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Original Article

Creation and development of technology of tincture from sedative collection of "Flegmen"

Nemat Olimov, Zaynab Sidametova

Department of Pharmacy, Tashkent Pharmaceutical Institute, Tashkent, Uzbekistan

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ABSTRACT

For the replenish of sedatives, we developed the composition of the plant collection "Flegmen", consisting of local medicinal plants: Turkestan motherwort grass, Phlomisregeli grass, licorice roots and peppermint leaves, containing a fairly rich complex of biologically active substances among which are present flavonoids. The appearance and numerical parameters of the drug were determined according to the requirements of the Global Fund XI. The developed indicators of the quality of the "Flegmen" tincture, a description of the appearance, authenticity, the content of ethyl alcohol, density, pH value, dry residue, and heavy metals will be included in the VFS project for the "Flegmen" tincture.

Key words: Flegmen, plant composition, percolation, tincture, standard technology, sedative.

Address for Correspondence: Nemat Olimov, Department of Pharmacy, Tashkent Pharmaceutics Institute, Tashkent, Uzbekistan

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INTRODUCTION

Modern life is replete with stressful situations. An information flurry of various, not always pleasant news, a difficult economic situation, troubles at work, intense study, and just life's vicissitudes make the nervous system strain, and it fails. In this regard, due to the occurrence of various stressful situations, the number of diseases associated with nervous disorders is increasing, which leads to an increase in the need for sedatives. Another problem - most modern medicines are often addictive. It is precisely because of this that many people still prefer the popular methods of treatment - soothing herbal tinctures, which are sold without prescriptions and also much more affordable. A variety of soothing infusions of nerves - an old, proven tool. There are many plants, preparations of which have been used for a long time and successfully both in folk and in official medicine as sedatives; these include tincture of valerian and tincture of motherwort [1,3,5].

The benefits of medicinal tinctures are completely determined by the healing properties of the plant at their base. For example, to obtain alcohol tinctures for the treatment of the cardiovascular system, use of medicinal plants such as hawthorn, motherwort, and yarrow. In addition, to relieve stress and strengthen the nervous system - use valerian, lavender and mint. Any medicinal tinctures have an antiseptic effect due to the content of alcohol, rather than the basic medicinal component. It disinfects and disinfects. The clear advantage of tinctures in comparison with other forms of the use of medicinal herbs (for example, decoctions and infusions on water) is a small dimension. Instead of a glass of medicinal decoction for the same effect, it is enough to take a couple of drops of tincture diluted with a spoon of water. Medicinal tinctures are distinguished by an increased effect on the body, since alcohol penetrates faster into the human blood, bringing more medicinal substances into it. In addition, tinctures, unlike decoctions and infusions, are stored much longer. Tinctures must be stored in dark bottles in a cool place, under such conditions they can stand for 1-3 years. However, alcohol is only an auxiliary component. All medicinal properties of tincture depend directly on the plant [2, 7, 8].

EXPERIMENTAL SECTION

Tinctures - liquid dosage form, which is usually colored alcoholic or aqueous-alcoholic extracts obtained from medicinal plant materials (dried or fresh), as well as from raw materials of animal origin without heating and removing the extractant. Tinctures are divided into simple, on the basis of one type of medicinal plant material, and complex (complex) from a mixture of several types of medicinal raw materials. Tinctures are obtained by maceration, percolation, or another validated method, using ethyl alcohol in the required concentration as the extractant [7,8].

In order to replenish the range of sedatives, we developed the composition of the plant collection “Flegmen”, consisting of local medicinal plants: Turkestan motherwort grass, Phlomisregeligrass, licorice roots and peppermint leaves, containing a fairly rich complex of biologically active substances. Among which are present and flavonoids. Creating drugs from medicinal plant materials in the form of a sedative tincture is beneficial in terms of efficiency and rationality of the use of medicinal raw materials, since in this case the maximum yield of biologically active substances (BAS) is ensured, the pharmacotherapeutic effect is increased, the problem of drug dosage is alleviated.

