RCMOS – Revista Científica Multidisciplinar O
Saber. ISSN: 2675-9128. São Paulo - SP.
Ano VII, v.1 2026 | submissão: 07/10/2026 | aceito: 14/10/2026 | publicação: 19/10/2026

Skin-restoring balm for radiotherapy-sensitized skin

Bálsamo dermorestaurador para pele sensibilizada por radioterapia
Bálsamo dermorrestaurador para piel sensibilizada por radioterapia

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Abstract:
Radiodermatitis is a common skin reaction in patients undergoing radiotherapy, causing dryness, inflammation, scaling, and impairment of the skin barrier. Given this, the aim of this study was to develop and characterize a skin-restoring balm for the care of skin sensitized by radiotherapy. The formulation included ingredients with moisturizing, humectant, emollient, antioxidant, and soothing properties. To characterize the formula, tests for pH, preliminary stability, occlusivity, and spreadability were conducted. The balm exhibited a mean pH of 4.55 ± 0.03, within the expected range, and showed a gradual increase in spread area as the applied mass increased. In occlusivity tests, the group treated with the balm showed lower water loss compared to controls, indicating occlusive potential under the experimental conditions. Preliminary stability assessment revealed a slight color change, from milky white to light beige, following exposure to thermal stress, but no phase separation occurred. The results demonstrate promising preliminary characteristics and suggest that the formulation has potential for further investigation as a complementary dermocosmetic option for the care of skin sensitized by radiotherapy. However, further studies are required to evaluate its long-term stability, safety, and clinical efficacy.

Keywords:
Radiodermatitis. Radiotherapy. Dermocosmetics. Skin barrier. Skin-restoring balm.

Resumo:
A radiodermite é uma reação cutânea comum em pacientes submetidos à radioterapia, causando ressecamento, inflamação, descamação e comprometimento da barreira da pele. Diante disso, este estudo teve como objetivo desenvolver e caracterizar um bálsamo dermorestaurador para o cuidado da pele sensibilizada pela radioterapia. A formulação incluiu ingredientes com propriedades hidratantes, umectantes, emolientes, antioxidantes e calmantes. Para caracterizar a fórmula, foram realizados testes de pH, estabilidade preliminar, oclusividade e espalhabilidade. O bálsamo apresentou pH médio de 4,55 ± 0,03, dentro do intervalo esperado, e mostrou aumento gradual na área de espalhamento à medida que a massa aplicada crescia. Nos testes de oclusividade, houve menor perda de água no grupo tratado com o bálsamo em comparação aos controles, indicando potencial oclusivo nas condições experimentais. Na avaliação preliminar de estabilidade, notou-se leve mudança de cor, de branco-leitosa para bege-clara, após exposição a estresse térmico, mas sem separação de fases. Os resultados demonstram características preliminares promissoras e sugerem que a formulação tem potencial para ser investigada como opção dermocosmética complementar no cuidado da pele sensibilizada pela radioterapia. No entanto, são necessários mais estudos para avaliar sua estabilidade a longo prazo, segurança e eficácia clínica.

Palavras-chave:
Radiodermite. Radioterapia. Dermocosméticos. Barreira cutânea. Bálsamo dermorestaurador.

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Resumen:
La radiodermatitis es una reacción cutánea frecuente en pacientes sometidos a radioterapia, que causa sequedad, inflamación, descamación y deterioro de la barrera cutánea. Este estudio tuvo como objetivo desarrollar y caracterizar un bálsamo dermorrestaurador para el cuidado de la piel sensibilizada por radioterapia. La formulación incluyó ingredientes con propiedades hidratantes, humectantes, emolientes, antioxidantes y calmantes. Para caracterizarla, se realizaron pruebas de pH, estabilidad preliminar, oclusividad y extensibilidad. El bálsamo presentó un pH medio de 4,55 ± 0,03, dentro del intervalo esperado, y un aumento gradual del área de extensión conforme aumentaba la masa aplicada. En las pruebas de oclusividad, el grupo tratado con el bálsamo perdió menos agua que los controles, lo que indica un potencial oclusivo en las condiciones experimentales. En la evaluación preliminar de estabilidad, se observó un ligero cambio de color, de blanco lechoso a beige claro, tras la exposición a estrés térmico, sin separación de fases. Los resultados muestran características preliminares prometedoras y sugieren potencial para investigar la formulación como opción dermocosmética complementaria para cuidar la piel sensibilizada por radioterapia. No obstante, se necesitan más estudios para evaluar su estabilidad a largo plazo, seguridad y eficacia clínica.

Palabras clave:
Radiodermatitis. Radioterapia. Dermocosméticos. Barrera cutánea. Bálsamo dermorrestaurador.

