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Biopharmaceutical Study of General Tonic Capsules by *in vitro* Method

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Abstract

One of the main quality indicators of modern drugs are biopharmaceutical indicators, in particular the test “Dissolution” – for solid dosage forms. This article presents the results of research on the development of the "Dissolution" test for Indian ginseng developed at the Tashkent Pharmaceutical Institute. Determination of dissolution rate of drugs from solid dosage forms carried out on the device “Rotating basket”.

According to the results of the experiments, the following conditions for determining the bioavailability of the capsules analyzed by the in vitro method selected. To determine the dissolution profile, two dissolution media used in succession – 0,1 M hydrochloric acid solution (capsules should not dissolve within 60 minutes). And – phosphate buffer solution with pH 7,4 (within 45 minutes, at least 75% of the active substances should secrete), the volume of the medium – 1000 ml, the rotational speed of the basket – 100 rpm, the temperature mode – 37±1℃.

Keywords: Indian ginseng, adoptive, capsule, “Dissolution” test, quantification

Introduction

The capsule dosage form is the simplicity of their use, which does not require any special skills from the patient (as compared to injections). A number of advantages make capsules an attractive form for drug manufacturers as well. Use capsules throughout the entire process of studying the effectiveness of the drug without the need to transfer them into another form for patients to take [2.3].

Despite the lower profitability of producing capsules compared to tablets, this dosage form still has a relatively low production cost. In addition, provides high stability of the encapsulated active ingredients Capsules are easy enough to develop their production technology. Since the main requirement for the encapsulate material is only to ensure uniformity of dosing, which allows manufacturers to bring new products to market faster [4,6].

Studies conducted in recent years by a number of scientists have shown that the absence of the pressing process in encapsulated dosage forms in most cases is the reason for the reduced disintegration time compared to tablets and draggers and, accordingly, more complete absorption in the body. In this regard, the current trend is to expand the range of drugs by developing both tableted and encapsulated dosage forms. [2,3,4,5].

To date, on the pharmaceutical market there are capsules with general tonic action. Taking into account the positive aspects of the capsulated dosage form, in the Tashkent pharmaceutical institute the composition and technology of capsules with adapt genic action selected and developed.

The purpose of these studies was to determine the bioavailability of the developed dosage form in in vitro studies with a preliminary scientifically based selection of conditions for the test “Dissolution”.

Materials and Methods

To study the rate of release of active substances from the analyzed encapsulated dosage form, the commonly used method “Rotating Basket” included in GF XI [6,7].

According to the literature data, when using the above method, the release of active substances influenced by various factors such as the rotation speed of the basket, the volume and pH of the dissolving medium, etc. In view of the above, studies carried out to select the optimal rotational speed of the basket in the “Dissolution” test for Indian ginseng capsules.

This method is also official in our Republic. The main reasons for the wide use of the “Rotating Basket” method are the high correlation of the research results in many cases with the results of in vitro experiments, the simplicity of the method, the ease of implementation and the low cost.

The main working part of the device is a cylindrical mesh with a diameter of 0.25 mm, which filled with a test tablet of up to 1 liter, rotating 50-200 times per minute and maintaining a temperature of 37 ° C. + 10C. Do not shake any part of the instrument. Water or other solvents (hydrochloric acid, buffer solutions with different pH) used as a solvent medium. Capsules dissolved at the following rotation speeds of the basket: 50, 100, 150, 200 rpm. The studies conducted at a temperature of 37±10 ^{0}C. Every 15 minutes from the beginning of the experiment samples taken to quantify diclofenac sodium and paracetamol transferred to the dissolution medium, after which the dissolution medium replenished in the same volume.

To determine the quantitative content of active substances, spectrophotometry used: the optical density of the obtained solution was measured at a wavelength of 510 nm (Indian ginseng).

The content of active substances (Indian ginseng) in one capsule, in percentage calculated by the formula:

$$X = \frac{D_1 * a_0 * 1000 * V_2 * 100 * P}{D_0 * V_1 * a_1 * 100 * 50 * 100} = \frac{D_1 * a_0 * V_2 * 20 * P}{D_0 * a_1 * V_1}$$

D_1 – optical density of the test solution;

D_0 – optical density of the RDF solution of active substances;

a_0 – is the mass of the active substance RDF sample, in mg;

a_1 – the content of active ingredients in one capsule, in mg;

V_1 – volume of the aliquot, ml;

V_2 – volume of second dilution, ml;

P – content of active substances in RDF, %.

