



Specialized food product for diabetic diet “Inullact-Fito”

Ualikhan ZHUMABAYEV¹ , Mereke KYDYRALIEVA^{2*} , Elmira OSPANOVA³ ,
Raushan NAIMANBAYEVA¹ , Baktyly DUYSEMBAYEVA¹ 

Abstract

Diabetes mellitus is one of the most serious medical, social and economic health problems in countries of all worlds. The incidence of diabetes mellitus on the globe doubles every 10 to 15 years, acquiring the character of a non-infectious epidemic. According to the latest data from The International Diabetes Federation the number of patients with diabetes among adults (20-79 years old) in the world in 2015 was 415 million, that is, about 9% of the total population, of which more than 90% are patients with type 2nd diabetes. According to forecasts, by 2030, their number will be up to 439 million. In recent years, the interest of scientists around the world to study the pharmacological properties of medicinal plants has increased. Extensive factual material has accumulated on the beneficial effects of various medicinal plants and fees in the treatment and prevention of diabetes mellitus, as well as the possibility of correcting natural products, such as camel and mare's milk, containing ingredients that have a hypoglycemic effect. The aim of the study was to develop recipes and technologies for a specialized food product based on camel milk in combination with extracts of medicinal plants with antidiabetic properties and to evaluate the possibility of their use for the prevention and in the complex therapy of patients with type 2 diabetes mellitus. Taking into account the medical requirements for diet therapy for type diabetes the recipes and technology of a specialized food product of diabetic nutrition “Inullact-Fito” have been developed. The possibility of using medicinal extracts in the development of a specialized fermented milk product was evaluated, and the concentrations of applying medicinal extracts to the food product were worked out. The technology of step-by-step mixing contributed to the uniform distribution of biologically active substances in the mass of the product. The absence of sucrose and digestible polysaccharides in the composition of the developed specialized food product of diabetic nutrition was established. The results of laboratory tests indicate an improvement in the quality characteristics without any stabilizers and preservatives. The humidity does not exceed the standard values for similar products, the values of the “milk acidity” indicator are characteristic of products with low acidity, along with improved organoleptic properties, which justifies the microbiological stability of the developed product during storage. The products are balanced in amino acid composition, have a high score of essential amino acids due to the introduction of a combination of proteins from medicinal plant extracts. The consumption of one serving (200 g) of the product in the form of bio-yogurt provides the average daily requirement for essential amino acids by 12-21%, polyunsaturated fatty acids ω -3 – by 10%, ω -6-by 20%, B vitamins – by 12-17%, C-by 33%, β -carotene-by 22%, E-by 10%, macro- and microelements-by 12-30%. The content of polyphenols is 48% of the adequate level of consumption. The inclusion of a specialized food product of diabetic nutrition “Inullact-Fito” in the hypocaloric diet shows an antioxidant, immunostimulating effect and leads to the stabilization of postprandial blood glucose levels in patients with type 2nd diabetes mellitus.

Keywords: Inullact-Fito; diabetes; diet therapy; camel milk; food ingredients; medicinal extracts.

Practical Application: This study considers the production of specialized diabetic food “Inullact-Fito” which inclusion in hypocaloric diets of SFP is accompanied by an improvement in glycemic control in patients with type 2nd diabetes, manifested in less pronounced fluctuations in postprandial glycemia, an increase in the duration of the normoglycemia period and a decrease in the period of hyperglycemia, which positively affects the daily variability of glycemia due to stabilization of postprandial blood glucose levels in this contingent of patients.

1 Introduction

One of the most important reasons for the deterioration of the health indicators of the population around the world today is unsatisfactory, inadequate nutrition, which is determined by a number of factors associated with excessive consumption of saturated fats, sugar, a deficiency in the diet of polyunsaturated fatty acids (PUFA), dietary fiber, vitamins, macro- and trace elements, other biologically active substances that lead to the

emergence and spread of alimentary-dependent diseases, which include almost all cardiovascular diseases, obesity, diabetes, thyroid diseases, some forms of cancer (colon, esophagus), osteoporosis, etc. The detected violations of the nutritional status significantly reduce the effectiveness of therapeutic measures, increase the risk of complications, and lead to an increase in the cost of treating the patient (Klyaritskaya et al., 2018; Philpot & Johnson, 2019).