1. Introduction

Radiation-induced dermatitis negatively affects both patient quality of life and treatment effectiveness (FUZISSAKI et al., 2019; BURKE; FAITHFULL; PROBST, 2022). Dermatitis, or radiodermatitis, is inflammation occurring in the irradiated region. This very common side effect of cancer treatment can range from mild redness to wounds and skin desquamation (BOLDERSTON et al., 2006; HINDSON et al., 2022). Clinical manifestations vary between patients, with acute reactions generally appearing two to four weeks after radiotherapy begins (BOLDERSTON et al., 2006; CHAN et al., 2014).

The pathophysiology of radiotherapy-associated dermatitis is complex and involves multiple factors. These include treatment-related elements such as the radiation dose delivered and concomitant systemic therapies (SALVO et al., 2010; HINDSON et al., 2022). Patient-specific characteristics, including smoking, age, preexisting clinical conditions, body mass index, radiation target area, and medical history, also significantly influence the severity of dermatological reactions (SZCZEPANIAK et al., 2022; CHAN et al., 2014).

Exposing skin to ionizing radiation can induce cellular senescence in epidermal keratinocytes, a phenomenon associated with DNA damage and loss of proliferative capacity (MCCART et al., 2017; RÜBE et al., 2024). Approximately 90 to 95% of epidermal cells are keratinocytes, which are crucial to skin barrier formation, maintenance, and function

(WIKRAMANAYAKE; STOJADINOVIC; TOMIC-CANIC, 2014). Recent evidence also indicates that ionizing radiation can induce changes in senescent keratinocytes, including oxidative stress, DNA damage, and modulation of the cellular inflammatory response (CHEN et al., 2024).

Under radiation-induced stress, senescent cells begin releasing a series of proinflammatory mediators, playing a significant role in activating inflammatory processes in the skin. The cytokines and chemokines generated by these cells are crucial for intercellular communication, promoting activation of resident skin immune cells and recruitment of circulating inflammatory cells into the epidermis and dermis. This mechanism triggers and sustains the inflammatory response associated with radiation-induced tissue damage and constitutes one of the principal processes involved in radiodermatitis pathophysiology.

Radiodermatitis is an adverse effect that can be prevented or reduced when patients, families, and/or caregivers receive early guidance and interventions focusing on specific skin care. Based on these findings, balms and creams containing soothing, moisturizing, and healing active ingredients have been proposed for prevention and post-radiation skin care. Dermocosmetic formulations containing components such as Aloe vera, D-panthenol, chamomile, vitamin E, hyaluronic acid, and sunflower oil may combine moisturizing, humectant, emollient, antioxidant, and soothing properties of interest for sensitized skin care.

Against this background, this study aimed to develop and characterize a skin-restoring balm for radiotherapy-sensitized skin, combining active ingredients with moisturizing, humectant, emollient, antioxidant, and soothing properties. The qualitative and quantitative composition and preparation procedure were defined; pH and compatibility with physiological skin pH were evaluated; preliminary stability was tested using freeze–thaw cycles and heat exposure; occlusive effects were assessed gravimetrically using a porcine skin model; and spreadability was determined by the extensibility method. The proposed formulation is expected to contribute as a supportive dermocosmetic alternative for radiodermatitis management, complementing existing clinical strategies for prevention and care of irradiated skin.

2. Theoretical background

2.1 Skin structure and barrier function

The skin is the largest organ in the human body and the main interface between the body and its external environment. It is organized into three superimposed layers: epidermis, dermis, and hypodermis, each with specific cellular composition and functions that work together to maintain tissue integrity (MCGRATH; UITTO, 2024).

The epidermis is the outermost layer, formed by stratified squamous epithelium comprising four to five sublayers: stratum basale, stratum spinosum, stratum granulosum, stratum lucidum—found only in thick skin such as palms and soles—and the outermost stratum corneum (MCGRATH; UITTO, 2024). Cellular differentiation proceeds upward: cells proliferate in the basal layer, move progressively through the layers, and reach the stratum corneum flattened, rich in keratin, and without nuclei (GUPTA et al., 2024).

Keratinocytes are the most abundant epidermal cells, accounting for approximately 90% of the total (GUPTA et al., 2024). Besides their structural role, they have active immunological functions: they produce ceramides, cholesterol, and fatty acids forming the intercellular lipid matrix of the stratum corneum, a hydrophobic barrier that regulates water loss and prevents external agent penetration (GUPTA et al., 2024). They also secrete cytokines and chemokines such as TNF, IL-1β, and IL-6, which modulate local inflammatory responses and recruit immune cells into injured tissue (GUPTA et al., 2024).

