STUDY ON PREPARATION TECHNOLOGY OF COMPOUND SILYMARIN SOFT CAPSULE

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Abstract Preparation of Compound Silymarin Soft Capsule by Silymarin Oil as thinner is presented in this paper. Ethanol refluxing method, room temperature impregnation method and ultrasonic assisted extraction were used to extract silymarin,respectively, and the content of silymarin was determined by high performance liquid chromatography (HPLC). Based on the comprehensive analysis, the author believes that silymarin oil can insted ordinary vegetable oil as thinner of soft capsule for the comprehensive utilization of Silybum resources to provide new ideas and direction.

Keywords: silymarin, silymarin oil, soft capsule

Silymarin has been extensively studied as an active ingredient of Silybum marianum and prepared into a variety of dosage forms such as tablets, capsules, pills, granules and nanocomposites. But silymarin and silymarin oil are not yet used together in the dosage form without in the Chinese and English literature.

Objective Three methods of silymarin were extracted and the preparation of compound silymarin soft capsules was discussed.

1 Materials and Methods

1.1 Material Silage thistle seeds (Yichun,China) ,Glycerin (Shanghai,China.), gelatin (Tianjin,China.) n-hexane (AR),95% ethanol (AR),silybin standard (China Food and Drug Administration Institute) ,methanol (GR) ,ultra-pure water.

1.2 Methods Extraction of silymarin

At room temperature, n-hexane was used to remove hydrophobic components the seeds of milk thistle after pulverization for 24 h. In short, the finely divided Silage thistle seeds powder was added with 95% ethanol at a ratio of 1:15, and Ethanol refluxing method, room temperature impregnation method and ultrasonic assisted extraction were used to extract silymarin,respectively, the extract was vacuum drying to calculate the extraction rate of the extraction rate. The experiment was repeated three times.

Content determination Determination of the content of extracts from three extraction methods by high performance liquid chromatography and the mobile phase was Water methanol (55:45; v/v), The detection wavelength was 288nm; the flow rate was kept at 1ml/min-1 and the column temperature was 35℃. Sample volume 10 μL.

3 Results Linear relation test The regression equation was Y=47096X-38167, R2=0.9994.The results showed that the concentration of silybin was in good linear relationship with the peak area in the range of 5~60 μg.ml-1.

Precision experiment Simultaneous injection of the silymarin injection solution prepared by the extraction process at room temperature was carried out 6 times for each injection. The RSD ' s of the analytical results were less than 0.6%,The results show that the reproducibility of the method is good.

Recovery experiment The RSD ' s of the analytical results were less than 2%,The results showed that the recovery rate was good and the accuracy was in accordance with the content determination.

Determination of content The concentration of 20 μg / ml-1 was used as the sample solution, injection 10 μl, the total area of the peaks of silybin and the content of silybin was calculated by regression equation.Finally the content is 10.18% 16.29 % 12.14% , respectively, ethanol reflux method, room temperature impregnation method and ultrasonic assisted extraction method.

Results and discussion The chromatographic conditions allow the separation of the active ingredient silybin peak, and the methodological study shows that the method is accurate, accurate and reproducible.

Subsequent formulation studies show that silymarin oil could be a successful substitute for common vegetable oil as diluent for silymarin soft capsules.The preparation of the compound silymarin soft capsules in the application of health care products has great potential.

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