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¹Department of General Surgery and Pharmacology, Faculty of Medicine, Khoja Akhmet Yassawi International Kazakh-Turkish University, Turkestan, Kazakhstan

²Department of Biotechnology, M. Auezov South-Kazakhstan State University, Shymkent, Kazakhstan

³Department of Preventive Medicine, Faculty of Medicine, Khoja Akhmet Yassawi International Kazakh-Turkish University, Turkestan, Kazakhstan

*Corresponding author: kydyr.pub@myrambler.ru

Diabetes mellitus (DM) is recognized worldwide as one of the most important non-communicable diseases. It is the fourth leading cause of death in developed countries. The number of patients with diabetes mellitus is constantly increasing due to the growth in the number and age of the population, the urbanization of territories, the increase in the prevalence of obesity due to the development of modern technologies and a sedentary lifestyle. Overweight and obesity are the most powerful factors in the occurrence and development of diabetes and its complications (Mazhaeva et al., 2018; Starostina, 2018; Cosentino et al., 2020). According to the latest data from The International Diabetes Federation IDF, the number of patients with diabetes among adults (20-79 years old) in the world in 2015 was 415 million, that is, about 9% of the total population, of which more than 90% are patients with type 2 diabetes. According to forecasts, by 2030, the number of patients with diabetes in the world will be 439 million and will exceed 10% of the total population (International Diabetes Federation, 2015).

One of the ways to reduce the risk of developing diabetes, according to nutritionists and diabetologists, is a dietary correction of the diet, which consists in reducing its caloric content, optimizing the amount and quality of protein, fat, carbohydrates, fortification with vitamins, minerals, and the use of biologically active substances that have a hypoglycemic effect (Kochetkova et al., 2018; Mazo et al., 2018; Sharafetdinov et al., 2019).

The most promising in the organization of dietary nutrition are sour-milk products, which are sources of living cells of microorganisms that are involved in the micro ecology of the human gastrointestinal tract. The high significance and future of modern fermented dairy products are achievements in the field of biotechnology and bioengineering (Alenisan et al., 2017). In this regard, in recent years, the interest of scientists around the world in the prevention and treatment of diabetes, the possibility of correction of natural products, such as camel and mare's milk, has increased significantly.

The chemical composition of camel milk differs significantly from other dairy products and contains a large amount of proteins, fats, vitamins and minerals. Camel milk is very valuable and nutritious for humans and is consumed in whole or processed form (Alavi et al., 2017).

Camel milk contains a number of important trace elements, in particular, calcium, copper, iron, magnesium, zinc, phosphorus, sulfur, as well as vitamins A, D, B group, and especially vitamin C and unsaturated fatty acids. It has high calorie content from 787 to 911 kcal. Contains vitamin A-0.38 mg/L, vitamin B₂-0.66-1.75 mg/L, vitamin B₁₂-2.72 mg/L; lysozyme, agglutinins, antitoxins, *bacteriolytins*, which provide its bacteriostatic property (Hajian et al., 2020; Orazov et al., 2018; Tasturganova et al., 2018). Camel milk contains less casein, which makes it difficult for the body to digest dairy products, and more sugar lactose, which provides nutrition to the brain and the nervous system as a whole (Dikhanbaeva et al., 2018). Recent studies have shown that camel milk can be used to treat type 1st diabetes.

Along with this, it is advisable to use some extracts from medicinal plants in the prevention and treatment of diabetes mellitus. In folk medicine, especially in Central Asia and the

countries of the East, the attention of researchers is attracted by plant antidiabetic agents, in particular, antidiabetic collection containing the leaves of the common bean fruit, the herb *galega* (*goatgrass*) medicinal, motherwort, leaves of nettle dioecious and green tea leaves. The collection is intended for obtaining an infusion.

This dosage form, along with a number of advantages, has significant disadvantages associated with preparation in the appropriate mode, the inability to accurately dose, and a short shelf life. It does not allow the full use of the complex of biologically active substances contained in plant raw materials (Kvasova, 2012).

An important hypoglycemic effect has a group of tonic herbal preparations, such as zamanikha, ginseng (Romanov et al., 2018), eleutherococcus, golden root, as well as the most commonly used in the treatment of diabetes mellitus blueberries (decoction of leaves and berries) (Mazo et al., 2016; Shipelin & Sidorova, 2017), wild strawberries and lingonberries. Valuable sugar-lowering herbal remedies include jerusalem artichoke (Koltsov, 2015), elecampane and chicory (Saybel et al., 2015).

The most promising direction for inclusion in the diet of sweeteners as a sugar substitute is the use of products from the processing of the stevia plant (*Stevia Rebaudiana* Bertoni) — a natural sweetener of a non-carbohydrate nature, which has unique therapeutic, preventive and health-improving properties. It is rich in glycosides (stevioside, rebaudioside (A, C, D, E), dulcoside, steviolbioside), which help to improve carbohydrate metabolism, stimulate insulin secretion in diabetes mellitus; vitamin C, minerals, zinc and selenium, which have antioxidant properties (Magomedov et al., 2019).

In order to provide the population with the most complete food products, including dairy products that meet the modern requirements of nutrition science, modern manufacture is in the regular searching of the new considerations, possibilities, and decisions. One of them is searching for new raw materials for producing food products safe for consumers and profitable for manufactures. In this regard, the task of scientific and practical justification of the possibility of using camel milk in order to expand raw materials and create products based on it that meet the requirements of a rational diet is very urgent. But this economics sector needs the personal business motivation of the farmers in case to producing the qualitative products as a material for future food products (Dedov et al., 2017; Akhmetshin et al., 2018; Aharonovich, 2019).

