

Formulation of a body mud cream for clinically proven draining and firming efficacy in association with a dedicated massage technique.

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1. Introduction

In recent years, the personal care industry has observed a significant shift towards multifunctional products that offer both efficacy and enhanced sensory experience [1]. Along with this, consumers are increasingly seeking quick and easy solutions with firming and draining efficacy [2]. Leave-on mud-cream body formulations have emerged as a novel category, combining the benefits of mineral-rich muds with the convenience and spreadability of creamy textures, meeting the desire for spa-like experiences at home. The main challenge of this product category is to balance the formulations without compromising sensoriality; parameters such as stickiness and oily residue are crucial for a satisfying experience. The efficacy of mud-based products is well-documented; they are known for their detoxifying, remineralizing, and soothing properties, primarily due to the presence of different minerals [3-4]. In tissues where water retention and cellulite are present, venous circulation is compromised, excess adipose tissue accumulates, causing fluid leakage into the interstitial space. Hypertonic solutions made of salts can activate osmotic processes, aiding the drainage of excess fluid trapped between cells [5-7]. Magnesium salts are widely used in topical products for their anti-inflammatory and vasodilatory effects. They boost skin hydration, elasticity, and aid fluid drainage, making them effective in reducing fluid retention and firming the skin [8]. Another well-known ingredient widely used to treat cellulite is escin, derived from horsechestnut. Thanks to its vasoprotective and anti-edematous effects, escin plays a key role in improving capillary tone and reducing swelling, further supporting its inclusion in draining and firming cosmetic products [9]. Despite their functional benefits, the incorporation of active ingredients, particularly salts and clays, into a single product requires careful balancing to avoid undesirable textures (such as grittiness or excessive dryness) that can lead to skin discomfort, including itching or irritation [10]. Ensuring efficacy, a pleasant sensory profile, and a high degree of naturality are key priorities in cosmetic formulation, requiring meticulous design and thorough testing to meet consumer expectations. Some studies observed that the

type and concentration of salt do not influence the initial droplet size of the emulsions [11]. However, thermal and isothermal stability decrease with increasing salinity, as higher salt levels lower the cloud point due to accelerated coalescence. Dilution with water significantly improves thermal stability, increasing the cloud point by reducing salt levels in the aqueous phase. Storage stability is also dependent on salt concentration. The additional challenge is integrating clays into an emulsion containing salts [12]. As already highlighted, salts have a destabilizing effect on emulsions, compromising their stability; at the same time, if not properly formulated within the emulsions, clays tend not to be uniformly suspended, resulting in deposits at the bottom of the system. Alongside formula development, another important factor to consider when developing cosmetic products with draining benefits is the type of massage used to apply the product. Lymphatic drainage is an ancient massage technique that employs a whole-body rhythmic motion to stimulate the lymphatic system, starting from the ankles and up to the waist, effectively encouraging the movement of fluid throughout the body. Lymphatic drainage massage is widely used not only in medical treatments but also in professional wellness centers, where it is incorporated into a variety of body and facial treatments [13-15]. The evaluation of draining and firming efficacy of cosmetic products usually integrated several assessment methodologies. High-frequency ultrasound imaging has emerged as a validated, non-invasive tool for assessing skin structure and fluid dynamics, particularly in the context of cellulite-related signs and interstitial water accumulation [16-17]. In particular, skin echogenicity plays a pivotal role in detecting treatment-induced modifications [18]. In fact, solid, collagen-rich or fibrotic tissues exhibit higher echogenicity, appearing brighter, while edematous or fluid-rich areas present reduced echogenicity appearing darker, reflecting interstitial water accumulation especially at an early-stage cellulite. A decrease in dermal echogenicity is thus directly associated with increased tissue edema. The aim of this study was to formulate and rigorously test the effectiveness in use of a topical treatment primarily targeting the accumulation of fluids caused by water retention.

