

Probiotics and Ascorbic Acid Specialized Product: Production and Quality Indicators

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Abstract:

A new type of probiotic coated tablets for particular nutritional uses has been developed, intended for children and adults, including pregnant and breastfeeding women. Probiotics are live microorganisms or products cultivated from them that have a beneficial effect on the human body, mainly by improving the health of the gastrointestinal tract (GIT). Experimental and industrial samples of Probiopan dragées enriched with bifidobacteria and lactobacilli were the subject of the study. Comprehensive studies of the product intended for particular nutritional uses allowed us to establish its high quality as regulated by applicable standards, as well as the shelf life of 1 year at a temperature of $25\pm 5^{\circ}\text{C}$ and a relative humidity of 75%. The obtained data indicated a fairly high stability of vitamin C, the preservation of which was 91.6%. Based on the studies conducted, the use of the product was recommended in the amount of three dragées per day to provide at least 30% of the daily requirement for vitamin C, bifidobacteria, and lactobacteria, which can serve as a factor in normalizing the microflora of the gastrointestinal tract and preventing the development of dysbacteriosis in children, adults, and women during pregnancy and breastfeeding. Probiopan dragées are also recommended for type II diabetes, because they contain no sugar. It was also found that when consuming calcium together with the developed confectionery product, the body absorbs calcium better because of the lactic acid bacteria *Lactobacillus plantarum* (strain 337D).

Keywords: Food supplements, vitamin and mineral complex, production, quality, functional properties.

1. Introduction

The development of products for particular nutritional uses, including biologically active food supplements (BAFS), is one of the most accessible and effective ways to improve the nutrition and health of modern man. This branch of nutritional science is of both theoretical and practical importance for implementation of the concept of state policy in the field of healthy nutrition of the population for

the period up to 2030, the Resolution of the Government of the Russian Federation and the Presidential Decrees on the development of the food and processing industry [1-5].

The development of novel probiotic products is of particular importance [6-13]. Probiotics are live microorganisms or products cultivated from them that have a beneficial effect on the human body, mainly by improving the health of the gastrointestinal tract (GIT).

A new type of probiotic coated tablets for particular nutritional uses has been developed, intended for children and adults, including pregnant and breastfeeding women. Based on available literary sources and our own research, the functional properties of the main ingredients of the formula are characterised [14-22].

2. Materials and Methods

Experimental and industrial samples of a new probiotic dragées enriched with bifidobacteria and lactobacilli were the subject of the study. Standard and special methods for testing the quality and safety of the products for particular nutritional uses were used in accordance with the requirements of the technological regulations of the Customs Union 027/2012 on the assessment of the quality and safety of such products.

3. Results and Discussion

As a source of microorganisms, a microencapsulated form of probiotic bacteria was introduced into the product - balls 30-50 μm in size in a gum arabic shell, which is resistant to the acidic environment of the stomach and ensures the preservation of probiotics [23-26]. The shell is capable of dissolving in the slightly alkaline environment of the intestine, thereby ensuring the release of active bacteria. The proposed microencapsulation technology contributes to the preservation of bacteria in the finished product throughout the entire shelf life [27-31].

The ingredients of the dragées have a synergistic effect in terms of preventing dysbacteriosis, restoring the disturbed balance of microorganisms, improving the functioning of the digestive tract, maintaining the child's body at the proper functional level and the well-being of the expectant mother [32].

The composition of the dragées is given in Table 1.

Table 1. Ingredients of Probiopan dragées.