Creating effective and safe medicines is possible only with the use of standard technologies, as well as modern methods of standardization, providing quality control of finished drugs. Standardization methodologies must simultaneously satisfy several criteria, namely: unification and harmonization, at all stages of production from medicinal plant materials to finished medicinal product, which corresponds to the system of “end-to-end standardization”.

For quality control, such methods are used as high-performance liquid chromatography, gas chromatography and spectrophotometry. Many modern physicochemical methods are used in the use of pharmaceutical analysis, providing unique information and allowing to implement modern requirements for the quality, depth and range of analysis of drugs and drugs. Physicochemical methods have become crucial in the study of the composition, structure, properties and transformations of drugs at all stages from the creation and development of drugs to their use in drug therapy. The combination of these methods allows you to successfully solve the problem of separation of complex multicomponent mixtures, determine their qualitative and quantitative composition, as well as the nature of the individual components [4,5,6].

The main task is to develop a technology for obtaining tincture from a 4-component sedative collection, containing the most complete complex of biologically active substances and having sedative activity. Herbal medicinal fees are the most popular and widely used form of processing of medicinal plant materials. However, to expand the range of medicines, it is important to develop a rational dosage form based on it - tincture, which is the most appropriate option for increasing the shelf life and accuracy of dosing.

Currently, from the sedative collection “Flegmen” was obtained dosage form in the form of tincture. The infusion was obtained using the percolation method [8]. As the extractant was used 70% ethyl alcohol. The object of our research was tincture (1:5), obtained from the sedative collection “Flegmen”. The tincture was obtained by percolation using 70% ethyl alcohol as an estrogen agent. The technology of obtaining the

tincture from the sedative collection "Flegmen" consists of three stages: wetting of the raw material, infusion, percolation. For soaking, 25 g of the collection (crushed to a size of 2 mm) were placed in a flask with a glass stopper, moistened with 25 ml of 70% alcohol, stirred and left for 4 hours. A 3-4 ply piece of gauze was placed on the bottom of the percolator, raw materials were placed on it, tamped with a glass rod, and a piece of filter paper with a load was placed on top. To remove air, the drain valve was opened and the extractant (70% ethyl alcohol) was quickly poured along the percolator wall. Flowing liquid from the receiver was poured back into the percolator. The crane was closed and topped up with 70% alcohol to a mirror surface above the raw material with a thickness of 1-2 cm. Percolator top closed with a double layer of polyethylene and left to insist for 24 hours. At the end of the infusion, the percolator bottom drain valve was opened, adjusting it so that an extractor equal to 1/24 or 1/48 of the working volume of the percolator was delivered from the percolator for 1 hour. To continuously obtain the extract, a clean extractant was fed into the top of the percolator at a rate equal to the rate of exhaust flow. Percolation continued to obtain 125 ml (1:5) tincture. The prepared tincture for cleaning from ballast substances was left for 5-6 days at a temperature of 80°C, filtered through a dry folded filter.

Technological scheme for obtaining tinctures from the sedative collection “Flegmen” is shown in Figure 1.

