

### 1. Introduction

Provision of citizens' working ability by maintaining their health through the availability of effective medicines is a priority for scientists and practitioners of pharmacy.

The development of a medicinal product is a very complex, multifactorial and multistage process. The ultimate goal of this process is to obtain a quality product. Information obtained during the research in the course of pharmaceutical development can serve as a basis for managing the risks to quality. It is important to understand that quality can not be only checked in preparations – quality should be considered in the design.

Pharmaceutical development of a new drug is based on such components as development of the methodological approach, medical and biological requirements for medicines, pharmacotechnological tests, marketing analysis of the modern pharmaceutical market, etc. [1].

The aim of the work is to develop and justify the composition of a new pharmaceutical preparation in the form of hard gelatin capsules based on a dry extract of hop cones for use in gastroenterological practice.

### 2. Methods

A search and generalization of the data of information and scientific primary sources concerning preparations based on the *Humulus lupulus* and the fields of their application have been performed. As information sources were used data from the State Register of Medicines of Ukraine, the directory "Compendium", phytotherapeutic reference books, Internet resources. The modern marketing method of SWOT-analysis, which allows determining the approaches to improving the competitive potential of a product, clarifying the main directions in the formation of a marketing program for creating and launching a new drug and a loyalty program has also been used.

### 3. Results

According to the purpose of this work, a research methodology, presented in the form of a flowchart in **Fig. 1** has been developed.

The effectiveness of drugs of both local and general action depends on the influence of a whole set of interrelated factors, the most important of which is the ability of the active in-

## SUBSTANTIATION OF THE MEDICINE WITH DRY EXTRACT OF HOP CONES IN THE FORM OF HARD GELATINE CAPSULES FOR TREATMENT OF GASTROINTESTINAL DISEASES DEVELOPMENT EXPEDIENCY

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**The aim of the work** was to justify the feasibility of developing a new drug with a dry extract of hop cones in the form of hard gelatin capsules for the treatment of gastrointestinal diseases.

**Methods.** In order to study the range of medicines based on hop cones on the pharmaceutical market of Ukraine, a marketing analysis of registered drugs has been conducted. The marketing analysis was carried out using the information of retrieval system "Drugs" by "Morion" LLC and the State Register of Medicines of Ukraine, which allows quickly tracking changes in the structure of offers. To systematize the main characteristics of the studied drug of hop cones, to assess its strengths and weaknesses, opportunities and threats, a modern marketing method – SWOT-analysis has been used. In the process of research, methods of system analysis, monitoring, logical generalization, grouping of marketing research, etc. were used.

**Results.** The methodology of research has been developed and justified. The main types of pharmacological activity of extracts from hop raw materials have been reviewed. A comprehensive study of the drug from hop cones using the SWOT-analysis method has allowed analyzing its strengths and weaknesses, which can contribute to or hamper the progress and consolidation of this drug in a certain market segment. It was revealed that the strengths of the drug are much greater than the weaknesses, and this speaks in favor of its competitiveness in the pharmaceutical market of Ukraine.

**The discussion of the results.** The medical and marketing expediency of developing a new medicinal preparation with a dry extract of hop cones in the form of capsules for use in gastroenterology have been proved.

**Keywords:** dry extract of hop cones, hard gelatin capsules, methodology, marketing methods of analysis, development, SWOT-analysis, GI diseases.

redient to optimally affect the damaged target tissues, as well as the characteristics of the dosage form auxiliaries that provide this capability. That is why, when creating new and improving existing medicines, the first task is to find an effective and safe active substance.

Common Hop, or Hop (lat. *Humulus lupulus*) – a species of herbaceous perennial plants of genus *Humulus* family Cannabaceae. In natural conditions hops inhabit the territories of North America and Canada [2].

Hops cones (female inflorescences) were originally used for the preparation of beer, berg and honey, later they were used in bakery and medicine.

Hop is a valuable medicinal plant. The main substances that determine the biological activity of hop cones are bitterness, phenolic compounds and essential oil. In addition, hop cones contain asparagine, triterpene compounds (hopanone and hydroxy-hopanone), vitamins (rutin, C, E, B1, B3, B6, H and PP). Medicines from hop cones have versatile pharmacological properties – soothing, analgesic, hypnotic, anti-inflammatory, capillary-strengthening, antiulcer [3].

The positive effect of galenic medicines of hop on metabolism, especially on the regulation of fat, mineral and water metabolism has been noted. The neurotropic effect of galenic preparations from cones of hop is associated with the presence of lupulin, which has a calming effect on the central nervous system. Anti-inflammatory, analgesic, bactericidal and antiallergic properties of

herbal preparations of the plant determine their therapeutic effectiveness in diseases of the skin and mucous membranes, accompanied by inflammatory lesions, allergic manifestations, itching and other symptoms [4, 5].

Hops are widely used in folk medicine. Infusion or decoction of hop cones intensifies digestion, they are recommended in kidney and liver diseases, gastritis, dropsy, jaundice, neuralgia, insomnia [6].

