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DEVELOPMENT OF CARBOHYDRATE GEL BASED ON *PERESKIA ACULEATA* MILLER (ORA-PRO-NOBIS)

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Abstract: The use of dietary preparations and nutrient intake are ancient practices, with carbohydrate supplements in gel form capable of effectively assisting nutritional status, becoming yet another alternative in reducing complications with food transport and digestion, all of this associated with improved quality of life with daily lifestyle changes. The objective of the present study was to develop and evaluate the stability of a carbohydrate gel based on *Pereskia aculeata* Miller, ora-pro-nobis to evaluate the organoleptic characteristics and stability of the product. The pharmaceutical forms manipulated in triplicates with samples of 10g each being stored under different conditions: 3°C to 5°C, 45°C, 60°C. All samples showed few changes in their organoleptic characteristics. The samples that were at a high level were those that showed the most changes in terms of the oxidative process.
Keywords: stability; herbal medicines; carbohydrate gel; *Pereskia aculeata*; medicinal plants.

INTRODUCTION

Medicinal plant can be defined as any and/or any plant sample that presents, in its constituent organs, root, stem, leaf, flower or fruit, potentially active molecules that can be used for therapeutic purposes according to the World Health Organization. Health (WHO). Added to this, the National Health Surveillance Agency (ANVISA) defines herbal medicines as manipulated medicines that have medicinal plants as their starting point (Brazil, 2006).

It is worth mentioning that the use of vegetables as an alternative to the treatment of diseases dates back to the beginning of man's history and, throughout his evolution, he began to realize that the use of plants for medicinal purposes could somehow promote pain relief, for example, or even curing diseases (Lorenzi; Matos, 2002). The use of medicinal plants is valued by the WHO in health units through traditional medicine associated with conventional medicine. Without forgetting precepts such as quality, safety and effectiveness, seeking their rational use (Michiles, 2004).

The use of vegetables with medicinal potential as a way to ward off diseases has become a faithful practice, due to the presence of substances that provide the opportunity for the development of products with medicinal purposes (Melhorança Filho; Pereira, 2012). Taking into consideration, the inputs used for the production of carbohydrate replacement gels on the current market, which use fructose and other additives that can generate undesirable long-term effects, a gel with a natural formulation was developed, using the Pereskia aculeata plant. Miller popularly known as ora-pro-nóbis or Barbados gooseberry, found in tropical and subtropical regions, having a climbing characteristic and widely used in the central-western region of Brazil (Mandelli, 2016). P. *aculeata* has a high antioxidant index, protein properties and is rich in vitamins A, C and E, being commonly used as a food source. (Silva *et al.,* 2023). The leaves and fruits of the vegetable also contain mucilage composed of the biopolymer arabinogalactan, which has technofunctional properties as a thickener (Silva *et al.,* 2023), with its mucilage having great potential for the development of pharmaceutical gel forms (Porto *et al.*, 2022). In view of the above, the aim of the work is to develop a carbohydrate gel based on the leaf of *Pereskia aculeata* Miller (Ora-pro-nobis) with the aim of evaluating the organoleptic characteristics (color, odor and appearance) based on pre-tests. stability of the developed product.

LITERATURE REVIEW

Herbal medicine has been a source of medicines and there have been many attempts to use herbal medicines for the treatment of various diseases (Kooti *et al.*, 2016). The Ministry of Health, through the National Policy on Integrative and Complementary Practices (PNPIC), has encouraged the provision of Acupuncture, Homeopathy, Phytotherapy, Hydrotherapy and Anthroposophic Medicine in the Unified Health System (SUS) since 2006 (Mattos et al., 2018*).*

Phytotherapy can make use of medicinal plants, which are defined by ANVISA as a plant whose main objective is to treat a certain unwanted pathology, it can come from the plant or it can be its plant derivative (Brazil, 2023). There are many laws that deal with medicinal plants and cosmetics, such as the Resolution of the Collegiate Board of Directors – RDC No. 26, of May 13, 2014, of ANVISA, according to which phytotherapeutic medicine is considered to be one obtained from active raw material. vegetable. Its safety and effectiveness are based on clinical evidence and characterized by quality. It is not considered a certain herbal medicine if it contains isolated active substances of any origin in its composition, nor is it considered to be related to plant extracts (Brazil, 2014).

The vegetable *Pereskia aculeata* Miller (Figure 1) is a recognized source of protein; dietary fiber; vitamins and minerals make the leaves of this plant, raw, cooked and sautéed, an important ally against protein and micronutrient deficiencies (Silveira *et al.,* 2020).

Figure 1: (A, B) Flowers (C, D) leaves of *Pereskia aculeata* Miller.

