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DETERMINATION OF INCREASE IN THE DEGREE OF HESPERIDIN DISSOLUTION IN THE COMPOSITION OF A CENTRIFUGALLY FORMED SOLID DISPERSION SYSTEM

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Hesperidin is a flavanone glycoside obtained from the skin of citrus fruits. This compound has an anti-inflammatory and antioxidant effect [1]. An obstacle in the use of this glycoside is its low solubility in water, therefore, to increase solubility, centrifugally formed solid dispersion systems (SDS) from pharmaceutically acceptable polymers with hesperidin in the composition are being developed. This material is devoted to checking the solubility of one of the SDS.

Methodology: the study of dissolution profiles was carried out according to the methodology of the European Pharmacopoeia (EPh) 8.0 (2.9.3) [2]. Apparatus 2 (a paddle apparatus) and Vankel Varian VK7000 dissolution test equipment with a VK750D external water heater were used. The volume of the dissolution medium was 500 ml ±1%. The temperature of the dissolution medium is 37.0±0.5 °C. The speed of rotation of the stirring element, the blade, was 50 rpm. Sampling was carried out at the indicated time (5, 10, 15, 30, 45, 60, 90, 120 minutes after the start of the test) from the area in the middle between the surface of the dissolution medium and the upper part of the rotating blade, at no closer than 1 cm from the vessel wall. The selected aliquot for analysis (5 ml) was compensated with an equal volume of fresh dissolution medium heated to a temperature of 37.0±0.5 °C [2].

During the SDS dissolution test of hesperidin, buffer solutions with a controlled value of the hydrogen index (pH) were used. A medium with hydrochloric acid pH 1.20±0.05, acetate buffer solution pH 4.50±0.05 and phosphate buffer solution pH 6.80±0.05 were used. The pH value was monitored at the beginning and end of the test.

Quantitative determination of hesperidin released from SDS was carried out according to the calibration chart spectrophotometrically according to the validated method. The method of quantitative determination of hesperidin meets all acceptance criteria. The quantitative determination of the hesperidin content in SDS is based on the qualitative reaction of hesperidin with ferric (III) chloride, while a colored compound is formed, the maximum optical absorption of which is observed at a wavelength of 602 nm.

The solution was characterized by the value Q (degree of dissolution), which is calculated by Eq. (1):

$$Q\ (\%) = \frac{(\text{API concentration at the specified time,g/l})}{(\text{Nominal content of API,g/l})} * 100\ \% \qquad (1)$$

The degree of release of hesperidin from SDS was compared with the degree of solubility of pure hesperidin.

When comparing the dissolution profiles of pure hesperidin and hesperidin in the composition of SDS in an environment with a pH of 1.2, it was found that SDS has a significantly higher degree of dissolution compared to pure hesperidin. In the first 5 min, the degree of dissolution of hesperidin in SDS is 38.2±2.5%, while for pure hesperidin Q=5.5±0.5% ($p<0.05$). At 45 minutes, the degree of dissolution of hesperidin in the composition of SDS reached a value of 51.5%, which is 8.3 times more than the degree of dissolution of pure hesperidin.

When conducting an experiment in an acetate buffer medium of pH 4.5, it was established that the degree of hesperidin release from SDS in the first 5 minutes is about 50.0%. 10 minutes after the start of the experiment, the degree of dissolution of hesperidin released from SDS was 65.0%, which is 12.0 times higher than the degree of dissolution of pure hesperidin under identical conditions ($p<0.05$).

In a phosphate buffer with a pH of 6.8, hesperidin in SDS is released much more slowly, but has a higher degree of solubility than pure hesperidin (14.0% in SDS versus 5.0% in pure hesperidin). The dissolution profile of hesperidin in SDS increased over an hour and after one hour was 4.0 times higher than the degree of dissolution for pure hesperidin.

The results of the study indicate that SDS with hesperidin in the composition allows to achieve a greater degree of solubility than that of pure hesperidin. Hesperidin from SDS is best released in acetate buffer (pH 4.5), the degree of solubility in 60 minutes reaches 65.0%. In an acidic environment, an 8.3-fold increase in the degree of solubility of hesperidin in SDS was achieved compared to pure hesperidin.

[1] R. Cao, Y. Zhao, Z. Zhou, X Zhao, Enhancement of the water solubility and antioxidant activity of hesperidin by chitooligosaccharide, Journal of the Science of Food and Agriculture **98(6)**, 2422-2427 (2018).
[2] European Pharmacopoeia. 8th edition. Vol. 2. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM); Dissolution test for solid dosage form, 288-295 (2013).