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RESEARCH ARTICLE

Methodology for Development of Pediatric Medicines for Complex Treatment of Diseases of Immune-Dependent Nature

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Abstract

The objective of the work is to substantiate methodology for development of pediatric medicines for complex treatment of diseases of immune-dependent nature. Materials and Methods: at the first stage of research, their objective was set, its significance for science and practical pharmacy was shown. At the information search stage, the need for new children's medicines was identified. The second stage of research involves determining the main directions of achieving the objective. The third stage is the choice and justification of means aimed at achieving the objective, namely, the objects and methods of research. The fourth stage is devoted to the complex of experimental studies on the development of pediatric medicines for complex treatment of diseases of immune-dependent nature. At the final stage of research technical conditions, relevant sections of registration dossier and projects of quality control methods for proposed medicines were developed. Results: based on the created general methodological concept of the development of pediatric medicines for complex treatment of diseases of immune-dependent nature, we have compiled a plan of experimental research, which is given in the article. Conclusion: methodology for development of pediatric medicines for complex treatment of diseases of immune-dependent nature has been substantiated.

Keywords: *Methodology, Development, Pediatric medicines, Diseases of immune-dependent nature, Treatment.*

Introduction

At the current level of development of the pharmaceutical industry, creation of new medicines is possible only in theoretical and experimental substantiation of the process of planning and conducting research. A methodological approach to pharmaceutical development allows optimizing the research on the development of medicine [1]. That is why, at the first stage of research, we were tasked with – to substantiate methodology of creation of pediatric medicines for complex treatment of diseases of immune-dependent nature. General algorithm for carrying out the planned theoretical and experimental studies is shown in Fig.

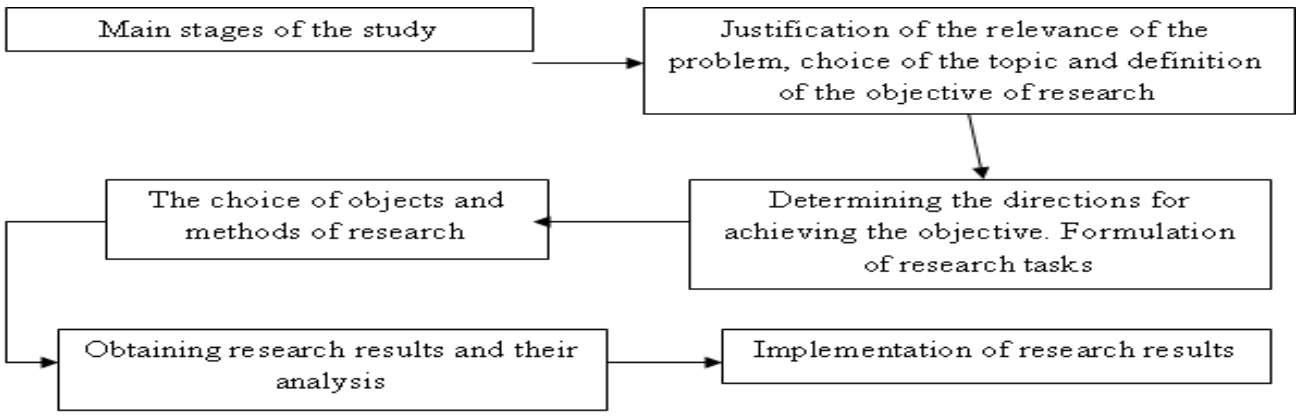

Fig.: General algorithm for carrying out the planned theoretical and experimental studies

Materials and Methods

As can be seen from the Fig., at the first stage of the implementation of research, their objective should be set, the definition of which requires a multifaceted substantiation of the relevance of the problem and the chosen topic, its significance for science and practical pharmacy. After analyzing the statistical data on the incidence of childhood, we concluded that today a growing number of diseases are becoming widespread, the underlying development of which is one or another violation of the immune system.

The pediatricians most often encounter different viral diseases, allergic inflammations of the skin, inflammatory processes of the mucous membrane of the mouth, etc., which require complex pharmacotherapy with medicines, both systemic and local effects [2].

At the information search stage, we identified the need for new children's medicines, primarily systemic action rectal suppositories with antiviral and immunomodulatory effects, as well as soft medicines for use in dermatology and dentistry. The promise of the creation of these medicines was confirmed by the search for competitive analogues in the pharmaceutical market. The second stage of research involves determining the main directions of achieving the objective. At the same time, great attention should be paid to the scientific novelties of future results, the practical and theoretical significance of the work. In addition, at this stage, the main tasks of research should be defined, each of which should flow from the objective of the work and linked organically to specific research areas.

The limited number of natural immunomodulators for children in the form of rectal suppositories and the presence of a very limited range of soft medicines for the treatment of diseases of the skin and oral cavity of the immune-dependent nature in the modern pharmaceutical market has set the objective of our research.

It is development of a number of medicines for complex treatment of diseases of immune-dependent nature in children in the form of rectal suppositories (systemic exposure medicine), ointment and dental gel (local action medicines). The above-mentioned determined the topic and the objective of our scientific research. The main objectives of research are presented in the Table.

