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VIABILITY OF HUMAN MILK COLOSTRUM POWDER AS A STRATEGY FOR OPTIMIZED CONSERVATION AND DISTRIBUTION

VIABILIDADE DO COLOSTRO EM PÓ DO LEITE HUMANO COMO ESTRATÉGIA PARA OTIMIZAÇÃO DA CONSERVAÇÃO E DISTRIBUIÇÃO

VIABILIDAD DEL CALOSTRO EN POLVO DE LECHE HUMANA COMO ESTRATEGIA PARA SU CONSERVACIÓN Y DISTRIBUCIÓN OPTIMIZADAS

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ABSTRACT

Human milk is recognized as the ideal food for newborns, especially premature and low birth weight infants, due to its nutritional composition and the presence of essential immunological and bioactive components. Colostrum, produced in the first days of lactation, stands out for its high concentration of proteins, immunoglobulins, cytokines, growth factors, and antimicrobial compounds, playing a fundamental role in the maturation of the immune system and protection against infections. However, the availability of human milk can be limited by maternal or logistical factors, and traditional preservation methods, such as pasteurization and freezing, can partially compromise its bioactivity. In this context, the present study evaluated the viability of lyophilizing human colostrum as a strategy to optimize its preservation and distribution in human milk banks. Colostrum samples were subjected to lyophilization under controlled conditions, and the yield and moisture content of the final product were evaluated. Freeze-dried human colostrum showed an average yield of 14.12%, with a moisture content of 4.72%, a value compatible with the standards established by current legislation. These results demonstrate efficiency in water removal, favoring greater product stability and reducing the risks of oxidative, enzymatic, and microbiological degradation. It is concluded that the freeze-drying of human colostrum is a promising strategy for preserving its nutritional and functional characteristics, as well as facilitating storage, transport, and distribution, especially in regions with limited infrastructure, expanding safe access to human milk.

Keywords: Human Colostrum. Freeze-Drying. Human Milk Banks. Preservation.

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RESUMO
O leite materno é reconhecido como o alimento ideal para recém-nascidos, especialmente prematuros e de baixo peso ao nascer, devido à sua composição nutricional e à presença de componentes imunológicos e bioativos essenciais. O colostro, produzido nos primeiros dias de lactação, destaca-se pela alta concentração de proteínas, imunoglobulinas, citocinas, fatores de crescimento e compostos antimicrobianos, desempenhando um papel fundamental na maturação do sistema imunológico e na proteção contra infecções. No entanto, a disponibilidade de leite materno pode ser limitada por fatores maternos ou logísticos, e os métodos tradicionais de conservação, como a pasteurização e o congelamento, podem comprometer parcialmente sua bioatividade. Nesse contexto, o presente estudo avaliou a viabilidade da liofilização do colostro materno como estratégia para otimizar sua conservação e distribuição em bancos de leite humano. Amostras de colostro foram submetidas à liofilização em condições controladas, e o rendimento e o teor de umidade do produto final foram avaliados. O colostro materno liofilizado apresentou um rendimento médio de 14,12%, com teor de umidade de 4,72%, valor compatível com os padrões estabelecidos pela legislação vigente. Estes resultados demonstram a eficiência na remoção de água, favorecendo maior estabilidade do produto e reduzindo os riscos de degradação oxidativa, enzimática e microbiológica. Conclui-se que a liofilização do colostro humano é uma estratégia promissora para preservar suas características nutricionais e funcionais, além de facilitar o armazenamento, o transporte e a distribuição, especialmente em regiões com infraestrutura limitada, ampliando o acesso seguro ao leite humano.

Palavras-chave: Colostro Humano. Liofilização. Bancos de Leite Humano. Conservação.

