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MEDICAL TECHNOLOGIES. PHARMACEUTICAL COSMETOLOGY, COSMECEUTICALS BASED ON HERBAL MEDICINES: MODERN TRENDS AND REGULATORY APPROACHES

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Introduction

Modern cosmetology is characterized by the active integration of medical technologies, pharmaceutical and cosmetic approaches, which has led to the formation of a new interdisciplinary direction – cosmeceuticals. Cosmeceuticals occupy an intermediate position between drugs and traditional cosmetics, combining the properties of skin care with pharmacological activity. Unlike classic cosmetic products, cosmeceuticals affect pathophysiological processes in the skin, including inflammation, oxidative stress, impaired barrier function and aging processes [1].

The relevance of the development of cosmeceuticals is due to the increase in the prevalence of dermatological conditions (acne, atopic dermatitis, rosacea, photoaging), as well as the increased demand for effective and safe long-term products. It is important that cosmeceutical products are increasingly being developed according to the principles of medical and pharmaceutical technologies, considering the standards of quality, safety, and evidence, which brings them closer to medicines [2].

A special place in cosmeceuticals is occupied by herbal remedies that contain biologically active substances of plant origin and are widely used in dermatology and cosmetology. Their use is due to high biocompatibility, complex (pleiotropic) action and relative safety. Plant components contain a wide range of active compounds, among which flavonoids (for example, quercetin, luteolin), carotenoids (β-carotene), triterpene saponins (oleanolic acid derivatives), phenolic acids (caffeic acid, chlorogenic acid), as well as essential oils (terpenoids) are of key importance [3-7]

Preparations based on calendula officinalis L., which is a source of pharmacologically active substances with proven anti-inflammatory, antiseptic and reparative effects, are widely used in cosmeceuticals [8, 9].

Such drugs include:

- Calendula ointment (International Nonproprietary Name (INN): Calendula extract; chemical constituents: triterpenoid esters, flavonoids)
- Bepanthen ointment (INN: dexpanthenol; chemical name: (R)-2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide)
- Panthenol cream (INN: dexpanthenol; chemical name: alcohol analogue of pantothenic acid)

Although some of these remedies are not exclusively herbal remedies, their combination with herbal ingredients is characteristic of modern cosmeceuticals, which provides a synergistic effect.

Herbal remedies in cosmeceuticals affect various biological mechanisms, including inhibition of pro-inflammatory cytokines, neutralization of free radicals, stimulation of cell proliferation and restoration of the epidermal barrier. Due to this, they are widely used in the treatment and prevention of dermatological and cosmetic problems.

At the same time, the use of plant raw materials in cosmeceuticals is associated with several challenges, including the variability of chemical composition, the need for standardization and ensuring the stability of finished forms. In this context, the harmonization of quality requirements with leading pharmacopoeias, particularly the German Pharmacopoeia, which sets high standards for the identification, purity and quantitative content of biologically active substances, is of particular importance.

Thus, herbal remedies are a promising direction in the development of cosmeceuticals, combining traditional knowledge with modern pharmaceutical technologies and opening new opportunities for creating effective and safe skin care products.

Purpose of the work

The purpose of this study is a comprehensive analysis of the role of herbal remedies in modern cosmeceuticals with an emphasis on products based on Calendula officinalis L. (calendula extract), which are widely used in dermatological and cosmetic practice.

To achieve this goal, it is envisaged to solve the following tasks:

- to characterize modern approaches to the use of herbal remedies in cosmeceuticals and their pharmacological properties;
- to analyze the composition, biologically active components (flavonoids, triterpenoids, carotenoids) and mechanisms of action of calendula-based drugs;
- to investigate the range of cosmeceuticals containing calendula extract, as well as combined preparations (for example, dexpanthenol-(R)-2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide);

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- to conduct a comparative analysis of the quality requirements for plant raw materials and calendula preparations in accordance with national approaches and Deutsches Arzneibuch (DAB) [10, 11];
- perform SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis to assess strengths and weaknesses, opportunities, and threats to the development of phytocosmeceuticals;
- to carry out a PESTEL (Political, Economic, Social, Technological, Environmental, Legal) analysis considering political, economic, social, technological, environmental, and legal factors affecting the cosmeceutical market.

The results obtained will substantiate the prospects for the use of herbal remedies in cosmeceuticals and determine the directions for improving their quality, efficiency, and competitiveness.

Materials and methods

The paper uses a complex of general scientific and special pharmaceutical research methods that provide a systematic approach to the analysis of herbal remedies in cosmeceuticals.

The materials of the study were:

- scientific publications on pharmaceutical cosmetology, dermatology, and herbal medicine [12-17];
- regulatory documents, in particular DAB requirements for plant raw materials Calendula officinalis L.;
- data on the composition and properties of biologically active substances (flavonoids, carotenoids, triterpenoids, phenolic acids);
- Cosmeceutical preparations based on calendula and combined products, in particular:
  - Calendula ointment (INN: Calendula extract; chemical constituents: triterpenoid esters, flavonoids)
  - Bepanthen (INN: dexpanthenol; chemical name: (R)-2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide)
  - Panthenol (INN: dexpanthenol; alcohol analogue of pantothenic acid)

Educational and methodological materials on pharmaceutical cosmetology were also used.

In the process of research, the following methods were used:

1. Documentary analysis. An analysis of scientific sources and regulatory documentation has been carried out to summarize modern data on the use of herbal remedies in cosmeceuticals.
2. Comparative analysis. A comparison of the quality requirements for medicinal plant raw materials Calendula officinalis in accordance with national approaches and DAB, in terms of identification, purity and standardization, has been carried out.
3. Pharmacological analysis. The mechanisms of action of biologically active substances (quercetin, β-carotene, oleanolic acid derivatives, caffeic acid) and their effect on the physiological processes of the skin (anti-inflammatory, antioxidant, reparative effect) have been evaluated.
4. Assortment analysis. The modern market of cosmeceuticals based on calendula and combined preparations has been studied with the determination of their composition, dosage forms and areas of application.
5. SWOT analysis. It is used to determine the strengths and weaknesses of phytocosmeceuticals, as well as opportunities and threats to its development.
6. PESTEL analysis. It is used to assess the influence of the macroenvironment on the development of cosmeceuticals, considering political, economic, social, technological, environmental, and legal factors.

The study is based on an interdisciplinary approach that combines pharmaceutical, dermatological, and economic analysis, which allows a comprehensive assessment of the effectiveness and prospects of the use of herbal remedies in cosmeceuticals.

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Research results

The analysis showed that herbal remedies occupy a leading place in the structure of modern cosmeceuticals due to the combination of pharmacological activity and a high safety profile. It has been established that, unlike synthetic components, herbal ingredients are characterized by a multicomponent composition, which ensures their multifunctional effect on various links in the pathogenesis of dermatological conditions.

