ABSTRACT

Nutraceuticals are food or part of food that provides medical or health benefits including the prevention and/or treatment of a disease and avoid side effect. The major diseases for the prevention or treatment of which nutraceuticals have been associated are heart failure, cancer, hypertension and diabetes. The nutraceutical lozenges contain Antioxidants, Polyunsaturated fatty acids, Prebiotics, probiotics, Omega-3-fatty acids and Dietary fibres. Nutraceutical lozenges are one of the widely used solid dosage forms. Nutraceutical lozenges are also for systemic effect provided the drug as well as absorbed through the buccal linings or when it is swallowed these are flavoured medicated dosage form intended to be sucked and held in mouth or pharynx. The nutraceutical lozenges contain naturally antioxidants like transferin, lactoferin, glutathione, carotenoids, amla, myrobalan, lemon and their plant pigments, Polyunsaturated fatty acids like vegetable oils and marine animals, safflower, corn oil, mustard oil, soyabean oil, Probiotics like Bifidobacterium and lactobacilli species, fibres are like rice, banana, cassava, vegetables, whole grain, cereals, oats, barley, sorghum, oats, dried beans, legumes, chicory etc. which shows tremendous health benefits to the mankind with less side effects. Due to the increasing popularity with health-conscious consumers, functional food science is becoming popular and creating new interest in marketing the products.

KEYWORDS: Nutraceutical, Antioxidants, Dietary fibres, Lactobacilli, Dried beans etc.
INTRODUCTION

Nutraceuticals are the chemical substances which can be considered as the food or its part, in addition to its normal nutritional value provides health benefits including prevention of disease or promotion of health. The major diseases for the prevention or treatment of which nutraceuticals have been associated are heart failure, cancer, hypertension and diabetis. The other diseases which related with role of nutraceuticals are osteoporosis, arthritis and neural tube defects. \(^1\) The explosive demand growth for bioactive ingredients for nutraceuticals and functional foods is being driven by frequently cited health concerns: Cardiovascular disease, Breast, skin, colorectal, and brain cancers, Female health concerns, CNS disorders, Metabolism management, Gastrointestinal disorders and Immuno modulation. \(^2\)

The quality of life in terms of income, spending and lifestyle has improved with economic development. However, it has also thrown up a major challenge in the form of 'lifestyle diseases'. The first thing of this lifestyle change has been food habits. Consumption of junk food has increased manifold, which has led to a number of diseases related to nutritional deficiencies. Nutraceuticals can play an important role in controlling them. No wonder more and more people are turning to nutraceuticals. \(^3\)

Increasing awareness levels about fitness and health, spurred by media coverage are prompting the majority of people to lead healthier lifestyles, exercise more, and eat healthy. The expanding nutraceutical market indicates that end users are seeking minimally processed food with extra nutritional benefits and organoleptic value. This development, in turn, is propelling expansion in the nutraceutical markets globally. The emerging nutraceuticals industry seems destined to occupy the landscape in the new millennium. Its tremendous growth has implications for the food, pharmaceutical, healthcare, and agricultural industries. \(^4\)

Nutraceutical lozenges also possess nutritional value; this preparation can be considered as an alternative, cost effective, safer and potential medicine to treat many diseases. Due to the increasing popularity with health-conscious consumers, functional food science is becoming popular and creating new interest in marketing the products. It is hoped that serve to develop cost effective, safer and potential preparation for various chronic and sub chronic diseases. Designing a proper food to maintain proper health has gained recognition and acceptance worldwide. Due to this, the food industry in many countries is modifying their products as
responsible for consumer goods. The nutraceutical lozenges contain Antioxidants, Polyunsaturated fatty acids, Prebiotics probiotics, Omega-3-fatty acids and Dietary fibres.\(^5\)

Antioxidant nutraceuticals contain vit-C, E, A and carotene. They are present in some fixed oils, fruits, vegetables, and fishes. Antioxidants present in such food materials which prevent the formation of free radicals or scavenging activity. Some of the naturally antioxidants are which c transferin, lactoferin, glutathione, carotenoids and their plant pigments. The oxidation of LDL cholesterol increases the chance of atherosclerosis, Tocopherols reduce platelet role in thrombus formation, Various plants like amla, myrobalan, lemon, prevent oxidation and scavenging of oxygen free radicals. Beta carotene and vit-A shown antioxidant effect.\(^6\)

Polyunsaturated fatty acids are present in various vegetable oils and marine animals. These source include safflower, corn oil, musturd oil, soyabeen oil, they help reduce cholesterol formation. Vegetable oil contain PUFA belonging to Linolenic group. Some marine fishes contain PUFA belonging to omega-6 type, omega-3 type. These reduce thromboxane formation and hence useful as preventive measures of atherosclerosis.\(^7\)

Probiotics are living microorganisms, which when taken with or without food, It improve the intestinal microbial balance and in turn functioning of large intestine. Probiotics include Bifidobacterium and lactobacilli species like L.Acidophilus. These microorganisms exert their effects by producing substances and conditions which inhibit the growth of harmful bacteria in the large intestine. The dairy products like sour milk, yoghurt containg probiotics.

