Formulation and Evaluation of Nutraceutical Tablet for the replacement therapy

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ABSTRACT

With the ageing of the population worldwide, there is a growing demand for cheap and safe therapy for ageing diseases. The present work aimed at the formulation of a nutraceutical tablet from two nutrient-dense millets, Eleusine coracana (Finger millet) and Echinochloa frumentacea (Barnyard millet), with high calcium, iron, fiber, antioxidant, low glycemic index, and gluten-free contents—making them suitable for ageing people. Two formulations of the tablet, F1 (lactose) and F2 (mannitol), were tested. Both conformed to Indian Pharmacopeia but, as a result of mannitol's hydrophilic property, F2 demonstrated better disintegration and dissolution. It thus proved more suitable for use by elderly patients.

This research formulated and characterized nutraceutical tablets from *Eleusine coracana* and *Echinochloa frumentacea* to address the dietary requirements of the elderly. Two were prepared and evaluated: F1 (with lactose) and F2 (with mannitol). Both were found to conform to pharmacopeial specifications, with uniform weight, good hardness (>5 kg/cm²), friability (<1%), and fast disintegration (<1.5 minutes). F2 was superior in terms of disintegration and dissolution because of the hydrophilic nature of mannitol. The results affirm millet-based nutraceuticals as efficient, secure, and cost-effective age-related condition supplements that ensure healthy aging with less dependency on synthetic drugs.

Keywords- *Eleusine coracana,* Echinochloa frumentacea, *Nutraceuticals, pharmacopeial, supplements*

INTRODUCTION

The oral route is still one of the most favored routes for drug administration because of its simplicity, easy patient compliance, low sterility demands, and the ease with which different dosage forms can be designed. Of these, tablets are widely in use. They are a unit dose, tamper-evident solid dosage form of one or more active pharmaceutical ingredients (APIs) [5.] Nevertheless, traditional oral dosage forms like tablets and capsules are generally formulated for immediate release, i.e., rapid dissolution in the gastrointestinal tract (GIT). Although this promotes quick absorption into the circulatory system, it can also result in a steep peak of plasma drug levels. These sudden peaks, commonly called plasma concentration peaks, can precipitate undesirable side effects, decreased therapeutic efficacy with long-term use, and the need for frequent dosing to achieve the required therapeutic levels. Consequently, increased attention has focused on modified-release products (e.g., sustained-release or controlled-release products), which are designed to release drugs at a predetermined rate, minimize dosing frequency, and provide more uniform plasma drug concentration[1].

The concept of utilizing food for health-promoting purposes beyond its basic nutritional value is increasingly gaining acceptance within both the public domain and the scientific community. Nutraceuticals consist of health-supporting ingredients or natural constituents that possess therapeutic or preventive health benefits[6].

A *nutraceutical* is defined as a product isolated or purified from food sources and typically presented in a medicinal form not commonly associated with conventional food. These products are intended to exert physiological benefits or provide protection against chronic diseases and long-term health conditions[7]. Nutraceuticals typically contain varying amounts of lipids, proteins, carbohydrates, vitamins, minerals, and other essential nutrients, depending on their intended purpose. The range of nutraceuticals available in the market includes both conventional and unconventional food products. When a supplement tablet is consumed, the body is responsible for digesting and absorbing the contained nutrients. Nutraceuticals can encompass a broad category of products, including isolated nutrients, dietary supplements, herbal products, and other processed foods designed to support health and prevent disease[8].

Nutrition plays a vital role in maintaining health, preventing disease, and managing chronic conditions in elderly populations. However, geriatric individuals are particularly vulnerable to malnutrition due to factors such as decreased appetite, difficulty in chewing or swallowing, poor absorption, medication side effects, and cognitive impairment. These nutritional gaps can worsen age-related health issues such as osteoporosis, cardiovascular disease, cognitive decline, and weakened immunity[9].

Over the past few years, nutraceuticals have emerged as a promising method of enhancing health, preventing illnesses, and improving overall well-being[16]. A novel nutraceutical tablet is a solid dosage product having nutritional as well as therapeutic advantages, generally with bioactive substances in the form of vitamins, minerals, amino acids, antioxidants, herbal products, and various functional ingredients. These tablets are specifically formulated to provide support for certain health conditions while delivering vital nutrients that are deficient in the regular diet. In contrast to traditional drugs, nutraceutical tablets are usually employed as preventive applications and tend to be safer for long-term applications. The tablet form ensures precise dosing, convenience, stability, and increased patient compliance, which makes them a favorite among consumers. With increasing demand for health-sustaining

supplements, research on development and assessment of nutraceutical tablets has become a significant field of study in pharmaceutical and nutrition sciences[17].