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The main pharmacological effects of herbal remedies in the composition of cosmeceuticals are anti-inflammatory, antiseptic, regenerative, antioxidant and moisturizing effects. The realization of these effects is due to the presence of biologically active substances, such as flavonoids (quercetin, luteolin), carotenoids (β-carotene), triterpenoids (oleanolic acid derivatives), phenolic acids (caffeic acid, chlorogenic acid) and essential oils (terpenoids).

The results obtained made it possible to systematize the main properties of phytocomponents used in cosmeceuticals.

Table 1. The main pharmacological effects of herbal remedies in cosmeceuticals

Pharmacological effect	**Main active ingredients**	**Mechanism of action**	**Cosmetological significance**
Anti-inflammatory	flavonoids (quercetin), triterpenoids	inhibition of pro-inflammatory cytokines	Erythema reduction, acne treatment
Antiseptic	essential oils (terpenoids)	Disruption of the membranes of microorganisms	prevention of skin infections
Regenerative	triterpenoids, carotenoids	stimulation of cell proliferation	wound healing, skin restoration
Antioxidant	polyphenols, carotenoids	neutralization of free radicals	Prevention of photoaging
Moisturizing	polysaccharides	water retention in the epidermis	improving skin hydration

An analysis of the range of herbal components showed that the most common in cosmeceuticals are Calendula officinalis L. (calendula extract), Matricaria chamomilla L. (chamomile extract), Aloe vera (aloe extract), Salvia officinalis L. (sage extract) and Hypericum perforatum L. (St. John's wort extract). They are part of creams, ointments, gels, tonics, and serums.

Table 2. The most common herbal components in cosmeceuticals

Plant	**INN / English Name**	**Main active substances**	**Main effects**
Calendula officinalis L.	calendula extract	flavonoids, triterpenoids, carotenoids	anti-inflammatory, regenerative
Matricaria chamomilla L.	chamomile extract	apigenin, bisabolol	anti-inflammatory, soothing
Aloe vera	aloe extract	polysaccharides, acemannan	moisturizing, regenerative
Salvia officinalis L.	sage extract	essential oils (thujone, cineole)	Antiseptic
Hypericum perforatum L.	St. John’s wort extract	hypericin, flavonoids	anti-inflammatory, antibacterial

It has been established that phytocomponents simultaneously affect several pathogenetic mechanisms, which is their key advantage in comparison with monotarget synthetic substances. Calendula extract combines anti-inflammatory, antimicrobial, and reparative effects, which makes it effective in treating skin lesions, irritations, and acne.

In addition, it has been found that modern cosmeceutical preparations often contain combinations of herbal components with pharmaceutical active substances, such as dexpanthenol (chemical name: (R)-2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide), which provides a synergistic effect and increases the effectiveness of therapy.

Thus, the results of the study confirm that herbal remedies are a key component of cosmeceuticals due to their multicomponent composition, multifactorial mechanism of action and high level of safety, which determines their widespread use in modern dermatological and cosmetic practice.

Further analysis showed that cosmeceuticals based on Calendula officinalis L. (calendula extract) occupy one of the leading places among herbal remedies used in dermatology and cosmetology. This is due to the high concentration of biologically active substances and proven pharmacological efficacy.

It has been established that the main active ingredients of calendula are flavonoids (quercetin, isorhamnetin), carotenoids (β-carotene, lycopene), triterpenoid saponins (oleanolic acid derivatives) and essential oils (terpenoids). It is these compounds that provide a wide range of pharmacological activity.

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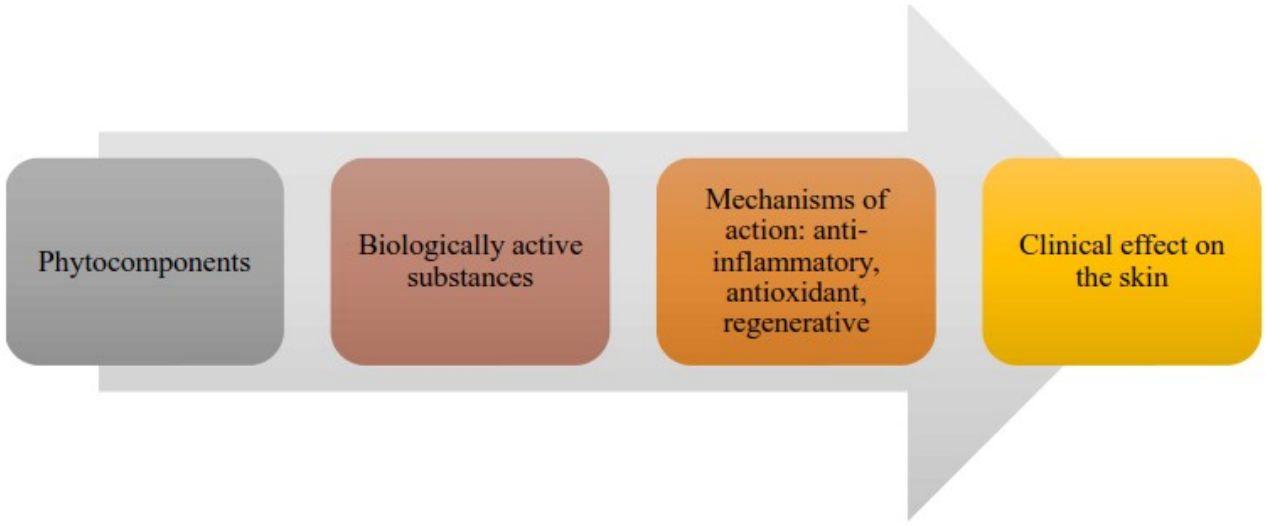

Fig. 1. Scheme of mechanisms of action of herbal remedies in cosmeceuticals

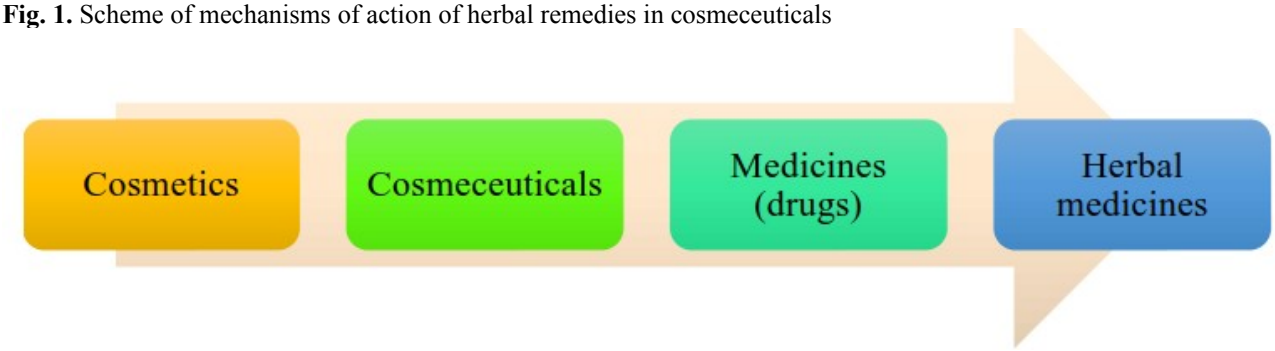

Fig. 2. The place of herbal remedies in the structure of cosmeceuticals

Table 3. The main biologically active substances are Calendula officinalis L.

