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Development of the Composition and Production Technology of Floating Tablets Against Helicobacter Pylori and Determination of Quality Criteria

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Abstract

Despite the fact that a large number of synthetic drugs are currently used to prevent Helicobacter pylori infection, the problem remains relevant. The development of the technology of floating tablets of plant origin is important and significant in preventing the complications caused by the infection. Floating tablets are new drug delivery systems that allow the release of active substances intermittently by keeping them in the gastric environment for a long time. For this purpose, a Phyto composition with an optimal composition of garlic, black cumin, and ginger plants in a ratio of 7:2:1 against gastrointestinal infection Helicobacter pylori was formulated in the Pharmaceutical Technology Laboratory of the Azerbaijan Medical University and a phytoextract was prepared based on it. It was determined that the extraction method - high-speed extraction; device rotation speed - 3300 rpm; solvent - 90% ethyl alcohol; exposure time - 7 min; temperature regime - 25°C; pH - 6.5; density - 0.823 g/cm3; when the maximum biologically active substances are 2.5%. This optimal composition had a positive sensitivity to Helicobacter pylori. The technology of floating tablets based on the developed phytoextract (phytoextract, Carbopol, xanthan gum, microcrystalline cellulose, sodium bicarbonate, lactose, magnesium stearate, Aerosol, rosemary aromatic water; gelatin-microcrystalline cellulose-rosemary aromatic water for the coating) was developed and the quality criteria were studied: average weight - 0.7g, compressive strength - 7.0 ± 0.51 Pa, thickness - 4.21 ± 0.23 mm, diameter - 11.20 ± 0.26mm, floating ability: for a regular tablet - 5 min, for a coated tablet - 14 min. The release of biologically active substances from floating tablets was proven by ex vivo studies, and the amount of BFM diffusing into a buffer solution (pH-1-2) within 12 hours was 95.58 ± 1.20%. The phytoextract and floating tablet were tested for microbial contamination and proved to be clean during microbiological tests.

Keywords: Helicobacter Pylori; Phytoextract; Floating Tablet; *In vitro; Ex vivo;* Release of Biologically Active Substances; Floating Time

Introduction

Recent studies have shown that the gastrointestinal infection Helicobacter pylori (H. pylori) occur in approximately 80% of people over the age of 60. In general, almost 70 out of every 100 people are infected with H. pylori. In developed countries, it is 10-50%, and in developing countries, it is 80%. The main reason for this is socio-economic differences. Higher living standards and education, as well as better health conditions, affect the statistics of infection. Since the infection in developing countries usually occurs in childhood and persists throughout life, a large proportion of older people experience long-term consequences of H. pylori infection [1].

During the study of literature, it was found that floating tablets play an important role in the prevention of this infection. It is known that the advantages of floating drug delivery systems (LDS) are increased drug absorption time with a narrow "absorption window", targeted release of drugs directly into the stomach for local action, and reduced undesirable effects in other parts of the gastrointestinal tract. The use of sustained-release technologies not only improves bioavailability, but also provides controlled release ("zero-order" kinetics). Floating systems that are retained in the stomach for a long time can help reduce the frequency of drug intake. Delivery systems can be useful for

the administration of aspirin and other substances that cause gastric irritation. The principles of creating LDS can be used for a variety of drug substances. To ensure maximum therapeutic potential, various gastro-protective drug formulations have been developed and used: floating microspheres (aspirin, Griseofulvin, p-nitroaniline, ibuprofen, terfenadine), floating granules (diclofenac sodium, indomethacin, prednisolone), floating capsules (diazepam, furosemide, misoprostol, pep statin), floating tablets and pills (acetaminophen, acetylraftisylic acid, ampicillin, atenolol, diltiazem, fluorouracil, theophylline) [2-9]. Raft-forming (raft-SAL) systems have attracted considerable attention for the treatment of infectious diseases of the gastrointestinal tract and for the delivery of antacids. The system consists of gel-forming polymers and gas-generating agents (sodium/potassium bicarbonate and calcium/magnesium carbonates) that form carbon dioxide bubbles upon contact with gastric juice and provide buoyancy for the resulting raft.

