

RESEARCH ARTICLE

Development of the Composition and Technology of Obtaining a Dental film with *Portulacaoleracea* extract

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ABSTRACT:

According to the concept of the World Health Organization (WHO), oral health is the main indicator of the overall level of health and well-being, quality of life. Currently, improving oral health, treatment and prevention of chronic diseases of the mucous membrane are relevant. The creation of new dosage forms is an urgent problem, since existing dosage forms have both advantages and disadvantages. Dental film based on biologically active compounds of plant materials is a promising dosage form. The article presents the results of a study on the selection of ingredients for the rational composition of dental films based on carbon dioxide extract of *Portulacaoleracea*. Model formulations with various excipients have been developed for the selection of ingredients. In order to select the rational composition, a study was conducted on such characteristics as description, average mass, deviation from average mass, pH value, solubility, and the results of the study were described. The rational composition of the dental film with the conditional name "DentaPort" was established: the active substance is carbon dioxide extract of *Portulacaoleracea*, the formative substance is sodium alginate, a moisture-saving substance and a plasticizer is glycerin, powdered sugar is a corrigent, purified water is a solvent. The excipients were selected taking into account their compatibility with each other and the extract of *Portulacaoleracea*.

KEYWORDS: Carbon dioxide extract of *Portulacaoleracea*, Dental film, Oral cavity, Polymer, Models.

INTRODUCTION:

Ensuring a healthy lifestyle and improving the well-being of people of all ages is an important component of sustainable development¹.

According to the WHO, oral diseases affect 3.5 billion people around the world, and 3 out of 4 sufferers live in middle-income countries.

According to the concept of the WHO, oral health is the main indicator of the overall level of health and well-being, quality of life. At the moment, the improvement of oral health, treatment and prevention of chronic diseases of the mucous membrane are the subject of study at the international level^{2,3,4}. Oral diseases occupy the third place in the overall morbidity structure of the population of the Republic of Kazakhstan⁵.

According to world research data, periodontal disease ranked eleventh in the world⁶. It is considered one of the main causes of tooth loss, which compromises chewing and aesthetics, self-confidence and quality of life^{7,8}.

In the prevention and treatment of inflammation of the mucous membrane of the oral cavity, not only the choice of the acting substance is important, but also the dosage form and the route of its administration^{9,10}.

The range of dosage forms used in modern dental practice is wide: ointment, gel, paste, lozenges, spray, rinsing solutions, special toothpastes. Despite the variety of dosage forms for the treatment of oral diseases, it is currently important to create new dosage forms that provide high therapeutic activity with minimal side effects, with the possibility of regulating the duration of action^{9,4}. The creation of new dosage forms is an urgent problem, since existing dosage forms have both advantages and disadvantages^{11,12}.

Dental film is one of the most promising dosage forms that allows to deliver drugs through the oral mucosa, control the kinetics of the release of active substances, prolong the therapeutic effect, combine medicinal drugs with different pharmacological and physico-chemical groups as part of a single composition. In addition, it is safe and convenient to use, and the patient can use it personally^{10,11,13,4,14}.

One of the main components of dental films is a polymer, which plays the role of a carrier (matrix) of medicinal preparations and gives the dosage form the necessary structural-mechanical, technological, consumer properties. In the process of creating a dental film, synthetic, semi-synthetic, natural polymers are used as an auxiliary substance in different ratios and concentrations as a matrix. For this purpose, hydrophilic compounds with high mucoadhesive properties are often used: collagen, gelatin, cellulose, alginic acid derivatives, polyvinylpyrrolidone, polyvinyl alcohol^{15,11,16,17,18}.

So, a medicinal film is a dosed solid medicinal drug mold in the form of a rectangular, oval or other shaped plate, consisting of one or more thin layers of usable size, which includes one or more drugs, excipients, film-former, plasticizer, preservative^{16,17,19}.

Phytofilms containing biologically active substances obtained from plant raw materials are a type of transdermal therapeutic systems. Phytofilms are hydrophilic systems that, when in contact with water or biological fluids, absorb it in a certain amount and contribute to the dissolution of biologically active substances. Medicinal phytofilms differ from synthetic polymer therapeutic systems in that they are made as matrix transdermal therapeutic systems in natural carriers (agar-agar, gelatin, collagen, sodium alginate, etc.). Therefore, the safety and compatibility of phytofilms with living organisms is high^{17,20}.

