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Development I Standardization of “Coldmaster” Granules

Usmanova Markhabo Balkhievna, Muradova Rayilya Rustamovna
Assistant, Samarkand State Medical University

Abstract. *A technology has been developed for producing granules from dry plant extract "Coldmaster." The resulting granules are standardized according to the main biologically active substances: flavonoids, glycyrrhizic acid, ascorbic acid; installed numerical indicators of granules. Quality control methods have been developed, on the basis of which a draft Pharmacopoeial monograph for the Coldmaster Granules enterprise was compiled.*

Key words: *Coldmaster granules, standardization, numerical indicators, ascorbic acid acid, glycyrrhizic acid, flavonoids.*

Intruduction

Foreign medicinal drugs are widely used in medical practice in Uzbekistan.

Products that are granules plant based. Most of these drugs are intended for the prevention and treatment of colds, inflammatory processes of the upper respiratory tract and flu symptoms. Foreign medicinal drugs are widely used in medical practice in Uzbekistan. products that are granulesplant based. Most of these drugs are intended for the prevention and treatment of colds, inflammatory processes of the upper respiratory tract and flu symptoms. Drugs such as Insti (Herbion Pakistan Private Limited, Pakistan), Travamax (Marion Biotech® Pvt. Ltd, India) and others are a prime example of this. It should be noted that organizations allocate significant funds. Unfortunately, research on the development of domestic drugs with similar pharmacological effects is practically not carried out Meanwhile, the flora of Uzbekistan widely medicinal plants with effective anti-inflammatory, expectorant, vasodilator and other properties. Combining these drugs

plants, it is possible to develop highly effective drugs similar actions. We conducted research to study the pharmacological properties of a dry extract of a plant collection, conventionally called “Coldmaster”. Included in the herbal collection domestic medicinal products were included plants that are pharmacopoeial [1]. Studies have shown that the dry extract “Coldmaster” is not inferior in pharmacological activity to the drug Insti (Herbion Pakistan Private Limited, Pakistan) It is known that many medications used for the prevention and treatment of colds are used in mainly in the form of granules for oral administration. An example is medicinal preparations containing paracetamol and acetylsalicylic acid. Taking granules diluted in warm water accelerates the absorption of the active substances, as a result of which the therapeutic effect of the drug occurs faster. In this regard, it was decided to develop a dosage form of this dry extract in in the form of granules. This study is devoted to the development of technology for obtaining and standardizing granules "Coldmaster" based on the same name dry extract. This drug is planned released in sachet form to treat symptoms colds, flu and inflammatory processes

Purpose of the study. Technology development production and standardization of Coldmaster granules.

Methodology

The methodology for producing Coldmaster granules involved the development of a standardized process for preparing and evaluating the final product. Initially, a dry plant extract of Coldmaster was obtained, characterized by its hygroscopic nature, dark brown color, herbal odor, and strong sweet taste. The granules were prepared by mixing 52.5 g of Coldmaster dry extract with 544 g of refined sugar and 3.0 g of potato starch. A 10% starch paste was prepared, which was then used to combine the ingredients into a uniform mixture. The mixture was dried in a cabinet at 65-70°C until the residual moisture content was reduced to no more than 4%. The dried mass was ground and sifted to obtain granules with a consistent size. Subsequently, 15 ml of 96% alcohol, dissolved with 0.5 g of menthol, was sprayed onto the granules, and the granules were dried at 40-45°C for an additional 30 minutes. Once dried, the granules were packaged in sachets, each containing 6.0 g of the product.

For standardization, the granules were tested for key quality indicators, including appearance, dissolution time, microbial contamination, and heavy metals. Identification and quantification of biologically active substances such as flavonoids, glycyrrhizic acid, and ascorbic acid were performed using various chemical and chromatographic methods. Flavonoids were identified through color reactions with iron chloride and aluminum chloride, while ascorbic acid was determined by its ability to decolorize a specific reagent. Glycyrrhizic acid was quantified using high-performance liquid chromatography (HPLC). The results were used to develop a draft pharmacopoeial monograph for the Coldmaster granules.