Source: Nogueira et al, 2023.

It originates from tropical climates and belongs to the cacti family, widely found in the Central-West, North and South regions (Brazil *et al.*, 2011). It is a plant rich in proteins, for every 100g it is around 25g (Almeida *et al,* 2014), magnesium, phosphorus carbohydrates and their antioxidant self-power, which drew our attention to replacing the use of animal protein with vegetable protein, further adding its health advantages. Its leaves have mucilage and its fruits are small, generally called berries, which are orange in color and ideal for consumption (Mandelli, 2016).

Its antioxidant power is suitable for replacing the use of hydroxybutyltoluene (BHC), a synthetic antioxidant that causes liver damage and also possible tissue cancer called carcinoma with prolonged use (Sousa et al., 2014*).* Its level of toxicity is practically zero, and its indication applies to anti-inflammatory, healing, reducing the level of diabetes, cholesterol, and helps in the treatment of cancer and ulcers (Augusta; Nascimento, 2013).

Carbohydrate gels are an alternative for those who do not want to consume a complete

diet, and see these fast-absorbing gels as an alternative, where the sugar in the gel helps to stabilize the Krebs glucose cycle.

Athletes' diets require adequate energy, mainly from carbohydrates (CHO) present in the bloodstream or stored in the muscles and liver, with supplementation being common after intense physical activity and/or to improve performance during exercise (Johann et *al.*, 2015).

Currently, this market has grown a lot since after the Covid-19 pandemic people found themselves in a scenario of seeking better health since in a certain period the vast majority of the population was "stuck" in their respective homes and had an increase unwanted weight (Costa *et al.*, 2021). In 2010 this sector already had revenues of around R$73 billion, of which R$1.3 billion in Brazil, as a result we have new products appearing every day in the USA, there are around 55 thousand existing products with the prospect of an average of 1000 new products being launched annually (Felipe, 2019).

The compositions on the current market do not meet the needs of vegan groups who avoid any product that exploits animals and their origins. Veganism is a lifestyle choice and has gained a lot of voice in recent years, with new products being manufactured focused on niche (Valdez, 2022). Added to this, the use of preservatives, dyes, sweeteners and other synthetic adjuvants generates damage in the long term of use, which happens since many do not evaluate the amount of such additions in the industrialized products they consume and can cause problems such as stomach cancer, ulcers, DNA changes (Honorato *et al,* 2013).

Nutrition plays a crucial role in performance, reducing fatigue, injuries and contributing to the overall health of athletes. Maintaining an ideal pace during these events requires targeted physical training and adequate energy consumption. The energy substrate used depends on the nature, intensity and duration of the exercise, as well as individual factors. Ora-pro-nobis extract has a unique composition, being protein and antioxidant with carbohydrates, vitamins, minerals and growth factors. It can be explained by phytohormones, such as cytokinins, which influence physiological responses in plants. This is an example that can be used in carbohydrate gels (Felipe, 2019).

METOGOLOGY

The present work consisted of experimental research and bibliographical basis for the development of a certain herbal formulation using ora-pro-nobis. The stability aspects of the gel were evaluated after its development, for this purpose parameters such as organoleptic characteristics, centrifugation test, pH and viscosity of the packaging material in the pharmaceutical form and time to verify organoleptic changes (color, odor and aspects) and presence of microbiological contaminants.

The leaves of *Pereskia aculeata* Miller (Ora-pro-nobis) were acquired in August 2023, with remnants of plant organs other than leaves being removed. One kilogram of raw material was purchased, processed and labeled in primary packaging for later use. Triplicates of 10g each were manipulated, with a total of nine carbohydrate gels, and placed in plastic containers in the form of laminated sachets in order to avoid degradation upon contact with light, due to photolysis.

The pharmaceutical form was based on a mixture of organic inputs such as chia, dates, sugar cane molasses, coconut oil, lemon, sodium chloride, strawberries, citric acid and cocoa nibs (Table 1). All inputs were purchased by the researcher and handled at the UNICEPLAC educational institution.

Excipients	Quantities	Functions within the formulation
P. aculeata extract 1:10	0.5mL	Protein source
Wheezing	150mg	Gelling
Date	3 units	Antioxidant
Sugar cane molasses	10mL	Sweetener
Coconut oil	5mL	Emollient
Lemon juice	5mL	Antimicrobial preservative
Sodium chloride	0.5g	Thickener
Strawberry	6 units	Flavoring
cocoa nibs	0.5g	Antioxidant
Citric acid	0.10g	pH regulator
Purified water	150mL	Vehicle

Table 1: Components, their respective quantities used in the gel formulation and their functions.

Source: From the author, 2023.