Prebiotics are the food substances which reach to colon in intact form, without getting depleted by gastric pH. These are nutraceuticals which promote the flourishing the probiotics. Before reaching the colonic region, the probiotic microorganisms have to survive against the digestive enzymes and acids in the upper gut. To overcome this problem, nutraceuticals in the form of probiotics available. Example: inulin polyfructose obtained from raw chicory.\(^8\)

Dietary fibres play a critical role in maintenance of health. They can be defined as such parts of plant stems, leaves and seeds. Which human body cannot digest and absorb. High fibre intake gives variety benefits to human body. Dietary fibres are generally categorized into two groups water soluble and water insoluble. Insoluble fibres mainly help in bulking of stools and their quick passage through digestive canal. Soluble fibres dissolve in water and forms
that binds the stool. Insoluble fibres mainly present in brown rice, banana, cassava, vegetables, whole grain, cereals, oats, barley, sorghum. Soluble fibres are present in oats, dried beans, legumes, chicory etc.\[9\]

The current trends in biodrugs indicate the commercial utility of omega-3-fatty acids, spirulina, soya, garlic, and royal jelly. Omega-3-fatty acids are Eicosapentaenoic acid and docosahexanoic acid DHA. They are polyunsaturated fatty acids mainly in the marine groups. They are found in the cold water fishes, cod, salmon, tuna, sardines, blue fish, mackerel and harring.\[10\]

Nutraceutical lozenges contain one or more medicaments in a flavoured and sweetened base and are intended to treat local irritation or infection of mouth or pharynx and may also be used for systemic drug absorption.\[11\] Lozenges are intended to achieve local effect as soothing and pyring the throat. Something they are used to relieve cough.

Nutraceutical lozenges are also for systemic effect provided the drug is well absorbed through the buccal linings or when it is swallowed these are flavoured medicated dosage form intended to be sucked and held in mouth or pharynx. They provide ease of administration for paediatric patients. The drugs having a large dose can be easily administered formulating as lozenges. Patient compliance is high with buccal delivery due to the accessibility of the cheek and lack of invasive measures.\[12\] Most of the illness is associated with high body temperature, fever, head ache and body ache. It is very difficult to manage these complications in pediatrics patients. The medicated lozenges are generally prepared by molding and compression techniques mostly in acacia or gelatin base- Pastilles and sugar as base- Troches. The oral or buccal cavity is highly vasculated which adds an advantage of maximum local activity thus minimizing systemic activity.\[13\]

Nutraceutical lozenges with antimicrobial and local anaesthetics as active ingredient are mostly advised for patients with swallowing problems, gastrointestinal blockade, paediatrics and geriatrics as they can be sucked easily into the saliva, providing localized drug delivery to the mouth, tongue and throat etc. Lozenges as the pharmaceutical dosage forms have several advantages than the oral administration as they can be manufactured with several excipients such as sweeteners for increasing solubility, colourants for elegant appearance, dyes to prevent photo degradation.\[14\]
**Classification of nutraceutical lozenges**

Lozenges can be classified into various classes based on various methods like A. According to site of action; a) Local effect eg: Antiseptics b) Systemic effect eg: Vitamins, nicotine B. According to texture and composition; a) chewery and caramel based medicated lozenges b) compressed tablet lozenges c) soft lozenges d) hard lozenges.

**Methods of nutraceutical lozenges:** Lozenges are formulated in such a way that they are stable, provide a good medium for administration of drug. The ingredients which are used for formulation of Lozenges are as follows.[15][16]

**Soft candy lozenges**

Soft lozenges are either meant for chewing or for slow dissolution in mouth. They can be made from PEG 1000 or 1450, chocolate or sugar-acacia base while some soft lozenge formulations can also contain acacia and silica gel. Acacia is used to provide texture and smoothness to the lozenge and silica gel is used as a suspending agent to avoid settling of materials to the bottom of the mold cavity during the cooling. The formulation requires heating process at about 50°C hence is only suitable to heat resistant ingredients.[17]

**Hard candy lozenges**

Hard candy lozenges are mixtures of sugar and other carbohydrates in an amorphous (noncrystalline) or glassy state. They can also be regarded as solid syrups of sugars. The moisture content and weight of hard candy lozenge should be between, 0.5 to 1.5% and 1.5-4.5g respectively. These should undergo a slow and uniform dissolution or erosion over 5-10min., and should not disintegrate. The temperature requirements for their preparation is usually high hence heat labile materials cannot be incorporated in them.