2. Materials and Methods

2.1. Formulation development and screening application test

The initial phase of the formulation study was dedicated to selecting the optimal combination of gums, emulsifiers, oils, and film-forming esters. After screening over 15 formulations, two compositions were identified, differentiated by the type of emulsifiers and gums, which demonstrated positive results in preliminary tests such as centrifugation and thermal stress. The selected ingredients include: a combination of two clays (white and green) which give an appearance similar to mud; dimer dilinoleyl dimer dilinoleate that is a 100% plant-derived polymer ester and provides adhesiveness, and magnesium aluminum silicate which

contributes to the spreadability and cosmetic elegance of topical products. These formulations were subsequently evaluated in comparison in application in our internal skincare test space by 1 expert professional evaluator where the preliminary results helped confirm the desired texture target. The product was tested on 7 subjects suffering from water retention in the legs.. The parameters evaluated were general features of the product and sensorial evaluation (rating scale from 1=unacceptable to 4=excellent) and immediate perception of efficacy (rating scale from 1 =not effective at all to 4 =very effective).

2.2. International extended panel

Following this, we proceeded to test the formula that emerged as the most promising in an extended panel under proper at-home usage conditions over a period of 28 days by a panel of 56 female participants. Participants aged between 25 and 55 years were recruited, all of whom self-reported experiencing feelings of heaviness, swelling, and occasionally pain in the legs, along with signs of fluid retention and uneven tissue texture. Each subject was instructed to apply the product to the legs and abdominal area, following our setup draining massage technique that mimics professional techniques, suitable for home-use. The technique involves three distinct steps, starting from the ankles and progressing towards the groin, concluding with a massage of the abdominal region. At the end of the 28-days period, participants were asked to complete a self-assessment survey to collect data on: general features of the product, fragrance, critical parameters, tolerability and efficacy perception, following the same rating scale adopted by our internal skincare test space.

2.3. Efficacy test protocol

We performed a prospective single-center, blinded, two-legs controlled study to evaluate the clinical efficacy of the selected formula in comparison with a standard formula.

Table 1. Comparison of the composition of the two formulas used in the efficacy test

| | ACTIVE FORMULA 3 | STANDARD FORMULA |
|------------------------------------|------------------|------------------|
| INGREDIENTS CATEGORY | % | % |
| GUMS | [0 – 1] | [0 – 1] |
| EMULSIFIER | [0 – 7] | [0 – 3] |
| OILS | [0 – 15] | [0 – 5] |
| DIMER DILINOLEYL DIMER DILINOLEATE | [0 – 5] | / |
| MAGNESIUM ALUMINUM SILICATE | [0 – 5] | / |
| GLYCOLS | [0 – 15] | [0 – 5] |
| CLAYS | [0 – 3] | / |

The study has been carried out according to the Helsinki declaration (Ethical Principles for Medical Research Involving Human Subjects), according to: European Regulation No.

1223/2009 - Commission Regulation (EC) No. 655/2013. Consent was obtained immediately after the participants were provided with information about the objectives of the study. The criteria for inclusion in the study were female subjects; age > 22 years; presence of grade I cellulitis according to the Nurnberger–Muller scale [19]. Exclusion criteria were subjects with dermatopathies; subjects with pharmacological products in progress; pregnant or breastfeeding subjects. Twenty female panelists (22-55 years old) were enrolled after the investigator checked all inclusion and non-inclusion criteria. The subjects were given two formulas in a blind manner: they were asked to apply the active formula 3 once daily to one leg using our setup draining massage technique, while the contralateral leg received standard formulation without active ingredients with any massage technique for 28 days.

At the baseline and follow-up visits (T28days), the following information were acquired:

- clinical assessment determined according to predefined rating scales shown in Table 2.

