GAP ANALYSIS AND SWOT ANALYSIS OF PHARMACOPOEIAL QUALITY STANDARDS OF CALENDULAE FLOS: EXPERIENCE OF UKRAINE AND FRANCE

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Introduction

Standardization of medicinal plant raw materials is one of the key elements in ensuring the quality, efficacy, and safety of medicinal products [1]. Herbal preparations occupy an important place in modern pharmaceutical practice, and their quality control is based on clearly defined pharmacopoeial requirements. The flowers of Calendula officinalis L. (marigold) are one of the most common and sought-after types of herbal raw materials due to their anti-inflammatory, antiseptic, and reparative properties [2]. They are widely used in the production of dosage forms for dermatology, dentistry, and gynecology, which emphasizes the relevance of their quality standardization [3].

In the context of Ukraine's integration into the European pharmaceutical space, the harmonization of national pharmacopoeial requirements with the requirements of the world's leading pharmacopoeias is of particular importance. Compliance of domestic standards with European ones will contribute to increasing confidence in the products of Ukrainian manufacturers and create the prerequisites for expanding the export of medicinal products of herbal origin. In this process, a comparative analysis of the requirements of the SPhU and the Pharmacopée française for calendula flowers, which are a typical example of medicinal plant raw materials with a long tradition of use and a wide presence on the international market, is important [2, 4].

The purpose of the study was to conduct a comparative analysis of the quality indicators of calendula flowers according to the monographs of the State Pharmacopoeia of Ukraine (SPhU) and the Pharmacopée française using the tools of SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis and GAP (Gap Analysis Process) analysis. The objectives of the study are:

- systematization and comparison of pharmacopoeial requirements for Calendulae flos;
- identification of similarities and differences between the Ukrainian and French approaches to standardization;
- assessment of the strengths and weaknesses, opportunities, and threats of national approaches in the context of harmonization;
- formulation of practical recommendations for improving pharmacopoeial standards in Ukraine.

Materials and methods

The study used official pharmacopoeial sources: the monograph "Calendulae flos" SPhU and the corresponding monograph Pharmacopée française [1, 2].

For an in-depth comparison, additional regulatory and methodological documents were used: European Pharmacopoeia (11th edition, 2023) [4], World Health Organization Monographs on Selected Medicinal Plants [5], ESCOP Monographs [6], as well as the report of the European Medicines Agency on Calendula officinalis [7].

The supporting materials were scientific publications devoted to the issues of standardization of medicinal plant raw materials, chemical composition, and pharmacological activity of Calendula officinalis [8-21]. This allowed integrating official regulations with current scientific data.

The research methodology was based on several approaches:

- *Comparative analysis:* a comparison of key quality indicators (macro- and microscopic features, identification reactions, impurities, ash content, loss on drying, quantitative determinations) in SPhU and Pharmacopée française was carried out.
- *SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis:* used to identify the strengths and weaknesses of the national and French pharmacopoeial systems in regulating the quality of calendula flowers, as well as to assess opportunities and threats in the context of harmonization of standards.
- *GAP (Gap, Analysis, Process) analysis:* used to identify discrepancies between the requirements of SPHU and Pharmacopée française with an emphasis on identification tests, purity indicators, and quantitative methods.
- *Analytical tables:* general comparative tables were constructed, demonstrating the similarities and differences of the requirements of the two pharmacopoeias.

This approach provided a comprehensive study of the harmonization of pharmacopoeial standards for Calendulae flos and made it possible to develop recommendations for improving the national pharmacopoeia.

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Results and discussion

Calendula officinalis L. is one of the most common and well-studied medicinal plants, which has a centuries-old history of use in folk and official medicine. In different countries of the world, it has been used as a means for healing wounds, treating skin diseases and as a natural antiseptic. In modern medicine and pharmacy, it retains its importance due to a rich complex of biologically active substances, among which flavonoids, triterpenoids, saponins, essential oil, carotenoids and phenolic compounds play a key role. Flavonoids provide antioxidant action, help reduce inflammation and strengthen the vascular wall; triterpenoids and saponins exhibit a pronounced anti-inflammatory and reparative effect; carotenoids cause antioxidant and immunomodulatory properties, and essential oil and phenolic compounds enhance antiseptic and antimicrobial effects [22].