Experimental part. Nami was previously a dry extract was obtained, which is

hygroscopic mass of dark brown color, with a pleasant herbal odor and strong

sweet taste [3]. Based on this extract, granules of the following composition were prepared per 100 sachet package:

Coldmaster dry extract

(internal special) 52.5 g

Racemic menthol

(F.USA, Br.F, Eur.F) 0.5 g

Potato starch

(Br.F, Eur.F, USF) 3.0 g

Refined sugar

(GOST 31361-2008) up to 600.0 g

To obtain Coldmaster granules we proceeded as follows. Previously

After weighing 3.0 g of starch, we prepared a 10% starch paste. Then 544 g of sugar was evenly mixed with 52.5 g of dry extract "Coldmaster." After which the resulting mixture was evenly mixed with the prepared previously starch paste. Received the mass was laid out in a thin layer on pallets drying cabinet and dried at a temperature of 65-70°C to a residual moisture content of no more than 4%. The resulting mass was lightly ground into mortar and sifted through a sieve with pore size 1.5 mm. Screened granules at constant while stirring, sprayed with 15 ml of 96% alcohol ethyl, in which 0.5 g of menthol was previously dissolved. After which the received the mass was again laid out on the pallets of the drying cabinet and dried at a temperature of 40-45°C for 30 min. Then the resulting granules were packaged in sachet bags of 6.0 gThe next stage of our research was the standardization of the resulting granules. Based on the requirements of the "General Technical Regulations for the Safety of Medicines," adopted by Decree of the Cabinet of Ministers of the Republic of Uzbekistan No. 365 of 27.10.2016, the granules must be standardized according to the following indicators: description, authenticity, average weight and deviations from mean weight, dissolution time, total ash, heavy metals, microbial contamination, assay, packaging, labeling, storage, shelf life The resulting granules were not described armed eye and noted features their appearance. The main

biological active substances of medicinal plants included in composition of granules are flavonoids, glycyrrhizic acid, ascorbic acid. In connection with this, identification methods were used to identify the above substances. Flavonoids were determined using their characteristic chemical reactions. For alcohol extraction of granules was previously obtained for this purpose. A drop was added to a small volume of alcohol extraction 3% aqueous iron oxide chloride solution. In the presence of flavonoids, the mixture is colored in a dirty dark greenish color. The presence of flavonoids was also established as follows: 3% was added to the alcohol extraction an alcoholic solution of aluminum chloride, at this yellow color intensified and gained slightly greenish tint The presence of ascorbic acid was established by a characteristic reaction: to part of the alcohol extraction of the granules was added 0.015% 2,6-dichlorophenolindophenolate sodium. The ascorbic acid in the pellets discolored the reagent.

For determination of glycyrrhizic acid Detailed analysis conditions are described if quantified. HA was identified by the coincidence of the retention time of its chromatographic peak with the time retention of the working ammonium glycyrrhizinate reference standard. The content of total ash was determined according to the method described in SP XI, issue 2, p. 24 [4]. The results obtained in this case are given in table. Based on the data obtained the standard content of total ash is not more than 3%.The procedure described in Rus. Pharm. XI, issue 1, p. 172. For this parameter the resulting granules withstood the requirement, for dry extracts (not more than 0,001%). Results of performed tests are given in Table. The method presented in Rus. Pharm. XI, issue 2, p. 193 and Change was used to determine the "Microbiological Purity" parameter. No. 2 dated 12.10.2005. Studies were conducted on the basis of the microbiological laboratory of JSC «O`zkimyofarm». As a result of the studies, it was found that the obtained granules meet the requirements of category 3 B. In the next phase of the study, we tested methods for the quantitative determination of HA - a component of licorice and the sum of flavonoids, which are greater or less contained in all plants that are the starting material for the production of Coldmaster granules For determination of HA content in granules HPLC method developed bypreviously for HA Assay in Dry Coldmaster Extract To do this, weigh 1 g (accurately weighed) powder of crushed granules. Weighed into 25 mL volumetric flask, a small volume of mobile phase was poured, which was used for HPLC and mixed. Then the solution was diluted to volume with this mixture. The resulting solution was filtered through a 0.45 μm membrane filter. Next, an ammonium glycyrrhizinate working standard solution (hereinafter referred to as PSO) was prepared. To do this, weigh 0.050 g (accurately weighed) of ammonium PSO glycyrrhizinate (POF 42 Uz-25389499-3376-2018). The weighed amount was placed in 50 mL volumetric flask, 15-20 mL of mobile phase was added and dissolved. Volume the solution was diluted to volume with the same liquid. Then 5.0 mL of the resulting solution was transferred into a 25 mL volumetric flask and dilute to volume with mobile phase. Agilent 1260 series liquid chromatograph with UV detector and isocratic pump was used. HA determination was performed under the following conditions:- metal column 4.6 mm x15 cm filled with Zorbax Eclipse sorbent Plus C-18 with a particle size of 5 μm;