Bitter acids of hops possess antibacterial and antifungal activity. In particular, the activity of humulone and lupulone in relation to gram – positive bacteria has been established. Antiviral action of iso- $\alpha$ -acids against DNA and RNA viruses was also established [7].

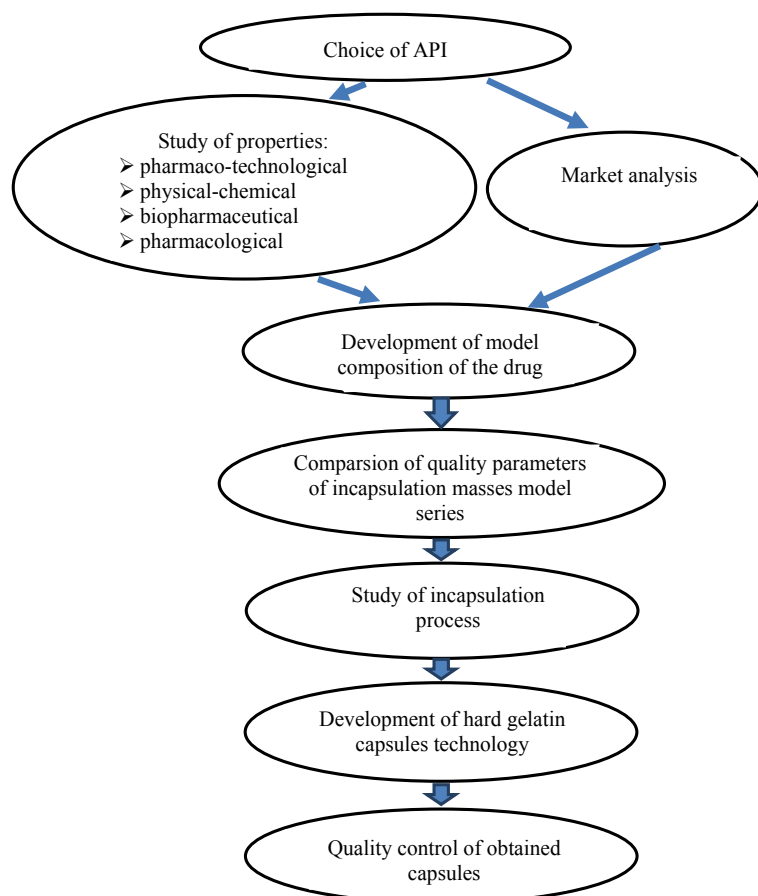


Fig. 1. The research methodology for the development of a drug in the form of hard gelatin capsules

The therapeutic effect of hops in diseases of the gastrointestinal tract is caused by bitter compounds that are part of the lupulin. Water infusions from mature hop inflorescences are prescribed to improve appetite, digestion in chronic hyposecretory gastritis, gastroenteritis, diseases of the gallbladder and liver. In patients with chronic gastritis with secretory deficiency, the use of a decoction of hop cones (1:5) promotes strengthening of gastric secretion and evacuation function of the stomach [8, 9].

An analysis of the modern pharmaceutical market has been conducted which has shown that extracts from the raw material of hop are included in the composition of the drugs presented in Table 1.

A similar composition and indications for use have some preparations produced in Germany – dragee “Ardeyson”, “Nervenruh forte”, tablets “Seda Kneipp”; in Hungary – tablets “Hovaletten”; in Slovenia – drops “Valosedan”. Also, the data on the use of substances from hops in the production of many food supplements with a recommendation for use as sedatives and hypnotics have been found [10, 11].

As can be seen from the results given in Table 1, pharmaceuticals with hops are used in the treatment of insomnia and nervous disorders, as well as in diseases of certain parts of the gastrointestinal tract.

At the same time, data from literature sources and studies conducted at the departments of pharmacognosy and physiology with the fundamentals of anatomy of the National University of Pharmacy (Kharkov, Ukraine), indicate the presence of anti-inflammatory and reparative activity in the dry extract of hop cones.

Table 1  
Nomenclature of preparations based on common hop

Name of medicinal product	The form of release, manufacturer	Type of substance from common hop	Pharmacologic effect
Cones of common hop	Blend PJSC "Lektravy", Ukraine	Medicinal plant raw materials	Sedative, anti-inflammatory, reparative
Valocordin	Drops; Krewel Meuselbach, Germany	Essential oil	Sedative, hypnotic, spasmolytic
Corvaldin	Drops; PJSC Farmak, Ukraine	Essential oil	Sedative, hypnotic, spasmolytic
Herbion	Drops; KRKA, Slovenia	Water-alcohol extract	Sedative, hypnotic
Detoxifit	Blend SIC "Aim" Ltd, Ukraine	Medicinal plant raw materials	Cholagogue, antispasmodic, anti-inflammatory, capillaroprotective and decongestant
Calming blend	Blend PJSC "Lektravy", Ukraine	Medicinal plant raw materials	Sedative
Sedative blend number 2	Blend CJSC PF "Viola", Ukraine	Medicinal plant raw materials	Sedative
Nervoflux	Instant tea; Aventis/Rhone-Poulenc Rorer, France	Dry extract	Sedative, hypnotic
Novo-Passit	Solution, tablets; Galena, Czech Republic	Extract	Sedative, anxiolytic
Sanason	Tablets; Lek, Slovenia	Extract	Sedative, hypnotic
Lekson	Solution SE «GNTSLs», Ukraine	Water-alcohol extraction	Sedative, hypnotic
Sedavit	Tablets, solution; Arterium Corporation, Ukraine	Extract	Anxiolytic
Urolesan	Capsules; Drops; Arterium Corporation, Ukraine	Extract	Antibacterial, choleric
Trivalumen	Capsules; PJSC SPC "Borschagovsky CPP", Ukraine	Extract	Sedative, anti-inflammatory, diuretic, choleric