Besides keratinocytes, the epidermis contains other cell types with well-defined roles. Melanocytes are located in the basal layer at a ratio of approximately one per ten keratinocytes (MCGRATH; UITTO, 2024). They produce melanin, transferring it through dendritic processes to neighboring keratinocytes to provide pigmentation and protection against ultraviolet radiation (MCGRATH; UITTO, 2024). Langerhans cells occupy the stratum spinosum and are the main epidermal dendritic cells. Derived from bone marrow precursors, they capture antigens in the skin microenvironment and transport them to lymph nodes for presentation to the adaptive immune system (MCGRATH; UITTO, 2024).

The dermis lies beneath the epidermis and consists mainly of fibroblasts, collagen and elastin fibers, blood and lymphatic vessels, nerve endings, and skin appendages such as hair follicles and sebaceous glands (MCGRATH; UITTO, 2024). Because it is avascular, the epidermis depends on the dermis for nutritional support. The deepest layer, the hypodermis,

consists of adipose tissue and provides thermal insulation, mechanical cushioning, and energy storage (MCGRATH; UITTO, 2024).

2.2 Skin barrier and transepidermal water loss

Skin barrier function fundamentally depends on stratum corneum integrity. Its organization is often compared to bricks and mortar: corneocytes act as bricks, while the intercellular lipid matrix acts as mortar (GUPTA et al., 2024). This matrix consists of approximately 50% ceramides, 25% cholesterol, and 15% free fatty acids, forming lamellar layers that make the stratum corneum virtually impermeable to water and external substances (AICH et al., 2024).

Transepidermal water loss is the standard parameter for assessing this barrier's integrity (AICH et al., 2024). It represents the amount of water passively diffusing through skin per hour and unit surface area. Loss remains low when the barrier is intact. Following injury from trauma, inflammation, or radiation, lipid structure becomes disorganized, corneocytes lose cohesion, and loss increases, indicating impaired water retention (AICH et al., 2024). This mechanism is central to radiodermatitis because ionizing radiation compromises stratum corneum integrity, increases water loss, and exposes deeper layers to dehydration and infection risk (RÜBE et al., 2024). Occlusive formulations such as balms form a physical surface layer that reduces water loss while the barrier recovers (AICH et al., 2024).

2.3 Skin pH and acidity

The skin surface naturally maintains a slightly acidic environment, with pH between 4.5 and 6.0 in healthy adults (KUMAR; DAS, 2023). This protective film, called the acid mantle, results from the combination of sebaceous and sweat gland secretions with keratinocyte metabolic products such as lactic acid and free amino acids (KUMAR; DAS, 2023).

Acidic pH performs essential functions in skin health. At the stratum corneum surface, it inhibits pathogenic microorganism colonization by creating an unfavorable growth environment (BROOKS et al., 2025). In deeper layers, acidity is necessary for enzymes processing the lamellar lipids that seal the barrier (KUMAR; DAS, 2023). When pH rises, proteolytic enzymes become more active, desquamation becomes excessive, and lipid repair is impaired, resulting in dry, irritated skin with deficient barrier function (BROOKS et al., 2025).

This has direct application to cosmetic formulation. Products outside the physiological pH range can alter the acid mantle and worsen skin already compromised by radiotherapy

(BROOKS et al., 2025). Consequently, pH assessment is mandatory when developing skin-restoring balms for oncology patients, with compatibility with natural skin pH serving as an acceptability criterion (KUMAR; DAS, 2023). Maintaining this balance is particularly crucial during radiotherapy because pH changes can intensify irritation and inflammation; this study therefore adopts 4.5–6.5 as the criterion for dermocosmetics applied to irradiated skin.

2.4 Radiotherapy and radiodermatitis

Radiotherapy is a widely used cancer treatment employing ionizing radiation to destroy malignant cells or inhibit their development. Its mechanism involves energy transfer into target tissues, causing direct cellular DNA damage and producing reactive oxygen species (ROS), which intensify cellular injury. Consequently, cancer cells lose their capacity to replicate and die.

Although radiotherapy is planned to concentrate radiation primarily on the tumor, adjacent healthy areas can also be affected. Radiodermatitis is among the most frequent adverse effects, defined as a cutaneous inflammatory reaction caused by ionizing radiation exposure. Its intensity ranges from mild reactions to more severe conditions and is influenced by treatment-related factors and patient characteristics (CHAN et al., 2014; HINDSON et al., 2022).