Eleusine coracana (Finger millet) and Echinochloa frumentacea (Barnyard millet) are ancient cereal grains that are highly nutritious and hence of special value to the geriatric population. Finger millet has high content of calcium, iron, dietary fiber, and B-vitamins that help maintain bone health, mental functions, and blood glucose levels. Barnyard millet, being rich in protein, fiber, and minerals, helps control weight, enhances digestion, and possesses anti-inflammatory properties beneficial in conditions such as arthritis. Both millets have a low glycemic index and provide cardiovascular benefits by controlling blood pressure and enhancing heart health[18 19].

With their spectacular nutrient profiles and health-enhancing characteristics, these millets are great prospects for use in nutraceutical tablet formulations. Their application in geriatric nutrition can be an efficient replacement therapy, targeting health problems related to age and improving overall well-being[22].

MATERIALS AND METHODS

MATTERIALS:-

The grains of Echinochloa frumentacea (barnyard millet) and Eleusine coracana (Finger millet) were collected and purchased from local village near Ukhimath (village- Parkhandi), Rudraprage, Uttarakhand, India

S. No.	Ingredients	Properties
1	Echinochloa frumentacea	Nutritional
2	Eleusine coracana	Nutritional
3	Lactose	Binder/diluent
4	Sodium saccharin	Sweeting
5	Mannitol	Binder/ diluent
6	Talc	Glident
7	Magnesium Stearate	Lubricant

Table 1: Ingredients with their properties

METHOD:-

1. **Weighing of Ingredients:**

   All ingredients, including active pharmaceutical ingredients (Echinochloa frumentacea and Eleusine coracana) and excipients (lactose or mannitol, sodium saccharin, talc, and magnesium stearate), are accurately weighed according to the formulation requirements. Two formulations are prepared:

   - F1 uses lactose as the diluent.
   - F2 uses mannitol as the diluent.

2. **Sifting:**

   The weighed powders, except talc and magnesium stearate, are passed through a #40 mesh sieve to break agglomerates and ensure uniform particle size distribution. This step improves blending efficiency and content uniformity.

3. **Blending:**

   The sifted ingredients are transferred to a clean, dry mortar or blender and mixed thoroughly for 10 to 15 minutes to achieve a homogenous blend. Uniform mixing is essential to ensure that each tablet contains an accurate dose of the active ingredients.

4. **Addition of Lubricants:**

   Talc and magnesium stearate, which function as glidants and lubricants, are passed through a #60 mesh sieve and added to the blend. The mixture is then gently blended for an additional 2 to 5 minutes. Over-mixing should be avoided, as excessive lubrication may impair tablet compressibility and hardness.

5. **Tablet Compression:**

   The final blend is compressed into tablets using a single-punch or rotary tablet compression machine fitted with suitable punches and dies. Tablets are formed by applying pressure that compacts the powder into the desired shape and size (typically 500 mg). Parameters such as tablet weight, thickness, and hardness are monitored during compression to maintain quality and consistency.

The nutraceutical tablet of 500 mg was prepared as followings:-

S. No.	INGREDIENTS	F1 (in mg)	F2 (in mg)
1	Echinochloa frumentacea	125	125
2	Eleusine coracana	125	125
3	Lactose	240	-
4	Sodium saccharin	2	2
5	Mannitol	-	240
6	Talc	4	4
7	Magnesium Stearate	4	4

Table 2: Formulation table of nutraceutical tablets for replacement therapy

Evaluation of Nutraceutical Tablets

Pre-compressional studies

Pre-formulation study is an important first step in the future process of drug development, being the starting point study to obtain the essential information for the known properties of the compound. This step is useful in giving information on the chances of developing a compound into a new dosage form without the existence of major hurdles to the formulation and development. The most important goal of a pre-formulation study is to evaluate the physical and chemical properties of the active pharmaceutical ingredient (API) and determine the developmental timeline for the drug formulation[22].