Research and observations in the field of health care have shown that food has not only nutritional properties, but also a positive effect on the functions of the human body. In particular, special-purpose dairy products are the most important and effective way to ensure human health.

An exceptional role in the rational nutrition of a person is played by fermented milk products, which serve as an important factor in the prevention and treatment of various gastrointestinal and other diseases.

Thus, rational nutrition is the basis of complex therapy of diabetes mellitus. Numerous studies and clinical observations

conducted in many countries of the world clearly demonstrate that properly organized and based on modern scientific achievements, nutrition plays an important role in optimizing glycemic control, compensating for metabolic disorders, reducing the risk of vascular complications, and improving the quality of life of patients with diabetes mellitus (Dedov et al., 2017).

By changing the nature of nutrition, you can regulate the metabolism in the body and thereby actively influence the course of a particular disease.

The accumulated experience shows that diet therapy does not require large expenditures and allows increasing the effectiveness of complex treatment of diabetes mellitus and reduces the need for expensive hypoglycemic drugs (Danne et al., 2017; Matsumura et al., 2017; Antsiferov et al., 2019).

Given the important role of diet therapy in the prevention and treatment of alimentary-dependent diseases, the creation of specialized food products (SFP) for the prevention and treatment of patients with diabetes mellitus on a fermented milk basis is currently relevant.

The objectives of this study were to develop recipes and technologies for a specialized food product based on fermented milk with the inclusion of extracts of medicinal plants intended for the prevention and treatment of patients with type 2nd diabetes, to study their physical and chemical properties, nutritional and energy value, as well as to evaluate the possibility of using this product in combination with medicinal extracts in complex therapy for this disease.

2 Material and methods

In the development of formulations of specialized food product of diabetic nutrition "Inullact-Fito" was used as a dairy basis – camel milk, bacterial starter consisting of pure cultures of thermophilic *Streptococcus* (*Streptococcus thermophilus*) and Bulgarian bacillus (*Lactobacillus bulgaricus*), a natural sweetener with low calorie stevioside the extract from stevia leaves, sugar-reducing medicinal extracts: (dry extracts: from Jerusalem artichoke tubers, chicory root, blueberry fruit, ginseng Root) and iron lactate-food additive e585.

All ingredients in terms of safety met the requirements established by the technical regulations of the Customs Union TR CU 021/2011 "on food safety", TR CU 033/2013 "on safety of milk and dairy products", TR CU 029/2012 "safety Requirements of food additives, flavors and technological AIDS". The food additives used were used in quantities not exceeding the normative values established in TR CU 029/2012.

The technological process of preparing samples of a specialized food product was carried out by mixing methods, including the process of fermentation and mixing it with the remaining prescription ingredients in appropriate concentrations at different temperatures with a time exposure: 95-96 °C lasting 25-30 seconds; at a temperature of 97-98 °C lasting 15-20 seconds; at a temperature of 99-100 °C With a duration of 5-10 seconds. The sterilized milk was cooled for 15-20 minutes to a temperature of 38-40 °C, then a 2% working bacterial starter culture containing a pure culture of thermophilic streptococci (*Streptococcus thermophilus*) and

Bulgarian bacillus (*Lactobacillus bulgaricus*) was added and resuspended. Next, the ingredients were added in the following ratios: 0.1% stevia extract-stevioside with a sweetness coefficient of 250; 1% jerusalem artichoke extract; 1% chicory extract; 1% ginseng extract; 1% blueberry extract; 0.02% iron lactate and the volume was adjusted to 1000 mL with camel milk. After that, fermentation was carried out in a yogurt maker at a temperature of 38-40 °C from within 6-8 h. After the formation of the clot, the mixture was homogenized and the resulting specialized food product was packed in sealed glass jars with a capacity of 200 grams, cooled in the refrigerator to +4 °C, +6 °C for subsequent storage for 60 days from the end of the technological process.

The appearance and consistency of the resulting specialized food product is homogeneous, moderately viscous, and cream-colored. It is recommended that adults take 1 glass jar 1 time a day during (after) meals.

In the test samples comprehensive studies of quality indicators: organoleptic, physicochemical properties (moisture content, fat, protein, dry matter and titratable acidity), microbiological assessment (total number of mesophilic-aerobic and facultative anaerobic microorganisms, bacteria, coliform, pathogenic microorganisms, including *Salmonella*) and vitamin content.