Table 2. Parameters clinical evaluated

| | |
|--------------------------------------|--|
| Imperfection severity degree | 0 = None; 1 = Almost none; 2 = Mild; 3 = Moderate; 4= Severe |
| Skin redness | 1-2 = Not flushed at all ; 3-4 = Slightly flushed; 5-6 = Flushed; 7-8 = Very flushed |
| Superficial alteration | 1-2 = Slight; 3-4 = Moderate; 5-6 = Severe ; 7-8= Serious |
| Tissue laxity | 1-2= Not lax at all; 3-4 = Slightly lax ; 5-6 = Lax ; 7-8 = Very lax |
| Number of dimples/area | 0 = no dimples; 1 = ≤6 dimples / area; 2 = 7-11 dimples / area; 3 = 12-16 dimples / area; 4 = ≥17 dimples / area |
| Depression degree and pain sensation | 0: Absent depression; no pain; 1 : Slight depression; no pain; 2 : Slight depression; pain; 3 : Moderate depression; no pain; 4: Moderate depression; pain; 5: Severe depression; pain |

- high-resolution images of the skin surface by an optical method and complex mathematical algorithms to obtain 3D images and measurement thanks to a dedicated software of topographic parameters using Antera 3D (Miravex Limited, Dublin, Ireland). Investigated indicator: Volume (mm³) of interested area
- ultrasound evaluation of skin tissue thickness (µm) and echogenic intensity (A.U.) of the subcutaneous tissue using a DermaLab Combo Ultrasound Standard probe (Cortex technology, Hadsund, Denmark), visualization of structures up to a depth of 17.6 mm.
- Skin Drain Index (SDI), a calculated parameter starting from ultrasound images acquisition: it derived from the ratio between dermal echogenic intensity (skin's ability to reflect ultrasound waves) and dermal thickness. This index serves as a quantitative indicator of tissue drainage efficiency. A lower SDI is indicative of fluid retention, whereas a higher SDI may be related to improved drainage. This index correlates two aspects of drainage involving both areas of low echogenicity and tissue disorganization due to fluid presence, which likely can compromise structural organization.

All measurements were made in an air-conditioned room with controlled temperature and humidity ($T\ 22^{\circ}\text{C}$, r.h. $50 \pm 5\%$); subjects were preconditioned for at least 15 minutes before the measurements. The data obtained were processed both as a descriptive statistical analysis and as statistical analysis with comparison tests for parametric and nonparametric data. A significant level of 5% was chosen, so the changes were considered statistically significant for $p < 0.05$.

3. Results

3.1. Formulation development and screening application test

The results of the formulas tested are represented below in Figure 1.

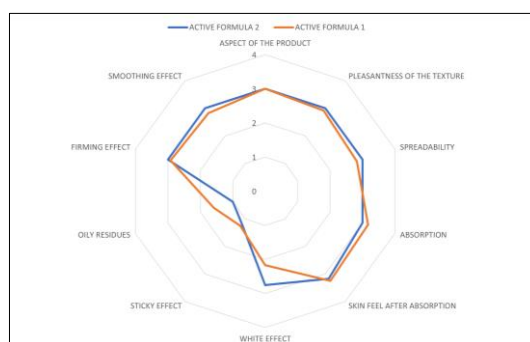


Figure 1. Comparison between formulas evaluated by internal skincare test space

As highlighted by the chart, active formula 2 demonstrated better performance than active formula 1 in some critical parameters, such as oily residue and sticky effect. However, both formulas were scored above 2 for the white effect parameter indicating a present white cast. Following these results, it was decided to further refine the active formula 2 to minimize this aspect. To achieve this goal, a set of ingredients has been incorporated, consisting of specific esters, along with glycols and cellulose derivatives, including powders and gels. It is important to note that, given the high percentage of natural ingredients (95% according to ISO 16128 standard) and the inclusion of kaolin, this issue is inherent to the composition of the formula. A new formula, named active formula 3, was selected to be tested on a panel of 56 subjects.

3.2. International extended panel outcome

An extended international panel of 56 female participants was involved to test the active formula 3 using our setup draining massage technique for 28-days treatment and at the end they were asked to evaluate the pleasantness in use and perceived efficacy of the product by using a self-assessment survey. The results are shown in Figure 2. No panelist reported any discomfort (burning, redness, itching) during or after the product application. White effect, greasy effect, sticky effect, and pilling effect after product absorption were all rated as absent or acceptable by all panelists.