Radiodermatitis pathophysiology involves cellular and molecular processes activated by ionizing radiation. Initially, direct DNA damage occurs in epidermal and dermal cells, particularly basal keratinocytes, which play a fundamental role in epidermal renewal. Simultaneously, reactive oxygen species generate oxidative stress, worsening cellular injury and triggering local inflammatory responses (SALVO et al., 2010).

Recent research shows that radiation also induces epidermal keratinocyte senescence. These cells remain metabolically active and begin releasing inflammatory mediators collectively termed the senescence-associated secretory phenotype (SASP). These include proinflammatory cytokines, chemokines, and growth factors that intensify inflammation, recruit immune cells, and contribute to persistent tissue damage. This deteriorates skin protective function, increases epidermal water loss, reduces tissue regeneration, and increases vulnerability to infection, promoting the onset and progression of radiodermatitis.

Radiodermatitis severity is commonly graded using standardized systems such as the Radiation Therapy Oncology Group (RTOG) scale and Common Terminology Criteria for Adverse Events (CTCAE). It is generally divided into four main grades. Grade I involves mild

redness, dryness, itching, and subtle desquamation. Grade II includes moderate redness, edema, and localized moist desquamation, particularly in skin folds. Grade III involves extensive moist desquamation, intense pain, and more pronounced loss of skin integrity. Grade IV is the most critical form, including deep ulcers, necrosis, and spontaneous bleeding requiring specialized care (BOLDERSTON et al., 2006). This classification is essential for prevention and treatment strategies and for evaluating products intended to manage radiation-induced skin reactions.

2.5 Formulation technology: balms and emulsions

Dermocosmetics intended to prevent and treat radiodermatitis should help restore the skin barrier, ensure hydration, and protect against external irritants. Appropriate dosage form selection is fundamental to formulation performance, influencing stability, acceptability, and application characteristics.

Emulsions consist of two immiscible liquids, usually water and oil, stabilized by emulsifiers. They are classified as oil-in-water (O/W) or water-in-oil (W/O) according to the continuous phase. In O/W emulsions, oil droplets are dispersed in a continuous aqueous phase, providing less greasiness, easier application, and greater comfort. W/O emulsions disperse water droplets in a continuous oily medium, providing more pronounced occlusion and skin barrier protection (LACHMAN; LIEBERMAN; KANIG, 2001).

Balms differ from conventional emulsions by having more lipid ingredients and less water, producing semisolid formulations that form a protective skin layer. This helps reduce water evaporation and improve hydration, particularly benefiting sensitive or irradiated skin. Compared with creams and lotions, balms retain more water because they are more occlusive; lotions have lower viscosity and more water, making them more suitable for large areas or less dry skin; creams occupy an intermediate position, combining hydration and emollience. Balms may therefore be beneficial for radiodermatitis management, particularly when skin protection is significantly compromised.

Skin-restoring formulation efficacy depends directly on a balanced combination of emollient, occlusive, and humectant ingredients. Emollients fill spaces between skin cells, providing softness and greater elasticity; common examples include vegetable oils, butters, and lipid esters. Occlusives form a physical barrier on the outermost skin layer, reducing water loss and supporting barrier recovery; petrolatum, natural waxes, and vegetable butters are often used. Humectants such as glycerin, D-panthenol, propylene glycol, and hyaluronic acid attract and retain water molecules in the stratum corneum. These integrated mechanisms underpin

occlusivity tests measuring a formulation's ability to reduce cutaneous water loss, including animal-derived experimental models such as porcine skin.

Stability is fundamental to cosmetic product quality, safety, and efficacy. A stable formulation must retain its physical, chemical, microbiological, and functional properties throughout the intended storage period. Temperature, light, humidity, lipid oxidation, and raw material incompatibilities affect emulsion and balm stability and can cause phase separation, changes in color, odor, and texture, and reduced active ingredient activity. Preliminary stability assessment commonly employs centrifugation, heating and cooling cycles, organoleptic analysis, viscosity measurement, and pH monitoring to detect instability before accelerated and long-term studies (BRASIL, 2004).

2.6 Dermocosmetics in radiodermatitis management

Radiodermatitis can substantially affect patient quality of life and, in severe cases, temporarily interrupt cancer treatment. Various strategies have therefore been proposed to prevent or mitigate radiation-induced skin damage, especially topical products with moisturizing, anti-inflammatory, protective, and skin barrier repairing properties (PATEL et al., 2025).

Dermocosmetics used for radiodermatitis include moisturizers, emollients, protective films, topical corticosteroids, and formulations containing bifunctional active ingredients. Moisturizers and emollients are widely used to restore the barrier, minimize transepidermal water loss, and relieve dryness, itching, and discomfort. Protective films form a physical barrier, reducing friction and protecting areas prone to moist desquamation. Topical corticosteroids are valued primarily for anti-inflammatory action, helping reduce erythema (HINDSON et al., 2022).

