DEVELOPMENT OF THE TECHNOLOGY FOR RECTAL SUPPOSITORIES BASED ON LOCAL PLANT RAW MATERIALS FOR THE TREATMENT OF HEMORRHOIDS

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Abstract

This study is devoted to the development of a technology for rectal suppositories intended for the treatment of hemorrhoids based on local plant raw materials. In the course of the research, liquid and dry extracts were obtained from a herbal mixture consisting of calendula, horse chestnut, yarrow, chamomile, plantain, and other medicinal plants using a three-stage fractional maceration–circulation method. Based on the dry extract, suppositories were prepared using hydrophobic (GXM-5T) and hydrophilic (gelatin–glycerin) bases. The quality parameters of the finished products, including appearance, uniformity, mechanical strength, average weight, deformation, and melting time, were evaluated in accordance with the requirements of the State Pharmacopoeia. The results obtained indicate that all quality indicators of the developed suppositories meet regulatory standards and demonstrate promising potential for use in the treatment of hemorrhoidal disease.

Keywords: plant raw materials, dry extract, maceration–circulation, suppositories, hemorrhoids, quantitative parameters.

Introduction

Hemorrhoids is one of the most common and socially significant proctological diseases, characterized by varicose dilation of the venous vessels of the rectum. This

condition is distinguished by its chronic course, frequent relapses, and a pronounced negative impact on patients' quality of life. According to literature data, hemorrhoids occur in 44–86% of the adult population and are observed regardless of gender, predominantly among individuals over 50 years of age, people leading a sedentary lifestyle, those prone to chronic constipation, as well as women during pregnancy and the postpartum period [1–2].

Currently, a wide range of pharmaceutical preparations with systemic and local effects are used in the treatment of hemorrhoids. Most of these agents are aimed at symptomatic therapy, including pain relief, suppression of inflammation, control of bleeding, and elimination of itching. Local dosage forms, particularly rectal suppositories, are characterized by high therapeutic efficacy, ease of administration, and direct action on the pathological focus [3].

In recent years, there has been a growing demand for medicinal products of natural origin, especially those based on local plant raw materials. This trend is explained by their relatively high safety profile, multicomponent composition, complex pharmacological effects, and suitability for long-term use. Extracts obtained from medicinal plant raw materials possess anti-inflammatory, hemostatic, venotonic, analgesic, and regenerative properties, making them particularly relevant for the treatment of hemorrhoids [4–5].

In this regard, the development of a technology for effective rectal suppositories with complex therapeutic action based on local plant raw materials, meeting regulatory quality requirements, is of significant scientific and practical importance for pharmaceutical and medical practice. In particular, the development of technologies for preparing suppositories using liquid and dry extracts on hydrophobic and hydrophilic bases, as well as the comparative evaluation of their quality characteristics, represents a topical and relevant research objective.

Materials and Methods (Methodology)

Study Object and Materials

The objects of the study were liquid and dry extracts obtained from local medicinal plant raw materials, as well as rectal suppositories prepared on their basis. The study utilized a herbal mixture rich in biologically active compounds with anti-inflammatory, hemostatic, and regenerative properties, including flowers of Calendula officinalis L., flowers of Aesculus hippocastanum L., nettle leaves, aerial parts of Achillea millefolium L., flowers of Matricaria chamomilla L., leaves of Plantago major L., and the herbs Polygonum aviculare and Polygonum hydropiper. The plant raw materials were collected, dried, and stored in accordance with the relevant pharmacopoeial requirements.

Method for Obtaining Liquid and Dry Extracts

To ensure the maximum extraction of biologically active substances from the herbal mixture, a three-stage fractional maceration–circulation method was applied. A hydroalcoholic mixture meeting pharmacopoeial standards was used as the extractant. During the maceration process, the plant raw material was mixed with the extractant in a predetermined ratio and subjected to regular circulation for a specified period.

The resulting liquid extract was concentrated at low temperature using a water bath and subsequently dried in a drying cabinet at 40 ± 2 °C to obtain a dry extract. The appearance, color, and homogeneity of the dry extract were assessed visually.

Selection of Suppository Composition and Preparation Technology

For the preparation of rectal suppositories intended for the treatment of hemorrhoids, both hydrophobic and hydrophilic bases were selected. The hydrophobic base was GXM-5T, consisting of hydrogenated cottonseed oil and emulsifier T-2, while the hydrophilic base was a gelatin–glycerin mixture prepared in accordance with the requirements of the XI State Pharmacopoeia.