Ingredient	Quantity, mg/1 dragée	Quantity, g/ 100 g
Dry milk substitute	759.26	75,926
Crystalline fructose	80	8.0
Bifidobacterium adolescentis ($1 \cdot 10^{10}$ CFU/g)	5.0	0.5
Lactobacillus plantarum ($1 \cdot 10^{10}$ CFU/g)	0.25	0.025
probiotic sourdough Lactobacillus acidophilus ($1 \cdot 10^{10}$ CFU/g)	0.25	0.025
Jerusalem artichoke root powder	50	5.0
Inulin	40	4.0
Ascorbic acid	9.0	0.9
Natural flavor: grapefruit or lemon	5.0	0.5

Stevioside	1.0	0,1
Natural dye " turmeric " or "carmine" + " turmeric "	0.24 or 0.16 and 0.08	0.024
Total weight of the core	950	-
Gum arabic	5.0	0.5
Maltitol	45.0	4.5
Total weight of the coated dragée	1000.0 mg	-

All raw materials used for production meet the hygienic requirements for food safety and are accompanied by documents confirming their quality.

The Production Technology

The coated tablets are produced using tableting process.

Preparation of Raw Materials

The raw materials have passed the incoming inspection of the company's Quality Control Department (QCD) with an analytical passport for compliance with the legal documentation. The use of excipients is authorised in accordance with a certificate or certificate of state registration and the manufacturer's data report [33-38].

In order to deagglomerate and remove mechanical impurities, the raw materials are sieved on a vibrating sieve with a mesh size of 0.5 mm and poured through a bowl into a container.

The fructose is first sieved through a No. 20 metal sieve and ground in a micro-mill.

The component composition is taken as a proportion by mass in the ratio specified in the recipe.

The weighed proportions of the functional ingredients - vitamin premix, trimagnesium orthophosphate, zinc citrate, copper aspartate, iron carbonyl, plant extracts, flavourings, dry apple juice - are mixed with a small amount of dry milk whey, thoroughly blended to achieve an even distribution and sieved through a No. 22 silk sieve.

An aqueous solution is used to add and distribute potassium iodide evenly. For this purpose, a weighed portion of the preparation is dissolved in water, poured onto a weighed portion of microcrystalline cellulose (MCC) and mixed thoroughly [39, 40]. Then the mixture is sifted through a silk sieve No. 22. The prepared components are placed in a SMU-150 mixer and mixed for 30–40 minutes. The finished mixture is unloaded into polyethylene bags, weighed and the weight of the formulation is recorded in the process log. The quality of mixing is controlled: by the even distribution of components, by coloring, a sample is taken to determine the mass fraction of moisture.

Tableting is carried out on the ZP 1100 press. The diameter of the die is 16 mm, the shape of the core is biconvex [41-44].

After the core has been produced, it is dedusted using a ZWS137 rotary deduster.

The dragée core is coated with a shell on a BQ 1000 coating machine using the dragée technique. For the coating, an aqueous gum arabic solution (with a dry substance content of 25-30%) is prepared according to the technological instructions. Then the cores are loaded into the drum according to the

calculated quantity, the drum is rotated and the coating is applied by alternately pouring the solution and drying each layer with warm air (temperature 30 - 40° C), the coating is applied until a uniform glossy coating appears [45-47].

During tableting and coating, the mass and appearance of the coating are checked. Once the appearance has been assessed, the dragées are unloaded into trays and sent for weighing and packaging. Organoleptic, physicochemical, microbiological and toxicological indicators of quality and safety were studied during production and storage [48-50]. The product was stored in polymer jars for 15 months at a temperature of $25 \pm 5^\circ\text{C}$ and a relative humidity of no more than 75%. The content of active components was studied considering the functional positioning of the product. The assessment of organoleptic properties of the dragées during storage is presented in Table 2.

Table 2. Change in organoleptic indicators of Probiopan dragées during storage (n=8).

Shelf Life, months	Quality Indicators, points			Average Total Quality Score, points
	Colour	Taste	Odour	
0	4,9 $\pm$ 0,5	4,5 $\pm$ 0,4	4,1 $\pm$ 0,5	13,5 $\pm$ 0,7
6	4,9 $\pm$ 0,5	4,4 $\pm$ 0,4	4,0 $\pm$ 0,5	13,3 $\pm$ 0,7
15	4,9 $\pm$ 0,5	4,1 $\pm$ 0,4	3,7 $\pm$ 0,3	12,7 $\pm$ 0,6

The results of physicochemical, microbiological and toxicological studies are shown in Table 3.