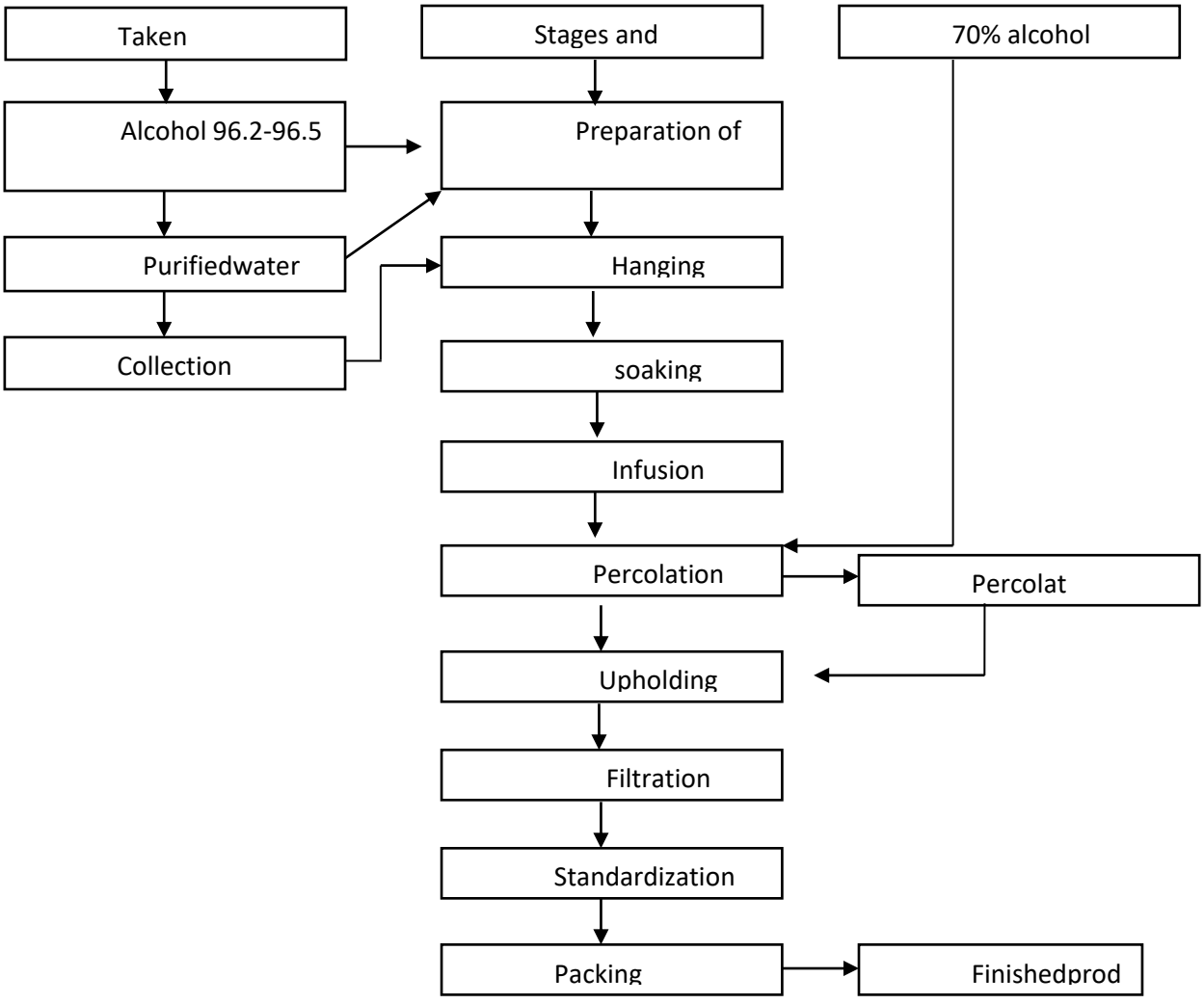

Fig. 1. Technological scheme of obtaining tincture from the sedative collection "Flegmen"

The appearance and numerical parameters of the drug were determined according to the requirements of the Global Fund XI, the alcohol concentration was determined by the boiling point, dry residue, and heavy metals. It was established experimentally that the concentration of alcohol in the “Flegmen” tincture was 66%.

The pH was determined by a potentiometric method.

One of the main indicators of the quality of tinctures is the dry residue, which shows the amount of extractive substances isolated from vegetable raw materials. The determination of the dry residue was carried out according to the method described in GF XI, vol. 2 p.148.

5.0 ml of tincture was placed in a pre-dried bottle, at a temperature of 100–105°C to constant weight, and precisely weighed to the accuracy of 0.0001 g, and evaporated in a water bath to dryness, then dried in an oven for 2 hours at a temperature (102,5±2.5)ºC, cooled in a desiccator (over anhydrous silica gel, anhydrous calcium chloride) for 30 min and weighed. The result was expressed as a percentage. The content of dry residue corresponded to the limits specified in the regulatory documentation. In the course of studies conducted on several experimental batches of the drug, it was established that the dry residue in the tincture was 4.18%.