Microbiological studies were carried out: on Lactic acid microorganisms according to GOST 10444.11-89 food products. Methods for the determination of lactic acid microorganisms; *Bacteria of the Escherichia coli group (BECG) (coliforms)* according to GOST 31747-2012 Food products. Methods for detecting and determining the number of bacteria of the group of *E. coli (coliform bacteria)*; *Staphylococcus aureus (St. Aureus)* according to GOST 10444.2-94 Food products. Methods for detecting and determining the number of *Staphylococcus aureus*;

Pathogenic microorganisms including salmonella according to GOST 31659-2012 food products. Method for detecting *Salmonella* bacteria; Molds and yeasts of colony-forming units (CFU) according to GOST 10444.12-88 Food products. Method for the determination of yeast and mold fungi.

Methods for the determination of lactic acid microorganisms were based on the standards of food and fermented milk products, starter cultures, bacterial concentrates from lactic acid bacteria.

The physical and chemical parameters of a specialized food product were determined by standard methods: the mass fraction of moisture, the percentage of dry substances – according to GOST 3626-73 Milk and dairy products. Methods for determining moisture and dry matter; the proportion of acidity titrated in degrees of Turner ($^{\circ}T$) – according to GOST 3624-92 Milk and dairy products. Titrimetric methods for determining acidity; density – according to GOST 3625-84 Milk and dairy products. Methods for determining the density; the content of iron and zinc – according to GOST 30178-96; the content of mono – and disaccharides-according to P 4.1.1672-03 Guidelines for quality control and safety of biologically active food additives.

Organoleptic parameters were evaluated by assessing the smell and taste – according to GOST 28283-89; the content of vitamins: vitamin B₂ was determined according to GOST 30627.6-98; vitamin PP – according to GOST 30627.4-98 Dairy

products for baby food. Method for measuring the mass fraction of vitamin PP (niacin); vitamin C according to GOST 30627.2-98 Dairy products for baby food. Methods for measuring the mass fraction of vitamin C (ascorbic acid); vitamin E according to GOST 30627.3-98 Dairy products for baby food. Method for measuring the mass fraction of vitamin E (tocopherol); β -carotene according to GOST 30627.1-98 Dairy products for baby food. Method for measuring the mass fraction of vitamin A (retinol).

The nutritional and energy value, the percentage of satisfaction of the average daily need for food substances and energy, the amino acid composition and the amino acid score were determined by calculation methods, using the data of the reference book (Tutelyan, 2012) on the chemical composition and caloric content of food ingredients included in the composition of a specialized food product, taking into account the data on the recommended levels of daily consumption of food substances and energy in accordance with TR CU 022/2011 "Food products in terms of their labeling", "Unified sanitary-epidemiological and hygienic requirements for goods, subject to sanitary and epidemiological supervision (control)" of the Customs Union of the Eurasian Economic Community, as well as the specifications of the manufacturers of the ingredients used.

The possibility of using "Inullact-Fito" diabetic nutrition specialized food product in complex therapy – glycemic variability – was evaluated in 60 patients with type 2nd diabetes aged 45-65 years with disease duration of 3 to 10 years, with an initial body weight of 65-85 kg and receiving standard hypoglycemic therapy. SFP diabetic nutrition "Inullact-Fito" included in the hypo caloric diet (1500 kcal/day) in the form of bio-yogurt (200 g), for the second Breakfast instead of carbohydrate-containing dishes. All patients were previously informed about the procedure of the study, the rules of conduct during the study, received informed consent of all patients to participate in the study, which was approved by the ethics Committee of the Akhmet Yassawi International Kazakh-Turkish University dated October 21, 2019 according to the Code of the Republic of Kazakhstan dated 18.09.2009 No. 193-IV "on the health of the people and the health care system" (amended as of 21.04.2016).

To determine the amplitude of fluctuations in glycaemia, the system of continuous glucose monitoring IPro2 (Medtronic, USA) was used with the determination of glucose concentration in interstitial (intercellular) fluid using a sensor installed in subcutaneous fat. Within 15 days, the indices of glycemic variability (average, minimum and maximum glycemic levels, average amplitude of glycemic fluctuations, etc.) were evaluated.

Statistical data processing was carried out using the program «Statistical Package for the Social Sciences» SPSS Statistics 21.0. The results are presented in the form of mean values and standard error of mean value ($M \pm m$). The assessment of the reliability of the differences in the mean values was carried out using the student's t-test. The differences were considered significant at a significance level of $p < 0.05$.

3 Results and discussion

The algorithm for the development of a specialized diabetic food product "Inullact-Fito" included the following stages: the

formation of biomedical requirements for the composition and properties of the finished product; justification and selection of ingredients that form the food matrix and have a given physiological effect; the development of recipes and technologies for a specialized food product; the study of technological and organoleptic compatibility of ingredients; the development of experimental samples; study of microbiological parameters, physics and chemical, organoleptic properties and safety indicators.

In accordance with the medical and biological requirements, a specialized food product must have a homogeneous, moderately viscous form, lactic acid microorganisms within the permissible norm, the presence of pathogenic microorganisms, including *Salmonella*, *Escherichia coli* bacteria, and there should be no *coliform bacteria*.

