Technology for the production of the substance of the drug donaxin hydrochloride

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Abstract: A technology has been created for the production of the substance donaxin hydrochloride from the aerial part of the donax plant. On the basis of the created technology, apparatuses were selected and a production line was installed. This line produced the first industrial samples of donaxin hydrochloride substances from the aerial part of donax.

Key words: Donax, extraction, extract, chloroform, sulfuric acid, alkaloid, donaxin hydrochloride, substance, technology.

Introduction. When employees of the Institute of Chemistry of Plant Substances carried out pharmacotoxicological studies of donaxin hydrochloride, isolated from the aerial part of the A.donax plant, it was revealed that this substance has a high aphrodisiac activity. To study the chemical composition of the aerial part of the donax plant, the alkaloid donaxin was previously isolated in several ways, as given below. The crushed leaves of the A.donax plant are soaked in a 10% ammonia solution and loaded into a percolator, extracted with dichloroethane. From the dichloroethane extract, the amount of alkaloids is extracted with a solution of hydrochloric acid. Then the hydrochloric acid extract is alkalized with sodium hydroxide, extracted with diethyl ether. The latter is dehydrated with potassium carbonate. Then, the dehydrated extract is evaporated to dryness to obtain the amount of alkaloids. From the sum of alkaloids, donaxin is precipitated with acetone. The crushed leaves of the A.donax plant are soaked in 25% ammonia solution and loaded into the extractor. Then extracted with chloroform. The resulting chloroform extract is filtered, evaporated to an aqueous residue. From the latter, alkaloids are extracted with a solution of sulfuric acid. The acid extract is alkalinized with 25% ammonia solution, extracted with chloroform. The obtained chloroform extracts are combined and the amount of alkaloids is obtained by evaporation. The total amount of alkaloids is dissolved in acetone and treated with hydrochloric acid solution to pH 1. Precipitated donaxin hydrochloride is isolated by filtration. The above methods for obtaining donaxin hydrochloride from the raw materials of the A.donax plant are laboratory methods and have been used for the qualitative and quantitative study of the alkaloid composition of this plant species. In the above laboratory methods, expensive organic solvents harmful to health are used in large volumes, thus the use of these methods for industry is impractical. Earlier, we reported on the study of the process of extraction of the alkaloid donaxin hydrochloride by the method of water-alcohol extraction of the aerial part of the A.donax plant, the factors affecting the process were studied. This article presents the scientific results obtained in the development of technology for obtaining the substance of the drug donaxin hydrochloride from the isolated extract obtained from plant materials. As a result of the research, a flowchart was developed for the production of the substance of the drug donaxin hydrochloride from donax plant raw materials. Based on the research, a technology was developed for the production of the substance donaxin hydrochloride from the aerial part of A.donax, on the basis of which a pilot plant was created on the basis of the Pilot Production of the Institute of Chemistry of Plant Substances. Technological scheme for the production of the substance donaxin hydrochloride. According to the technology developed by us, raw materials (donaxin content 0.14% by weight of raw materials) are crushed in a mill (M-1) to 2-5 mm, weighed on a scale (B-2) 50 kg, loaded into an extractor (E-3) and from the measuring tank (Sb-4) pour 180 liters of 80% ethyl alcohol. After 6 hours, the first drain is drained in the amount of 100 liters, and 100 liters of 80% ethyl alcohol are poured into the extractor. Thus, the second drain is produced after 5 hours, the third - 4 hours, the fourth and fifth plums after 3 hours. The combined extract in the amount of 520 l is concentrated in a vacuum circulation apparatus (VCA-5) to the volume of the aqueous residue of 52 l and left in the refrigerator for 12 hours. The precipitate formed is filtered off through a suction filter (NF-6), 51 l of the aqueous part is alkalized with

ISSN NO: 2770-0003

Date of Publication: 22-05-2022

https://zienjournals.com Date of Publication: 22-05-2022

NaOH solution to pH 10-12 in a separating column (DK-6). From an alkaline solution, the amount of alkaloids is extracted with chloroform from a measuring tank (Sb-7) 6 times in 10 liters. The resulting 60.1 chloroform extract is concentrated in a vacuum circulation apparatus (VCA-5) to a volume of 6 l and poured into a separating column (DK-8). From chloroform, alkaloids are extracted with a 10% solution of sulfuric acid from a measuring tank (Sb-9) 4 times in 1 liter. The resulting sulfuric acid extract in the amount of 4 l is alkalized with a solution of NaOH to pH 1012 in a separating column (DK-10) and extracted with chloroform 6 times in 1 l. 6 l of chloroform extract is concentrated on a rotary evaporator (RI-11) until chloroform is completely removed. 235.5 g of the dry amount of alkaloids are placed in a flask, dissolved in 500 ml of ethyl alcohol, boiled in a water bath (Wb-12) and cooled. The precipitate formed is filtered and dried with 50 g of technical Donax ina is placed in a crystallizer (K-3), an alcoholic solution of hydrochloric acid is added to a pH value of 5-6 and left for 12 hours. The formed precipitate is filtered through a suction filter (NF-14) and dried. 56.5 g of technical donaxin hydrochloride is dissolved in a flask with ethyl alcohol in a water bath (Wb-15), 1.01.5% activated carbon is added, boiled and filtered.

A package of draft regulatory and technical documentation for the substance and for the finished dosage form - tablets of 1 mg, as well as samples of substances and tablets of donaxin hydrochloride, were submitted to the Pharmacopoeia Committee of the Ministry of Health of the Republic of Uzbekistan to obtain permission to conduct extensive clinical trials of the drug.

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ISSN NO: 2770-0003