RESUMEN
La leche materna es reconocida como el alimento ideal para los recién nacidos, especialmente los prematuros y los de bajo peso al nacer, debido a su composición nutricional y a la presencia de componentes inmunológicos y bioactivos esenciales. El calostro, producido en los primeros días de lactancia, destaca por su alta concentración de proteínas, inmunoglobulinas, citocinas, factores de crecimiento y compuestos antimicrobianos, desempeñando un papel fundamental en la maduración del sistema inmunitario y la protección contra infecciones. Sin embargo, la disponibilidad de leche materna puede verse limitada por factores maternos o logísticos, y los métodos tradicionales de conservación, como la pasteurización y la congelación, pueden comprometer parcialmente su bioactividad. En este contexto, el presente estudio evaluó la viabilidad de liofilizar el calostro humano como estrategia para optimizar su conservación y distribución en los bancos de leche materna. Se sometieron muestras de calostro a liofilización en condiciones controladas y se evaluó el rendimiento y el contenido de humedad del producto final. El calostro humano liofilizado mostró un rendimiento promedio del 14,12%, con un contenido de humedad del 4,72%, un valor compatible con los estándares establecidos por la legislación vigente. Estos resultados demuestran la eficiencia en la eliminación de agua, lo que favorece una mayor estabilidad del producto y reduce los riesgos de degradación oxidativa, enzimática y microbiológica. Se concluye que la liofilización del calostro humano es una estrategia prometedora para preservar sus características nutricionales y funcionales, además de facilitar el almacenamiento, el transporte y la distribución, especialmente en regiones con infraestructura limitada, ampliando así el acceso seguro a la leche materna.

Palabras clave: Calostro Humano. Liofilización. Bancos de Leche Humana. Preservación.

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1 INTRODUCTION

Breastfeeding is widely recognized as one of the most effective interventions for promoting neonatal health, especially in premature and low-birth-weight newborns. Human milk is considered the ideal food during this phase, as it combines essential nutrients with immunological and bioactive factors that promote the growth and maturation of the immune system (Ballard; Morrow, 2013).

The composition of human milk is unique and adapts throughout the lactation period. In the first few days after birth (up to seven days), colostrum is produced. This thick, yellowish fluid is highly concentrated in proteins, immunoglobulins, regulatory cytokines, antimicrobials, and growth factors (Castro et al., 2022a; Ientz et al., 2023). This strengthens the intestinal barrier, matures the immune system, and protects against infectious and inflammatory processes (Dimitroglou et al., 2022; Ratti, 2001), ensuring significant postnatal protection and adaptation (Briana et al., 2017). After this phase, transitional human milk is produced (between seven and fourteen days), followed by mature human milk (after fifteen days), which provides greater energy support to the infant (Agência Nacional de Vigilância Sanitária, 2008; Muxfeldt et al., 2025).

Despite its importance, the supply of human milk faces limitations, such as low maternal production, diseases, hospitalization, or even maternal death, which may restrict the infant's direct access to this food. In this scenario, human milk banks play a fundamental role in ensuring breastfeeding support (Ientz et al., 2023). To ensure microbiological safety, these services predominantly use pasteurization, although this thermal process may compromise the stability of human milk bioactive compounds (Ferreira et al., 2025), and designate rigorous preservation under freezing (Agência Nacional de Vigilância Sanitária, 2008).

In this sense, given the importance of colostrum and human milk for neonatal health, the development of strategies capable of favoring the preservation of bioactive properties of human milk without significant losses becomes essential. In this context, lyophilization stands out as a promising technological alternative to ensure greater stability of human milk bioactive compounds (Alves et al., 2023). The technique consists of a dehydration process by sublimation at low temperatures and reduced pressure, resulting in stable powdered human milk, easy to handle (Souza et al., 2022), store, and transport, thus expanding its availability to newborns (Manin et al., 2019). In addition, lyophilized human milk represents a strategic solution to expand distribution in regions with limited infrastructure, enabling longer storage

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time without the need for a cold chain (Agência Nacional de Vigilância Sanitária (Anvisa), 2024; Blackshaw et al., 2022).