According to WHO estimates, 80% of the world's population relies on traditional medicine. Medicinal plants are considered one of the main resources of traditional medicine and an important source of many modern medicines²¹⁻²⁴.

The global market for plant-based products is estimated at \$83 billion and is growing. Plant components have the ability to prevent the development of some chronic diseases. Showing a synergistic effect, medicinal plants show certain pharmacological and therapeutic properties^{21,25}. Plants and natural products are widely used in pharmaceutical production, as they form the basis of traditional and modern medicine²⁶.

Modern advances in dentistry have contributed to the use of various herbal and natural products for the treatment of oral diseases^{4,27}.

One of the plants of great interest for official medicine and pharmacy is the *Portulacaoleracea* L. the plant, the component composition of which is rich in biologically active substances, is widely used in folk medicine in many countries as an anti-inflammatory, antipyretic, reducing sugar levels, cardiovascular diseases, gastrointestinal diseases^{28,29}.

Ahn et al. reported that *Portulacaoleacea*L. exhibits various pharmacological effects, such as antibacterial, antifungal, anti-inflammatory, antioxidant and anti-ulcer effects, which are the result of various active components, including alkaloids, fatty acids, flavonoids, polysaccharides and terpenoids³⁰.

Our results of the previous study show that the main groups of compounds for the carbon dioxide extract of *Portulacaoleacea* were established triterpenoids: Lupeol, β -Amyrin, γ -Sitosterol; phytosterols: Campesterol, Stigmasterol; diterpenes Phytol; Vitamin E; monounsaturated fatty acids 9,12-Octadecadienoic acid, ethyl ester, Linoleic, Ethyl linolenate, Linoleic acid, methyl ester, Ethyl-9,12-octadecadienoate, 9,12-Octadecadienoic acid; polyunsaturated fatty acids Linolenic acid, Ethyl icosanoate; fatty acids Hexadecanoic acid, Palmitic acid, methyl ester, Palmitic acid, ethyl ester, Palmitic acid, of which terpenoids make up 18.30%, fatty acids 34.11%²⁸. Thus, the rich composition of medicinal plant *Portulacaoleracea* L. can be used for the development of new herbal medicines.

In connection with the above, we set the goal of developing the rational composition and technology of dental film based on the carbon dioxide extract of *Portulacaoleracea*.

MATERIALS AND METHODS:

The research work was carried out on the basis of the NJSC «Kazakh National Medical University named after S.D. Asfendiyarov» of the Republic of Kazakhstan.

Materials:

For research work, we selected the carbon dioxide extract of *Portulacaoleracea* as the active ingredient due to its antibacterial and antioxidant properties^{28,31}. To choose the rational composition of the dental film, we selected auxiliary substances that meet the requirements of regulatory documents. Polyvinyl alcohol, sodium alginate, sodium carboxymethylcellulose, gelatin were used as a formative substance, glycerin as a moisture-saving substance and plasticizer, powdered sugar as a corrigent, purified water as a solvent. The excipients were selected taking into account their compatibility with each other and the carbon dioxide extract of *Portulacaoleracea*.

Methods:

The methods of controlling the organoleptic (according to the description of its shape, color, smell), physico-chemical parameters of the dental film were used. The length, width and thickness were measured using a micrometer.

Experimental:

Preparation of model samples:

All developed model samples are different in composition, and the preparation of all ten models is the same. To prepare a solution of polymers: sodium alginate – 3,4,5 models, polyvinyl alcohol – 1,2 models, sodium carboxymethylcellulose – 6,7 models, gelatin – 8,9,10 models were weighed on scales of the brand Ohaus AV264C (USA, assembled in China), placed in a glass beaker, filled with purified water and left to swell for 30-45 minutes. The swollen mass was heated in WB-4MS (Russia) stirred water bath until a transparent solution was obtained. Glycerin, powdered sugar were added to the transparent solution and mixed.

After the introduction of the active substance into the polymer solution, the homogenization of the mass was carried out by stirring for an hour. Centrifuged in a centrifuge brand CM-6M (Latvia) for two hours to remove air bubbles.