Group of substances	Representatives	Pharmacological action	Importance in cosmeceuticals
Flavonoids	quercetin, isorhamnetin	anti-inflammatory, antioxidant	reducing skin irritation
Carotenoids	β-carotene, lycopene	Antioxidant	Prevention of photoaging
Triterpenoids	oleanolic acid derivatives	reparative, anti-inflammatory	skin healing
Essential oils	terpenoids	Antimicrobial	Infection prevention

The results obtained indicate that calendula realizes its effect through several mechanisms: inhibition of the synthesis of pro-inflammatory mediators, stimulation of fibroblast proliferation, increased angiogenesis, and antioxidant protection of cells. This ensures its effectiveness in treating skin lesions and dermatological conditions.

Analysis of the cosmeceutical assortment showed that calendula extract is widely used both in mono-preparations and as part of combined products. A frequent combination with the following active substances has been established:

- dexpanthenol (chemical name: (R)-2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide)
- allantoin (chemical name: 5-ureidohydantoin)
- zinc oxide (chemical name: ZnO)

Such combinations provide enhanced reparative and anti-inflammatory effects.

It has been established that the use of calendula in cosmeceuticals is most appropriate for the following conditions:

- inflammatory dermatoses
- Acne vulgaris
- Skin irritation and dryness
- microdamage to the skin
- age-related changes

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Table 4. Examples of cosmeceutical preparations based on calendula

Medicine name	INN	Chemical name	Release form	Main action
Calendula ointment	Calendula extract	mixture of triterpenoid esters and flavonoids	Ointment	anti-inflammatory, regenerative
Bepanthen plus	dexpanthenol + chlorhexidine	(R)-2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide + chlorhexidine digluconate	Cream	antiseptic, reparative
Panthenol cream with calendula	dexpanthenol + calendula extract	alcohol analogue of pantothenic acid + plant extract	Cream	healing, moisturizing

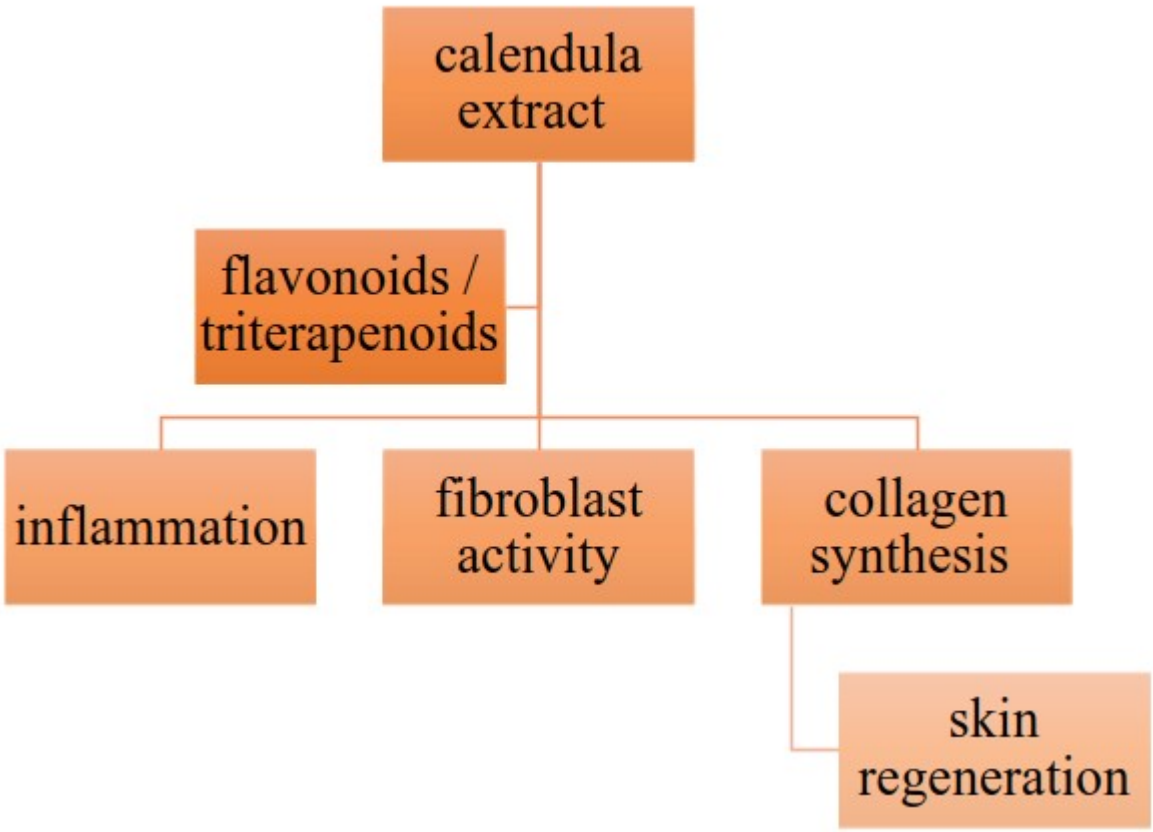

Fig. 3. Mechanism of action of Calendula officinalis in the skin

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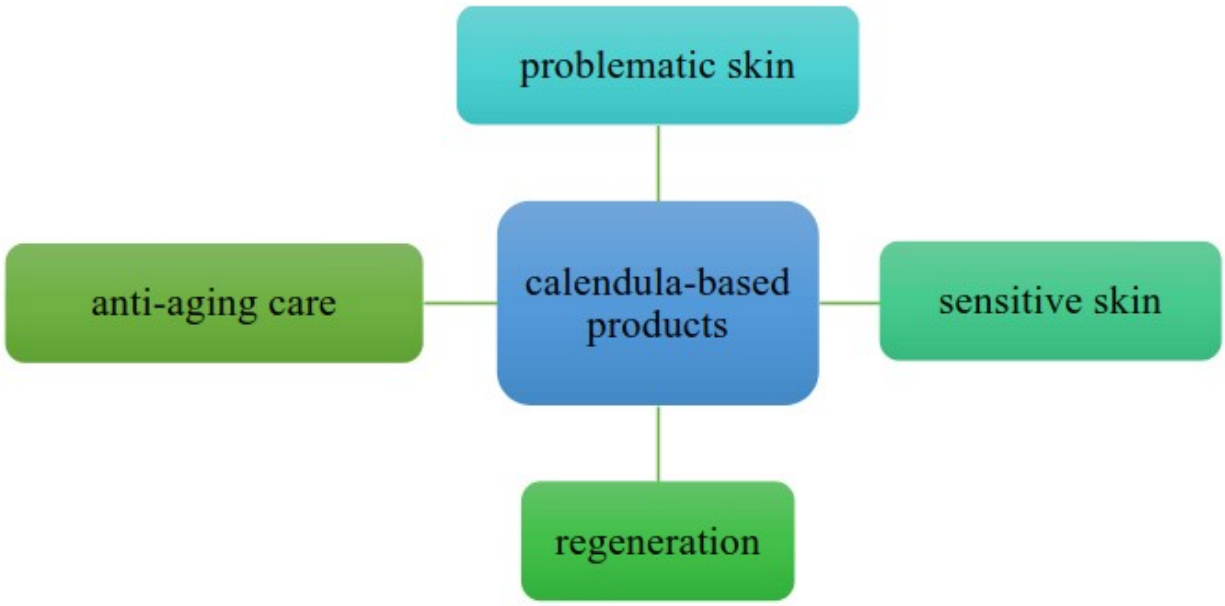

Fig. 4. Directions of application of calendula in cosmeceuticals

Thus, the results of the study confirm that Calendula officinalis L. is one of the key components of modern cosmeceuticals, which provides a complex therapeutic effect and has broad prospects for further use in pharmaceutical cosmetology.

