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Research On The Choice Of "Ambronat" Syrup Technology

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ABSTRACT

This article is devoted to the study of factors influencing quality indicators in experimental research (identification - analytical) and in determining the quality of the finished product. Dedicated to the research on the selection of the composition of "Ambronate" syrup, it contains the results of research on the selection of excipients and technology, as well as the quality of the finished syrup.

KEYWORDS

Syrup, organoleptic, critical stages, technological, bioactive, specification, pH environment, ingredient, temperature, organoleptic, critical stage.

INTRODUCTION

One of the main tasks facing local pharmaceutical scientists today is to reduce the cost of development and production of new drugs, which in turn will replace import-substituting drugs with local raw materials, improve existing forms of generic drugs that are widely used in practice.

Ambroxol has a complex effect. Therefore, it has a serolytic effect on the secretion of bronchial glands. Ambroxol determines the function of the serous and mucous glands in

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the bronchial mucosa, and activates the product of the serous component. This, in turn, is a much-needed effect in chronic lung disease. In addition, ambroxol normalizes the excretion of bronchial secretions. In addition, ambroxol regulates airway protective factors.

According to the literature, sucrose, glucose, fructose, sorbitol, mannitol, maltitol, xylitol are used as the basis of syrup in the preparation of the recommended syrup. Preservatives (alcohol, nipagin, nipazole, sorbic acid, etc.), stabilizers, corrigents are also added to the syrups as needed.

Based on the above, we conducted research on content selection based on three different methodological approaches. These are: information-theoretical, the results of personal research and identification-analytical.

Preliminary research (informational-theoretical) was devoted to the analysis of the literature on the prevalence of upper respiratory diseases and drugs used in their treatment in order to determine the current situation and research plans for the selection of ingredients for syrup. In this direction (individual research) was devoted to the selection of specific content and technology.

RESULTS AND DISCUSSION

The research was conducted on the selection of the technology of "Ambronate" syrup. The dose of ambroxol hydrochloride in the recommended syrup was selected on a volume scale. The maximum dose of ambroxol hydrochloride is 10 ml 3 times a day for adults and children over 12 years, 5 ml 2-3 times a day for children from 6 to 12 years; 2.5 ml (1/2 teaspoon) 3 times a day for children from 2 to 6 years; Children under 2 years of age are instructed to take 2.5 ml (1/2 teaspoon) 2 times a day.

Ambroxol should be taken with a large amount of fluid after a meal, which leads to an increase in the mucolytic effect of the drug. The duration of treatment is 4-14 days. In this case, a dose of 15 ml (one tablespoon) was selected and recalculated to the next 100 ml. 0.3 g of ambroxol hydrochloride was obtained, taking into account the storage of 15 doses of 100 ml of syrup.

The first stage of research in the technological process was focused on the preparation of simple syrup. The technology of "Ambronate" syrup is as follows: in a pot for boiling syrup is poured purified water and heated to a temperature of 50-60 ° C, and the required amount of sugar is added, stirring constantly. The speed of the mixer is taken as 30-40 per minute. It takes 30 minutes to make a simple syrup. The readiness of the syrup is determined by determining its concentration. The concentration of normal syrup is determined using a refractometer. Then add the required amount of sodium benzoate to the finished syrup. The amount of sodium benzoate was given above and it was around the percentage given in the literature and the remaining ingredients were added. The mixer speed was set at 60 rpm. Cool the syrup to 50 ± 3 °C (SPh XIII), stirring for 20 minutes. Ambroxol hydrochloride is then dissolved in ethyl alcohol and added to the solution and mixed well. The prepared syrup is filtered.

It is known from the literature that there are stages of the process that require special attention in the stages of preparation of syrup. Therefore, we studied the issue of prevention of possible adverse processes that may occur in the technological processes of

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"Ambronate" syrup obtained in the proposed composition and technology. The critical stages of the technology of obtaining "Ambronate" syrup include the fact that the pH is not at the required level of the environment, temperature, speed of rotation of the mixer, microbiological purity. The results of the problematic stages of the proposed syrup are included in the commentary. Here are the events that can occur in critical processes. For example, in the preparation of ordinary jam, the sugar in the jam may caramelize due to the rise in temperature. In the process of obtaining "Ambronate" syrup, high concentrations of sugar slow down the dissolution of the main, ie bioactive and excipients, as well as the role of the environment in this process, the acidic environment can lead to inversion of sucrose, and in this process the dose uniformity can change.

