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RESEARCH ARTICLE **OPEN ACCESS**

PREPARATION AND EVALUATION OF PROBIOTIC CHEWABLE TABLETS

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ABSTRACT

Probiotics are Probiotics are live bacteria and yeast that are good for our digestive system. Probiotics are often called 'good' or helpful bacteria because they keep our gut healthy. Probiotics can be obtained by supplements and in some food like yogurt. Probiotic gum replenishes good bacteria and the body while we chew and freshen our breath.

TYPES OF PROBIOTICS

Lactobacillus

Most common.

- Found in yogurt and other probiotic foods.
- Different strains can help with diarrhea and may help people who are lactose intolerant.

***Bifidobacterium*:**

- Found in some dairy products.
- May help ease symptoms of irritable-bowel syndrome and some other conditions.

***Saccharomyces boulardii*:**

- Is Yeast found in Probiotic?
- Appears to help fight diarrhea and other digestive problems.

Streptococcus:

- *Streptococcus thermophilus*
- Streptococcus faecalis

Clostridium butyricum:

PROBIOTIC FUNCTION

- Treats irritable bowel syndrome.
- Treats inflammatory bowel disease.
- Treats infectious diarrhea (caused viruses, bacteria or parasites.)
- Treats diarrhea caused by antibiotics.

MARKETED PROBIOTIC

- Yakult probiotic health drink= *Lactobacillus casei Shirota* 6.5 billion.
- Doctor's Best digestive probiotic-

a) *Bifidobacterium lactis* strain HN019.
b) *Bifidobacterium lactis* strain BI-04.
c) *Bifidobacterium lactis* strain BI-07.
d) *Lactobacillus acidophilus* strain LA-14.
e) *Lactobacillus salivarius* strain Ls-33.
f) *Lactobacillus paracasei* strain Lpc-37.

BIFILAC-lozenges contains

- Lactobacillus sporogenes **50 million,**
- Streptococcus faecalis **T-110 30 million,**
- Clostridium butyricum **TO-A 2 million**
- Bacillus mesentericus **TO-A 1 million**

PROBIOTIC GUM AVAILABLE

- Focus nutrition and pure probiotic gum=
  Refreshing sweet mint-30 pieces. Probiotic used- Ganedenbc30.

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Chewable tablets are tablets intended to disintegrate smoothly in mouth at moderate rate either with or without chewing. Characteristically they have smooth texture upon disintegration. They are pleasant tasting and leave no bitter or unpleasant aftertaste. Chewable tablets are required to be broken and chewed in between teeth before ingestion. Geriatric and pediatric patients and travelling patients, who may not have ready access to water, are most needy of energy swallowing dosage forms like chewable tablets. One of the most innovative approaches can be that of Probiotics as chewable tablets. Probiotics improve immune system, digestive support and oral health. Oral health is important not only to how we feel about our self but also to how we feel inside. The replacement of bad bacteria with good bacteria balances digestive health, boosts immune support and improves oral environment to help decrease bad breath, plaque formation, risk of tooth decay and gingivitis. Chewable tablets have their compositions as a basic gum core which may or may not be coated. The core is an insoluble gum base with fillers, waxes, antioxidants, sweeteners, flavoring agents. The percentage of gum base varies from 30-60% depending upon the base used and its properties. Flavoring agents make it more palatable. There are various factors involved in the formulation of chewable tablets like that of flow, lubrication, disintegration, organoleptic properties, compressibility, compatibility and stability.

There are various advantages of Chewable Tablets. They are

- Better bioavailability through bypassing disintegration. This increases dissolution.
- Improved patient compliance because of taste.
- Patient convenience by removing the need to swallow.
- Substitute for liquid dosage forms where rapid onset is required.
- Absorption of the drugs is faster.
- Product distinctiveness through marketing prospective.
- Large size of dosage forms are difficult to swallow, where the chewable tablets provide us the advantage at these situations.
- Effectiveness of therapeutic agents is improved by reduction in size that occurs during mastication of tablet before swallowing.