Due to this diverse composition, calendula is a universal herbal remedy. It exhibits anti-inflammatory, antimicrobial, antiseptic, reparative, antispasmodic and choleretic properties. Preparations based on calendula flowers are widely used in dermatology for the treatment of eczema, dermatitis, cracks, and burns; in dentistry – for gingivitis, stomatitis, and periodontitis; in gynecology – for the treatment of cervical erosion, vaginitis, and cervicitis; in gastroenterology – as an adjuvant for peptic ulcer, gastritis, and colitis [23].

In the pharmaceutical industry, calendula flowers are used as raw materials for the manufacture of a wide range of dosage forms. Based on officinal and standardized extracts, infusions, liquid extracts, ointments, gels, creams, rinse solutions, suppositories, phytocompositions, as well as combined preparations in combination with other medicinal plants are produced. In addition, calendula is a component of dietary supplements, cosmetics, and veterinary drugs [1].

The growing interest in this medicinal plant in the world is associated with the trend towards the use of natural and safe remedies, as well as with proven effectiveness in many diseases, which is confirmed by modern clinical and pharmacological studies. That is why the issue of standardization and harmonization of quality requirements for calendula flowers is extremely relevant in the context of the development of pharmacopoeial systems and the integration of Ukraine into the European pharmaceutical space [7].

In the State Pharmacopoeia of Ukraine, the monograph on calendula flowers (Calendulae flos) contains clearly formulated quality criteria that ensure the authenticity and safety of medicinal plant raw materials. First, the document defines identification requirements, which include both macroscopic and microscopic characteristics. Macroscopic features include the color of the ligulate flowers, which varies from light yellow to bright orange, the structure of the basket wrapper, and the characteristic weakly aromatic odor. Microscopic features include the specific structure of the epidermis, the presence of glandular and simple trichomes, and the characteristic shape of pollen grains, which allows us to clearly distinguish this plant material from possible impurities [1].

Modern instrumental methods are used to confirm the identity. Thin-layer chromatography allows us to detect the characteristic spectrum of flavonoids and other phenolic compounds inherent in Calendula officinalis. Additionally, spectrophotometry can be used, which provides a quantitative assessment and confirms the presence of marker substances [1].

Purity indicators include moisture (determined by loss in mass upon drying), the content of total and acid-insoluble ash, the presence of foreign impurities of plant or mineral origin, and compliance with the requirements of microbiological purity. These criteria are important for preventing microbial contamination and ensuring the safety of raw materials for their further use in the production of medicinal products.

Quantitative determination in SPhU is based on the determination of the content of flavonoids, which are considered marker biologically active substances of calendula flowers. Most often, the content is expressed in terms of hyperoside or other standard compounds, which allows for a unified approach to quality control. Such an approach not only guarantees the stability of pharmacological activity, but also creates the basis for harmonization with European and international standards.

The Pharmacopée française contains a monograph on Calendulae flos, which is similar in structure to the provisions of the SPhU, but has several specific features that reflect modern trends in pharmacopoeial regulation. Particular attention is paid to detailed macroscopic and microscopic identification. The macroscopic description includes not only the visual characteristics of the color and shape of the ligulate flowers, but also the exact parameters of their size, which allows to avoid confusion with other types of plant materials. Microscopic characteristics cover the structure of pollen grains, their morphometric parameters, as well as the presence of specific secretory structures that are diagnostically significant [2].

Analytical identification in the French Pharmacopoeia is based on the mandatory use of thin-layer chromatography. In this case, the profile should include both flavonoids and triterpene saponins, which provides a more comprehensive control of the chemical composition. The regulated conditions for the method allow for reproducible results and comparison with the corresponding standard samples.

The “Purity” section of the Pharmacopée française contains several provisions that distinguish it from national standards. In addition to the requirements for loss in mass upon drying, total and sulfated ash content, and control of foreign impurities, the French edition provides for mandatory testing for residual

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pesticides, mycotoxins, and heavy metals. This approach reflects the pan-European trend towards increasing the safety of medicinal plant raw materials in the face of modern environmental challenges and the intensification of agricultural production.