- **Determination of true/bulk density**

10g of seed powder into 50ml (M) of glass measuring cylinder and bulk volume (Vo) determined. Now bulk density (Db) calculated form the following formula:

Bulk Density=Mass/Volume Occupied

Db=M/Vo

- **Determination of Tapped Density**

Tapped density was determined by tapping 10g of powder after the bulk density determined. The powder was tapped to a constant rate and volume recorded. Tapped density (Dt) calculated from the following formula:

Tapped Density=Mass/Volume
Dt=M/V

- **Determination of Angle of repose**

Angle of repose was determined by funnel method. Accurately weight powder was taken in funnel and height of funnel was adjusted in such a way that the tip of the funnel just touched the apex of the hip. The powder was allowed to flow through the funnel freely onto surface. The diameter of the powder cone was measured and angle of repose was calculated with following formula;

$\tan \theta = h/r$

Where:

θ = angle of repose (in degrees)

h= height of the powder cone (cm or m)

r= radius of the base of the cone (cm or m)

- **Determination of Hausner ratio**

Hausner ratio is the determination of interparticulate friction. It was determined by following formula:

Hausner Ratio=Bulk Density/Tapped Density

Where:

Tapped Density = mass of the powder / tapped volume

Bulk Density = mass of the powder / bulk (loose) volume

Post-compressional studies

Post-formulation study is a pivotal stage in drug development that is done after the formulation of a drug product. It is crucial to assess the performance and stability of the drug in its ultimate dosage form. Nutraceutical tablets were tested for a range of parameters following pre-formulation consideration to overcome formula preparation errors[24].

- **Physical appearance**

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

- **Weight variations**

The Weight Variation Test is performed by weighing 10 tablets separately. The average weight of these tablets is then determined and compared to the average weight of an individual tablet. This test serves as an acceptable method for measuring the uniformity of drug content within tablets. By ensuring that each tablet has a consistent weight, the test helps guarantee that each tablet contains the correct amount of active pharmaceutical ingredient (API), contributing to the quality and efficacy of the final dosage form.

- **Hardness**

Hardness also called tablet crushing strength. The tablet hardness was measured by Monsanto hardness tester. The tablet was positioned lengthwise between upper and lower plunger and pressure exerted by revolving a threaded bolt until tablet breaks and measured hardness of tablet in Kg/cm.

- **Friability**

Friability is the measure of a tablet's tendency to crumble or break into smaller pieces. Weighing ten tablets, they are put inside a Roche fribilator drum. With each revolution, the effervescent tablet descends six inches as it spins at 25 rpm

- **Disintegration time**

Beaker was filled with water and temperature was maintained at 37 ± 2°C**.** Tablets are placed in each of the six tubes of the disintegration apparatus and discs are inserted in each tube above the tablet. Operation was continued until no residue remains on the screen of each tube.

- **Dissolution time**

Vessel was filled with the dissolution medium and temperature maintained at 37 ± 0.5°C**.**Tablet placed in the basket and basket was placed at the specified height (25 mm) above the bottom, at a specified speed (usually 50 or 75 rpm) basket rotate until table completely dissolve.

RESULTS AND DISCUSION

Eleusine coracana and Echinochloa frumentacea nutraceutical tablet was prepared by direct compression technique. This technique was applied to traditional form nutraceutical tablet that reduces steps of process and avoided wetting and drying process. Physiochemical property of Eleusine coracana and Echinochloa frumentacea nutraceutical tablet exhibits satisfactory result by nutraceutical tablet which are within range of standards prescribed for investigation of current study.

PRE-EVALUATION TEST

Pre evaluation tests show the flow property of powder assess the flowability**,** compressibility, and handling behavior**,** Eleusine coracana and Echinochloa frumentacea show average to good flowability properties.

The final results of post-evaluation tests are indicated in Table 5.

Millet	true/bulk density (g/ml)	Tapped Density (g/ml)	Angle of repose	Hausner ratio
Eleusine coracana	0.60	0.79	35	1.31
Echinochloa frumentacea	0.61	0.80	32	1.25

Table 5:- Pre formulation evaluation table of Eleusine coracana and Echinochloa frumentacea powder

5.1 POST-FORMULATION TEST

Two different formulation tables were prepared with different types of excipients to get the best results, as explained in Table 1. Nutraceutical tablets of 500 mg were formulated. Uniform tablet thickness was obtained by uniform die filling, good flow properties, proper pressure, and controlled punch movement.

All the formulations passed the weight variation limit of 0.50 ±10 g, as indicated in Table 4. The friability of all the formulations was less than 1%, which indicates tablet stability. Tablet hardness was determined using a hardness tester, with values between 40 and 80 N. This indicates tablets strength and its resistance to mechanical stress.

Both formulations show high dissolution and disintegration time profile it makes them fall in the category of fast dissolving tablet**.** Rapidly disintegrate and dissolve after oral administration, allowing the active pharmaceutical ingredient (API) to be quickly absorbed into the bloodstream.