There are various disadvantages of Chewable Tablets. They are

- Contains sorbitol which causes diarrhea and flatulence.
- Flavoring agents may cause ulcer in oral cavity.
- Prolonged chewing of chewable tablet results in pain facial muscles.
- They are hygroscopic in nature, so we have to keep them in dry place.
- Show the fragile , effervescent granules property.
- They have insufficient mechanical strength, so they require careful handling.
- They require proper packaging for safety and stabilization of stable drugs.

Probiotics can be defined as living microbes, or as food ingredients containing living microbes, that beneficially influence the health of the host when used in adequate numbers. Both definitions have in common the idea that probiotic microorganisms are living. Furthermore, the efficacy and safety of probiotics should be scientifically proven. Probiotic effects are strain specific; thus each individual bacterial strain must be tested separately for the health benefit in question, and the effects described for one strain cannot be directly applied to others. Traditionally, probiotics have been associated with gut health, and most clinical interest has focused on the prevention or treatment of gastrointestinal infections and diseases; however, during the last decade, an increasing number of established and proposed health effects of probiotic bacteria have been reported, including enhancement of the adaptive immune response, treatment or prevention of urogenital and respiratory tract infections, and prevention or alleviation of allergies and atopic diseases in infants. Several investigators have also suggested probiotics for oral health purposes. Interestingly, probiotics are also suggested to increase the lifetime of voice prosthesis by inhibiting the adhesion of unwanted microbes.

POTENTIAL MECHANISMS OF PROBIOTIC EFFECTS IN THE ORAL CAVITY

The general mechanisms of probiotics can be divided into three main categories: Normalization of the intestinal microbiota, modulation of the immune response, and metabolic effects. The mechanisms of probiotic action in the oral cavity could be analogous to those described for the intestine. Possible ways that probiotics might affect oral health are summarized in Figure 1. Thus far oral colonization by probiotic bacteria has often been considered essential for them to exert oral effects; however, the possibility of systemic effects cannot be excluded, although the total sIgA levels in saliva seem unaffected by probiotic use. Interestingly, maternal use of some probiotic strains seems to influence the composition of breast milk.Several studies suggest that consumption of products containing probiotic lactobacilli or bifidobacteria could reduce the number of mutans streptococci in saliva. 20-28

The tendency toward a decreased number of mutans streptococci in the saliva seems to be independent of the product or strain used; however, such effect has not been observed in all studies. 29 The discrepancies between results cannot be explained by only the use of different probiotic strains, as different results have also been obtained using the same strains. In most of these studies, the levels of salivary lactobacilli have also been measured. With three products, an increase in the number of salivary *Lactobacillus* has been observed.23,29 Unfortunately, with respect to dental caries, the study groups have mainly been relatively small, and the studies fairly short. Furthermore, it is important to realize that the salivary level of caries-associated microbes does not equate to dental caries. In fact, the microbiota of unstimulated whole saliva resembles that of the tongue more than of dental plaque.30 Thus, no conclusive statement about the effects of probiotic bacteria on dental caries can be made. Probiotics contain different types of microorganisms such as yeast (saccharomyces boulardii) and bacteria (such as lactobacillus, bifidobacterium). Micro-organisms (flora) are naturally found in the stomach/intestines/vagina. Some conditions (such as antibiotic use, travel) can change the normal balance of bacteria/yeast. Probiotics are used to improve digestion and restore normal flora.

Probiotics have been used to treat bowel problems (such as diarrhea, irritable bowel), eczema, vaginal yeast infections, lactose intolerance, and urinary tract infections. Probiotics are

available in foods (such as yogurt, milk, juices, soy beverages) and as dietary supplements (capsules, tablets, powders). Some probiotic products may contain live bacteria (such as bifidobacteria). Antibiotics may prevent these products from working well. Hence the patients should take any product containing live bacteria at least 2 to 3 hours before or after taking antibiotics.