After weighing the raw materials, they were placed in a mortar and macerated until homogenized. To increase the viscosity of the product and its suitability for gel, the chia was hydrated with strawberry juice obtained by mixing it with distilled water.

Soon after manufacturing the ora-pro-nobis gels, they were packaged in plastic containers coated with a laminated source with a capacity of 10g each and closed to protect them from extrinsic factors such as: oxidation and photolysis, capable of causing degradation due to contact with light.

The hydrogen potential was measured using a Mettler-Toledo model FiveEasy F20 pH meter. Calibration was performed using device-specific standards. In the centrifugation test, 5g of the sample was used, which was centrifuged at 1500 rpm for 6 minutes at room temperature, and the test was carried out in triplicate.

For density, an amount of the sample was weighed and introduced into a beaker to measure the volume and the values obtained were introduced into the apparent density formula.

Calculation: $D = m / v$

Where: D = apparent density in g/mL, m = sample mass in g, v = final volume in mL (ANVISA, 2008).

The samples were divided into three temperatures from 2° to 5° C, and three at temperatures from 45° to 60° degrees in triplicate and at different temperatures and locations. The samples were subjected to initial accelerated stability tests, designed to accelerate possible chemical degradation and/or physical changes of active pharmaceutical ingredients under forced storage conditions (Brazil, 2012), to verify the organoleptic changes tested, which determine the parameters of product acceptance: color, odor and appearance according to ANVISA (2004).

To evaluate organoleptic characteristics such as odor, smell was used as a sense, color was evaluated by visual identification, and in addition all ointments were duly photo documented throughout the observation process, for 4 days. RDC No. 45 (2012) recommends that accelerated stability tests be carried out at 0, 3 and 6 months to evaluate the impact of short exposures, and that storage conditions must be determined depending on the climatic zone, at present work considered the zone called IV with storage conditions for semi-solid pharmaceutical forms of 40ºC ± 2°C / 75% RH ± 5% (Brazil, 2005), however, and the present work ended after 5 days due to the beginning of degradation of the manipulated gel dosage form.

RESULT AND DISCURSIONS

Organoleptic characteristics are the characteristics of substances and products that refer to the sensory profile identified by: appearance, color, odor, flavor and sensation to touch (BRAZIL, 2004).

Organoleptic tests are procedures used to

evaluate the characteristics of the product, detectable by the senses: appearance, color, odor, taste and touch. To carry out organoleptic tests, the physical form and characteristics of the product must be considered, such as volatile liquids, non-volatile liquids, semisolids and solids (BRAZIL, 2004).

The samples after manipulation presented a reddish brown color (figure 2), sweet and citrus aroma present and moderate viscosity. The pharmaceutical form had a uniform appearance and a gel-like appearance. No preservatives were incorporated.

Figure 2: Sample after manipulation.

Source: From the author, 2023.

After four days of packaging the sachets at different temperatures, two gel samples at room temperature were brown, with a citrus odor and low viscosity, only one sample had a brown color, sweet aroma and high viscosity. The samples subjected to low temperature presented a brown color, sweet aroma and high viscosity (figure 3). Finally, the gels at a temperature of 60ºC had a light brown color, low viscosity and remained full of sweetness. The increase in heat may interfere with the denaturation of the excipients used in the formulation (JESUS, 2012), this may have been one of the factors that interfere with the results of the samples stored in the oven. Another factor that may have influenced these results is the presence of water in the formulation, since its content in the fruit pulps, strawberry, date and lemon juice, were not evaluated, used since the water present in formulations accelerates degradation reactions. of them (SILVA, 2009).

Figure 3: Sample after 4 days of manipulation.

Source: From the author, 2023.

For the preliminary investigation of physical-chemical stability, the formulation must be subjected to a centrifugation test, where phase separation must not occur. The preservation of a single phase offers signs that the product is stable and, therefore, any indications of instability indicate the need to reformulate the pharmaceutical form (BRAZIL, 2008; FRIGUEIREDO, MARTINI, MICHELIN, 2014).

The centrifuge test determines the force of gravity that acts on the products, causing their particles to shake inside them. Centrifugation promotes pressure on the analyzed sample, appearing to increase gravity, increasing the fluidity of the particles and predicting plausible instabilities. These can be noted in the form of precipitation, phase separation, formation of dense sediments (Caking) and coalescence. The sample is centrifuged at a

standardized temperature, time and speed (BRAZIL, 2004).

After the procedure, signs of phase separation were observed (figure 4) in the aqueous phase gels, indicating the need for adjustment in the formulation.

