THE STUDY ON DEVELOPMENT OF THE TECHNOLOGY OF THE SYRUP WITH THE HEPATOTROPIC AND CHOLERETIC ACTION

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Among the most dangerous diseases of the hepatobiliary system (GBS), and gallbladder there are chronic and acute viral hepatitis, cirrhosis and fibrosis of the liver, cholestases, cholecystitis, fatty liver, etc. Despite the large number of diseases, as well symptoms and syndromes accompanied them the main pathogenic factors are destruction of hepatocytes, formation and outflow of the bile. Due to the combined composition the herbal drug developed in the form of syrup has a complex action. The problem of its administration in patients with diabetes mellitus and obesity is solved by using sorbitol and a natural sweetener – the herb of stevia. Development of the technology for “Cholophyt” syrup is based on physicochemical and technological properties of ingredients included in its composition. The main principle of the technology was to obtain the base of the syrup – the sorbitol concentrate with a preservative mixed with the concentrated combined aqueous extract. The critical stages of the technological process such as duration and the temperature of heating, the rate of mixing, the time and conditions of dissolution of ingredients have been determined.

Treatment of diseases of the liver and gallbladder is a rather complex and long process. Despite the various forms and types of diseases there are several approaches to their therapy: etiological, pathogenetic and symptomatic. The maintenance therapy is important since it aims to protect the cells of the liver from the action of toxic substances, improve metabolism of hepatocytes, normalize formation and excretion of the bile, and reduce inflammation. Recently, during the maintenance therapy of GBS, herbal drugs are increasingly used since they have a wide spectrum of the pharmacological activity, they are also safe and environmentally friendly [1-3, 5].

The use of drugs in the form of liquid oral forms, such as syrups, is relevant because of the ease of dosing, high pharmacokinetic properties, the possibility of correcting unpleasant tastes, odours, and colours. However, the use of syrups traditionally prepared with sucrose is significantly restricted in patients with diabetes mellitus and obesity [4, 6-8].

Previously the original syrup without sucrose in its composition was developed. It contains the aqueous extract of the artichoke leaves, rose hips, the herb of stevia, the immortelle flowers, corn silk; sorbitol; glycerine; hydroxyethylcellulose (HEC); potassium sorbate; citric acid.

The aim of this work was to substantiate the technology of “Cholophyt” syrup created on the basis of the original composition of the medicinal plant raw material (MPRM) for treating diseases of the hepatobiliary system and gallbladder.

Materials and Methods

The manufacturing process of “Cholophyt” syrup obtaining was performed using the standard technological equipment taking into account the physicochemical properties of the ingredients included in its composition. Purified water, potassium sorbate, sorbitol, citric acid were sequentially loaded in the reactor in the required amounts and heated to the temperature of 90°C for 1 h stirring until complete dissolution of the ingredients. After obtaining a homogeneous solution hydroxyethylcellulose previously weighed and the combined aqueous extract with MPRM were added to the reactor. The frame mixer was switched on, and the mixture was stirred removing air bubbles by vacuum until formation of a homogeneous mass, which was left to swell for a day. After that glycerine was added to the reactor and mixed for 1 h by the frame mixer at 300 rpm. Using vacuum the syrup was filtered to the collector. The syrup in the dose of 100.0 g was dispensed into containers of a dark glass. The flowchart of manufacturing “Cholophyt” syrup is given in Fig.

Results and Discussion

As can be seen from Fig., the flowchart of manufacturing for “Cholophyt” syrup consists of 9 stages: weighing of the raw material, obtaining of the syrup base, obtaining of “Cholophyt” syrup, filtration of the syrup, preparation of containers and packing material, dispensing of the syrup in containers, labelling of containers, packing of containers in packs, packing of packs in boxes.

The critical stages of the manufacturing process of “Cholophyt” syrup are presented in Table.

Based on data from Table the critical parameters of the manufacturing process of “Cholophyt” syrup are the temperature and time of heating; the rate and time of mixing of the solution and dissolution of the ingredients included in the composition of the drug; as well as microbiological purity.
The critical stages of the manufacturing process for “Cholophyt” syrup

| The critical parameter       | The critical technological stage | Substantiation                                                                 |
|------------------------------|----------------------------------|-------------------------------------------------------------------------------|
| The time and temperature of heating | Stage 2                          | In case of the insufficient temperature and time of heating HEC does not form the homogenous solution |
| The rate and time of mixing   | Stage 2, Stage 3                  | The insufficient rate and time of mixing can cause incomplete dissolution of the components of the syrup, and as a result, a precipitate is formed |
| Uniformity                    | Stage 4                          | Depending on the type of the filter material and particle size the syrup can contain particulate matter |

Fig. The flowchart of manufacturing for “Cholophyt” syrup.
CONCLUSIONS
1. The flowchart of manufacturing “Cholophyt” syrup with hepatotropic and choleretic action has been developed.

2. The critical parameters of the manufacturing process of the drug developed have been determined.

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