IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

ISOMALT LOZENGES

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ABSTRACT : Lozenges are palatable unit dosage form administrated in the oral cavity, which is the most common route and easiest way of administering a drug and have a bright future as novel method of delivering drugs for local and systemic effect. Lozenges are solid preparations that contain one or more medicaments, usually in a flavoured, sweetened base, and are intended to dissolve or disintegrate slowly in the mouth. The main objective present study to formulate medicated lozenges by useing isomalt sugar.The physical characteristics of the tablets were relatively stable after half a year storage at different humidities as a result of the low hygroscopicity of isomalt.Isomalt is a sugar substitute with a wide range of potential pharmaceutical applications as a result of its physicochemical properties.The benefits of the medicated lozenges is they increase theretention time of the dosage form in oral cavity which increases bioavailability, reduces gastric irritation and bypasses first pass metabolism. The acceptance for lozenges as a dosage form is high by adults and also more by children.

KEYWORDS : Loxenges, isomalt sugar, palatable, sweetened, flavoured, medication.

INTRODUCTION

The demand for low-fat and lowcalorie confectionery increases steadily worldwide. Consumers understand the message and functions of these product categories which serve their demands for “healthy eating” when thinking about less calories and kind-to-theteeth functions. Nowadays new sugar replacers like isomalt can be used providing sugar comparable taste and texture to guarantee good quality products. In addition to sugar free chewing gum and breath mints, which are already well established, sugar free hard candies and cough drops start playing an important role in the sugar free market.Isomalt, a sugar substitute derived from sucrose, plays

a major role in these fields of sugar free products due to its sugar-comparable taste and preferred shelf-life properties.Isomalt started to sell in the U.S.when the intense sweeteners acesulfame K and aspartame were regulated for the use in confectionery early in 1994 (which was important as isomalt is less sweet than sugar).There are still few companies in the U.S. that are using isomalt, compared to Europe where some major brands build their success in sugar free on the properties of isomalt.This paper will briefly describe the manufacture of isomalt, its properties and especially the use of isomalt in sugar free hard candy applications.

Isomalt belongs to the chemical group of disaccharide alcohols and is derived from sucrose. Research work carried out by Südzucker's central lab showed that the isomerizing action of the microorganism protaminobacter rubrum transforms the non-reducing sucrose into a reducing disaccharide 6-O-α-Dglucopyranosyl-D-fructose. This new 'sugar' was called isomaltulose and given the brand name Palatinose® after the German place where it was discovered—Obrigheim in der Pfalz (in Latin: Palatinum). The main difference compared with sucrose is that the 1,2 bond between the sugar components glucose and fructose is isomerized into a much more stable 1,6 bond, making isomaltulose considerably more resistant to acids and microbial influences. By means of a further processing step, hydrogenation, it was possible to obtain the sugar alcohol isomalt from isomaltulose.A simplified flow-chart of the production process is given

Isomalt may be a good substitute for lactulose, which is a mixture of the two sugar alcohols (polyols), i.e. 6-O-α-d-glucopyranosyl-d-sorbitol and 1-O-α-d-glucopyranosyl-d-mannitol dihydrate. Furthermore, this compound has been used as an excipient in a variety of pharmaceutical preparations and does not undergo Maillard-type condensation reactions. In addition, isomalt is neither absorbed nor metabolised in the stomach and small intestine but is degraded by colonic microflora to glucose and mannitol/sorbitol, which are then further degraded into organic acids

Isomalt was observed to lower the pH at a slower rate compared to that of lactulose, which could be due to the degradation of isomalt to one glucose molecule and one mannitol/sorbitol molecule. The sugar alcohol (polyol) does not contribute to lowering the pH (12), suggesting that only the glucose molecule is responsible for this decrease. In contrast, lactulose degrades into one molecule of glucose and one molecule of fructose. Both monosaccharides are separately degraded into short-chain fatty acids, leading to a faster rate of pH lowering. Due to enzymes being substrate specific, different enzymes are speculated to be responsible for the degradation of glucose and fructose . Lactulose was also reported by Lee et al. to have a better performance over isomalt. The authors reported that higher percentage of hydrogen gas was expelled from breath of healthy human volunteers administered lactulose compared to isomalt.