We have chosen the most common and often used casting method for the development of films. The resulting mass was poured into a plastic mold. Drying was carried out at room temperature for 48 hours. The resulting film was cut into separate films with a size of 20x10x0.25mm.

Evaluation of the quality of dental film based on *Portulacaoleracea* extract:

Average mass and deviation from the average mass:

The test was carried out on 20 samples of films prepared on the basis of *Portulacaoleracea* extract. Each film was measured on the Ohaus AV264C laboratory analytical scale with an accuracy of 0.0001g and the average mass was calculated. The deviation of the films from the average mass should not exceed $\pm 10\%$.

Decomposition: In distilled water should not be more than 15 minutes.

Dissolution: The test was carried out using the "rotating basket" apparatus (Erweka, Germany), dissolution medium – water, volume – 900ml, speed of rotation of blades – 100rpm, temperature - $37^{\circ}\text{C}\pm 0.5$, dissolution time – 45min.

Weight loss during drying: Drying was carried out at atmospheric pressure, at room temperature. Dental films were weighed on laboratory electronic scales Ohaus Av264C, placed on glass pads and dried in a desiccator. Films were measured after 2, 4, 6, 8 and 24hours.

pH solution: The dental film was dissolved in 20ml of distilled water and the pH value (827 pH lab, Switzerland) was determined. The experiment was conducted at room temperature.

Microbiological purity: The sum of aerobic bacteria and fungi is not more than 10^2 . *Pseudomonas aeruginosa* and *Staphylococcus aureus* should not be present.

Determination of adhesion: An arm balance scale is used to determine the adhesion of the films. On one side of the lever of the scale there is a plate for the weight, and on the other side there is a glass plate balanced with it. The studied samples are placed on a glass surface with a drop of water in advance using a micropipette. The sample is covered with the glass plate attached to the lever of the scale, pressed with a standard load of 100 g for 10 seconds. Gradually increase the mass of the load on the plate until the film does not detach from the glass plate.

RESULTS AND DISCUSSION:

Development of the rational composition of the dental film based on the *Portulacaoleracea* extract:

We have developed model compositions of dental films with carbon dioxide extract of *Portulacaoleracea*. In all samples of dental film, carbon dioxide extract of *Portulacaoleracea* was taken in the amount of 1.0 g. In order to create the rational composition of dental films, we have developed model samples of films (Table 1).

Table 1: Models of dental films with carbon dioxide extract of *Portulacaoleracea*

Ingredients	№1	№2	№3	№4	№5	№6	№7	№8	№9	№10
Carbon dioxide extract of <i>Portulacaoleracea</i>	1	1	1	1	1	1	1	1	1	1
Polyvinyl alcohol, g	7.0	10.0	-	-	-	-	-	-	-	-
Sodium alginate, g	-	-	2.0	4.0	5.0	-	-	-	-	-
Sodium carboxymethylcellulose, g	-	-	-	-	-	7.0	10.0	-	-	-
Gelatin, g	-	-	-	-	-	-	-	7.0	10.0	20.0
Glycerin, g	2.0	3.0	6.0	6.0	4.0	2.0	6.0	2.0	3.0	4.0
Powdered sugar, g	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Purified water, up to 100 ml	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

Description of the mass and individual dental films:

During the production of the mass and after the production of individual films, we described the formed films. The results of the research are presented in table 2.

Table 2: Description of the mass and individual dental films

Model	Description of the mass and formed film	Cut into individual films
Model 1	It had an inhomogeneous consistency and did not provide smooth contact with the tissues	The film layer hasn't formed
Model 2	Thick and lacked flexibility	The film layer hasn't formed
Model 3	Thin and fat	The film layer was torn, during cutting
Model 4	Smooth, transparent, colorless and homogeneous	Easy
Model 5	Tight and not elastic enough	With uneven layer
Model 6	Hard, not elastic	The film layer broke, during cutting
Model 7	Hard, not elastic	The film layer broke, during cutting
Model 8	Lost a lot of weight during drying	The film layer hasn't formed
Model 9	Smooth, transparent, colorless and homogeneous	Easy
Model 10	Although initially showing elasticity, after some time it hardened and broke during bending	The layer broke, during cutting

According to models No.1, No.2 polyvinyl alcohol-based films were uneven. The model No.1, which contained 7g of polyvinyl alcohol, had an inhomogeneous consistency and did not provide a sufficient degree of adhesion and smooth contact with the tissues, while model No.2, consisting of 10 g of polyvinyl alcohol, did not have much thickness and elasticity.