The fat component should contain mono - and polyunsaturated fatty acids, including the ω -3 family, which improve the lipid spectrum of the blood and help to reduce the level of total cholesterol. The carbohydrate component may contain a small amount (no more than 0.75 g/1 kg of body weight per day) of fructose, which forms the sweet taste of the product and, at the same time, to a lesser extent than other carbohydrates, increases the level of postprandial glycemia in patients with type 2 diabetes mellitus (Sharafetdinov et al., 2002)

To create a sweet taste, it is recommended to use sugar substitutes-polyatomic alcohols (*xylitol*, *sorbitol*, *maltitol*, *erythritol*, etc.), but it should be borne in mind that their excessive consumption can have an adverse effect on the functional state of the gastrointestinal tract, causing diarrhea. When using dietary fibers, there is an improvement in the functioning of the gastrointestinal tract, indicators of lipid and carbohydrate metabolism, an increase in the feeling of satiety, normalization of the intestinal microflora due to prebiotic properties, etc., which cause their inclusion in the recipes of products for patients with diabetes mellitus (Tutelyan et al., 2014).

To determine the technological and organoleptic compatibility of the selected ingredients and to avoid the negative influence of pathogenic microorganisms, experimental experiments of camel milk sterilization were carried out under laboratory conditions, taking into account time and temperature conditions, with maximum preservation of physical, chemical, nutritional properties and energy value.

Samples of a specialized food product in 3 variants and a sample of camel milk shubat (for the control experiment) were developed, their microbiological parameters, physico-chemical and organoleptic properties were studied.

The results of the study of microbiological indicators presented in Table 1 indicate that lactic acid microorganisms are contained within the permissible limits established by GOST 10444.11-89 Food products. Methods for the determination of lactic acid microorganisms, the presence of pathogenic microorganisms including *Salmonella*, *Escherichia coli* and *coliform bacteria*, bacteria of the genus *Staphylococcus aureus* are not detected.

The data given in Table 1 is used in technological practice in the management of processes that determine the quality of dairy products. The analysis of microbiological indicators of fermented milk products as a significant risk point is an opportunity to predict the suitability of these products for long-term storage, to assess their quality and safety during storage.

Table 1. Microbiological indicators of specialized food products of diabetic nutrition.

Name of indicators, units of measurement	Permitted limits	Actually received			Test methods normative documents
		15 days	45 days	72 days	
Lactic acid microorganisms, CFU/g/mL not less	1×10^7	1×10^8	1×10^7	1×10^7	GOST 10444.11-89
<i>E. coli</i> group bacteria (<i>coliforms</i>), in 1 g	Not valid	Not found	Not found	Not found	GOST 31747-2012
<i>St. aureus</i> , in 1,0 d (mL)	Not valid	Not found	Not found	Not found	GOST 10444.2-94
Pathogenic microorganisms including <i>Salmonella</i> in 25 degrees mL	Not valid	Not found	Not found	Not found	GOST 31659-2012
Mold, CFU/g/mL not more	50	< 10	< 10	< 10	GOST 10444.12-88
Yeast, CFU/g/mL not more	50	< 10	< 10	< 5.0×10^1	GOST 10444.12-88

CFU: colony-forming unit.

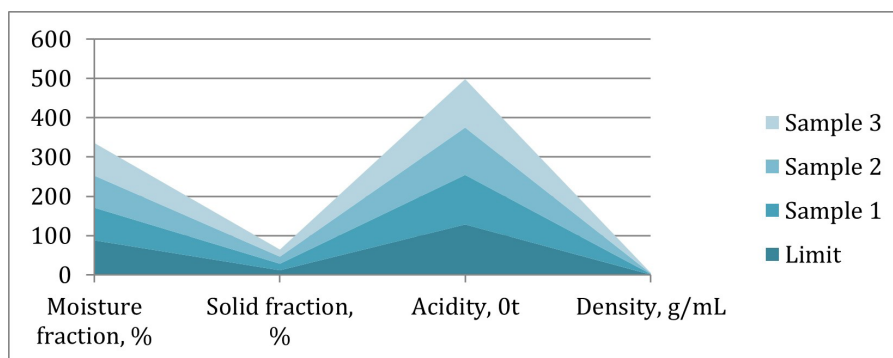
**Figure 1.** Physics and chemical variants parameters of the specialized food product for diabetic nutrition.

Figure 1 presents the results of the study of physical and chemical properties, indicate that the moisture and dry matter content in the samples of a specialized food product does not exceed the values of this indicator for a similar group of products established by GOST 3626-23 Milk and dairy products. Methods for determining moisture and dry matter (as Amended No. 1,2,3)". The density of milk is an indicator of its naturalness, as the density of milk consists of the density of its components: milk fat, lactose, proteins, acid salts and reflects their ratio in milk, which is an important indicator of its quality. The acidity is an indicator of the freshness of the milk. Fresh milk is safe because it does not contain harmful microorganisms.