Table 3. Consumer properties of Probiopan dragées during storage (n=3).

Indicator	Requirements according to applicable regulations	Test result after production and during storage, months		
		Upon expiry of 0 months	Upon expiry of 6 months	Upon expiry of 15 months
1	2	3	4	5
Physicochemical indicators				
Moisture content, %, no more than	6,5	5,8 $\pm$ 0,1	5,0 $\pm$ 0,1	4,9 $\pm$ 0,1
Microbiological indicators				
Bifidobacterium content (Bifidobacterium adolescentis), CFU/ 100 g, not less than	5,0 * 10 ⁹	6,25 * 10 ⁹	5,81 * 10 ⁹	5,15 * 10 ⁹
Lactobacillus content (Lactobacillus plantarum и Lactobacillus acidophilus),	5,0 * 10 ⁸	5,9 * 10 ⁸	5,6 * 10 ⁸	5,1 * 10 ⁸

CFU/ 100 g, not less than					
Product weight (g), which does not allow:	Coliform Bacteria (coliforms)	0,1	Not detected in 0.1 g	Not detected in 0.1 g	Not detected in 0.1 g
	Pathogenic, including salmonella	25	Not detected in 25 g	Not detected in 25 g	Not detected in 25 g
Yeast, CFU /g, not more than		50	Not detected	Not detected	Not detected
Mold, CFU /g, not more than		50	Not detected	Not detected	Not detected
Toxicological indicators					
Toxic elements	Lead	1,0	0,3±0,02	0,3±0,02	0,3±0,2
	Arsenic	1,0	0,1±0,01	0,1±0,01	0,1±0,01
	Cadmium	0,1	0,03±0,01	0,03±0,01	0,03±0,01
	Mercury	0,01	0, 005±0,001	0, 005±0,001	0, 005±0,001
Radionuclides	Cesium-137	160	7,0±0,1	7,0±0,1	7,0±0,1
	Strontium-90	100	1,0±0,05	1,0±0,05	1,0±0,05

It follows from the presented data that the analyzed indicators of the quality and safety of the dragées remain practically unchanged during the entire testing period. High stability of the introduced bifidobacteria and lactobacteria was noted, the losses of which during the entire storage period (considering the safety margin) amounted to 17.6% and 13.6%, respectively. The preservation of ascorbic acid, the most labile component of the formulation, was also studied (Figure 1).