Recent clinical studies have investigated moisturizer and emollient efficacy for preventing and treating radiodermatitis. Findings generally indicate that adequate skin hydration can mitigate dermatological reaction severity, improve comfort, and support barrier restoration. Formulations containing soothing and regenerative components such as Aloe vera, D-panthenol, hyaluronic acid, and vitamin E have shown promising results, although evidence quality varies considerably between studies (BURKE; FAITHFULL; PROBST, 2022).

Multinational Association of Supportive Care in Cancer (MASCC) guidelines emphasize preventive skin care throughout radiotherapy, particularly regular moisturizer use and skin barrier protection (BEHROOZIAN et al., 2023). Despite advances, there is no

consensus gold-standard product for radiodermatitis prevention and treatment. Variable protocols, formulations, and research methods hinder comparisons, and many marketed products were developed for general hydration without considering irradiated skin pathophysiology. Developing dermocosmetics combining moisturizing, emollient, soothing, and barrier-restoring ingredients is therefore a potentially beneficial approach for oncology patients.

3. Materials and methods

3.1 Formulation development

The formulation was developed using the ingredients in Table 1, selected according to their technological functions and compatibility with irradiated skin.

Table 1 – Qualitative and quantitative composition of the skin-restoring balm.

Ingredient	**Conc. (% w/w)**	**Function**
Lanette cream	54.3	Emulsifying base / vehicle
Sunflower oil	8.0	Emollient
D-panthenol	8.0	Humectant / healing agent
Aloe vera extract	8.0	Soothing / anti-inflammatory
Chamomile extract	8.0	Anti-inflammatory / soothing
Hyaluronic acid	8.0	Humectant / moisturizer
Vitamin E (tocopherol)	5.3	Antioxidant
Methylparaben	0.2	Preservative
Propylparaben	0.2	Preservative
Total	100	—

Source: the author (2026).

Although “balm” is frequently associated with anhydrous lipid-based formulations, this study developed a semisolid emulsion using Lanette cream as emulsifier because its functional characteristics resemble a skin-restoring balm: a high oily-phase concentration, dense texture, low fluidity, and occlusivity. This choice reflects production feasibility in a small pharmaceutical compounding laboratory, compatibility with the active ingredients, and the ability to form a protective film on irradiated skin. Lanette cream-based semisolids are widely used in dermocosmetic development because of their stability, ease of preparation, and good cutaneous acceptance (LACHMAN; LIEBERMAN; KANIG, 2001).

Preparation involved three independent replicates (n = 3), produced on different days to assess repeatability. The procedure comprised: (1) melting the lipid phase (Lanette cream + sunflower oil) in a water bath at 70 °C; (2) incorporating D-panthenol and vitamin E while still warm (~50 °C), with constant stirring; (3) adding Aloe vera and chamomile extracts, hyaluronic acid, and preservatives after cooling to ~40 °C; (4) homogenizing until completely solidified; and (5) packaging in previously sterilized containers (Figure 1).

Figure 1 – Raw materials and equipment used to prepare the skin-restoring balm.



Source: the author (2026).

3.2 pH determination

Formulation pH was determined using a pH meter previously calibrated with pH 4.0 and 7.0 buffers, at 25 ± 1 °C. Readings were performed in triplicate (n = 3) and expressed as mean ± standard deviation. Results were compared with the study's adopted physiological skin range of 4.5–6.0. Based on Kumar and Das (2023), formulations with pH 4.5–6.5 were considered acceptable; values outside this range would indicate a need for adjustment.

3.3 Preliminary stability

Preliminary formulation stability was evaluated using freeze–thaw cycles and heat exposure. Containers were stored in a domestic freezer (−5 °C to −10 °C) for 24 hours and then returned to room temperature (~25 °C) for 24 hours, repeated for three cycles. An additional heating cycle followed the Cosmetic Product Stability Guide (BRASIL, 2004), with oven