The raft is formed in the upper part of the stomach, floats and has an almost neutral pH value. In the acidic gastric environment, the alginate raft hardens: calcium and magnesium cations "cross-link" the alginic acid polymers that form the supramolecular matrix structure. The raft, floating on the surface of the gastric juice, prevents the reflux of gastric contents into the esophagus, acts as a barrier between the stomach and the esophagus, and in the form of a regurgitation or reflux gel enters the esophagus, where it has a neutralizing effect when hydrochloric acid and pepsin enter the esophagus [6,10-16].

During the analysis of scientific literature, it became clear that the technology of floating tablets has been developed separately from the plants we chose as the object of research: cultivated garlic (Allium sativum L.), common oregano (Origanum vulgare L.) and medicinal ginger (Zingiber officinale Roscoe) [17,18].

However, a joint combination of these plants has not been developed. Considering the synergistic effect of the aforementioned plants in the treatment of the gastrointestinal infection Helicobacter pylori, we aimed to conduct research on the preparation of floating tablets using different polymer combinations and coating materials.

Materials and methods

Cultivated garlic, common scallion and medicinal ginger were used as the objects of the study. The effect of these plants against H. pylori was presented in our previous works [19,20]. Also, phytochemical, microbiological, statistical, biopharmaceutical methods were used in the study. Extracts (10 substances) obtained by high-speed extraction method were submitted to microbiological studies. Of the Phyto-extracts 1-5, as well as HP1 (garlic-ginger-origani 2:7:1), HP2 (garlic-ginger-origani-1:2:7), HP3 (garlic-ginger-origani-7:1:2), HP4 (garlic-ginger-origani-licorice-4:3:2.5:0.5), HP5 (garlic-ginger-origani-5:2:3), only HP3 has the property of inhibiting the causative agent of Helicobacter pylori. According to the results of the microbiological study, the next experiments were continued with the HP3 Phyto-extract, which has a more effective effect.

It should be noted that the components (1,2,3,4,5 and HP4) containing licorice do not cause any sensitivity to Helicobacter pylori. At the same time, the sensitivity of the extracts obtained during extraction with 70% alcohol continued in the same way. The best result was obtained in the composition HP3 (cultivated garlic-medicinal ginger-common fenugreek 7:1:2) as a result of extraction with 90% ethanol. This was consistent with the materials we obtained from the literature. That is, all in and allicin, as well as essential oils and flavonoids, are better extracted with such a concentrated solvent [21,22].

During the experiments conducted in laboratory conditions, incompatibility between these plants also occurred. Thus, during the preparation of extracts containing licorice + ginger, licorice + origani + ginger, licorice + garlic + ginger + origani, licorice + origani, color change and sediment were observed after 1 day. Thus, the components active against Helicobacter pylori were 90% alcoholic extract of garlic+ ginger + origani plants.

Identity reactions related to biologically active substances in the optimal extract

Table 1: Results of identity reactions in phytoextract sensitive to Helicobacter pylori.

Plants	BAS	Identical reaction	Color change	Stability (pH, temperature, light)
Garlic	Allicin, alliin	$FeCl_3$ + ethanol extract	Light brown-green	Sensitive: pH < 5 and > 8 unstable, decomposes in light and heatunstable, decomposes in light and heat
	Sulfur compounds	Pb $(CH_3COO)_2$ + HCl	White precipitate (PbS)	It oxidizes quickly with oxygen and temperature, so it should be stored cold.
Ginger	Gingerol, shogaol	Vanillin-HCl reagent	Reddish-orange	Gingerol converts to shogaol in heat, pH 4-6 stable, light sensitive
	Phenolic compounds	$FeCl_3$ (1%)	Blue-purple	Moderate stability: Risk of decomposition in light and high temperatures
Origani	Carvacrol, thymol	$FeCl_3$ (1%) or NaOH + HCl	Yellow to dark brown	Partially stable: well, preserved between pH 5–7
	Flavonoids	Shinoda test (Mg + HCl)	Red	High stability, but possible decomposition under ultraviolet light
	Phenolic acids	$FeCl_3$ (1%)	Green	Good stability, but decomposition may occur at pH < 3

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Identity reactions were carried out to prove the presence of the main biologically active substances in the prepared extract. For this purpose, 1 ml of the obtained extract was taken and placed in a clean test tube and the appropriate reagents were added to it. The active substances were identified according to the characteristic colors (Table 1).