**Evaluation of lozenges:** All the formulations prepared were subjected to different evaluation tests as subjected below.[18]

**Hardness:** It was determined by using Pfizer tablet hardness tester. The test was performed for three lozenges and standard deviation was calculated.

**Thickness and diameter:** Diameter and thickness of the lozenges were measured using vernier callipers. The test was performed for three lozenges and standard deviation was calculated.
Drug content and uniformity: The content uniformity was tested by powdering one lozenge and dissolving the powder content in 60ml of methanol in a 200ml volumetric flask and make up the volume using phosphate buffer pH 6.8. From this 10ml was diluted with phosphate buffer pH 6.8 up to 100ml and absorbance was recorded at 249.

Moisture content: The moisture content was determined by Karl Fischer Titration.

Candy base: It has to be check for following parameters-Corn syrup, sugar delivery gears, Temperature, steam pressure and cooking speed of precookers and temperature, steam pressure, cooking speed and vacuum of candy base cookers.

Weight variation: USP weight variation test is done by weighing 20 lozenges individually, calculating the average weight and comparing the individual weights to the average.

Drug interaction excipients studies: Determined by FTIS.

Friability: Determined by Roche Friabilator operated at 25rpm for 4min.

In vitro drug release: -This is carried out in USP II paddle type dissolution apparatus.

Microbial check: In this test the presence of any bacterial, mold or spore contamination is checked in raw materials, finished products, machinery, cooling tunnels, environmental conditions and storage drums. Laboratory microbial testing should include the following counts: Total plate, Total coliform, Yeast and mold, E.coli, Staphylococcus and Salmonella.[19]

Stability test: Lozenges are subjected to stability testing under following conditions 1-2 months at 60°C 3-6 months at 45°C 9-12 months at 37°C 36-60 months at 25° C and 4°C.

Packing of lozenges: Hard candies are hygroscopic and usually prone to absorption of atmospheric moisture. Consideration must include the hygroscopic nature of the candy base, storage conditions of the lozenges, length of time are stored and the potential for drug interaction. These products should be stored in light containers to prevent drying. This is especially true of the chewable lozenges that may dry out excessively and become difficult to chew. It is best to slip this unit into a properly labelled, sealable plastic bags.[20]
Storage of lozenges
Lozenges should be stored away from heat and out of reach of childrens. They should be protected from extremes of humidity depending upon the storage requirements of both the drug and base, either room temperature or refrigerator temperature is usually indicated.

Advantages of lozenges: It can be given to those patients who have difficulty in swallowing, Easy to administer to geriatric and pediatric patients. It has a pleasant taste, it extends the time of drug in the oral cavity to elicit a specific effect, Easy to prepare, with minimum amount of equipment and time, Do not require water intake for administration. Technique is non invasive, as is the case with parenterals. Many diets are rich in phenolics component and are daily consumed by human beings. They rarely have any side effects. They have relatively long half-life. They can be easily absorbed in the intestine after ingestion. They do not require on appointment with a health care provider and are easily available without prescription. Many people believe this approach is more natural than using prescription drug. They feel dietary supplements will help them feel stronger and healthier, give them more energy and prevent illness. Some people turn to these products when they feel standard treatments for their specific illnesses have failed.\(^\text{[21]}\)

Disadvantages of lozenges: It could be mistakenly taken as candy by children, hence should be kept out of the reach of children. The non ubiquitous distribution of drug within saliva for local therapy. Possible draining of drug from oral cavity to stomach along with saliva.

DISCUSSION AND CONCLUSION
The nutraceutical revolution will lead us into a new era of medicine and health, in which the food industry will become a research, oriented one similar to the pharmaceutical industry. Although nutraceuticals have significant role in the promotion of human health and disease prevention, health professional, nutritionists and regulatory toxicologist should strategically work together to plan appropriate methodologies to provide the ultimate health and therapeutic benefit to human beings.\(^\text{[22]}\)

Clinical studies are required to scientifically validate the nutraceuticals in various medical conditions. The interaction of nutraceuticals with food and drugs is should be taken into consideration. The effect of different processing techniques on the biological availability and effectiveness of nutraceuticals to be determined. Since the ingredients used in nutraceutical lozenges also possess nutritional value, this preparation can be considered as an alternative,
cost effective, safer and potential medicine to treat many diseases. Due to the increasing popularity with health-conscious consumers, functional food science is becoming popular and creating new interest in marketing the products. It is hoped that the study serve to develop cost effective, safer and potential formulation for various chronic and sub chronic diseases.

REFERENCES