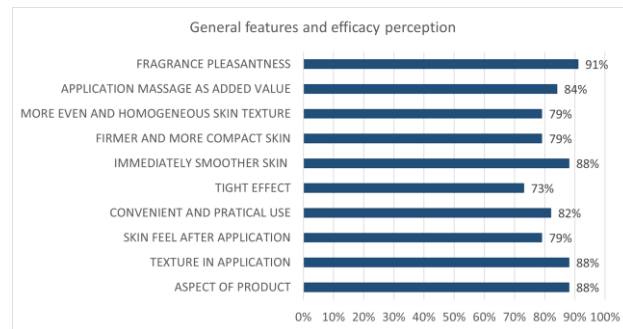


Figure 2. Percentage of panelists who voted positively on the parameters investigated.

3.3. Outcome of the clinical evaluation

After 28 days, all clinically assessed parameters showed significantly greater improvement with the active formula 3 compared to the standard formula, as illustrated by the percentage variations in Figure 3.

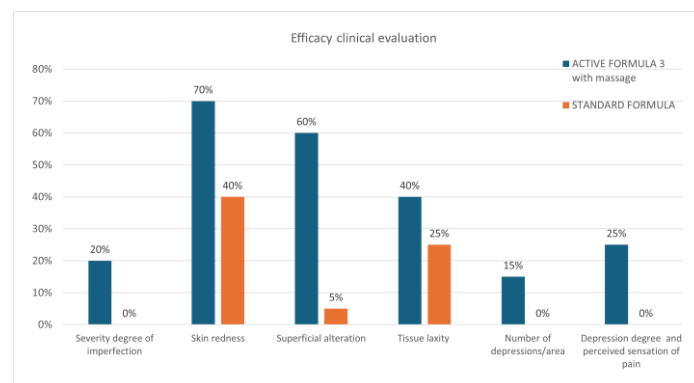


Figure 3. Percentage variations in improvement for each individual feature considered in the clinical evaluation for both active and standard formula.

3.4. Outcome of the Antera 3D measurement

The Antera 3D measurement was conducted to assess changes in skin superficial alterations and the smoothing effect of the product on the skin. The results after 28 days are presented in Figure 4A. The percentage variation of the evaluated parameter after 28 days of treatment between the standard formula and the active formula 3 is statistically significant: the active formula 3 applied with our setup draining massage technique demonstrated a 12% greater skin-smoothing effect. In Figure 4B are presented images of acquisition area and corresponding skin volumes of one panelist at T0 and after 28 days, comparing active formula 3 and standard formula application.