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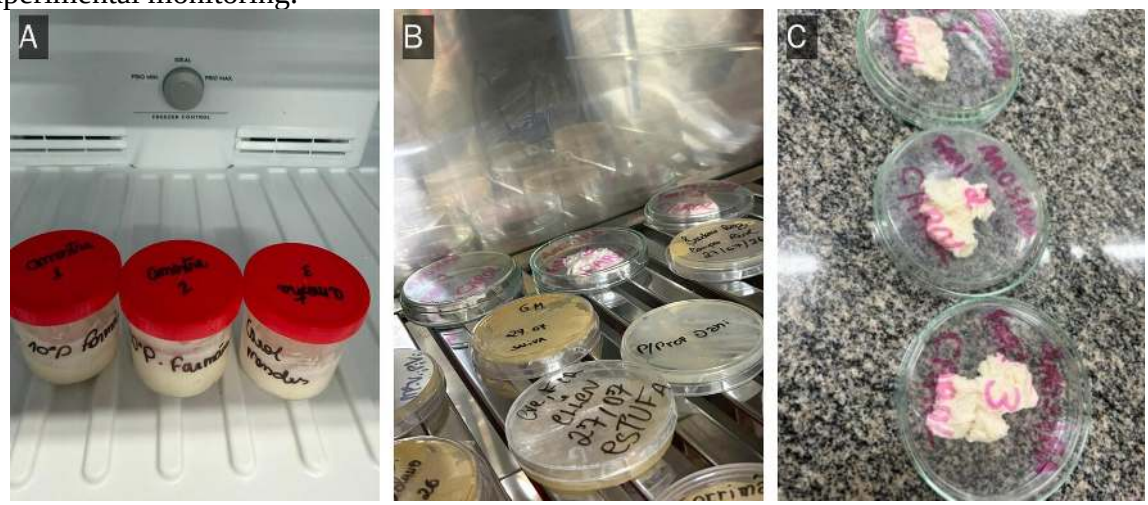
Saber. ISSN: 2675-9128. São Paulo - SP.
Ano VII, v.1 2026 | submissão: 07/10/2026 | aceito: 14/10/2026 | publicação: 19/10/2026

storage at 40 ± 2 °C for 15 days (Figure 2). At the end of each condition, samples were assessed for phase separation and color and odor changes, using freshly prepared T0 samples as reference. Results were recorded through standardized descriptions (homogeneous / slightly heterogeneous / separated) and photographs. Any phase separation constituted formulation failure.

Figure 2 – Preliminary stability assessment: (A) samples 1, 2, and 3 in a domestic freezer for freeze–thaw cycling; (B) samples kept in an oven; (C) labeled samples on a plate for experimental monitoring.



Source: the author (2026).

3.4 Occlusivity testing on porcine skin

Porcine skin fragments obtained from a local slaughterhouse or butcher as food byproducts were used for occlusivity testing. Preparation involved removing subcutaneous tissue, standardizing thickness, and hydrating fragments in buffer solution for 30 minutes (Figure 3). Fragments were placed over beakers containing water maintained at 32 °C to simulate approximate skin surface temperature (Figure 4).

Three experimental conditions were evaluated, using one porcine skin fragment each: the skin-restoring balm group, with a standardized 2 mg/cm² layer; a positive control with solid petrolatum, the reference occlusive, applied at the same density; and a negative control without product. Systems rested for two hours at 32 °C maintained by water bath and checked with a thermometer. Water mass loss was determined gravimetrically as the difference between initial and final system mass. Lower water loss indicated greater occlusive behavior.

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Figure 3 – Test preparation: (A) materials for occlusivity and spreadability tests; (B) porcine skin preparation; (C) fragment hydration in buffer solution for 30 minutes.



Source: the author (2026).

Figure 4 – Experimental systems during occlusivity testing.

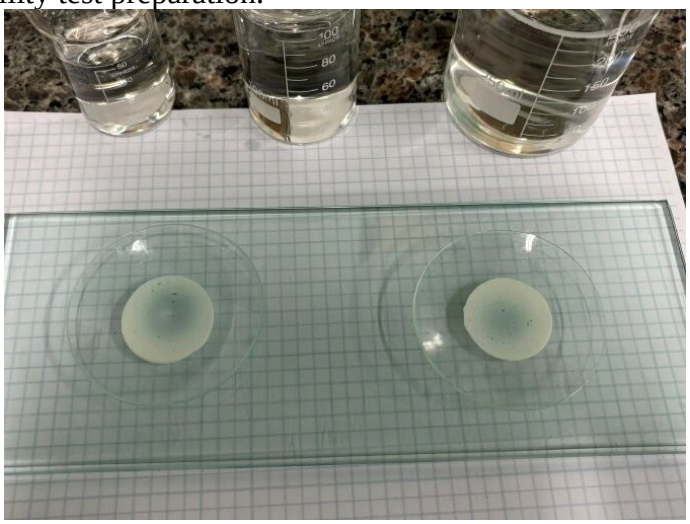


Source: the author (2026).