The comparative analysis showed that the quality requirements for medicinal plant raw materials Calendula officinalis L. (calendula extract) in DAB are more stringent and detailed compared to national approaches, which is of fundamental importance for ensuring the effectiveness and safety of cosmeceuticals.

It has been established that the quality control system in DAB is based on a combination of modern analytical methods, standardization by marker compounds and mandatory validation of methods. This minimizes the variability of plant materials and ensures the reproducibility of the pharmacological effect.

The analysis showed that DAB widely uses modern quality control methods, in particular TLC and HPLC, which allow the identification and quantification of key bioactive substances, such as quercetin and oleanolic acid derivatives. In national practice, these methods are used to a limited extent or are not mandatory.

DAB pays special attention to standardization by marker compounds, which is critically important for herbal medicines, since their pharmacological activity depends on the qualitative and quantitative composition. In the case of Calendula officinalis, these markers are flavonoids and triterpenoids, which determine anti-inflammatory and reparative activity.

Table 5. Comparative analysis of the requirements for Calendula officinalis L. in national approaches and DABs

Criterion	**Ukraine**	**DAB**	**Scientific and practical significance**
Identification	macroscopic and microscopic analysis	Additionally (TLC – (Thin-Layer Chromatography), HPLC (High-Performance Liquid Chromatography)	Improving the accuracy of identification
Active ingredient content	general indicators (sum of BAR)	Standardization by Marker Compounds (Flavonoids, Triterpenoids)	reproducibility of the pharmacological effect
Cleanliness	Basic requirements	Strict limits for heavy metals, pesticides, microbial contamination	Safety of use
Method validation	limited	Mandatory Validation of Analytical Methods	Reliability of results

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It has been established that the purity requirements in the German pharmacopoeia are much stricter, regarding the content of heavy metals (lead, cadmium), pesticides residues and microbial contamination indicators. This is of particular importance for cosmeceuticals, since such products are used for a long time and are in direct contact with the skin.

Separately, it should be noted that the validation of analytical methods in DAB is mandatory, which includes the assessment of specificity, accuracy, reproducibility, and linearity. This approach ensures a high level of reliability of quality control results.

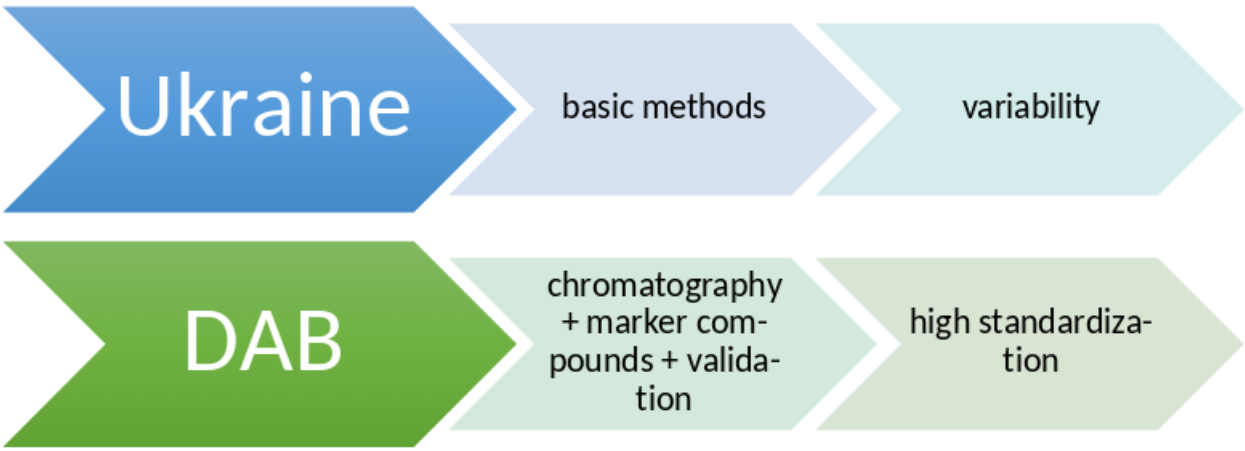

Fig. 5. Comparison of approaches to the standardization of herbal remedies

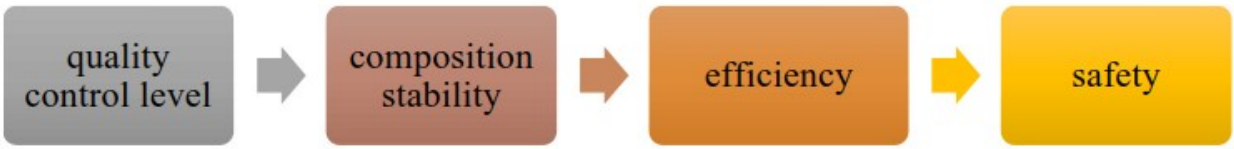

Fig. 6. Influence of the level of standardization on the quality of cosmeceuticals

Thus, the results of the study confirm that the German Pharmacopoeia provides a higher level of standardization of medicinal plant raw materials, which is critically important for the development and production of effective and safe cosmeceuticals based on Calendula officinalis L. This justifies the feasibility of harmonizing national requirements with European standards.

The SWOT analysis showed that phytocosmeceuticals based on Calendula officinalis L. (calendula extract) has significant development potential, but is characterized by the presence of both competitive advantages and limitations associated with the nature of plant raw materials and regulatory requirements.

It has been established that the key strengths are natural origin and high biocompatibility, which reduces the risk of adverse reactions and ensures good tolerability with long-term use. The multicomponent composition (flavonoids, carotenoids, triterpenoids, essential oils) provides a multifactorial effect on the skin, including anti-inflammatory, antioxidant, and reparative effects, which is a significant advantage compared to monofunctional synthetic components.

At the same time, it has been established that the weaknesses of phytocosmeceuticals are due to the variability of the chemical composition of plant raw materials, which depends on the conditions of cultivation, collection, and storage. This makes standardization and quality control difficult. In addition, natural ingredients often have limited stability, which leads to a shorter shelf life compared to synthetic counterparts.