A separate feature of the French monograph is the inclusion of methods for the quantitative determination of not only total flavonoids, but also carotenoids. This expands the range of controlled biologically active substances and allows for a more objective assessment of the quality of the raw material, considering its pharmacological activity. Thus, the requirements of the Pharmacopée française can be considered more detailed and comprehensive than those of the SPhU, making them a valuable reference for harmonizing national standards with European approaches.

The European Pharmacopoeia, in its monograph on Calendulae flos, provides requirements that are generally consistent with the standards of national pharmacopoeias, but are more detailed and unified. The European Pharmacopoeia defines macroscopic and microscopic characteristics, provides identification criteria by thin-layer chromatography, and quality parameters under the heading “Purity” (loss on drying, ash content, impurities). A special feature is the mandatory use of pharmacopoeial reference materials to ensure reproducibility of results, which increases the reliability of control [4].

The World Health Organization focuses primarily on the safety and traditional use of calendula flowers in its monographs. Publications of the World Health Organization emphasize the centuries-old practice of using this raw material for inflammatory diseases of the skin, mucous membranes, and gastrointestinal tract. At the same time, standardization of the drug is recommended mainly by the content of flavonoids, which are the main group of biologically active substances that cause pharmacological action [24].

The European Medicines Agency, particularly the Committee for Herbal Medicinal Products, in its reports recognizes the traditional use of Calendulae flos as justified, but emphasizes the need for strict control of the chemical composition. The European Medicines Agency draws attention to the importance of the absence of toxic impurities, pesticides, and heavy metals, as this is a critical factor for the safety of medicinal herbal raw materials. The documents of the Committee for Herbal Medicinal Products also emphasize the need for additional preclinical and clinical studies to confirm the effectiveness and safety of individual forms of drugs [25].

Thus, compared to the SPhU, the requirements of the Pharmacopée française and the European Pharmacopoeia are more detailed and harmonized in the European context. The World Health Organization and the European Medicines Agency play the role of a reference base, ensuring the consistency of the traditional use of calendula with modern criteria for safety and efficacy. This allows for a more holistic view of approaches to standardization and regulatory control of Calendulae flos in international practice.

A comparative analysis of the requirements of the SPhU and the Pharmacopée française for the standardization of Calendulae flos allows us to identify both common features and significant differences in the regulation of the quality of this medicinal plant raw material.

GAP analysis

To systematize the data, a GAP analysis was conducted, which covers the main groups of indicators: macro- and microscopic signs, identification reactions, purity criteria, physicochemical parameters, and quantitative determination of marker substances.

Table 1 presents key characteristics that allow comparing the positions of the two pharmacopoeias and outlining gaps in domestic regulatory provision.

Table 1. GAP analysis of requirements for Calendulae flos in SPhU and Pharmacopée française

Parameter	SPhU	Pharmacopée française	Differences/coincidences
Macroscopic features	Description of reed flowers, color, odor, structure of the integument	Detailed description of flower size, morphological details, including variations in shape and color	Concordance in general characteristics, but the French Pharmacopoeia provides more detailed morphometric criteria
Microscopic features	Structure of the epidermis, trichomes, pollen grains	Extended description of secretory structures, pollen morphometry, diagnostic tissue features	The French Pharmacopoeia is more detailed, includes specific markers
Identification reactions	Thin layer chromatography (flavonoids), spectrophotometry	Thin-layer chromatography with a regulated profile of flavonoids and saponins	The Pharmacopée française has a broader list of markers, and the control of chemical composition is more complex
Impurities (mineral, organic)	Determined impurities, regulated %	Clearly established maximum permissible values, pesticides and heavy metals are additionally regulated	The SPhU is less detailed, the FF has stricter environmental criteria