1.PRODUCTION PROCESS OF ISOMALT

Starting from a sucrose solution,isomaltulose is obtained through transglucosidation as already mentioned. (Figure 2.1) After crystallization, isomaltulose is hydrogenated in a neutral aqueous solution using a Raney nickel catalyst. This produces isomalt, a mixture of the isomers 1-O-α-D-glucopyranosyl-mannitol, 1,1-GPM-dihydrate, and 6-O-α-D-glucopyrano-syl-D-sorbitol, 1,6-GPS. (Figure 2.2)In the crystallization process,especially developed for isomalt,GPM crystallizes with 2 mol water whereas GPS crystallizes without water. As a result, isomalt contains approximately 5 percent water of crystallization. Finally, isomalt is an odorless, white, crystalline, sweettasting substance with a very low hygroscopicity.Crystal Structure and Surface The crystal structure and surface of isomalt differ from that of sucrose. Electron micrographs show clearly that isomalt is not made up of crystals with regular surface, as sucrose is, but of a bond of agglomerates that are made up of individual crystals—probably smaller than 5 µm. The surface of the crystals is of a design which promotes cohesion of the

crystals, a characteristic that is a distinct advantage when isomalt is compressed directly into tablets. Isomalt can be easily ground to grain sizes of < 100 µm which is desired for applications like chocolate or chewing gum.

MERITS OF ISOMALT :Isomalt is used as a sweetener, bulking, anti-caking and glazing agent in low-calorie candies, toffees. Isomalt is a sugar substitute that is derived from natural sources such as beets and corn. It has a low glycemic index, which means it does not cause a rapid spike in blood sugar levels. It is also low in calories and has a sweet taste, making it a great alternative to sugar. Additionally, Isomalt has been found to have several health benefits, including reducing the risk of tooth decay, improving digestive health, and helping to regulate blood sugar levels. It may also help to reduce cholesterol levels and improve heart health.

DEMERITS OF ISOMALT : Isomalt is a sugar alcohol that is used as a sugar substitute in many foods and dietary supplements. It is generally considered safe for consumption, but it can cause digestive issues such as bloating, gas, and diarrhea in some people. It can also cause a decrease in blood sugar levels, so it is important to monitor your blood sugar levels if you are taking isomalt. Additionally, it can interact with certain medications, so it is important to consult with your doctor before taking isomalt.

2.OBTAING STRUCTURE OF ISOMALT

Isomaltulose is found naturally in honey [6] and in sugar cane juice [7], but its amount is small to be extracted from them. For this reason, enzymatic methods have been developed for its industrial production, in which isomaltulose is obtained from sucrose [8]. Isomerization was catalyzed by an immobilized enzyme preparation of Protaminobacter rubrum cells, followed by crystallization. The enzymes that are used in the synthesis of isomaltulose are: Erwinia rhapontici, Serratia plymuthica, Protaminobacter rubrum, Serratia plymuthica, Enterobacter sp. FMB-1[9-13]. Isomaltulose is an isomer of sucrose and similarly it is a disaccharide composed of monomeric units of glucose and fructose. The difference between isomaltulose and sucrose is in the relationship between two monosaccharides. Isomaltulose has an <alpha> -1-6 bond compared to an <alpha> -1-2 bond in the sucrose molecule [14].

3.CHEMICAL AND PHYSICAL PROPERTIES OF ISOMALT.

The chemical name of isomalt is 6-o-D-glucopyranosyl-D-fructofuranose, and its chemical formula is C12H22O11; it has a molecular weight of 360.32 g/mol. Isomaltulose is more stable than sucrose in an acidic environment [14]. At pH = 1, 10% isomaltulose solution remains stable for 30 minutes when heated to 95 °C.

In contrast, under the same conditions, a 10% sucrose solution is completely hydrolyzed [15]. The stability of isomaltulose in cola drinks with pH = 2.3 when stored for 3 months was evaluated and compared with the stability of sucrose. The results of this study show that while 98% of sucrose has been hydrolyzed, isomaltulose remains stable [16]. The solubility of isomaltulose at 20 °C is 290 g/kg solution and increases to 700 g/kg solution at 90 °C. The heat of dissolution is -60.2 kJ/kg, which causes the cooling effect of isomaltulose Isomaltulose is one of the most active sugars in terms of antioxidant behavior. Although this property is far less pronounced than classical antioxidant agents, the concentration of sugars in some foods is high compared to classical antioxidant compounds and thus the antioxidant capacity may be sufficient to increase the shelf life of end products containing isomaltulose [18]. Isomaltulose shows less involvement in caramelization processes during heat treatment than sucrose. But unlike sucrose, isomaltulose is a reducing sugar that is actively involved in the Maillard reaction [15]. Like sucrose, isomaltulose is a white crystalline substance [19]. It has weak hygroscopicity. When stored at a temperature of about 25 °C and a relative humidity of 85%, there is no significant change in the absorption of moisture from the environment. This makes isomaltulose extremely suitable as a substitute for sucrose in the manufacture of chocolate products [15] The melting point of isomaltulose is about 123-124 °C and that of sucrose is about 170-180 °C [14]. Due to these physical and chemical properties, isomaltulose is considered to have the potential as a substitute for sucrose in the manufacture of most confectionery products [2.