The analysis of market trends has shown that there are significant opportunities for the development of phytocosmeceuticals. There is a growing demand for natural and organic skin care products, which stimulates the introduction of herbal ingredients in cosmetic products. A promising direction is the development of personalized cosmetology, where herbal remedies can be adapted to the individual needs of the patient. It is also important to combine phytocomponents with modern pharmaceutical technologies, in particular the use of active substances such as dexpanthenol (chemical name: (R)-2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide), which allows to increase the effectiveness of cosmeceuticals.

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At the same time, several threats have been identified that may hinder the development of this segment. Among them is competition from synthetic active ingredients that have a stable composition and predictable effect. Regulatory restrictions that impose strict requirements for quality, safety and evidence have a significant impact. A separate problem is the risks of falsification of plant raw materials, which can lead to a decrease in the efficiency and safety of finished products.

Table 6. SWOT analysis of phytocosmeceuticals based on Calendula officinalis L.

Category	Characteristics	Scientific and practical significance
Strengths	natural origin; high biocompatibility; multicomponent action (flavonoids, triterpenoids)	safety, complex impact
Weaknesses	variability of the composition; complexity of standardization; Limited stability	Quality control difficulties
Opportunities	growth in demand; personalized cosmetology; Integration with pharmaceutical technologies	Market expansion
Threats	competition of synthetic means; regulatory requirements; Falsification	Risks for the development of the industry

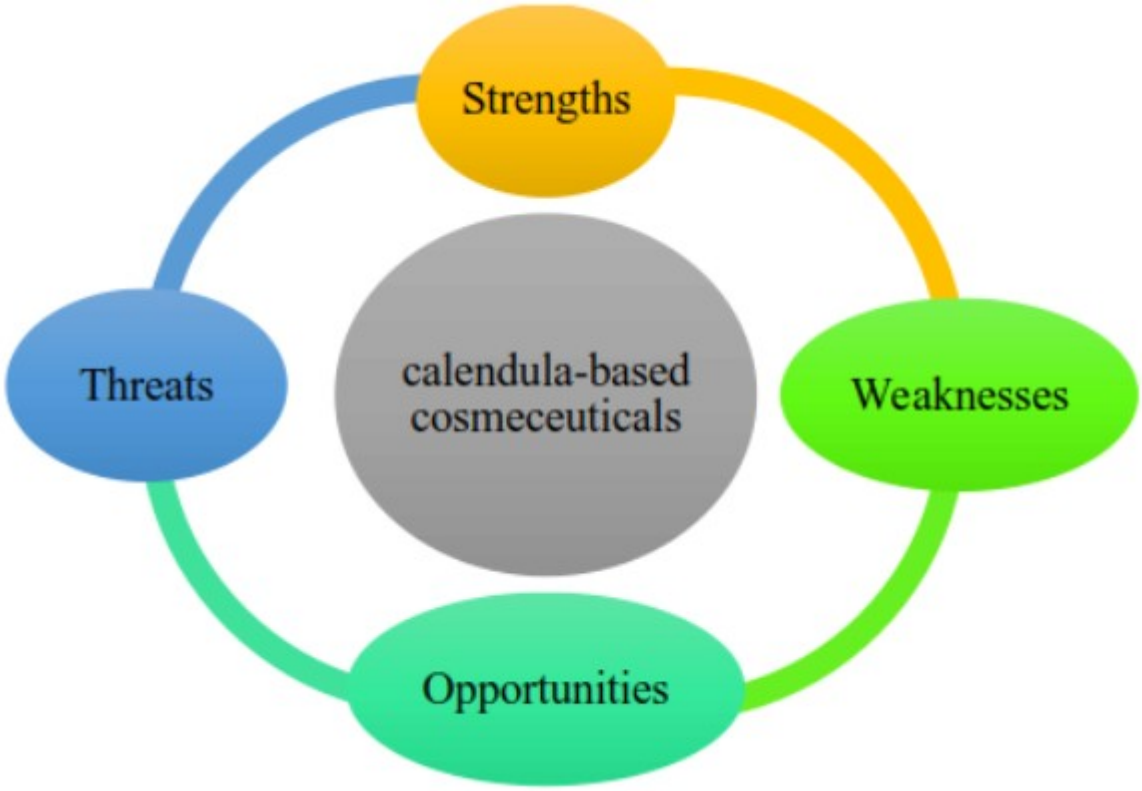

Fig. 7. SWOT profile of phytocosmeceuticals

Thus, the results of the SWOT analysis indicate a high potential of phytocosmeceuticals based on Calendula officinalis L., however, for its implementation, it is necessary to improve the system of standardization, quality control, regulatory support, digital medical technologies, telemedicine, telepharmacy [18].

The conducted PESTEL analysis showed that the development of cosmeceuticals, in particular products based on Calendula officinalis L. (calendula extract), largely depends on the influence of the macroenvironment, which forms both favorable conditions and restrictions for the functioning of the industry.

It has been established that political factors play an important role in the regulation of the cosmeceutical market. Harmonization of national legislation with the requirements of the European Union contributes to the improvement of quality and safety standards. At the same time, the tightening of regulatory requirements complicates the process of bringing new cosmeceuticals to the market, especially those containing herbal components with variable composition.

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Economic analysis has shown a stable growth of the cosmeceutical market, which is due to the increase in demand for products with proven effectiveness and safety. An important factor is also the relative availability of plant materials, in particular Calendula officinalis, which contributes to the development of the production of herbal medicines. At the same time, economic instability can affect the purchasing power of the population and the investment attractiveness of the industry.

Table 7. Influence of SWOT factors on the development of phytocosmeceuticals

Combination of factors	Nature of interaction	Influence on the development of cosmeceuticals	Practical significance
Strengths + Opportunities	synergy of internal advantages and external opportunities	stimulates the active development of phytocosmeceuticals, expansion of the range	Introduction of new products based on Calendula extract
Strengths + Threats	using strengths to neutralize risks	increases competitiveness relative to synthetic analogues	positioning as a safe and natural alternative
Weaknesses + Opportunities	Overcoming internal limitations through innovation	contributes to the improvement of standardization and stabilization technologies	HPLC implementation, standardization by marker compounds
Weaknesses + Threats	imposition of restrictions and external risks	inhibits development and reduces product confidence	the need to strengthen quality control, regulation, telemedicine, telepharmacy

Social factors are characterized by an increase in demand for natural and safe cosmetics. Increasing consumer awareness of the composition of products and their impact on health stimulates the choice of cosmeceuticals, especially herbal preparations. This creates favorable conditions for expanding the range of products based on calendula extract.

Technological factors determine the innovative development of cosmeceuticals. It has been established that the introduction of biotechnologies, as well as the use of modern systems for the delivery of active substances (particularly nanoformulations), can increase the bioavailability and stability of phytocomponents. The combination of plant extracts with pharmaceutical ingredients such as dexpanthenol (chemical name: (R)-2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide) is a promising direction for increasing the effectiveness of cosmeceuticals.