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Parameter	SPhU	Pharmacopée française	Differences/coincidences
Loss in mass upon drying	Regulated % (within pharmacopoeial standards)	Similar requirements, with clarification of the determination method	Concordance with minor technical differences
Ash content (total, sulfated, insoluble)	Determined total ash and acid insoluble matter	Total, sulfated and insoluble ash are determined	The Pharmacopée française has a broader range of ash values
Extractives content	Determination of the total content of extractives is provided	Can be given in the context of assessing the content of biologically active substances	The SPhU has a clearer focus on extractives
Purity tests	Microbiological purity, impurities	Pesticides, heavy metals, mycotoxins, microbiological purity	The Pharmacopée française has much broader purity control
Quantitative determination of marker substances	Flavonoids (in terms of hyperoside or other markers)	Total flavonoids and carotenoids, thin-layer chromatography for saponins	The Pharmacopée française has multicomponent control, while the SPhU is limited mainly to flavonoids

The obtained data indicate that the general approaches of the SPhU and the Pharmacopée française are comparable, however, the national pharmacopoeia demonstrates a lower level of detail and breadth of coverage of indicators. The most significant gaps were identified in the following areas:

1. *Control of impurities and purity.* The SPhU regulates the content of foreign impurities and microbiological purity to a limited extent, while the French pharmacopoeia sets strict requirements for residual pesticides, heavy metals, and mycotoxins. This makes the French standards more relevant to modern environmental challenges.
2. *Quantitative determination of biologically active substances.* The SPhU is limited to the determination of flavonoids, while the Pharmacopée française additionally considers carotenoids and saponins, which allows for a more comprehensive assessment of the quality of Calendulae flos.
3. *Identification methods.* Both pharmacopoeias provide for thin-layer chromatography, but the French version has a wider range of marker compounds and more detailed analysis conditions.
4. *Morphological and microscopic identification.* Although both documents describe macro- and microscopic features, the French Pharmacopoeia emphasizes morphometric parameters and secretory structures, which allows for increased accuracy of identification.

Thus, the GAP analysis demonstrated the need for a gradual expansion of the SPhU provisions, considering the best practices of the Pharmacopée française and the European Pharmacopoeia. This primarily concerns the introduction of modern approaches to raw material safety control and a comprehensive assessment of its biologically active composition.

The analysis of the results showed that the SPhU, in comparison with the Pharmacopée française, has several gaps that may limit the qualitative standardization of plant raw materials. First, it is worth noting the insufficient detail of identification tests: the SPhU provides general approaches to macro- and microscopic analysis, while in the French Pharmacopoeia these descriptions are more detailed and supplemented with additional identification reactions. This makes it difficult to standardize control for different batches of raw materials.

Another difference is the smaller list of purity indicators. In the SPhU, it is limited to basic parameters, while the Pharmacopée française pays more attention to impurities of various origins, including more detailed tests for mineral and organic contamination. This difference reduces the sensitivity of quality control in the national pharmacopoeia.

In addition, in the SPhU, quantification is limited to the total content of extractives, without isolating specific marker compounds (e.g. flavonoids or saponins). In contrast, the Pharmacopée française provides tools for a more targeted standardization by biologically active components. This is an important aspect, since it is the marker substances that determine the pharmacological activity of calendula and serve as the basis for the correlation between the quality of the raw material and its therapeutic effect.

The Pharmacopée française is distinguished by a more detailed and comprehensive approach to the standardization of Calendula officinalis flowers compared to the SPhU. Firstly, a much wider range of identification reactions allows for increased accuracy in controlling the authenticity of herbal raw materials and reducing the risk of falsification. Such requirements provide the possibility of confirming botanical origin from various analytical perspectives.

An important addition is the emphasis on the quantitative determination of specific marker compounds, in particular flavonoids. This creates a basis for the correlation between the qualitative composition and the therapeutic effect, which is of particular importance when using calendula in medical practice.

The Pharmacopée française also provides for more extensive control of impurities, including detailed criteria for mineral, organic and microbiological contaminants. This meets the modern requirements of the EU pharmacopoeia, where the safety of medicinal herbal raw materials is of key importance.

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Of particular note are the refined methods of quantitative determination, which use modern analytical approaches such as spectrophotometry or thin-layer chromatography. This allows for greater reproducibility and reliability of results compared to traditional methods that prevail in SPhU.