The models No. 6, No.7 based on sodium carboxymethylcellulose also did not satisfy the technological parameters, in particular, it was hard, inelastic, and difficult to remove from the lining.

The gelatin-based model No. 8 lost a lot of weight during drying, and the model No.10, although initially

elastic, hardened after some time and broke during bending. In addition, the final sample became sharp after drying, which, in turn, caused the risk of slicing during use in the oral cavity.

The model No.3 prepared on the basis of sodium alginate, turned out to be thin and greasy. This sample contained a high amount of plasticizer. Therefore, it was considered to reduce the amount of glycerin in the following samples. The model No. 5 was rather dense and not elastic enough.

According to the results of the conducted research, models No.4 and No.9 had satisfactory technological indicators. The properties of sodium alginate and gelatin as film-forming are practically similar, but considering that the bleeding ability of alginic acid and its salts is important in the treatment of oral mucosa, we chose model No.4.

Determination of quality indicators of dental film based on *Portulacaoleracea* extract:

Based on the description, film dimensions, average mass, decomposition and dissolution time, weight loss during drying, microbiological purity, pH, the quality indicators of dental film based on the *Portulacaoleracea* extract were determined, the results are shown in table 3.

Table 3: Quality indicators of dental film based on *Portulacaoleracea* extract

Quality indicators	Deviation norms, research results
Description	Light orange color, with a characteristic smell of the garden purslane plant, without slices, air bubbles, elastic, homogeneous plates
Film dimensions	Width (10±0,2) mm, length (20±0,2), thickness (0,251±0,5) mm
Average mass	0,105±0,079g
Decomposition	814±5 sec
Dissolution	30min
Weight loss during drying	Not more 5±0,5%
Microbiological purity	The sum of aerobic bacteria and fungi is not more than 10 ² . <i>Pseudomonas aeruginosa</i> and <i>Staphylococcus aureus</i> were not be detected in 1g of the drug.
pH solution	6,68

Most of the group of biologically active substances used in pharmaceutical practice are natural products. Therefore, it is important to expand the range of medicinal and therapeutic and cosmetic products of plant origin. Thus, in the work of Himansu Bhusan Samolet al, it was reported about the development of a dental film containing aloe vera for the treatment of periodontal diseases⁴. The observed effect is in good agreement with the results of the research developed by Alekseeva I.V. et al, in whose works it was reported that the composition and technology of phytofilms based on polymer materials using dry plant extracts with antibacterial, wound healing and anti-inflammatory properties⁹. This is consistent with our research results.

Thus, as a result of the conducted research, the fourth model was selected as the optimal composition of the dental film with carbon dioxide extract of *Portulacaoleracea* and the conditional name "DentaPort" was assigned (Table 4).

Table 4: The rational composition of dental film "DentaPort"

Ingredient name	Quantitative size	Functional purpose
Carbon dioxide extract of <i>Portulacaoleracea</i>	1.0	Active substance
Sodium alginate, g	4.0	Film forming
Glycerin, g	6.0	Plasticizer
Powdered sugar, g	2.0	Seasoning
Purified water, up to 100 ml	100.0	Solvent

Compared to some complex and expensive processes used in the production of various dosage forms, dental films are relatively easy to produce, a fast and inexpensive process^{15,19}. Therefore, dental films obtained from medicinal plants are relevant and economical.

CONCLUSION:

The rational composition of the dental film has been developed on the basis of the technological process, which consists of the stages of preparation of raw materials, base, homogenization, pouring of the film mass into the lining, drying of the films, cutting. Dental film based on sodium alginate had good physical and chemical properties.

Dental film "DentaPort" is recommended for the treatment of diseases of the oral cavity and the formation of further technological processes.

CONFLICTS OF INTEREST:

The authors declare that there are no conflicts of interest regarding the publication of this article.

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