Environmental factors play an increasingly important role in shaping the modern market. The focus on sustainable development and the introduction of the principles of organic production contribute to the popularization of phytocosmeceuticals. The use of environmentally friendly plant raw materials increases consumer confidence and competitiveness of products.

Legal factors include pharmacopoeia requirements and Good Manufacturing Practice (GMP) standards, which ensure control over the quality, safety, and efficacy of cosmeceuticals [17]. It has been established that strengthening legal regulation is a necessary condition for the development of the industry, but at the same time increases the requirements for manufacturers [19].

Table 8. PESTEL analysis of cosmeceuticals based on Calendula officinalis L.

Factor	Characteristics	Effects on cosmeceuticals
Political	harmonization with the EU; increased regulation	raising quality standards
Economic	market growth; Availability of raw materials	Expansion of production
Social	demand for natural remedies; Awareness	increase in consumption
Technological	biotechnology; nanotechnology-based formulations	Increase efficiency
Environmental	sustainable development; Organic production	Increasing competitiveness
Legal	pharmacopoeia standards; GMP	Quality and safety assurance

Figure 8. Structure of PESTEL factors in cosmeceuticals

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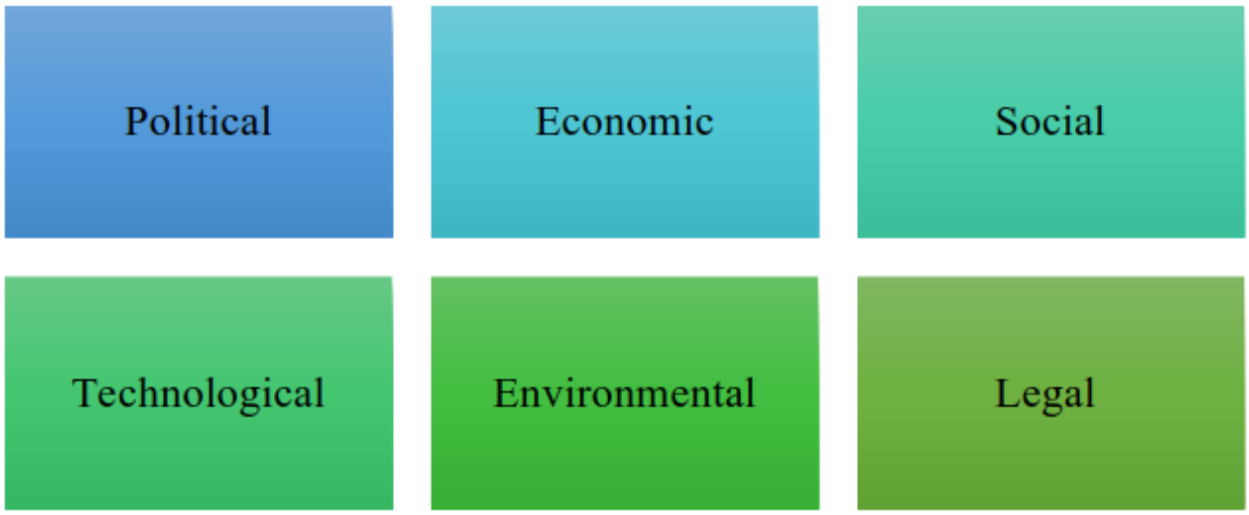

Figure 9. The influence of the macroenvironment on the development of phytocosmeceuticals

Thus, the results of the PESTEL analysis indicate that the development of cosmeceuticals based on Calendula officinalis L. is determined by the complex interaction of political, economic, social, technological, environmental, and legal factors, which must be taken into account when forming a strategy for the development of the industry.

Discussion

The results obtained indicate that herbal medicines, based on Calendula officinalis L. (calendula extract), form one of the key segments of modern cosmeceuticals, providing a combination of pharmacological efficacy and a high safety profile. It has been established that the multicomponent composition of plant raw materials (flavonoids, carotenoids, triterpenoids, phenolic acids) provides a multifactorial effect on the skin, which is a significant advantage compared to synthetic monoactive substances.

At the same time, the results of the study confirm that it is this multicomponent that simultaneously acts as both an advantage and a limitation. On the one hand, it provides a synergistic effect (anti-inflammatory, antioxidant, reparative) and, on the other hand, it makes it difficult to standardize, control the quality and reproducibility of the therapeutic effect. This is consistent with benchmarking data, according to which DAB pays special attention to standardization by marker compounds (quercetin, oleanolic acid derivatives) and the application of chromatographic methods (TLC, HPLC).

An important aspect is that the results of the SWOT analysis demonstrate an internal contradiction in the development of phytocosmeceuticals: the high demand for natural remedies is combined with the difficulties of standardization and the risks of falsification. This indicates the need to improve quality control systems and implement European approaches to regulation.

PESTEL analysis confirms that the development of cosmeceuticals is determined not only by scientific, but also by macroeconomic and social factors. In particular, the growing demand for natural products and the development of biotechnology create favorable conditions for the introduction of herbal remedies in cosmetic practice. At the same time, tightening regulatory requirements and the need to comply with GMP standards increase barriers to entry.

Particular attention should be paid to the tendency to combine herbal ingredients with pharmaceutical active substances. For example, the combination of calendula extract with dexpanthenol (chemical name: (R)-2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide) can increase the regenerative potential of drugs and provide a more predictable clinical effect. This approach corresponds to the modern concept of cosmeceuticals as a synergistic system that combines natural and synthetic components.

At the same time, the results of the study indicate the need for further scientific developments in the direction of:

- standardization of plant raw materials by clearly defined marker compounds;
- improvement of analytical methods of quality control;
- increasing the stability of phytocomponents in the composition of cosmeceutical forms;
- development of new systems for the delivery of active substances (nanocarriers, liposomal systems).

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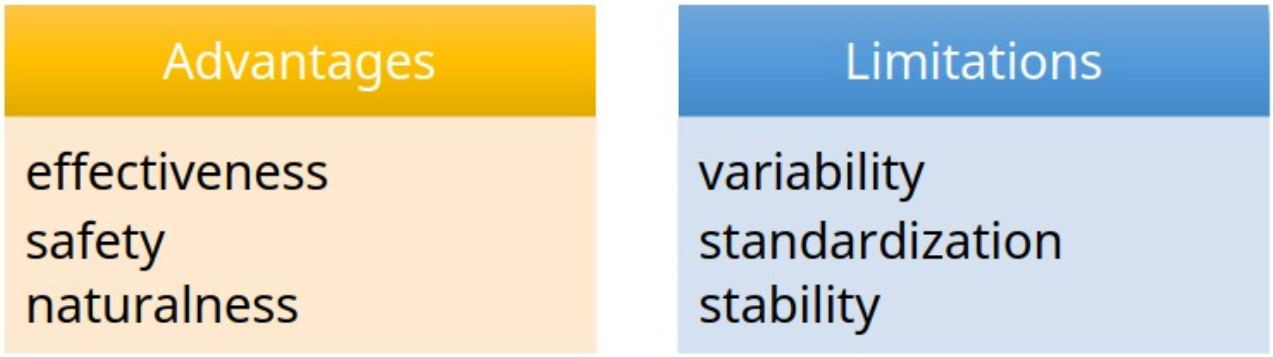