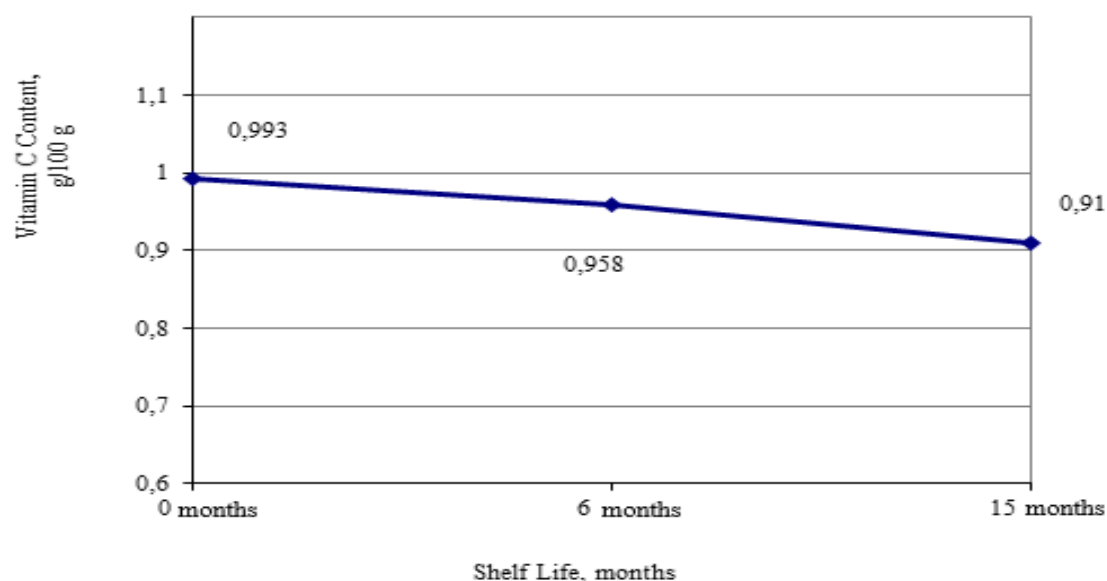


Figure 1. Dynamics of changes in the content of vitamin C in Probiopan dragées during storage.

The obtained data indicated a fairly high stability of the tested vitamin, the preservation of which was 91.6% [51-54]. Conducting comprehensive studies of a product intended for particular nutritional uses allowed us to establish quality indicators regulated by applicable standards (Tables 4 and 5) as well as the shelf life of the developed product of 1 year at a temperature of $25\pm 5^{\circ}\text{C}$ and a relative humidity of 75% (considering the safety margin of 3 months).

Table 4. Requirements for organoleptic and physicochemical quality indicators of Probiopan dragées.

Indicator	Description
Taste and Odour	Strong, characteristic of this flavoring and components, without any off-flavour or off-odour.
Colour	According to composition, depending on the taste - yellow or reddish-orange with dark inclusions
Visual Appearance	Smooth, glossy surface
Average weight of one dragée, g	$1,00\pm 10\%$
Moisture Content, %, not more than	6,5

Table 5. Nutritional and energy value of Probiopan dragées (per 100 g of product).

Item	Nutrition Value in 100 g	Amount in 1 dragée	Amount in 3 dragées
Vitamin C, mg	$900,00\pm 5$	$9,00\pm 0,5$	$27\pm 0,5$
Lactobacteria, CFU	$5,0 \cdot 10^8$	$5,0 \cdot 10^6$	$15,0 \cdot 10^6$
Bifidobacteria, CFU	$5,0 \cdot 10^9$	$5,0 \cdot 10^7$	$15,0 \cdot 10^7$
Fats, g	$20,5\pm 0,3$	$0,20\pm 0,03$	$0,6\pm 0,05$
Carbohydrates, g	$67,3\pm 0,8$	$0,67\pm 0,8$	$2,01\pm 0,1$
Energy Value, kcal	$453,8\pm 1,0$	$4,5\pm 0,05$	$13,6\pm 0,08$

Recommended consumption rates for the product intended for particular nutritional uses have been developed (Table 6).

Table 6. Recommended Daily Intake of Probiopan Dragées.

Age Group	Recommended Daily Intake, pcs/day
Children from 3 to 7 years old	2-3
Children from 7 to 11 years old	2-3
Children from 11 to 14 лет	3-4
Children from 14 years old, adults, pregnant or breast-feeding women	3-5

4. Conclusion

Based on the studies conducted, recommendations were made for the use of the new product. The use of the product in the recommended amount of three dragées per day provides at least 30% of the daily requirement for vitamin C, bifidobacteria, and lactobacteria, which can serve as a factor in normalizing the microflora of the gastrointestinal tract and preventing the development of dysbacteriosis in children, adults, and women during pregnancy and breastfeeding. Probiopan dragées are recommended for type II diabetes because they contain no sugar, whereas fructose, inulin, or Jerusalem artichoke powder do not have a negative effect in the case of this disease. It was found that when consuming dragées enriched with calcium, together with the developed confectionery product, the body absorbs calcium better because of the lactic acid bacteria *Lactobacillus plantarum* (strain 337D).

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