As can be seen from the Figure 1, the moisture and dry matter Content of the samples in different variants in comparison with the control group, is due to the presence in their composition of the ferment consisting of pure cultures of *Streptococcus thermophilus* and *Bulgarian Bacillus* and in the corresponding concentrations of prescription ingredients.

In the development of specialized food product diabetic nutrition "Inullact-Fito" based on camel milk, worked out various ratios of 25%, 20%, 15% for the selection of sourdough, 0.5%, 1%, 1.5% concentration made as a sweetener, stevia extract with a sweetness factor of 250 and prescription ingredients in appropriate concentrations in the finished product with a testing evaluation of organoleptic parameters of prototypes taking into account time and temperature regimes with a long shelf life.

As a result, it was found that the optimal variant of the preserved samples, with all the qualities, was variant 2 of the prototype, at a temperature of 97-98°C, lasting 15-20 seconds in a ratio of 1% stevia extract, the presence of 20% starter culture consisting of pure cultures of thermophilic streptococcus (*Streptococcus*

thermophilus) and *Bulgarian bacillus* (*Lactobacillus bulgaricus*) in a ratio of 1:1, which in many respects surpasses other variants of a specialized food product in organoleptic properties.. In violation of the ratio of starter 1:1, the product acquires a sharp sour taste, granular structure or quickly allocates serum.

The study of the characteristic components of the developed variants of specialized food product, which is the density, indicates that its values for the samples of option 2, exceed the values for other studied samples. The low level of acidity index 121^oT according to the modern classification, the studied samples belong to the group of food products with indicators of quality control, suitability of fermented milk products with low acidity, which justifies the prediction of microbiological stability of food products during storage under storage conditions.

Based on our research, we optimized the recipe composition of a specialized food product based on camel milk in combination with extracts of medicinal plants, which allows us to provide the specified characteristics of the finished product and determined the technological parameters of the mixing process, including the sequence of dosing of ingredients depending on the density and acidity of the raw materials used.

The results of the conducted research became the basis for the selection of optimal recipes and the development of experimental batches of specialized food products.

The study results indicate that according to the value of the quality indicator, the developed specialized food product "Inullact-Fito" belongs to the group of food products with low acidity (Table 2). The amount of dry matter and density is close to the value of the indicator for fermented milk products.

The content of the trace element iron selected as an indicator of the mixing process corresponds to their calculated value, which indicates the uniformity of the distribution of minor ingredients in the mass of a specialized food product made according to the developed known technology. The results of analytical studies reliably confirmed the optimized recipe composition of the specialized food product and revealed the absence of sucrose and digestible polysaccharides.

The nutritional value of fermented milk products depends on the composition and properties of the raw material, the quantitative

and qualitative composition of the components included in the recipe, the conditions and operating parameters at all stages of processing, as well as on the level of technological equipment.

According to the nutritional and energy value, the developed specialized food product as can be seen from Table 3, it meets the medical and biological requirements. The content of nutrients and energy in a serving of 200 grams of product corresponds to the average daily requirement for biologically active substances (proteins, fats, vitamins, minerals, polyphenols, PUFA ω -6 and ω -3), which provide the necessary level of enrichment.

Table 2. Physical and chemical parameters of specialized diabetic food products.

Indicator	Normalized values of indicators	Shubat drink	Specialized food product "Inullact-Fito"
Liquid specialized food product			
Mass fraction of moisture, % (not more)	85.0	87.9	81.8
Mass fraction of solids, % (not less)	15.0	12.1	18.2
Dry skim milk residue, % (not less)	9.5	10.75	11.12
Density, g/mL	1.030-1.034	1.026	1.033
Mass fraction of iron, mg/100 g (not less)	1.0	1.0	1.7
Mass fraction of calcium, mg/100 g (not less)	160	150	170
Carbohydrate profile (the contents of mono and disaccharides):			
– lactose, g/100 g (not more)	1.5	1.25	1.30
– fructose, g/100 g (not less)	0.7	-	2.25
Mass fraction of titrated acidity, °T	75-160	128	121

Table 3. The content of nutrients in a portion of a specialized food product of diabetic nutrition and the percentage of satisfaction of the average daily requirement.