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

Testing of nutraceutical tablets, conducted according to IP standards, confirmed uniformity in the dosage form. The final results of post-evaluation tests are indicated in Table 3.

Formulation	Weight Variation (gm)	Hardness (kg/cm2)	Friability (%)	Disintegration Time (min)	Dissolution time(min)
F1	1.1	5.5	0.84	1.2	1.4
F2	0.9	5.2	0.54	1	1.1

Table 3: Post formulation evaluation table of nutraceutical tablets

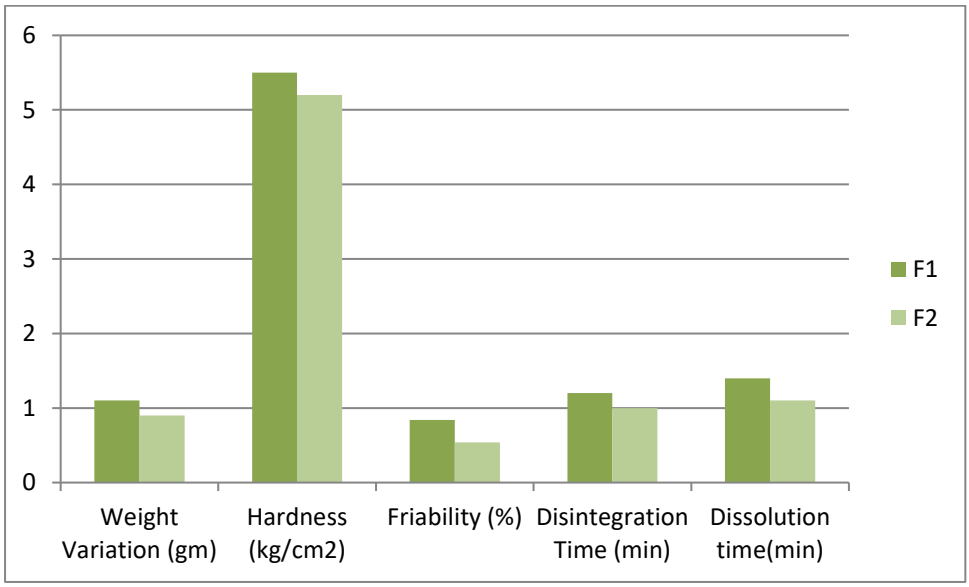

Fig 12: Graphical representation of Evaluation table

CONCLUSION

The objective of this study was the development and evaluation of a nutraceutical tablet from two nutrient-rich millets, Eleusine coracana (Finger millet) and Echinochloa frumentacea (Barnyard millet). The two millets are rich in calcium, iron, dietary fiber, and antioxidants, which have a significant function in regulation of age-related diseases such as osteoporosis, anemia, and cardiovascular disorders. Their low glycemic indices make them ideal for elderly patients suffering from metabolic disorders like diabetes, and their natural, gluten-free, and hypoallergenic status makes them ideal for the elderly patients. With the world aging, there is a higher need for effective and affordable therapies for age-related illnesses. Nutraceuticals providing health benefits beyond ordinary nutrition have become new challengers to become substitutes for traditional medication. Tablets, as a convenient and effective carrier for nutraceuticals, especially for long-term administration and mass production, offer a practical solution for elderly populations.

The evaluation showed that both F1 and F2 formulations met the standards of pharmacopeia, having uniform unit weight, good mechanical strength (hardness >5 kg/cm²), and minimal friability (<1%), which ensured tablet stability against compression and shipping shock. Disintegration of both preparations was less than 1.5 minutes, which reflected the rapid-dissolving property of the tablets—a characteristic most essential in elderly patients with compromised swallowing mechanism (dysphagia) or slowed gastrointestinal motility. F2, using mannitol as a diluent, was quite better in terms of disintegration and time to dissolution due to the hydrophilic and mouthfeel-contributing properties of mannitol.

In conclusion, this study successfully established the effectiveness and feasibility of developing a nutraceutical tablet from Eleusine coracana and Echinochloa frumentacea solely for the purpose of meeting the nutrition and physiological needs of older individuals. The product in its full form offers an inexpensive, natural, and safe supplement that aids in bone structure, immune system, digestive system, and metabolic balance. The study also indicates the potential of millet-based nutraceuticals for healthy aging and prevention of synthetic drug dependency. Future scope includes research on the potential of other bioactive molecules, long-term shelf life study, and clinical trials to determine efficacy and patient acceptability.

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