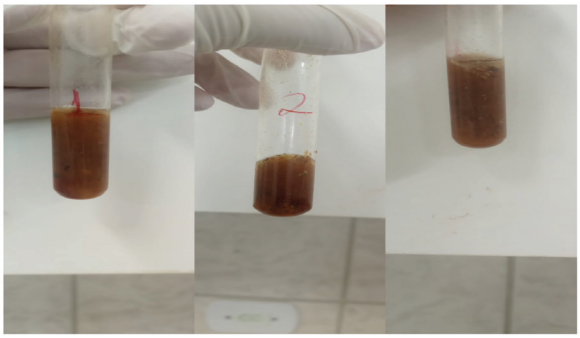

Figure 4: Samples subjected to the centrifugation test.

Source: From the author, 2023.

The pH value is defined as the degree of hydrogen ion activity in an aqueous solution and the potentiometric determination of pH is carried out by measuring the potential difference between two electrodes immersed in the solution under analysis. In general, an electronic pH meter is used, where the device's electrode is immersed in the product sample in aqueous solution, except in cases where otherwise specified in the monograph present in the pharmacopoeia. The device takes readings to determine the potential difference between the two electrodes - reference and measurement - and displays the pH value of the product on the electronic panel. Based on this data, it is necessary to compare it with the pH range recommended by ANVISA, to approve or make corrections if it does not comply with the specifications (BRAZIL, 2019). Formulations must maintain their pH values unchanged, or with non-significant changes, at room temperature (ROSÁRIO et al, 2021).

Regarding the determination of pH in the protein gel, in the verification carried out after manipulation, it was pH 4.0 for all formulated samples, which characterizes it as acid. In the reading carried out after 4 days, a value of 5.0 was found in two samples that were subjected to room temperature and the same value was observed in a sample at a temperature of 2°C to 5°C and one at 60°C. The remaining samples remained at unchanged pH, considering that the tested formulation remained within stability.

After manipulation, the density of the gels was an average of 1.91 g/mL and after four days the gels subjected to cooling and heating had a decrease in density, with an average value of 1.45 g/mL and the gel at room temperature had its density at an average value of 1.95 g/mL, within the stipulated scope.

For microbiological analyzes nine slides were prepared, one of each triplicate formulation and each one subjected to a temperature variation. Two magnifying lenses were used for analysis, the 4x0.1 lens and the 10x 0.25 lens. No microorganisms were detected in the formulations (Figure 5).

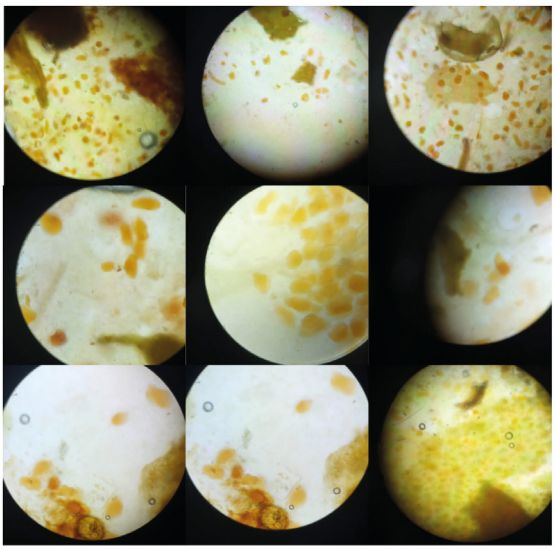

Figure 5: Analysis of samples for the presence of microorganisms.

Source: From the author, 2023.

CONCLUSIONS

The credibility and safety of a pharmaceutical product are directly linked to the stability of the pharmaceutical form, guaranteed when there is no internal or external interference that could affect it. The procedure for handling a product establishes the need for severity in each stage carried out, from the acquisition of inputs to the finished product, even more so when it comes to quality control, whether physical-chemical and/or microbiological, so that at the end of the procedure have a stable pharmaceutical form with an expected mechanism of action.

The present work consists of experimental research with a bibliographical basis on the development of a certain herbal formulation using ora-pro-nobis. The stability aspects of the gel were evaluated after its development and for this purpose parameters such as organoleptic characteristics, centrifugation test, pH, viscosity of the product contained in the packaging, verification of organoleptic changes (color, odor and appearance) and presence of microbiological contaminants were used.

From the results of the microbiological analysis tests, no microorganisms were detected, the pH and density values varied within the expected parameter and in the centrifugation test there was a slight phase separation caused by the increased fluidity of the particles. In this sense, the analysis revealed that ora-pro-nóbis gel is an alternative for the current market, however its analysis must be further in-depth to correct some variations presented, with more stability studies, and thus stipulate the expiration date of the product. product. The importance of carrying out clinical tests in order to prove the safety, efficacy and quality of protein increase or replacement is also highlighted.

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