3.5 Spreadability assessment

Spreadability was assessed using plates with increasing weights, adapted from Borghetti and Knorst (2006). A 0.5 g balm sample was placed at the center of a glass plate over graph paper and covered with a second glass plate of identical dimensions (Figure 5). After one minute, standardized weights were added sequentially (50 g, 100 g, and 250 g), at one-minute intervals. After each interval, spread diameter was read directly from the graph paper in two perpendicular directions. The mean diameter and then spread area (mm²) were calculated using $E = \pi \times (d/2)^2$, where E is spread area and d is mean diameter.

Figure 5 – Spreadability test preparation.



Source: the author (2026).

3.6 Data analysis and ethical aspects

Results were analyzed descriptively. Triplicate pH values were reported as mean ± standard deviation. Preliminary stability considered appearance, color, odor, and presence or absence of phase separation. Occlusivity involved one determination per experimental condition, with individual results compared descriptively. Spreadability involved two perpendicular diameter measurements per applied weight. No inferential statistical tests were applied.

The study used porcine skin obtained as a slaughterhouse food byproduct, involving neither humans nor live animals and therefore requiring no Research Ethics Committee (CEP) or Animal Use Ethics Committee (CEUA) approval.

4. Results and discussion

4.1 pH

The three replicate pH values were 4.55, 4.52, and 4.58, yielding a mean of 4.55 ± 0.03 (Table 2). Low between-measurement variation indicated formulation uniformity for this parameter; values remained within the predefined 4.5–6.5 acceptance criterion. The mean was also close to the physiological skin pH range adopted in this study, 4.5–6.0.

Table 2 – pH values obtained for the skin-restoring balm.

Sample	pH
1	4.55
2	4.52
3	4.58
Mean ± SD	4.55 ± 0.03

Source: the author (2026).

Maintaining slightly acidic pH is relevant for topical products, especially on sensitized skin, because values very different from those normally present on the skin surface can affect preparation tolerability. Under the criterion adopted from Kumar and Das (2023), pH 4.5–6.5 is considered compatible with irradiated skin.

The mean obtained (4.55) is also consistent with physiological skin pH literature, describing natural surface pH as predominantly below 5.0. In a multicenter study of 330 volunteers, Lambers et al. (2006) found mean skin pH around 4.7 after 24 hours without water or cosmetic contact—a value very close to the balm's. This proximity supports physiological compatibility, particularly relevant to radiotherapy-compromised skin whose acid mantle may be more susceptible to changes.

A formulation with near-physiological pH may therefore favor skin surface compatibility and reduce additional injury associated with unsuitable pH. However, the result demonstrates only suitability of the measured physicochemical parameter and cannot alone establish clinical benefits for irradiated skin.

4.2 Preliminary stability

At baseline (T0), all three samples had normal appearance, milky-white color, normal odor, and no phase separation (Table 3; Figure 6). Freeze–thaw cycles produced a slight color change from milky white to light beige without relevant changes in appearance, odor, or phase separation. Samples oven-stored at 40 °C were also light beige and smooth, with no phase separation.

Table 3 – Visual assessment of preliminary stability.

Condition	Sample	Appearance	Color	Phases
T0 – freshly prepared	1, 2, 3	Normal	Milky white	No separation
Freeze–thaw	1, 2, 3	Smooth	Light beige	No separation

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Condition	Sample	Appearance	Color	Phases
Oven at 40 °C	1, 2, 3	Smooth	Light beige	No separation

Source: the author (2026).

Figure 6 – Visual appearance of samples 1 (A), 2 (B), and 3 (C) after compounding.



Source: the author (2026).

The principal change observed was therefore a slight color alteration after thermal stress exposure. This may relate to temperature sensitivity of formulation components. However, color change alone, without phase separation or other relevant modifications, is insufficient to establish loss of preparation stability.

According to the Cosmetic Product Stability Guide (BRASIL, 2004), stability assessment should jointly consider appearance, color, odor, homogeneity, and phase separation. Results indicate satisfactory preliminary physical behavior. Nevertheless, preliminary assessment cannot definitively establish balm stability; longer studies including additional physicochemical and microbiological parameters are necessary.

4.3 Occlusivity

In the porcine skin model, the skin-restoring balm showed 12.59 g water loss, compared with 14.89 g for petrolatum, the positive control. The untreated negative control showed the highest loss, 17.11 g (Table 4). Thus, under the conditions evaluated, water loss increased in the order balm < petrolatum < negative control.

Table 4 – Occlusivity test results on porcine skin after 2 hours.

Experimental group	Initial mass (g)	Water loss (g)
Skin-restoring balm	97.16	12.59
Positive control – petrolatum	101.05	14.89

Experimental group	Initial mass (g)	Water loss (g)
Negative control – no product	114.54	17.11

Source: the author (2026).