SWOT analysis

To summarize the results of the comparison of pharmacopoeial requirements for Calendulae flos and determine the prospects for improving the national regulatory framework, it is advisable to conduct a SWOT analysis. This method allows you to systematically assess the strengths and weaknesses of the approaches, identify potential development opportunities and outline threats that may arise in the process of harmonizing Ukrainian standards with European ones. SWOT analysis is a useful tool for strategic planning, as it combines the internal characteristics of the object (strengths and weaknesses) with external factors (opportunities and threats).

In the context of pharmacopoeial standardization of calendula flowers, SWOT analysis allows you to identify the strengths of the SPhU. For example, the presence of unified basic quality indicators. As well as its weaknesses, in particular, a limited set of identification tests and less detailed purity requirements. On the other hand, opportunities lie in harmonization with international requirements and the introduction of modern analysis methods, while threats may be associated with the risk of lagging behind in the event of untimely updating of national standards.

Table 2. Results of SWOT analysis

Strengths:	**Weaknesses**
○ SPhU: availability of officially approved standards for Calendulae flos; basic identification tests; integration into the system of pharmacopoeial standards at the European level. ○ Pharmacopée française: more detailed requirements for marker substances (flavonoids); modern methods of quantitative analysis; a wider range of purity tests.	○ SPhU: insufficient detail on specific markers; limited quantitative methods; lack of extended microbiological purity indicators. ○ Pharmacopée française: possible discrepancies with the European Pharmacopoeia and other international standards; difficult to implement in laboratories with limited resources.
Opportunities	**Threats**
○ Harmonization of national standards with the Pharmacopée française and the European Pharmacopoeia. ○ Introduction of modern analytical methods into the practice of quality control of pharmaceutical products. ○ Expansion of the scientific and methodological base for the use of calendula in the pharmaceutical industry. ○ Increasing the international recognition of the national pharmacopoeia.	○ Risk of SPhU lagging behind European standards. ○ Possible failure to consider specific marker indicators during quality control. ○ Complications of exporting Ukrainian raw materials due to non-compliance with the requirements of foreign pharmacopoeias.

The SWOT analysis revealed both the advantages and disadvantages of the national pharmacopoeial system compared to European standards. Among the strengths, the SPhU has its own regulatory documents regulating the quality of plant raw materials, including calendula flowers, as well as its focus on modern scientific approaches in pharmacognostic analysis. At the same time, it is important that the SPhU is gradually integrating the provisions of the European Pharmacopoeia, which contributes to the harmonization of requirements.

The weaknesses relate to the insufficient detail of the requirements for the quantitative determination of marker substances (particularly flavonoids), a limited list of purity indicators and microbiological control, as well as the lack of unified modern analysis methods recommended in the Pharmacopée française and the European Pharmacopoeia.

The analysis of opportunities showed that harmonization with European pharmacopoeial standards creates the prospect of improving the quality of medicinal plant raw materials, ensuring their compliance with the requirements of the international market, and expanding the export of domestic drugs. In addition, the integration of modern analytical methods will improve the scientific and regulatory basis for pharmacopoeial control.

Among the threats identified are the risk of reducing the competitiveness of Ukrainian producers in case of delay in harmonization, a possible increase in the costs of implementing modern analytical methods, and the need for additional training of specialists.

In general, the results of the SWOT analysis indicate the need for further improvement and adaptation of the SPhU to European requirements. This will not only improve the quality and safety of medicinal plant raw materials, but will also ensure the integration of Ukraine into the global pharmaceutical community.

A comparative analysis of the SPhU and Pharmacopée française monographs shows that both documents are aimed at ensuring an adequate level of quality control of calendula flowers and are based on generally accepted principles of pharmacopoeial

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standardization. Similarities, in the macro- and microscopic characteristics of plant raw materials, confirm a certain unification of basic approaches, which allows for the correct identification of the medicinal plant and the prevention of falsifications. This is an important indication of the preservation of uniform criteria at the international level.