The dry extract was incorporated into the suppository formulation at a concentration of up to 3%. When incorporated into the hydrophobic base, the dry extract was first dissolved in a small amount of purified water and then emulsified

using anhydrous lanolin. The resulting emulsion was added to the molten base and mixed until a homogeneous mass was obtained. For the hydrophilic base, the dry extract was dissolved in a small amount of water and uniformly mixed with the gelatin–glycerin base.

The suppositories were prepared by the molding method using special molds and solidified by cooling. The finished products were removed from the molds and stored wrapped in parchment paper.

Methods for Evaluating Suppository Quality

The quality of the finished suppositories was evaluated in accordance with the current State Pharmacopoeia requirements. The following parameters were assessed:

- appearance and uniformity;
- average weight and weight variation;
- mechanical strength (hardness);
- complete deformation time of hydrophobic-base suppositories;
- melting time of hydrophilic-base suppositories.

All experiments were performed at least in triplicate, and the results were recorded as mean values [6–7].

Results and Discussion

Based on the dry extract obtained from local medicinal plant raw materials, rectal suppositories were formulated using hydrophobic and hydrophilic bases, and their quality characteristics were comparatively evaluated. The study results demonstrated that the suppositories prepared using the selected technologies fully complied with the State Pharmacopoeia requirements in terms of appearance, uniformity, and physicomechanical properties [8].

Suppositories prepared on the hydrophobic GXM-5T base had a smooth surface, uniform color, and no cracks, and were easily removed from the molds. In contrast, suppositories prepared on the hydrophilic gelatin–glycerin base were

transparent, elastic, and characterized by higher mechanical strength. In both formulations, uniform distribution of the dry extract was confirmed by visual inspection and weight uniformity testing [9–10].

The main quality parameters of the suppositories were determined using 20 samples, and the mean values are presented in Table 1.

Table 1.

Quality parameters of rectal suppositories

Parameter	Hydrophobic base (GXM-5T)	Hydrophilic base (gelatin–glycerin)	Pharmacopoeial requirement
Appearance	Smooth, uniform, crack-free	Transparent, uniform	Must be uniform
Average weight deviation, %	±2.3%	±3.2%	Not more than ±5%
Hardness, N	18 N	20 N	Sufficient mechanical strength
Complete deformation time (hydrophobic), min	5 min	—	3–15 min
Melting time (hydrophilic), min	—	20 min	Not more than 60 min

As shown in Table 1, hydrophobic-base suppositories softened and deformed more rapidly, ensuring faster release of active substances on the rectal mucosa. In contrast, hydrophilic-base suppositories exhibited a longer melting time, providing

a more gradual and sustained release of active compounds [11–12].

Mechanical strength values were slightly higher for hydrophilic-base suppositories, which can be attributed to the elasticity and structural stability of the gelatin–glycerin base. At the same time, the sufficient hardness of hydrophobic-base suppositories ensures shape stability during transportation and storage [13–14].

Overall, the results indicate that suppositories prepared on both bases are suitable for the treatment of hemorrhoids and meet pharmacopoeial quality standards. Hydrophobic-base suppositories provide a faster onset of action, whereas hydrophilic-base suppositories offer a more prolonged and stable therapeutic effect [15].

Conclusion

A technology for the preparation of rectal suppositories intended for the treatment of hemorrhoids based on local medicinal plant raw materials was developed. A dry extract rich in biologically active compounds was obtained from a herbal mixture using a three-stage fractional maceration–circulation method. The dry extract was successfully incorporated into suppository formulations using both hydrophobic and hydrophilic bases.

The conducted studies demonstrated that the finished suppositories comply with the State Pharmacopoeia requirements in terms of appearance, uniformity, mechanical strength, average weight, deformation time, and melting time. Hydrophobic-base suppositories were characterized by a faster onset of action, while hydrophilic-base suppositories provided a more prolonged and stable therapeutic effect.

The obtained results indicate that the developed suppository technology represents an effective, safe, and locally sourced pharmaceutical dosage form with strong potential for implementation in pharmaceutical practice for the treatment of hemorrhoidal disease.

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