4.PHYSIOLOGICAL FUNCTIONS AND NUTRITIONAL PROPERTIES OF ISOMALT.

Due to the more stable relationship between the two monosaccharides, glucose and fructose, the physiological and functional properties of isomaltulose differ from those of sucrose [15]. Isomaltulose has a "pure" sweet taste similar to that of sucrose, but less expressed. The sweetness of isomaltulose is about 50% of that of sucrose [21]. Isomaltulose is defined as a “slow” but fully digestible carbohydrate, which distinguishes it from other sugar alternatives such as tagatose, sugar alcohols and others [22]. Isomaltulose has a low glycemic index (GI = 32) and has little effect on blood sugar and insulin levels [23]. The low glycemic potential of isomaltulose in the replacement of sucrose in food formulations has been approved and confirmed by the relevant health claim by EFSA [24]. The energy value it provides to the body is 4 kcal/g similar to other sugars. Isomaltulose is well tolerated due to its gastrointestinal tolerance, which is comparable to that of sucrose [25]. Even when taken in large amounts during physical activity, no gastrointestinal discomfort has been reported [18]. Isomaltulose is defined as not causing tooth decay and it is the only sugar that is resistant to oral fermentation [22]. Isomaltulose is included in the list of non-cariogenic carbohydrate sweeteners the context of the FDA's approval of US health claims on carbohydrate sweeteners and dental caries. In Japan, isomaltulose has the status of "Food for Specific Use of Health" (FOSHU) due to its properties [18, 26].

5.APPLICATIONS OF ISOMALT

Application of isomaltulose in food Isomaltulose is "generally recognized as safe" (GRAS) by the US Food and Drug Administration (FDA) and approved as "Novel Food" in 2005 by the European Union [21, 27, 28]. Due to its physical, chemical, organoleptic and physiological properties, isomaltulose is used in a wide range of applications. Isomaltulose is a suitable alternative to sugar in the production of chocolate. Sugar acts as a structure-educator in chocolate products, therefore not all sweeteners and sugars may be suitable in the production of this type of food products. When using isomaltulose, the production process remains almost unchanged [8].

The resulting chocolate is characterized by gloss and shine, and the characteristic "popping" structure properties [18]. Jiamjariyatam [29] explores the possibility of obtaining jellies with gelatin and isomaltulose. The study shows that, with the same amount of gelatin, the increasing amount of isomaltulose (20, 30, 40, 50 and 100%) reduces the toughness, stickiness and hardness of jellies. It was found that jellies obtained with 100% isomaltulose were prone to crystallization. Chewing candies with good taste profile and stability can be produced with isomaltulose at levels between 30% and 35%. A combination of isomaltulose and polydextrose can be used to produce tooth-friendly chewing candies. Isomaltulose can be used in the production of chewing gum by replacing sugar in a 1: 1 ratio. As isomaltulose has a weak hygroscopicity, chewing gum with its participation is characterized by good stability and long shelf life [18]. A study was conducted on the use of isomaltulose in the composition of marshmallows [30].

The results of this study show that marshmallows obtained with isomaltulose have a higher sensory score than controls (obtained with sucrose and glucose syrup). A study was also conducted for the production of wafers with isomaltulose [31]. The study shows that the filling obtained with 100% replacement of sucrose with isomaltulose has a more pleasant mild sweet taste. Due to its low hygroscopicity, isomaltulose is a good alternative to sugar in the production of instant beverages [8]. Isomaltulose shows high stability against fermentation by most yeasts and bacteria. This can be effectively used in beer production for the production of low-alcohol or non-alcoholic beers [32].

6. Conclusion

They are utilized to join a wide scope of active ingredients. Improved and enhanced lozenges hold a prime spot in drug market. They are relied upon to procure more interest in drug creation as imaginative measurement structure for the powerful medications which appear to be an ideal dose structure.Due to its physicochemical, physiological and functional properties, differing from those of sucrose, isomaltulose is gaining more and more popularity as an alternative to sugar. The tendency of consumers to show an increasing interest in functional foods, the future of products containing isomaltulose seems increasingly promising. This necessitates the continuation of research on isomaltulose and its influence on the use of various categories of foods in the prescription composition.

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