- mobile phase: acetonitrile - water - glacial acetic acid (190:307:3);
- mobile phase velocity - 1.5 mL/min;
- detection at 254 nm.

At the beginning, 20 μL of the working reference standard solution was injected into the chromatograph injector 3 times, then the test solution of the granules "The Coldmaster"; 3 chromatograms were obtained for each solution. The averaged peak areas of the working standard solution and the test sample were calculated Coldmaster pellet solution. Based on data etermined HA content (X) in one sachet, in mg, according to the following formula: As a result of the studies have established a GC content of at least 10 mg/sachet. The HA results are shown in Table The method was used to quantify the sum of flavonoids spectrophotometry we used earlier to quantify the sum of flavonoids in dry extract "The Coldmaster" To do this, weigh 5.5 g (accurately weighed)powder of crushed granules. The weighed amount was placed in 50 mL volumetric flask, add

35 ml of 50% ethanol, shaken for 15 minutes. Then the volume of the solution was adjusted to the mark with the same solvent. The mixture was stirred and filtered through a paper filter. pre-washed with alcohol, discarding first portions of filtrate. Then 2.0 mL of the filtrate was placed in a volumetric flask.25 mL, 3 mL of 2% aluminum solution was added chloride, one drop of diluted acetic acid and the solution was diluted to volume with ethyl alcohol. The solution was stirred and placed in a dark place. After 40 min, the solution filtered through a paper filter "blue tape "and immediately measured the optical density obtained solution on a spectrophotometer at wavelength 410 nm in a cuvette with layer thickness 10 mm. The comparison solution used was solution prepared in the same manner, but without the addition of aluminum chloride solution. The absorbance of the rutin solution of the reference standard was measured in parallel. For preparation of RNO rutin solution 0.05 g (accurately weighed) of RNO routine (TU 64-4-127-96), previously dried at a temperature of 130-135 ° C for 3 hours, was weighed.

Weighed into a 100 mL volumetric flask and 85 mL of ethyl alcohol was added and dissolved by heating in a water bath. After dissolution, the contents of the flask were cooled to room temperature, then the solution was diluted to volume with the same alcohol and stirred. Then 1.0 mL of the resulting solution placed in a 25 mL volumetric flask and treated as in the preparation of the test solution Optical densities were determined test solution and standard solution sample. Total flavonoid content (X) in conversion to routine in granules, in mg, was calculated using the formula: D0

- absorbance of RNO routine solution;

D1

- absorbance of the test sample solution;

a0

- weight of RS sample, g;

a1

- weight of the drug sample, g;

b - average weight of one sachet, g;

P - rutin content in RS,%.

Based on the data obtained, the content of the sum of flavonoids was set at not less than 5 mg/sachet

Conclusion. Technology for the production of Coldmaster granules and methods for their identification and quantitative content of main active substances: ascorbic acid, glycyrrhizic acid, and flavonoids. The obtained data served as the basis for the development of the draft Pharmacopoeia monograph "Granules" The Coldmaster."

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