltd. New Delhi, India).

Table 1: Formulation table for neutraceutical tablet 400 mg

Ingredients	F1	F2	F3
Nigella sativa	100	100	100
Lactose	290	290	290
Sodium saccharine	2	2	2
Talc	4	4	4
Magnesium stearate	4	4	4

Evaluation of Nutraceutical Tablets

Pre-compressional studies

In development of new dosage form preformulations were studied like angle of repose, bulk density, tapped density, compressibility indices etc.

Angle of repose

The frictional force in a loose powder can be measured by the angle of repose. Angle of repose is the maximum angel between the surface of the pile of powder and horizontal plane. The sample was slowly passed along the wall of the funnel till the tip of the pile formed and touches the steam of the funnel. A rough circle was drawn around the pile base and the radius of the powder cone was measured.

Angle of repose was calculated from the average radius using the following formula.

$$\tan \theta = h/r$$

$$\theta = \tan^{-1}(h/r)$$

$\theta = Angle\ of\ repose$,h = Height of the pile ,r = Average radius of the powder cone

Bulk density

The bulk density of a powder primarily depends on particle size distribution, particle shape and the tendency of particles of particles to adhere together. Bulk density is very important in the size of containers needed for handling, shipping, and storage of raw materials and blend. Apparent bulk density (P_b) was determined by pouring blend into a graduated cylinder. The bulk volume (V_b) and weight of the powder (M) was determined. The bulk density was calculated by using the following formula

$$P_b = M/V_b$$

P_b = Bulk density (gm/cm^3), M = Weight of the sample in gm, V_b =Final volume of blend in cm^3

Tapped density

It is the ratio of total mass of the powder to the tapped volume of powder. The cylinder was tapped from height of 2 inches until a constant volume was obtained. Tap density is measured in 100taps volume occupied by the sample after tapping was recorded and tapped density was calculated by the following formula,

$$Pt = M/V_t$$

P_t=Tapped density (gm/cm^3), M=Weight of the sample in gm, V_t=Tapped volume of blend in cm^3

Percentage compressibility index

Compressibility is the ability of powder to decrease in volume under pressure. It is also one of the simple methods to evaluate flow property of powder by comparing the bulk density and tapped density. A useful empirical guide is given by the carr's compressibility or compressibility index.

Carr's index = (Tapped density-bulk density / Tapped density) x 100

Hausner ratio

It provides an indication of the degree of densification, which could result from vibration of the feed hopper.

Hausner ratio=Tapped density/bulk density

Table 2

S. No.	Parameter	Observation
1.	Angle of repose	21.12± 0.11
2.	Bulk density	0.45± 0.21
3.	Tapped density	0.49± 0.17
4.	Carr's compressibility index (%)	13.04± 0.16
5.	Hausner's ratio	1.14± 0.16

Post-compressional studies of prepared nutraceutical tablets

The nutraceutical tablets were evaluated for various parameters after consideration of preformulation to overcome errors during formulation preparation. These are like appearance, thickness, weight variation, hardness and friability. All the evaluation parameters of all formulations are given in Table 2.

Physical appearance

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

Thickness

The tablet thickness was calculated by Vernier calipers. Tablet was put in between two jaws vertically and measured thickness and 6 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/cm [6, 7].

Friability

It is determined by Roche friabilator, subjects a number of tablets to combined effects of abrasion and shock by utilizing a plastic chamber that revolves at 25 rpm, dropping tablet from inches distance operated for 100 revolutions. Pre weighed tablets were dusted and re-weighed and according to standard limit friability should be less than 1%. It is calculated by formula- % Friability = Initial weight – Final weight / Initial weight [8].

***In-vitro* drug release**

Dissolution profile of nigella sativa was determined at 37±0.5°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. Samples were filtered using Whatman filter paper and taken absorbance at wavelength of 366 nm by UV spectrophotometer [9].

Table 3

Formulation code	F1	F2	F3
Thickness (mm)	1.2±0.1	1.2±0.21	1.2±0.21
Weight variation (mg)	0.399±0.12	0.399±0.34	0.3991±0.12
Hardness	5.5±0.21.	4.8±0.11	4.31±0.12
Friability	0.23±0.2	0.31±0.012	0.14±0.045
In vitro drug release	90.23	86.33	88.64

RESULTS AND DISCUSSION

The nutraceutical tablet of nigella sativa 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.

PREFORMULATION STUDY

Organoleptic evaluation of pure drug

Nigella Sativa has a Yellowish-brown colour, Aromatic odour and Agreeable taste.

Precompression studies of neutraceutical tablet containing nigella sativa

Derived properties of Nigella Sativa such as angle of repose, bulk density, tapped density, Carr's compressibility index, and Hausner's ratio were shows in Table 2. The evaluation parameters such as angle of repose, bulk density, tapped density, Carr‟s index and Hausner‟s ratio was found to be 21.12±0.11, 0.45±0.21g/ml, 0.49±0.17 g/ml, 13.04 ±0.16, 1.14±0.16 respectively. After evaluation of preformulation parameters it showed that there is no presence of moisture in power and showed uniformity of powder blend 11. After study of flow rate, it concludes that powder blend exists optimum proportion that leads to maximum flow rate. So, the result showed that the powder has good flowing property which does not cause affect the process of tablet punching [10].

Post-compression study

The result from different physical parameters like thickness, hardness, weight variation, and friability of tablets was shown in table 3. The presence of active pharmaceutical ingredients, filler, glidant and lubricant is sufficient for provided bulk to the tablet which decrease risk during punching. The thickness, hardness, weight variation, and friability of nutraceutical tablet were founded to be in acceptable limit. It shows that the herbal drugs containing nutraceutical tablets have satisfactory disintegration profile due to their hardness within range of standard limit [(11)].

Physical appearance the general appearance of tablet was found to be round in shape, brown in color, smooth texture, and odourless.

Thickness The thickness of clove and cinnamon containing nutraceutical tablet was found to be 1.2± 0.1cm. It is depending upon the size of die and punches or a function of die fill and compression force.

Weight variation the weight variation was found to be 0.399 ±0.12 to 0.399 ±0.34. All the nutraceutical tablet containing nigella sativa passed weight variation test as the average percentage weight variation was within the USP limits ±5%.

Hardness The hardness of nutraceutical tablet was found to be 4.31± 0.12 to 5.5 ± 0.21 for nigella sativa containing formulations. Mannitol containing formulation code showed more friable and less hardness than lactose as diluent. It is depended upon the compression force of punching machine and showed that it is sufficient for tolerating mechanical strength. Tablets showed sufficiently hard to resist breaking during packaging, shipment, and normal handling.

Friability Friability of all formulations was found to be0.14±0.045 to 0.31±0.0.12 %. The friability of nigella sativa containing tablet was found to be in acceptable limit i.e. less than 1%. There no capping problem occurs in the tablets so it could be considered for commercial use. It produced no loss during shipping process.

***In-vitro* drug release** the in-vitro drug release of eugenol from all nutraceutical tablets in 0.1 HCL was found to be 85.34 to 90.23%respectively in 1 h. Various aliquot samples were withdrawn with replacement simulated fluid of same amount at 5, 10, 15, 30, 45, and 60 min respectively. Samples were filtered using whatmann filter paper and taken absorbance at wavelength of 366 nm by UV spectrophotometer.

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. The formulation containing Nigella sativa could be more beneficial as an nutritional effect. 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 supressing side effects and enhancing positive effects on the body.

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