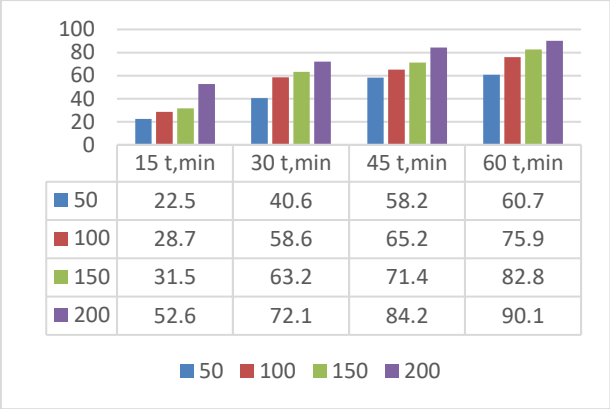
Conversion coefficient of optical density of scion at wavelength 0.925-510 nm for panaxosides.

In all experiments, studies conducted on six units of the dosage form.

Results

The results of studies on the release of Indian ginseng. The results obtained shown in Figure 1.

Figure 1. Determination of biopharmatic performance individuals of indian genshen dry extract-based cappula in *invitro* experiments



	15 t,min	30 t,min	45 t,min	60 t,min
50	22.5	40.6	58.2	60.7
100	28.7	58.6	65.2	75.9
150	31.5	63.2	71.4	82.8
200	52.6	72.1	84.2	90.1

According to the results obtained, at a basket rotation speed of 50 r/min, the release of dry extract of Indian ginseng was 75% less than require by the XIV edition of the State Pharmacopoeia, and amounted to 60.7%, and this speed excluded from the subsequent study.

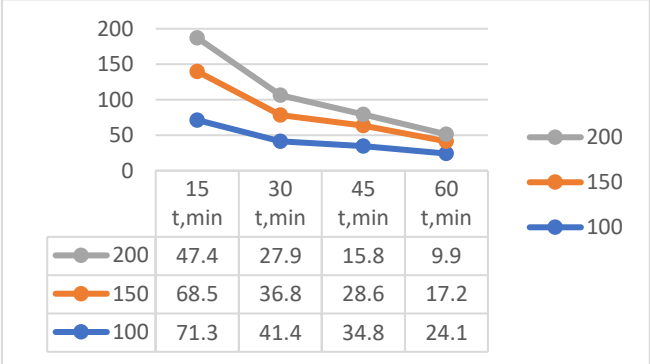
When the basket rotation speed was 100 r/min, 28.7% of the dry Indian ginseng extract extracted in 15 minutes, 58.6% of the dry Indian ginseng extract in 30 minutes, 65.2% in 45 minutes, and 75.9% in 60 minutes. At the following basket rotation speed (150 rpm), 31.5% of the dry ginseng extract extracted in 15 minutes, 63.2% of the dry ginseng extract in 30 minutes, 71.4% in 45 minutes, and 82.8% in 60 minutes.

At 200 r/min, 52.6% of the dry ginseng extract extracted in 15 minutes, 72.1% of the dry ginseng extract extracted in 30 minutes, 84.2% in 45 minutes, and 90.1% in 60 minutes. Thus, at speeds of 100 r/min, 150 r/min, 200-r/min basket reeased more than 75% of the active ingredient required in 45 minutes.

The antilogarithms of the obtained results calculated scientifically justify the chosen rotational speed of the basket.

The results obtained shown in Figure 2.

Figure 2. Antilogarithm of dissolution of capsule based on dry extract of Indian ginseng.



	15 t,min	30 t,min	45 t,min	60 t,min
200	47.4	27.9	15.8	9.9
150	68.5	36.8	28.6	17.2
100	71.3	41.4	34.8	24.1

Based on the results obtained, the following conditions for the experiments to assess the quality of the finished product from a biopharmaceutical point of view were determined: solvent medium – purified water, the volume of the solvent medium – 1000 ml, the speed of basket – 150 r/min. , temperature – 37 ± 10 ℃.

Conclusion

Based on the above, for further study of the quality of general tonic capsules from the biopharmaceutical point of view, the following conditions of in vitro experiments are recommended: The experiments were conducted at 4 different basket rotation speeds: 50, 100, 150, 200 r/min. The antilogarithms of the results obtained calculated for the scientific justification of the chosen speed of rotation of the basket**.**

The following conditions were determined for the in vitro experiments: the solvent medium was purified water, the volume of the solvent medium was 1000 ml, the rotation speed of the cayav was 100 rpm, and the temperature was 37 ± 10 ℃.

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