Table: the main objectives of research

Name of the objective	Research tasks
Development of composition and technology of children's rectal suppositories, ointment and dental gel for complex treatment of pediatric diseases of immune-dependent nature	• theoretical substantiation of the proposed medicines development; • conducting experimental research on the choice of a rational bases of medicines; • experimental substantiation of medicines composition; • development of technology of rectal suppositories, ointment and dental gel; • development of methods for analysis and study of stability of proposed medicines; • Discussion of results of biological research of created medicines.

The third stage of the work is the choice and justification of means aimed at achieving the objective, namely, the objects and methods of research. The choice of research objects was carried out based on studying the requirements of existing normative documents for medicines used in pediatric practice, as well as taking into account medicinal and biological requirements for rectal suppositories, ointments and dental gels.

After studying the pharmacological activity of natural plant raw material and some synthetic compounds, in particular with antifungal effect, as research objects extract of licorice root, terbinafine hydrochloride, essential oils of chamomile, tea tree, lavender, sage and peppermint were chosen [3]. The range of recipients that will be used in the experiment and the methods of research widely used in pharmaceutical practice (physical, chemical, technological, biological, etc.) were selected. The fourth stage of the work is devoted to the complex of experimental studies on development of pediatric medicines for complex treatment of diseases of immune-dependent nature. At this stage, development of compositions of medicines, their technologies, definition of quality indicators were done.

Results and Discussion

At the beginning of research, we studied physical, chemical and biological properties of the main biological active substance of licorice root extract-Glycerin, which may

affect functional characteristics of medicines and possibility of their production. Because of conducted research, it was concluded that in the pharmaceutical development of medicines with licorice roots extract, the most effective are local ones (ointments, gels, etc.). As for systemic medicines, it is necessary, first, to choose the optimal route for their administration and to ensure maximum release of active pharmaceutical ingredients from the dosage forms. The choice of active substances concentration in development of compositions of rectal suppositories, ointment and dental gel was carried out by microbiological and biological methods.

At the given stage of research, the auxiliary substances and their concentrations were also selected taking into account their influence on functional properties of medicines (rheological parameters, stability, release in experiments in vitro, etc.) and quality indicators using methods of mathematical planning of the experiment [4]. When developing composition of pediatric medicines, studies on evaluation of the compatibility of medicinal substances with excipients and medicinal substances among themselves in development of combined medicines are important.

To evaluate compatibility, we used chromatographic methods as one of the most promising ones, which allow us to evaluate the formation of new chemical compounds and products of substances decomposition.

The technology of proposed medicines should be developed taking into account their properties as disperse systems, as well as properties of all components that are the part of their composition. In the process of pharmaceutical development, critical parameters of the technological process should be set, in order to guarantee the required quality of medicines.

Thus, for soft medicines and suppositories, the following properties are specific:

- Rheological parameters;
- Particle size of the disperse phase of emulsions and suspensions;
- Homogeneity in appearance and distribution of medicinal substances in the volume of the medicine;
- Formation of an unpredictable siege;
- Formation of disintegration products of medicinal substances during production process;
- Microbiological purity.

That is why, when developing rational technology of proposed medicines, we investigated their rheograms at different temperatures, values of structural viscosity and its dependence on temperature. Conducted studies allowed determining optimal mixing regimes, the temperature of production process and dosage of medicines [5].

Based on the analysis of microphotographs of medicines specimens at different magnifications, their homogeneity and particles size of dispersed phase were studied. At the standardization stage of developed rectal suppositories, ointment and gel, we have proposed methods for qualitative and quantitative determination of active substances in their composition using high-performance liquid and gas chromatography methods.

Microbiological purity studies have been carried out, stability has been investigated, and the shelf life of developed medicines has been set [6, 7]. At the final stage of implementation of research results, we developed technical conditions, relevant sections of registration dossier and projects of quality control methods for proposed medicines.

Technological instructions for preparation of medicines in pharmacies have been introduced into the work of a number of pharmacy establishments. Based on presented general methodological concept of development of pediatric medicines for complex treatment of diseases of immune-dependent nature, we have compiled a plan of experimental research:

- Determination of prospects for development of medicines for complex treatment of pediatric diseases of immune-dependent nature;
- Determination of optimal concentration of active substances based on the generalization of conducted microbiological and pharmacological studies;
- Selection of auxiliary substances in composition of medicines based on technological, physical, chemical and

biopharmaceutical research using methods of mathematical planning of the experiment;

- Development of rational technology of rectal suppositories, ointment and dental gel in industrial and pharmacy conditions;
- Development of analysis methods of active substances and establishment of quality indicators of proposed medicines;
- Studying their stability and shelf-life;
- Approbation of proposed medicines technology in industrial conditions;
- Drafting of analytical and technological documentation;
- Studying the main pharmacokinetic parameters of Glycyram – the main biological active substance of licorice root extract and generalization of biopharmaceutical and biological research of developed medicines;
- Projection of competitiveness of the proposed medicines.

Conclusion

Methodology for development of pediatric medicines for complex treatment of diseases of immune-dependent nature has been substantiated.

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