Therefore, we consider it advisable to conduct research on the development of the composition and technology of a solid dosage form for the treatment of pathologies caused by inflammation in the internal organs, for example gastritis or gastric ulcer [4, 6].

According to the developed methodology (Fig. 1), a strategic approach to creating new medicines as vital goods requires marketing justification for their implementation. Considerable attention and efforts are given to the study of the macro- and microenvironment of the medicines' target market segment, determination of the social and medical need for a new drug, its competitiveness, innovation, economic efficiency and commercial attractiveness.

It was previously established that hop cones are used in official and folk medicine, in homeopathy, cosmetology and have sedative, antispasmodic, analgesic, anti-inflammatory, antiulcer, antiallergic, regenerative, bactericidal, fungicidal, diuretic action in the forms of tincture, oil, infusion, extract, blend, capsules, dragee, ointments [12].

In order to systematize the main characteristics of the drug from hop cones, to assess strengths, weaknesses, opportunities and threats, the modern marketing method of SWOT-analysis has been used. The results are given in Table 2.

Thus, conducted marketing and medical studies confirm the advisability of developing a new drug with a dry extract of hop cones in the form of complex action capsules for the treat-

ment and prophylaxis of patients with functional disorders of the gastrointestinal tract.

## 4. Discussion

The methodology for the creation of hard gelatin capsules for use in gastroenterology has been substantiated. It includes such basic stages of research as goal formation, marketing, technological, physico-chemical, biopharmaceutical and biological studies.

The properties of the active pharmaceutical ingredient, namely the dry extract of hop cones, which is selected as the object of the study in the development of a medicament for the treatment of gastrointestinal diseases, have been considered.

Marketing and medico-sociological studies were conducted, which confirmed the advisability of developing a new medicinal product with a dry extract of hop cones in the form of capsules for the treatment and prophylaxis of patients with functional disorders of the gastrointestinal tract.

A comprehensive study of the drug using the SWOT-analysis has allowed analyzing its strengths and weaknesses, which can contribute to or hamper the progress and consolidation of this drug in a certain market segment. It was revealed that the strengths of the drug are much greater than the weaknesses, and this speaks of its competitiveness in the pharmaceutical market.

The results obtained in the study might be used in the development and industrial implementation of hard gelatin capsules for GIT diseases treatment.

**Table 2**  
SWOT-analysis of medicines from dry hop cones extract

Strengths	Weaknesses
<ul style="list-style-type: none"> <li>– long-term successful experience of using the remedies from hop cones in folk medicine;</li> <li>– a wide range of pharmacological actions;</li> <li>– positive effect of the drug from medicinal plant material;</li> <li>– widely used in other countries;</li> <li>– used as a food additive;</li> <li>– are included in combined preparations, dietary supplements of domestic and foreign production;</li> <li>– absence of capsules with dry extract of hop cones;</li> <li>– variety of dosage forms;</li> <li>– wide range of prices from different manufacturers</li> </ul>	<ul style="list-style-type: none"> <li>– side effects:</li> <li>– light dizziness;</li> <li>– vomiting;</li> <li>– abdominal pain;</li> <li>– headache;</li> <li>– feeling tired and shattered;</li> <li>– dry mouth</li> </ul>
Opportunities	Threats
<ul style="list-style-type: none"> <li>– wide application for the prevention and treatment of diseases in various categories of patients;</li> <li>– application in combination with other agents;</li> <li>– significant expansion of the market segment;</li> <li>– expansion of indications for the use of the drug;</li> <li>– increase in the market share of the drug;</li> <li>– the possibility of applying a wide range of prices;</li> <li>– strengthening of information and promotional activities among target audiences;</li> <li>– carrying out of actions on increase of involvement of experts to preparations from hop cones;</li> <li>– increase in the number of offers on the market</li> </ul>	<ul style="list-style-type: none"> <li>– aggressive advertising of antiulcer drugs;</li> <li>– introduction of similar pharmacological action vegetable preparations on the market;</li> <li>– introduction of the new generation anti-ulcer drugs on the market;</li> <li>– conservatism of doctors;</li> <li>– "Price wars" of competitors;</li> <li>– the inclusion of competing drugs in the forms of patients treatment</li> </ul>

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