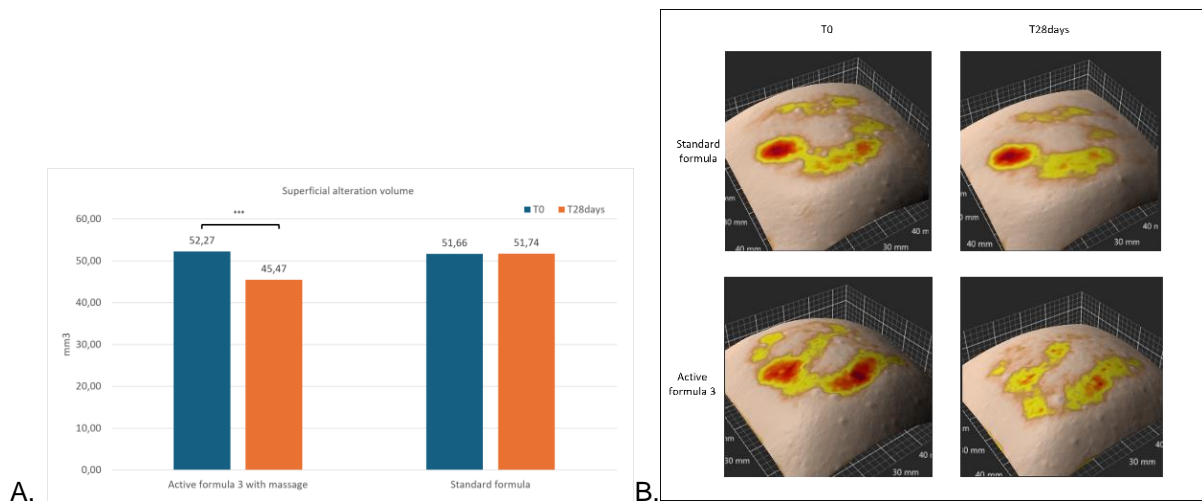


Figure 4. (A) Superficial alteration volume for the active formula 3 and standard formula at T28. *** statistically significant ($p < 0.0003$). (B) Antera 3D acquisition: the red color indicates the deep depressions of the skin superficial alterations; the reduction in red color and the consequent shift toward yellow result in a reduction in the depth of skin depression.

3.5. Outcome of the ultrasound evaluation

In the ultrasound images the dermis appears echogenic, with echoes originating from the network of collagen and elastic fibers. Fat accumulation and edema appear as low-echogenic areas. Measurement of skin thickness (μm) provides a quantitative parameter for evaluating the efficacy of the treatment in enhancing dermal firmness. The results after 28 days are presented in Figure 5A. The percentage variation of the evaluated parameter after 28 days of treatment between standard formula and the active formula 3 is statistically significant: the active formula 3 applied with our setup draining massage technique demonstrated a 7% greater dermal firmness effect. In Figure 5B ultrasound images of one panelist are presented, at T0 and after 28 days, comparing active formula 3 and standard formula.

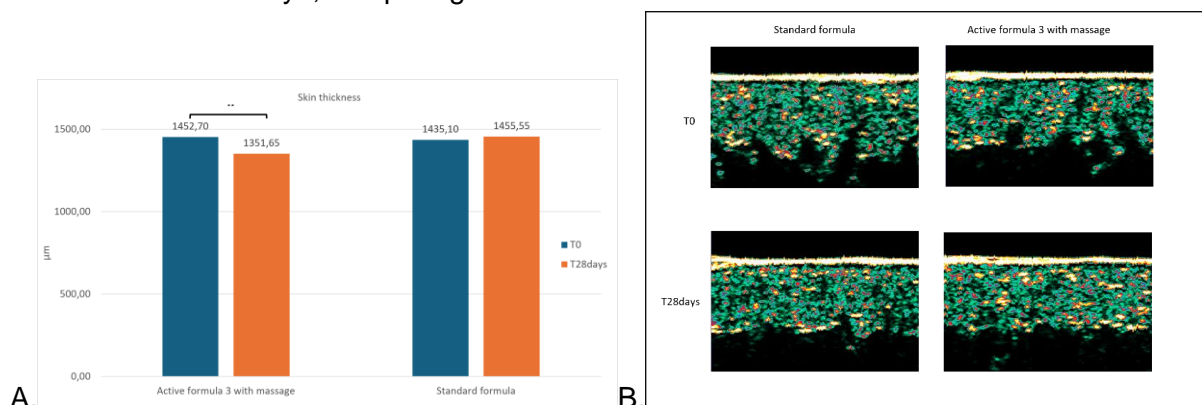


Figure 5. (A) Skin thickness measurement for active formula 3 and standard formula at T28. ** statistically significant ($p < 0.0034$). (B) Ultrasound images: the images show the dermis in terms of thickness and intensity. Black color indicates areas of lower intensity, while yellow

color indicates areas of higher intensity. The areas with higher echogenicity have an improvement in tissue homogeneity, integrity and density.

3.6. Skin Drain Index

The calculation of the SDI from echogenic acquisitions allowed us to assess the draining efficacy of the product. An increase in the SDI indicates an improvement in water retention and tissue drainage. The results after 28 days are presented in Figure 6.