Figure 10. Balance of benefits and limitations of phytocosmeceuticals

At the same time, the development of modern cosmeceuticals and the use of herbal remedies require considering not only pharmacological and technological aspects, but also legal and bioethical approaches that regulate the circulation of biological materials and medicines. It has been established that the formation of an effective system for ensuring the quality and safety of medical and pharmaceutical technologies, including phytocosmeceuticals, is closely related to the development of the regulatory framework and bioethical standards governing the use of cells, tissues, and innovative therapeutic approaches. At the same time, clinical aspects of the use of drugs, for tuberculosis lesions, confirm the importance of an integrated approach to the choice of therapy, analysis of the drug market and ensuring their availability, which is also important for the development of cosmeceuticals with proven efficacy and safety [20, 21].

Thus, the results of the study confirm that phytocosmeceuticals based on Calendula officinalis L. is a promising direction in the development of modern pharmaceutical cosmetology, but it requires further scientific justification, harmonization of quality standards and the introduction of innovative medical and pharmaceutical technologies to ensure the stability and reproducibility of the effect.

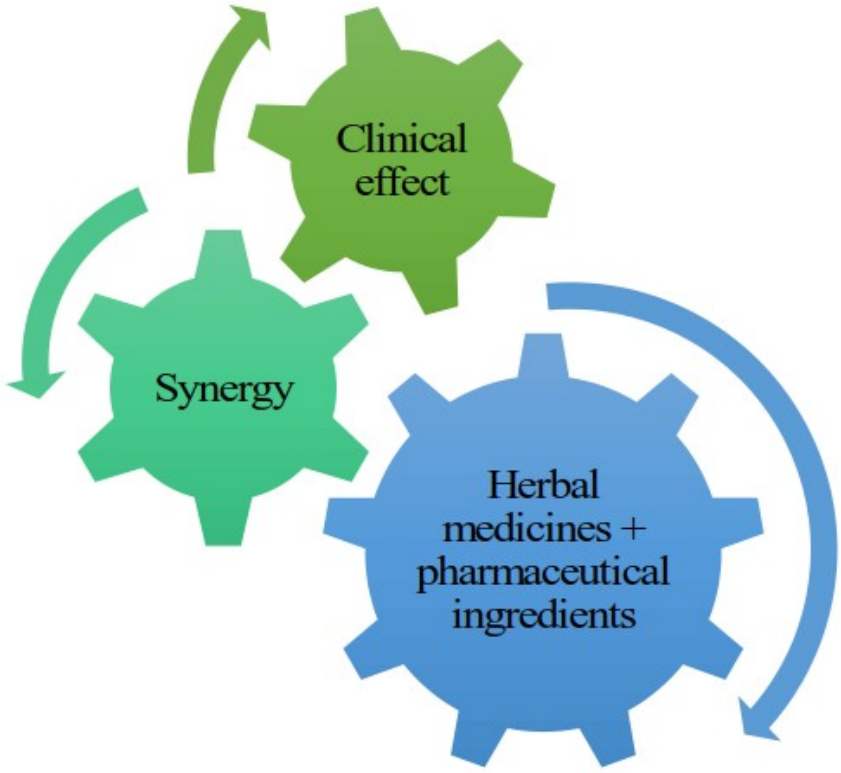

Fig. 11. Modern model of cosmeceuticals

Conclusions

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As a result of the study, it was found that herbal remedies are one of the key areas of development of modern cosmeceuticals, as they provide a combination of pharmacological efficacy, multicomponent action, and a high safety profile. Their use allows you to influence various links in the pathogenesis of dermatological conditions, including inflammation, oxidative stress, and skin regeneration disorders.

It has been proven that Calendula officinalis L. (calendula extract) is a promising ingredient in cosmeceuticals due to the presence of biologically active substances (flavonoids, carotenoids, triterpenoids) that provide anti-inflammatory, antimicrobial, and reparative effects. The use of combined forms, with dexpanthenol (chemical name: (R)-2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide), increases the effectiveness and expands the possibilities of using such agents in dermatological practice.

Comparative analysis with the requirements of DAB showed the need to improve national approaches to the standardization of plant raw materials, in particular, the introduction of chromatographic methods of analysis, standardization according to marker compounds and mandatory validation of analytical methods.

The results of the SWOT analysis showed the presence of a significant potential of phytocosmeceuticals, combining strengths (naturalness, biocompatibility, complex action) with certain limitations (variability of composition, complexity of standardization). PESTEL analysis confirmed that the development of cosmeceuticals is determined by the complex interaction of political, economic, social, technological, environmental, and legal factors.

Thus, phytocosmeceuticals based on Calendula officinalis L. is a promising direction of pharmaceutical cosmetology, which requires further development in the direction of harmonization of quality standards, introduction of innovative technologies and expansion of the evidence base of effectiveness and safety.

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Medical Technologies. Pharmaceutical Cosmetology, Cosmeceuticals Based on Herbal Medicines: Modern Trends and Regulatory Approaches

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Introduction. Modern cosmetology is characterized by the integration of medical technologies, pharmaceutical and cosmetic approaches, which led to the formation of cosmeceuticals as a separate direction. A special place in cosmeceuticals is occupied by phytopreparations that contain biologically active substances (flavonoids, carotenoids, triterpenoids) and provide a complex effect on the skin. **Purpose of the study.** To analyze the role of herbal remedies in cosmeceuticals on the example of Calendula officinalis L. (calendula extract), to conduct a comparative analysis with the requirements of Deutsches Arzneibuch (DAB), as well as to perform a SWOT (Strengths, Weaknesses, Opportunities, Threats)- and PESTEL (Political, Economic, Social, Technological, Environmental, Legal) analysis of the development of phytocosmeceuticals. **Materials and methods.** Documentary analysis of scientific sources and regulatory documentation, comparative analysis of pharmacopoeia requirements, pharmacological analysis of biologically active substances (quercetin, β-carotene, oleanolic acid derivatives), as well as SWOT and PESTEL analysis were used. Cosmeceutical preparations, in particular Calendula ointment (International Nonproprietary Name: Calendula extract) and dexpanthenol agents (chemical name: (R)-2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide) were studied. **Results.** It has been established that herbal remedies provide anti-inflammatory, antiseptic, antioxidant, and regenerative effects due to their multicomponent composition. Calendula extract has been shown to be effective in the treatment of inflammatory and degenerative skin conditions. It has been found that the requirements of DAB are more stringent and provide for standardization according to marker compounds and the use of chromatographic methods (TLC - (Thin-Layer Chromatography), HPLC (High-Performance Liquid Chromatography). SWOT analysis demonstrated the strengths of phytocosmeceuticals (naturalness, biocompatibility) and limitations (composition variability), while PESTEL analysis confirmed the significant impact of macroeconomic and regulatory factors on the development of the industry. **Conclusions.** Herbal remedies are a promising area of cosmeceuticals that combines effectiveness and safety. Calendula officinalis L. is one of the key ingredients in modern cosmeceuticals. It is necessary to improve the standardization system in accordance with European requirements and introduce innovative technologies to improve the quality of products.