The determination of the content of heavy metals was carried out according to the method described in GF XI. 10 ml of the tincture was evaporated in a porcelain dish to dryness on a water bath, 1 ml of concentrated sulfuric acid was added, carefully burned and calcined at a temperature of 600°C. To the residue obtained, 5 ml of a saturated ammonium acetate solution was added with heating, filtered through an ashless filter, washed with 5 ml of water, and the filtrate was adjusted to a volume of 100 ml with water; In this case, all the studied series of tinctures withstood the total requirement of not more than 0.001%.

The microbiological purity of the preparation was evaluated in accordance with the requirements of the GF XI "Methods of microbiological control of drugs" and change No.2 of September 29, 2005, category 3B. At the same time, in experiments conducted on five series of tinctures, satisfactory results were obtained corresponding to the specified requirements.

To assess the quality of sedative tincture, the term "organoleptic property" was used, meaning the definition of quality, which is perceived by the senses. High organoleptic properties of the tincture indicates that it has an attractive appearance, pleasant aroma and pronounced taste. Organoleptic evaluation is carried out by tasting - test. When determining the quality of a particular product by an organoleptic method, one or several quality indicators are taken into account and evaluated conditionally. Sensory analysis - analysis using the senses (highly specific receptor organs), provides the body with information about the environment through sight, hearing, smell, taste, touch, vestibular reception. When organoleptic control infusions checked the color, smell, uniformity, if necessary taste. Thus, the thus obtained tincture from the sedative collection "Flegmen" is a clear, brown liquid with a greenish tinge, with a characteristic odor, slightly burning, chilling taste.

To assess the quality and authenticity, qualitative reactions and chromatographic analysis of the preparation were performed. The numerical values of the resulting tincture are shown in table 1.

Table 1: Numerical indicators of sedative tincture "Flegmen" (in percent)

Form of remedy	Description	Concentration of alcohol	pH	Dryresidue	Heavymetals
Tincture	Transparent, brown liquid with a greenish tinge, with a characteristic odor, slightly burning, chilling taste	66%	6	4,18%	Less than 0,001%

When developing methods for the standardization of sedative tinctures, it was assumed that its pharmacological action is due to a complex of biologically active substances, primarily flavonoids, saponins and essential oils. Taking into account the noted circumstance, as well as literature data on the physiological properties of flavonoids, saponins and essential oils, we selected these groups of biologically active substances as a criterion for the quality of tincture. To establish the authenticity of the tincture, the following qualitative reactions are suggested:

The presence of flavonoids, saponins and essential oils was found in the "Flegmen" tincture with qualitative reactions. The qualitative composition of these compounds is detected by chromatographic analysis. Flavonoids were chromatographed using paper chromatography in a 15% acetic acid solvent system, followed by a 1% alcohol solution of aluminum chloride. At the same time not less than four substances of flavonoid nature are found.

Essential oil was determined by thin layer chromatography in a solvent system chloroform-benzene (3: 1) in the presence of menthol "witness" solution. At the same time, spots of violet-red color are found on the plate. The developer was a solution of vanillin (0.2 g) in concentrated sulfuric acid (10 ml).

FINDINGS

For the first time, a technology for producing percolation tinctures using 70% ethyl alcohol from the sedative collection “Flegmen” consisting of local medicinal plants: Turkestan grass motherwort, herbs of Phlomis Regelii, licorice roots and peppermint leaves, containing a fairly rich complex of biologically active substances. The appearance and numerical parameters of the drug were determined according to the requirements of the Global Fund XI. The developed indicators of the quality of the “Flegmen” tincture, a description of the appearance, authenticity, the content of ethyl alcohol, density, pH value, dry residue, and heavy metals will be included in the VFS project for the “Flegmen” tincture.

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