However, the effectiveness of lyophilization depends not only on the process itself, but also on storage conditions. Therefore, the choice of suitable packaging is decisive to protect human milk against environmental factors such as oxygen, moisture, and light, which may accelerate enzymatic degradation reactions and oxidation of bioactive molecules (Alves et al., 2023; Castro-Albarrán et al., 2016).

In view of this scenario, the present study aims to evaluate the feasibility of human colostrum lyophilization as a promising alternative for human milk banks, considering its applicability in the nutrition of premature and low-birth-weight newborns. The investigation seeks to understand and optimize the lyophilization process, aiming to consolidate powdered human colostrum milk as a safe and effective solution for preservation and distribution in different clinical contexts.

2 MATERIALS E METHODS

2.1 ETHICS COMMITTEE APPROVAL

The study has an approved link with the Certificate of Presentation of Ethical Appreciation (CAAE) No. 93048818.0.0000.0104 integrated with the research line of the APLE-A-CNPq group.

2.2 SAMPLE COLLECTION

Human milk colostrum samples (n = 7) were collected from the Human Milk Bank of the Maringá Regional University Hospital, following pre-defined research criteria, including the selection of human milk that did not meet the quality control standard (identified as dirty). After collection, a transportation protocol was followed, keeping it under a cold chain at a maximum of 4 °C, as recommended by the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária (Anvisa), 2024). Subsequently, the selection of individual vials was assessed for acidity by section 2.3, analyzing each vial for sampling selection. After sample selection, a pool was created by mixing the entire volume of human milk.

2.3 TITRATABLE ACIDITY

The acidity content was assessed individually after the collection of human milk samples, as a quality parameter for the research. For this purpose, 10 mL aliquots were

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collected from each collected vial, and titration was carried out using a sodium hydroxide titrant solution N/9 (Dornic solution), in the presence of 4 drops of the phenolphthalein indicator. For results, it was considered that each 0.1 mL of Dornic solution used to neutralize 10 mL of human milk is equivalent to 1 ºD (Castro et al., 2022b).

2.4 FREEZE DRYING

An approximate volume of 1,700 mL of pooled human milk was subjected to lyophilization. First, samples were prepared by transferring the volume to rectangular high-density polyethylene containers, weighing the mass of the empty container and the volume of added human milk on a semi-analytical balance (model ATY224, Shimadzu). The samples were then stored at -18 °C for 24 h. A liofilização foi realizada em um liofilizador (L108, LioBras) operando a -52 ºC e pressão de 11.2 µHg.

Lyophilization was performed in a freeze-dryer (L108, LioBras) operating at -52 °C and a pressure of 11.2 µHg. The processing time was calculated until a moisture content of 4% to 5% was obtained, monitored by an infrared analyzer (model I-Thermo, Bel Engineering), by the established standard for lyophilized human milk (Agência Nacional de Vigilância Sanitária (Anvisa), 2024). The operation was carried out during business hours (8:00 AM to 5:00 PM) under the supervision of the lead researcher, with the equipment turned off at night. The dried samples were then collected in a previously sanitized aluminum tray and ground to a fine, homogeneous powder. They were then individually packaged in silver-colored metal bags, vacuum-sealed, and labeled according to the storage analysis schedule.

2.5 PERFORMANCE

The mass of the initial and dry human milk colostrum was determined to estimate the yield, taking into account the water loss that occurred during the process. The yield was expressed as a percentage (%), calculated from the ratio of the total solids recovered after freeze-drying to the initial mass of the milk submitted to processing.

2.6 HUMIDITY

The moisture content of lyophilized human colostrum milk was evaluated using an infrared moisture analyzer (I-Thermo, Bel Engineering, Italy). The analysis was performed in triplicate at 102 ± 1 °C for approximately 3 min until a constant mass was obtained. The results were expressed as a percentage (%).