However, the analysis also revealed significant differences. The French Pharmacopoeia describes identification features in much more detail, including specific analytical profiles of flavonoids and saponins. In addition, the purity requirements in the Pharmacopée française are supplemented by standards for pesticide residues and heavy metals, which reflects modern European environmental and toxicological standards. While the SPhU offers more generalized approaches, the French standard demonstrates a higher level of harmonization with the provisions of the European Pharmacopoeia.

Thus, the similarities can be considered as a basis for international mutual recognition of standards, while the identified differences indicate potential areas for improving the national regulatory framework, which will increase its compliance with the modern requirements of the EU pharmaceutical market.

The results of the study have direct practical significance for the development of the domestic pharmaceutical industry. Firstly, increasing the level of standardization of medicinal plant raw materials, in particular calendula flowers, will ensure stable product quality at all stages of its production and circulation. This is especially important for ensuring the safety and effectiveness of finished dosage forms used in medicine and pharmacy.

Secondly, the results of the comparative analysis create a basis for improving domestic pharmacopoeial requirements, considering the best European practices. The identified gaps in the SPhU can become a reference point for scientists, standard developers and regulatory authorities when reviewing or updating national monographs. In particular, the integration of requirements for the quantitative determination of specific marker compounds, as well as the expansion of purity indicators to the level of European standards will contribute to more complete harmonization with the European Pharmacopoeia.

Thirdly, the implementation of improved requirements will increase the competitiveness of Ukrainian herbal raw materials on the international market. This opens prospects for expanding exports and integrating Ukraine into the EU pharmacopoeial space, which is an important step towards deepening cooperation with European pharmaceutical companies. A high level of standardization will also contribute to increasing trust from foreign partners and regulators, which has a positive impact on the investment attractiveness of the industry.

Thus, the analysis not only allows us to identify key differences in the requirements of different pharmacopoeias, but also determines strategic directions for improving the national regulatory framework to ensure the quality, safety, and effectiveness of herbal medicinal raw materials.

The analysis of the identified differences between the SPhU and the Pharmacopée française allows us to outline several strategic directions for improving the national pharmacopoeial requirements for calendula flowers and medicinal herbal raw materials in general.

First, it is advisable to introduce modern methods for identification and quantification of biologically active substances. The use of spectrophotometry, thin-layer and high-performance liquid chromatography will increase the accuracy and reproducibility of control results, as well as provide the possibility of simultaneous determination of several groups of marker compounds.

Secondly, a promising direction is to expand the spectrum of marker substances by which standardization is carried out. If at present the SPhU focuses mainly on the total content of extractive substances or flavonoids, then the inclusion of saponins and carotenoids in the list will allow obtaining a more comprehensive characterization of pharmacologically significant components of calendula.

Thirdly, it is necessary to clarify and detail the requirements for purity indicators. Modern international practice provides for mandatory control of microbiological purity, residual pesticides, heavy metals, and toxic impurities, which should be integrated into domestic standards to ensure the proper level of safety of raw materials.

Fourthly, an important step is the periodic updating of monographs considering the latest scientific data and experience of European countries. This will allow us to respond in a timely manner to changes in pharmacopoeial requirements, implement innovative analysis methods, and maintain the relevance of the national regulatory framework.

Finally, one of the key tasks is to further harmonize with the European Pharmacopoeia and Pharmacopée française as leading reference systems. This will not only contribute to the unification of requirements, but also ensure the integration of Ukraine into the European pharmacopoeial space, increasing international trust in domestic medicinal plant raw materials.

Within the framework of this study, we continue our work aimed at harmonizing national legislation and pharmacopoeial requirements with European standards. This corresponds to the current trends of Ukraine's integration into the common scientific and pharmaceutical space of the European Union, which is reflected in numerous scientific publications by domestic authors devoted to issues of regulatory policy, quality control, standardization, diagnosis of health disorders in accordance with ICD-11, pharmacoeconomics, pharmacotherapy and legal aspects of the circulation of medicinal products of various clinical-pharmacological, classification-legal and nomenclature-legal groups. [26–41]. Such studies form the scientific basis for the adaptation and improvement of the provisions of the SPhU, which will ensure greater transparency, trust, and

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competitiveness of Ukrainian pharmaceutical products on the international market.