Compared with the negative control, the balm reduced water loss by approximately 26.4%, versus approximately 13.0% for petrolatum. Compared directly with petrolatum, the formulation system showed approximately 15.4% less water loss. These findings suggest potential occlusive effects under the experimental conditions employed.

Occlusivity is relevant for formulations maintaining hydration because occlusive agents form a physical surface barrier and reduce water evaporation. Petrolatum is a reference agent because of its known ability to reduce stratum corneum water loss (GHADIALLY; HALKIER-SORENSEN; ELIAS, 1992). Although petrolatum reduced loss relative to untreated controls, the balm produced an even lower value under this experiment's conditions. Transepidermal water loss was not directly measured with dedicated equipment; the procedure assessed experimental water loss gravimetrically as an indirect indicator of occlusive behavior.

Pinto et al. (2022) evaluated sustainable petrolatum alternatives using transepidermal water loss in volunteers and showed that vegetable oils can achieve comparable occlusion over six hours, even without matching petrolatum's immediate effect. This agrees with the present findings: the balm, with sunflower oil and Lanette cream as its main lipid components, showed less water loss than petrolatum, suggesting that formulation composition contributed to the observed occlusive behavior.

Aich et al. (2024) associate lower water loss with preserved skin barrier integrity. Radiotherapy-induced epidermal and stratum corneum changes can impair this function and increase loss (RÜBE et al., 2024). Furthermore, in a prospective study of head and neck cancer patients, Miyamae et al. (2024) showed that pretreatment barrier impairment increased the risk of severe radiodermatitis, suggesting that barrier-maintaining interventions—including potentially occlusive products—may be strategic even before treatment begins.

These results require caution, however, because the porcine skin model used one determination per condition and gravimetric water loss measurement, which is insufficient to establish clinical efficacy or radiodermatitis prevention or treatment in radiotherapy patients.

4.4 Spreadability

Spread area progressively increased with applied weight (Table 5). At 50 g, mean diameter was 6.0 cm and area 2,827.43 mm²; at 100 g, these increased to 6.5 cm and 3,318.31 mm²; at 250 g, mean diameter was 7.0 cm and area 3,848.45 mm².

Table 5 – Spreadability test results.

Applied weight (g)	Diameter 1 (cm)	Diameter 2 (cm)	Mean diameter (cm)	Area (mm²)
50	6.0	6.0	6.0	2,827.43
100	7.0	6.0	6.5	3,318.31
250	7.0	7.0	7.0	3,848.45

Source: the author (2026).

Progressively increasing spread area demonstrates greater formulation distribution as pressure on the sample increases. This behavior is expected for semisolids subjected to the increasing-weight plate method adapted from Borghetti and Knorst (2006), demonstrating the physical ability to cover a larger area under force. Spreadability is important for topical preparations because it relates to uniform distribution over a surface.

Results can also be contextualized against other studies using the same methodological principle. Borella et al. (2010), assessing semisolids containing Calendula officinalis extracts, reported spread area-to-applied force relationships of approximately 0.33–0.34 mm²/g for the most spreadable formulations. Although calculation methods are not directly equivalent, this comparison suggests that the balm's consistent increase from 2,827.43 to 3,848.45 mm² falls within expected behavior for topical semisolids described in Brazilian pharmaceutical technology literature.

For radiotherapy-sensitized skin, adequate distribution may provide more uniform surface coverage. However, this test evaluated only physical spreadability; it cannot establish greater application comfort, reduced irritability, or clinical benefit for irradiated skin, which require specific safety, acceptability, and clinical efficacy studies.

5. Final considerations

A skin-restoring balm for radiotherapy-sensitized skin was developed and preliminarily characterized, using ingredients with moisturizing, humectant, emollient, antioxidant, and soothing functions to support hydration and skin barrier maintenance.

Mean pH was 4.55 ± 0.03, within the 4.5–6.5 acceptance range and with low variability. In porcine skin occlusivity testing, the balm showed the lowest water loss (12.59 g versus 14.89 g for petrolatum and 17.11 g for the negative control), suggesting potential occlusive effects under the experimental conditions despite indirect gravimetric evaluation. Spreadability progressively increased with applied weight from 2,827.43 to 3,848.45 mm², relevant to topical application. Under preliminary thermal stability testing, the only change was milky-white to light-beige color without phase separation, which alone does not establish instability.

Overall, results show promising characteristics for the intended purpose and potential for investigation as complementary radiotherapy-sensitized skin care. However, findings are preliminary and limited to physicochemical and functional properties, precluding claims that the balm prevents or treats radiodermatitis. Further research is needed, including longer stability assessment, microbiological analyses, safety and skin compatibility tests, and subsequently controlled clinical studies to evaluate safety and efficacy in people receiving radiotherapy.

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