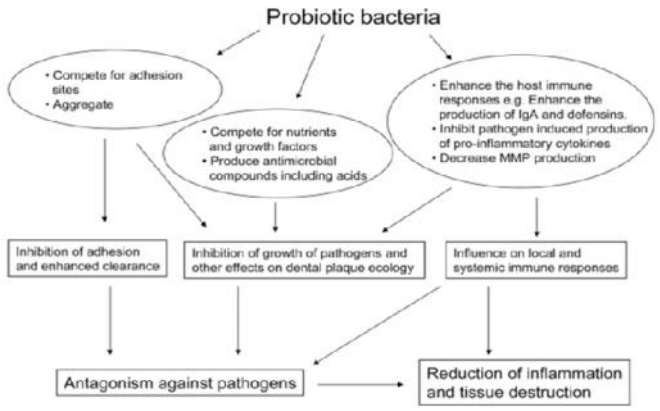

Figure 1. Potential mechanisms by which probiotic bacteria could affect oral health (Modified from 10, with additional references. 11,12, 13, 14, 15, 16, 17, 18, 19).

AIM OF THE PROJECT: To prepare and evaluate probiotic chewable tablets.

MATERIALS REQUIRED

Materials: Pure drug sample of Probiotic was procured from Bifilac capsules (10 capsules). All other ingredients *viz.* Mannitol USP, Lactose, Micro crystalline cellulose, Magnesium stearate used were of pharmaceutical grade.

METHOD

Direct Compression: All the ingredients were separately weighed and sifted using mesh no. 40. Probiotic powder, Lactose , Mannitol USP were passed through mesh no 22. Required quantities were blended for ten minutes in poly bag. Finally the above blend was lubricated with Magnesium stearate . The powder blend was evaluated for the flow properties and was found to be good. The evaluated blend was compressed into tablets of 600 mg weight each. A minimum of five tablets were prepared for each batch.

CURRENT FACTORS AFFECTING PROBIOTIC DELIVERY AND FUTURE RECOMMENDATIONS

With the issues already highlighted in this review and the necessary changes which have been taken by research to overcome these problems, certain issues still surround the effectiveness and safety of probiotic formulations. While recently, some researchers have questioned the effectiveness of probiotics in general to exert health benefits, the general consensus is that probiotics do supplement intestinal and uro-genital flora which by themselves exert functional health benefits. The safety of probiotic formulations have also been questioned with studies finding probiotic bacteria in some formulations harboring antibiotic resistance, which can further precipitate life-threatening pathogenic conditions (7). A further issue raised has been that the large numbers of probiotic bacteria in formulations are so high that it may inadvertently prevent the detection of contaminants. A study performed by Joosten *et al***.** (36) which showed that current methodology for the detection of Salmonella, a potentially serious pathogenic bacteria, was ineffective in infant formulas due to the high numbers of probiotic bacteria in the infant formulas. This study highlighting that the tested infant formulas can potentially contain a variety of pathogenic bacteria and a false-negative result of non-contamination seen during microbial tests. There is also no guarantee that natural products including probiotics are free of contaminants with cases of pathogenic bacteria, toxins and heavy metals being found in natural products (16). There is therefore a need for more stringent quality control in the preparation of probiotic formulations. Enterococci are a species of bacteria that have been linked to many pathological conditions in humans with many having the ability to transfer antibiotic resistance onto other bacteria, allowing for non-effective treatment in many patients. However, some species of Enterococci have been found to treat gastroenteritis as well as not harboring virulent genes and not being resistant to vancomycin, the chosen treatment for methicillin-resistant Staphylococcus infections (49). While it has been shown that probiotic and health benefits may differ between species of the same class of bacteria, many meat and dairy products containing Enterococci probiotics have been shown to harbor antibiotic resistance, placing the patient at a higher risk of serious infections while on probiotic treatment. With this issue of safety, microorganisms in food now have to undergo screening tests to be regarded as safe for consumption by humans (64). Further studies will also need to be conducted to distinguish between potentially pathogenic and beneficial species of bacteria to increase the number of functional probiotics on the market.

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