In addition to the above, in several processes of making syrup, for example, sanitary preparation of production, preparation of raw materials, simple syrup, "Ambronate" syrup and packaging may lose microbiological purity of syrup, change the color and smell of syrup, change the taste. . It is also possible for the syrup to fade and even to sink. Therefore, special attention should be paid to the norms of these critical processes.

The critical stages of the technology of "Ambronate" syrup are given in Table 1.

Critical of the technology of "Ambronate" syrup lines

Mode	Name of technological stages	NoteИзох
Temperature mode	TJ 4. Boil the sugar syrup	Heating leads to caramelization of the syrup
The amount of sugar in the jam	TJ 5. Getting “Ambronate” syrup	High concentrations of sugar slow down the dissolution of excipients
pH environment	TJ 5. Getting “Ambronate” syrup	An acidic environment leads to the inversion of sucrose
Mixer rotation indicator	TJ 5. Getting “Ambronate” syrup	In syrup, the dose affects the uniformity indicator

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Microbiological cleanliness	YI 1. Sanitary preparation of production YI 2. Preparation of raw materials TJ 3. Get a simple syrup TJ 5. Getting "Ambronate" syrup QYoJ 6. Packaging and packaging	Microbiological purity is lost. Syrup color, smell. The taste varies. Syrup thickens, sediment is formed.

Evaluation of the quality of ambronat syrup

The quality of the syrup obtained in the proposed composition and technology was studied in accordance with the requirements for syrups in the methods given in SPh XIII. Qualitative indicators such as appearance, authenticity, density, pH of the syrup, foreign substances in the syrup, microbiological purity and quantitative analysis were studied. The amount of the recommended syrup poured into the packaging was also studied.

The next stage of research was devoted to the study of the organoleptic properties of the prepared syrup. In this case, the assessment was carried out on a 100-point scale.

The results obtained are given in Table 2.

Organoleptic properties of "Ambronate" syrup study results

Appearance	**Grade**	**Colour**	**Grade**	**Taste and smell**	**Grade**	**Total score**
A clear, viscous liquid	100	white	100	Sweet delicious, orange scented	100	100

From the obtained data, it is clear that the syrup "Ambronate" obtained in the proposed composition and technology is at the level of demand for organoleptic indicators.

In subsequent studies, the appearance, authenticity, density, pH environment, foreign substances in the syrup, microbiological purity and quantitative analysis of the recommended syrup were studied in the methods given in XI SPh.

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The quality indicators of the recommended "Ambronat" syrup are given in Table 3.

Evaluation of the quality of Ambronat syrup

The indicators studied	**Specification (Norm)**	**The results obtained**
Appearance	Sweet, orange-scented, clear, sticky liquid	Fits
Reality	1. The main stain on the chromatogram of the test solution should be in line with the standard solution of ambroxol hydrochloride. 2. Chloride-specific reaction. 3. The reaction specific to primary amines. 4. The test solution should be consistent with the working solution of the main peak of propylene glycol on the chromatogram and held for 5 min. 5. Specific reaction of benzoate ion 6. Specific reaction to ethyl alcohol.	Fits Fits A yellow spot formed 4.5 minutes Pink - yellow sediment was formed A pale yellow precipitate formed
Density	1,200 to 1,240 g / cm3	1228 g / cm3
pH environment	5,0 - 7,5	6,3

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Substances	In addition to the main stain, up to two more spots are allowed on the test solution chromatogram. However, they should not be larger than the standard solution stain of Ambronate hydrochloride (each foreign substance should not be larger than 0.5%). Also, only one stain is allowed on the starting line. However, they should not be larger than the stain of a standard solution of ambroxol hydrochloride (each foreign substance should not be larger than 1%).	0,38% 0,89%
Filled volume in the package	The volume of the package can be deviated from ± 3% for 50 ml, 90 ml and 100 ml of solution, and ± 1.5% for 200 ml.	OST 64-492-85.
Microbiological cleanliness	3A Category	At the level of demand
Quantitative analysis: -Ambroxol hydrochloride	0.0027g to 0.0033 g per 1 ml of preparation	0, 0029 g

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- Sodium benzoate		0,0050 g

The fact that the criteria presented in Table 3 and the results obtained are at the level of demand indicates that the content and technology we are recommending have been chosen correctly.

CONCLUSIONS

The quality of the syrup obtained in the proposed composition and technology was studied in accordance with the requirements for syrups in the methods given in DF XIII. Qualitative indicators such as appearance, authenticity, density, pH of the syrup, foreign substances in the syrup, microbiological purity and quantitative analysis were studied. From the obtained data, it is clear that the "Ambronate" syrup obtained in the proposed composition and technology is at the level of demand for organoleptic characteristics, and a specific technology was selected.

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