Figure 6. Draining efficacy for the active formula 3 and standard formula at T28. ***statistically significant ($p < 0.0001$).

The percentage variation of the evaluated parameter after 28 days of treatment between the standard formula and the active formula 3 is statistically significant: the active formula 3 applied with our setup draining massage technique demonstrated a 22% greater draining efficacy.

4. Discussion

Over the past decades, cosmetic science has increasingly focused on multifunctional topical treatments that not only target specific structural concerns, such as cellulite and fluid retention, but also deliver a pleasing sensory experience. In this study, we investigated a leave-on mud cream composed of 95% natural origin ingredients, enriched with white and green clays, magnesium salts, and escin, in women presenting Grade I cellulite. The formulation process focused on finding the optimal combination of gums, emulsifiers, oils, and film-forming esters to balance stability, texture, and performance. After screening over 15 formulations, two were selected for their strong performance in stability tests. These formulations were differentiated by their emulsifier and gum compositions, which are key to the product's texture and spreadability; dimer dilinoleyl dimer dilinoleate and magnesium aluminum silicate played a fundamental role in contributing to the cosmetic elegance of the formulation. Our within subject, contralateralleg design permitted direct comparison of the active formulation against a standard cream, thereby reducing interindividual variability and strengthening the reliability of our findings. After 28 days of daily application paired with our setup draining massage

technique, the active mud-cream produced significantly greater improvements in skin surface topography, dermal firmness, and fluid mobilization. Optical imaging revealed a 12% greater reduction in skin depressions compared to standard formula. High-frequency ultrasound demonstrated a 7% increase in dermal thickness and echogenicity, consistent with osmotic and vasodilatory actions of magnesium salts. A key innovative contribution of this study is the application of the Skin Drain Index, an ultrasound-derived parameter designed to assess the draining efficacy of cosmetic products. By correlating structural and compositional changes within the dermal layer, the SDI represents a novel, integrative approach to evaluating tissue drainage, offering potential for broader applications in monitoring interstitial fluid shifts and related skin conditions. SDI was 22% higher with the active formula, suggesting enhanced interstitial fluid drainage, a key factor in mitigating the “orange peel” appearance of early stage cellulite. In addition, the extended panel reported very high levels of overall satisfaction. These findings align with consumer preferences for natural formulations that deliver professional grade performance without compromising comfort. This study demonstrated several key strengths. A robust, multifaceted measurement approach was employed, combining instrumental techniques with clinical scoring and self-evaluations, which provided converging lines of evidence for the product’s efficacy. The within-subject controlled design helped minimize inter-individual variability and increased the study’s statistical power. Despite these strengths, the study had some limitations. The clinical trial’s short duration and small sample size may limit the generalizability of the findings; although the 28-days period was sufficient to observe significant improvements, longer follow-up periods could offer better insight into broader applicability of the product. Additionally, although integrating a lymphatic drainage massage may augment product efficacy, it remains difficult to fully isolate the relative contributions of manual stimulation versus topical active ingredients. A randomized study employing passive application could help disentangle these effects.

5. Conclusion

In conclusion, the leave-on mud-cream investigated exploit the synergistic actions of mineral clays, magnesium salts, and escin to deliver significant improvements in skin smoothing, firmness, and fluid drainage, all within a high natural-origin, sensorially pleasing formula. These results contribute to a growing body of literature endorsing multifunctional, natural-inspired topical therapies for early-stage cellulite. By balancing efficacy, safety, and consumer desired sensory attributes, this formulation represents an attractive option for both professional and at-home body care regimens. A notable innovation of this study is the use of the SDI, a novel ultrasound-based parameter that offers an objective, integrative measure of tissue drainage efficacy, representing a promising tool to be applied and extended in future

research. Further research including prolonged treatment durations, and varied application protocols will help refine optimal use and long-term benefits.

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