Keywords: cosmeceuticals, herbal medicines, Calendula officinalis, calendula extract, flavonoids, dexpanthenol, pharmacopoeia, SWOT analysis, PESTEL analysis.

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References

1. Shapovalova V., Osyntseva A., Shapovalov V. Medical Technologies: Pharmaceutical Cosmetology, Cosmeceuticals - Opportunities and Limitations. *Annals of Mechnikov's Institute.* 2026. No.1. P. 30-38. DOI: https://doi.org/10.5281/zenodo.18887719
2. Klymyshyna S.O., Tsysnetska A.V., Rachkevych L.V. Pharmaceutical cosmetology. Lviv: Danylo Halytskyi Lviv National Medical University, 2008. P. 1-226.
3. Shapovalova V.O., Shapovalov V.V., Osyntseva A.O. Materials for ensuring the final control of the educational component Pharmacognosy. Rivne: DZ "LDMU" 2023. 36 p. (Protocol No. 1 dated August 31, 2023).
4. Kyslychenko V.S., Zhuravel I.O., Marchyshyn S.M. Pharmacognosy. Kharkiv: NFaU, 2015. 736 p.
5. Osyntseva A.O., Shapovalova V.O., Shapovalov V.V. Work program of normative educational component 32 "Resource science of medicinal plants". Rivne: DZ "LDMU". 2023. 18 p. (Minutes of the meeting of the university council on the quality of education dated August 31, 2023, No. 1).
6. Shapovalova V.O., Shapovalov V.V., Osintseva A.O. et al. Working program of normative educational component 26 "Pharmacognosy". Rivne: DZ "LDMU". 2023. 19 p. (Minutes of the meeting of the university council on the quality of education dated August 31, 2023, No. 1).
7. Tkachenko V.G., Shapovalova V.O., Shapovalov V.V. et al. A collection of preparation materials for the unified state qualification exam (UEKI) on the educational component of Pharmacognosy. Rivne: DZ "LDMU" 2023. 36 p. (Protocol No. 2 dated September 26, 2023).
8. Yurchenko T. Calendula Officinalis L.: Study for Prospects of Creating Combined Dosage Forms with Naturally Similar Properties. *SSP Modern Pharmacy and Medicine*. 2025. Vol.5. No.1. P.1-25. DOI: https://doi.org/10.53933/sspmpm.v5i1.175
9. Osyntseva A. Interdisciplinary Evaluation of Phytotherapy Resource Calendula Officinalis L. in Patients with Tuberculosis and Combined Pathologies. *SSP Modern Pharmacy and Medicine*. 2025. Vol. 5. No. 3. P. 76-92. DOI: https://doi.org/10.53933/8xgwaq64
10. European Directorate for the Quality of Medicines & HealthCare (EDQM). European Pharmacopoeia – New online-only 12th Edition. Council of Europe. 2025. Vol. 12. Iss. 1. P. 1-100. https://www.edqm.eu/en/european-pharmacopoeia-new-online-only-12th-edition
11. Deutsches Arzneibuch (DAB). German Pharmacopoeia. German Medical Association. 2022. Vol. 1. Iss. 1. P. 1-3000. https://www.bfarm.de
12. EMA Committee on Herbal Medicinal Products. Assessment report on Calendula officinalis L., flos. European Medicines Agency. 2017. Vol. 1. Iss. 1. P. 1-40. https://www.ema.europa.eu
13. Preethi K.C., Kuttan R. Wound healing activity of flower extract of Calendula officinalis. *Journal of Basic and Clinical Physiology and Pharmacology*. 2009. Vol. 20. Iss. 1. P. 73-79. DOI: https://doi.org/10.1515/JBCPP.2009.20.1.73
14. Della Loggia R., Tubaro A., Sosa S., Becker H., Saar S., Isaac O. The role of triterpenoids in the anti-inflammatory activity of Calendula officinalis flowers. *Planta Medica*. 1994. Vol. 60. Iss. 6. P. 516-520. DOI: https://doi.org/10.1055/s-2006-959562
15. Fonseca Y.M., Catini C.D., Vicentini F.T., Nomizo A., Gerlach R.F., Fonseca M.J. Protective effect of Calendula officinalis extract against UVB-induced oxidative stress in skin. *Journal of Photochemistry and Photobiology B: Biology*. 2010. Vol. 96. Iss. 1. P. 1-7. DOI: https://doi.org/10.1016/j.jphotobiol.2009.03.005
16. Benson H.A.E., Watkinson A.C. Transdermal and topical drug delivery: principles and practice. *Wiley-Blackwell.* 2012. Vol. 1. Iss. 1. P. 1-400. DOI: https://doi.org/10.1002/9781118140505
17. Gryzodub O., Shapovalov V. Quality systems in Pharmacy: multidisciplinary context of the State Pharmacopoeia of Ukraine. *SSP Modern Law and Practice.* 2023. Vol. 3. No. 1. P. 1-23. DOI: https://doi.org/10.53933/sspmlp.v3i1.81
18. Shapovalova V. Telemedicine and Telepharmacy in Modern Healthcare: Innovations, Medical Technologies, Digital Transformation. *SSP Modern Pharmacy and Medicine.* 2025. Vol.5. Iss. 3. P.1-19. DOI: https://doi.org/10.53933/r7f5xj91
19. Shapovalov V., Shapovalova V., Shapovalov V., Veits O., Diachenko A. & Osyntseva A. (2026). Vision 2035 - Medico-Pharmaceutical Law for Human Security. *Publisher: Scientific Research Establishment of Innovations for Future LLC. ISBN 979-8-9942371-3-7.* DOI: https://doi.org/10.53933/b91avw28
20. Shapovalov V., Nevzghoda O., Shapovalova V., Osyntseva A., Shapovalov V. Legal and bioethical foundations of human cell and tissue cryobanks in Ukraine: regulatory framework, challenges and prospects. *Problems of Cryobiology and Cryomedicine.* 2025. Vol. 35. No. 4. P. 167-180. DOI: https://doi.org/10.15407/cryo35.04.167
21. Shapovalova V.O., Nevzghoda O.A., Shapovalov V.V., Osyntseva A.O., Shapovalov V.V. Tuberculous Pleural Disease (Pleuritis, Empyema): Clinical Perspective on First-Line Antituberculosis Medicines and Manufacturer-Based Content Analysis. *Tuberculosis, Lung Diseases, HIV Infection*. 2026. No. 1. P. 36-40. DOI: https://doi.org/10.30978/TB2026-1-36

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