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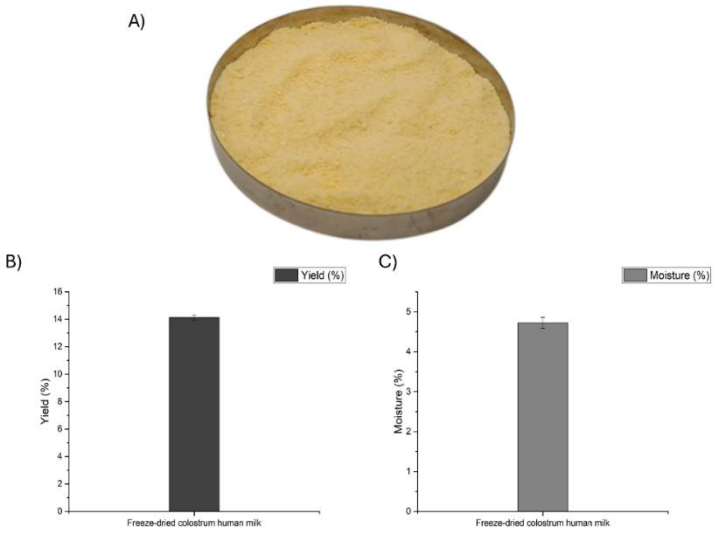
3 RESULTS AND DISCUSSION

3.1 YIELD AND MOISTURE CONTROL OF FREEZE-DRIED HUMAN MILK COLOSTRUM

The results obtained after freeze-drying human milk colostrum are presented in Figure 1.

Figure 1

Control of the freeze-drying process of freeze-dried human milk colostrum



The appearance of the powdered human milk colostrum (Figure 1a) indicates an intense yellow color, characteristic of the lactation phase of the sample. Additionally, the freeze-drying process yielded 14.12 ± 0.79% (Figure 1b), resulting in a powdered human milk colostrum with a moisture content of 4.72 ± 0.14% (Figure 1c).

Freeze-drying involves a sublimation process and consequent water removal(Alves et al., 2023). The calculated yield can contribute to the reconstitution of powdered human milk, as it allows the return of the natural content by adding water. Studies report that the process can reduce the water content of human milk by up to 86.5% (Martysiak-Żurowska; Rożek; Puta, 2022), which contributes to the stability of the food during storage. Studies report that freeze-drying offers less impact on the natural bioactivity of human milk functionality and better yield and recovery (Blackshaw et al., 2021), which favors the processing of colostrum human milk. The soluble solids content in human milk has previously been reported to range from 10.36 ± 0.12% to 9.13 ± 0.23% (Alves et al., 2023; Ferreira et al., 2025), while fat content

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has been reported to range from 1.56 to 4.62% (Santos et al., 2021), indicating the fraction to be preserved after water removal.

The moisture content is consistent with the literature, confirming the efficiency of the water removal process. Furthermore, the value found is within the range considered appropriate for human milk, which is a final moisture content between 4 and 5% (Agência Nacional de Vigilância Sanitária (Anvisa), 2024). The low moisture content obtained in this study favors the maintenance of the quality of human milk powder, as it reduces its susceptibility to lipid oxidation reactions, enzymatic degradation, microbiological growth, and solubility changes (Bolognese et al., 2024).

Furthermore, from a practical perspective, the freeze-drying process offers advantages for nutrient conservation and also addresses issues related to storage and distribution logistics, resulting in reduced volume, ease of transportation and distribution, especially in hard-to-reach areas, and greater flexibility in hospital storage (Manin et al., 2019).

4 CONCLUSION

The study demonstrated that freeze-drying human milk colostrum under the conditions described is an effective preservation strategy, allowing for volume reduction, good yield, adequate recovery, and ensuring the powder's reconstitution to restore its natural characteristics. The process resulted in moisture content below the limit established by ANVISA, favoring nutrient preservation and greater stability against extrinsic factors. Thus, the removal of water confirms the potential of freeze-dried human milk colostrum as a safe and stable alternative for distribution in human milk banks.

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