Conclusions

A comparative analysis of pharmacopoeial requirements for calendula flowers according to the SPhU and Pharmacopée française data using GAP and SWOT analysis tools made it possible to identify key differences and points of contact between the two regulatory systems. The GAP analysis showed that the SPhU does not provide sufficient detail in identification tests, the spectrum of purity indicators is less fully represented, and the quantitative determination of marker compounds is limited mainly to general parameters. In contrast, the French Pharmacopoeia is distinguished by an expanded set of identification reactions, clear regulation of the profile of marker substances (particularly flavonoids and carotenoids) and a modern approach to purity control, including analysis for pesticides, heavy metals, and microbiological indicators.

The SWOT analysis made it possible to identify the strengths of both systems, including the presence of clear macro- and microscopic criteria and the use of chromatographic identification methods. At the same time, the weaknesses of the SPhU were outlined, which consist in insufficient harmonization with modern European standards. The identified opportunities are related to borrowing the positive experience of the Pharmacopée française and the European Pharmacopoeia, while the threats relate to the risk of losing the competitive position of Ukrainian herbal raw materials on the international market if the current shortcomings persist.

The recommendations based on the results of the study are reduced to the need to introduce more modern methods of quantitative analysis (in particular, spectrophotometry and high-performance liquid chromatography), detailing the requirements for marker groups of compounds, expanding the list of purity indicators and microbiological control. An important strategic direction is the harmonization of the SPhU with the Pharmacopée française and the European Pharmacopoeia, which will contribute to bringing national standards into line with international requirements.

Improving the SPhU based on the identified gaps and opportunities will allow to increase the level of standardization of calendula flowers, ensure stable quality and safety of herbal preparations, and strengthen the competitiveness of Ukrainian pharmaceutical products on the global market.

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GAP-analysis and SWOT-analysis of pharmacopoeial quality standards of Calendulae flos: experience of Ukraine and France

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The article considers the issue of harmonization of requirements for standardization of medicinal plant raw materials using the example of Calendula officinalis flowers in the context of the State Pharmacopoeia of Ukraine and the Pharmacopée française. **Introduction.** The relevance of the topic is substantiated in connection with the need to improve the quality, safety, and competitiveness of domestic herbal medicines, as well as the integration of Ukraine into the European pharmacopoeial space. **Purpose.** The purpose of the study was to conduct a comparative analysis of the requirements of the State Pharmacopoeia of Ukraine and the Pharmacopée française for Calendulae flos, identify the strengths and weaknesses of domestic regulation and formulate recommendations for harmonization with European standards. **Materials and methods.** Methods of comparative analysis of regulatory documents, GAP (Gap Analysis Process), and SWOT (Strengths, Weaknesses, Opportunities, Threats) analyses were used to identify differences and similarities in the requirements for identification, purity, and quantification of marker substances. Additionally, data from the European Pharmacopoeia, the World Health Organization and the European Medicines Agency were used as a reference base. **Results and discussion.** Shown that the State Pharmacopoeia of Ukraine contains basic requirements for macro- and microscopic characteristics, thin-layer chromatography and purity indicators, but less detailed identification tests, a limited list of purity indicators and a narrower approach to quantification compared to the Pharmacopée française. The French Pharmacopoeia, unlike the Ukrainian one, focuses on specific marker compounds (flavonoids, carotenoids), control of impurities (including pesticides and heavy metals) and modern methods of analysis. SWOT analysis revealed the strengths of both systems, but showed the need to improve domestic standards. **Conclusions.** The analysis confirmed that the harmonization of the State Pharmacopoeia of Ukraine with the Pharmacopée française and the European Pharmacopoeia is an important condition for increasing the level of standardization of medicinal plant raw materials in Ukraine. The introduction of modern identification methods, expanding the list of marker substances and purity indicators will help guarantee the safety and effectiveness of medicinal products of herbal origin, and will also strengthen the competitive position of domestic products on the international market.

Keywords: Calendula officinalis, calendula flowers, State Pharmacopoeia of Ukraine, Pharmacopée française, standardization, quality of medicinal plant raw materials, GAP analysis, SWOT analysis, harmonization of pharmacopoeias.

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