Nutrient	Shubat drink		Specialized food product* "Inullact-Fito"	
	Content, g/100 g	% of Shubat drink per serving, 200 g	Content, g/100 g	% of SFP per serving, 200 g
Protein:	3.8	11	4.5	13
– animal	3.8	-	4.0	-
– vegetable	-	-	0.5	-
Fats:	3.0	8	3.4	9
– saturated fatty acid	1.34	18**	1.50	19**
– monounsaturated fatty acids	1.21	15**	1.40	16**
– polyunsaturated fatty acid	0.45	10**	0.50	11**
– linoleic acid	0.09	18**	0.10	20**
– α -linolenic acid	0.04	10**	0.05	10**
Carbohydrates:	2.6	-	3.8	-
– lactose	1.25	7**	1.30	7**
– fructose	-	-	2.25	7**
Polyphenols (in Gallic acid equivalents)	-	-	0.24	48**
Minerals, mg/100 g				
Calcium	150	30	170	18
Magnesium	50	25	58	30
Zinc	1.56	10	1.86	12
Iron	1.0	7.2	1.7	12
Vitamins, mg/100 g				
β -carotene	0.38	2	17.2	22
E	0.11	5	0.24	10
C	7.8	26	9.65	33
B ₂	0.10	8	0.15	12
PP	0.71	10	1.25	17
Energy value, kJ/kcal	355.3/85.4	3.1	395.2/95	4

*TR CU 022/2011; **Uniform sanitary-epidemiological and hygienic requirements for goods subject to sanitary-epidemiological supervision (control).

Presented data from Table 4 indicate that the distinctive features in accordance with Annex 5 to TR CU 022/2011 “Food products in terms of its labeling” are high protein content-about 30% of the energy value of a portion of the product, vitamins C, B₁, B₂, B₁₂, PP, E, folic acid, trace elements iron and calcium. The content of vitamins B₂, B₆, PP, E, K, carotenoids, flavonoids, ascorbic acid, trace elements of copper, manganese, etc.

The content of polyphenols (in gallic acid equivalents) in a serving of drinks is 48% of the adequate level of consumption (ALC). The fat component contains 42% saturated fatty acids, including 37% medium-chain triglycerides (C8-C10), 43% monounsaturated fatty acids, 15% polyunsaturated fatty acids containing 10% linoleic acid (ω -6) and 5% α -linolenic acid (ω -3). The content of linoleic acid in a portion of the product is 20%, α -linolenic acid-10% of the adequate level of consumption. This proves the high nutritional and therapeutic value of bio-yogurt based on camel milk.

The developed specialized food product contains all essential amino acids, therefore, the use of the protein composition in optimal ratios allowed us to obtain products with a balanced amino acid composition and high amino acid content (AMC) relative to the reference scale of the Food and Agriculture Organization of the United Nations (FAO) / World Health Organization.

The consumption of one serving (200 g) of a specialized food product provides an average daily requirement for essential amino acids by 12-21%, which is shown in Table 4.

The results of the study of the amino acid composition of a specialized food product, related to the degree of balance of its amino acid composition, confirmed the high biological value of the products, which is not inferior to the values of the FAO/WHO standard.

Thus, according to sanitary-chemical and microbiological indicators, the specialized food product of diabetic nutrition “Inullact-Fito” meets the current standards established by the technical regulations of the Customs Union TR CU 021/2011 “On Food safety” and TR CU 027/2012 “On the safety of certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition”.

Evaluation of the possibility of using a specialized food product of diabetic nutrition “Inullact-Fito”. The indicators of glycemic variability in patients with type 2nd diabetes mellitus, according to daily glucose monitoring, when taking 1 serving of a specialized food product against the background of a hypocaloric diet for 15 days are presented in Table 5.

Table 5 has demonstrated daily monitoring of glucose levels in patients with type 2 diabetes mellitus showed that the inclusion in the hypocaloric diet of the developed specialized diabetic food product “Inullact-Fito” was accompanied by a decrease in the maximum level of glycemia, an increase in the duration of the normoglycemia period, a decrease in the period of hyperglycemia, a decrease in the level of glycemia after breakfast, lunch and dinner. Thus, the use of a specialized

Table 4. The content of essential amino acids and amino acid score in a shubat drink and a specialized food product.

Essential aminoacids	Shubat drink			Specialized food product “Inullact-Fito”		
	Content, g/100 g	% of Shubat drink per serving (200 g)	Aminoacid scor %	Content, g/100g	% of SFP per serving (200 g)	Aminoacid scor, %
Isoleucine	0.30	18	134	0.35	21	126
Leucine	0.59	16	126	0.68	19	163
Lysine	0.41	15	168	0.43	16	160
Methionine	0.15	14	104	0.17	15	100
Phenylalanine	0.32	12	108	0.34	14	102
Threonine	0.17	12	105	0.18	12	101
Tryptophan	0.10	15	180	0.12	16	176
Valine	0.32	14	100	0.36	17	114

SFP: specialized food product.

Table 5. Indicators of glycemic variability in patients with type 2nd diabetes mellitus, according to daily glucose monitoring.

Indicator	Specialized food product “Inullact-Fito”			
	1st day	5th day	10th day	15th day
The average level of glycemia, mmol/L	6.95 ± 0.32	6.85 ± 0.31	6.78 ± 0.31	6.65 ± 0.29
Oscillation amplitude, mmol/L	5.37 ± 0.37	5.21 ± 0.28	5.02 ± 0.23	4.81 ± 0.21
The minimum level of glycemia, mmol/L	4.49 ± 0.21	4.81 ± 0.37	5.10 ± 0.25	5.40 ± 0.20
The maximum level of glycemia, mmol/L	10.2 ± 0.43	9.43 ± 0.41*	8.85 ± 0.38	8.27 ± 0.42*
Duration of normoglycemia, %	41.0 ± 0.2	60.0 ± 0.3*	76.0 ± 0.2	95.0 ± 0.3*
Duration of hyperglycemia, %	59.0 ± 0.3	40.0 ± 0.2*	24.0 ± 0.3	5.0 ± 0.2*
Duration of hypoglycemia, %	0	0	0	0
Glycemia after Breakfast, mmol/L	9.89 ± 0.32	8.75 ± 0.42*	7.85 ± 0.32	6.70 ± 0.40*
Glycemia after lunch, mmol/L	10.8 ± 0.54	8.92 ± 0.49*	7.95 ± 0.52	6.85 ± 0.51*
Glycemia after dinner, mmol/L	8.95 ± 0.45	7.85 ± 0.39*	6.93 ± 0.42	6.35 ± 0.29*

*Statistically significant differences, $p < 0.05$ (compared to the baseline level (day 1)).

food product “Inullact-Fito” in patients with diabetes mellitus, for example, after lunch for 15 days led to a decrease in the level of glycemia by 36.6%, ranging from 10.8 ± 0.54 mmol/L to 6.85 ± 0.51 mmol/L. The results obtained allow us to conclude that the inclusion in the hypocaloric diet of a specialized diabetic food product “Inullact-Fito”, which contains sugar-lowering extracts of medicinal plants, is accompanied by an improvement in glycemic control in patients with type 2 diabetes mellitus, manifested in less pronounced fluctuations in postprandial glycemia, an increase in the duration of the normoglycemia period and a decrease in the hyperglycemia period.

The inclusion of a specialized diabetic food product “Inullact-Fito” in the hypocaloric diet has a positive effect on the daily variability of glycemia due to the stabilization of postprandial blood glucose levels in patients with type 2 diabetes mellitus. Further clinical studies are needed to evaluate the effectiveness of hypoglycemic therapy with the inclusion of the developed specialized food product of diabetic nutrition “Inullact-Fito” in order to correct disorders of carbohydrate and lipid metabolism, as well as the antioxidant status in patients with type 2 diabetes mellitus.

4 Conclusion

Based on the biomedical requirements for the composition and properties of a specialized food product intended for inclusion in the diet of patients with type 2 diabetes mellitus, the selection of food ingredients and biologically active substances was carried out, taking into account their chemical composition, safety, physiological and technological properties.

The formulation and technology of a specialized diabetic food product “Inullact-Fito”, containing various combinations of proteins, medium-chain triglycerides, monounsaturated and polyunsaturated, including the families of ω -3 and ω -6, and a complex of polyphenols of extracts from medicinal plants with the revealed hypoglycemic effect, fat- and water-soluble vitamins, macro- and microelements, have been developed. The development was carried out by eliminating sugar from the recipe, which is traditionally used in drinks and cocktails, and adding a natural sweetener with a low calorie stevioside-an extract from stevia leaves.

The technology of preparing a specialized food product “Inullact-Fito”, mixing methods, including the process of fermentation and mixing it with the remaining prescription ingredients in appropriate concentrations at different temperatures with time exposure, provided a uniform distribution of micronutrients in the product and guaranteed their content in a portion of the food product, as evidenced by the results of monitoring the iron content selected as an indicator of the uniformity of mixing.

According to the density content and the value of the acidity index, the specialized food product “Inullact-Fito” belongs to the group of food products with low acidity, which makes it possible to predict its microbiological stability during storage.

According to the indicators of food and energy value, the developed specialized food product of diabetic nutrition “Inullact-Fito” meets the medical and biological requirements. The content of the main food substances in a serving weighing 200 grams

of a specialized food product “Inullact-Fito” corresponds to the average daily requirement for biologically active substances and does not exceed the upper permissible level of consumption.

The use of a composition of milk and vegetable proteins made it possible to obtain a specialized diabetic food product with a balanced amino acid composition and a high content of amino acids.

According to sanitary-chemical and microbiological indicators, the developed specialized food product “Inullact-Fito” meets the current hygienic standards.

The inclusion of a specialized diabetic food product “Inullact-Fito” in the hypocaloric diet is accompanied by an improvement in glycemic control in patients with type 2 diabetes mellitus, manifested by less pronounced fluctuations in postprandial glycemia, an increase in the duration of the normoglycemia period and a decrease in the hyperglycemia period, which positively affects the daily variability of glycemia due to the stabilization of postprandial blood glucose levels in patients.

Ethical approval

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Informed consent was obtained from all patients for being included in the study.

Conflict of interest

There are no conflicts of interest in the presented research in each possible case: intellectual, manufacture, or supporting.

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