Preparation of floating tablet and study of quality criteria

A floating tablet was prepared based on phytoextract, Carbopol, xanthan gum, microcrystalline cellulose, sodium bicarbonate, aerosol [18]. Some physicochemical and technological properties of the prepared tablet were studied (Table 2).

Table 2: Technological characteristics of the floating tablet-HP.

Weight fluctuation(mg)	thickness (mm)	Strength (kg/sm^2)	Friction (%)	Diameter (mm)	Composition of the drug (%)	Floating time of the tablet (min)	Density (g/sm)
700 ± 1.61	4.21 ±0.23	7.0 ±0.51	0.85	11.20 ± 0.22	99.91 ± 1.48	4.91 ± 1.56	0.92

In vitro studies on drug release from floating tablets

Table 3: Determination of the release rate of active ingredients from a floating tablet in an acidic environment.

Time, hours	Tablet-HP
1	5.81±1.5
2	19.18±1.4
3	33.21±1.34
4	45.63±2.10
5	58.66±1.2
6	67.73±1.57
8	80.27±1.83
10	90.31±1.59
12	95.58±1.20

The dissolution medium used to test the release of tablet formulations was 0.1N HCl for in vitro drug release. The release of BFM from floating tablets was tested and the results are shown in the table. Using dissolution profiles, the release profile of the drug with different polymer concentrations from batches can be compared. The gelling ability of the extract may be responsible for the long-term effect of the drug. It shows in vitro release. The drug release from the floating tablet was 95.58 ± 1.20 percent. In these systems, gases are generated using sodium bicarbonate. After contact with gastric acid, it forms gas. It is trapped in a water-soluble polymer matrix that floats in the acidic environment of the stomach (Table 3)

Targeted release of drugs in the stomach can be achieved using floating drug delivery systems. Phytoextract floating tablets are designed to keep the drug in the stomach for a longer period of time, increase bioavailability, and target gastric ulcers. Hydrocolloids (e.g. xanthan gum, chitosan and Carbopol 940, sodium bicarbonate) were used to expand a floating tablet. They were tested for their properties before compression, physical properties, buoyancy, lag time, in vitro release and swelling index before compression. It was determined which formulations worked best for different xanthan gum viscosity grades, Carbopol 940 concentrations and mixtures. The results of the experiment showed that Floating Tablet-HP was able to maintain the drug release (95 percent) and at the same time remained in water. We then applied a polymer coating to the surface of the tablet to ensure that it floated for a longer period of time.

Preparation of coating for floating tablet

To ensure long-term effect of the tablets, they were coated. For this purpose, a solution consisting of gelatin, microcrystalline cellulose and rosemary scented water was prepared and placed in a spray bottle. Then, it was sprayed on the prepared tablet samples. After drying for 1 day, the solution was sprayed on the tablets again. After the floating tablets were completely dry, their floating time was observed in an environment with pH-1.0-2.0. The results are given in (Table 4).

Table 4: Coating composition and floating time for floating tablets.

Floating time of the tablet (min)	Gelatine	MCC	Rozmarin aromatic water
14,06 ± 2,24	5	3	92

Technological process

Ingredients: Gelatin – 5%; MCC – 3%; Rosemary scented water – 92%

Technological process:

a) Gelatin is soaked in rosemary water at 40-45°C for 15 minutes and allowed to swell.

b) Complete dissolution is achieved by vigorous mixing.

c) MCC is dispersed in a small amount of water before

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being added directly, and then added to the mixture.

d) When a solid but fluid consistency is obtained, it is cooled and used.

Determination of microbiological purity

The substances submitted for microbiological studies were first heated in a water bath, liquefied and cultured using a sterile pipette in 0.1 ml of 4 different sterile nutrient media (EPA and Saburo) using sterile buffer. The cultures were evaluated after 18-24 hours of incubation at 370°C. No microbial cell growth was recorded in the nutrient media used.

Conclusion

The main direction of the research is the use of suitable polymer coatings to prepare tablets with long-term buoyancy against gastrointestinal infection Helicobacter pylori. In the research work, the synergism of Carbopol + xanthan gum allowed the tablet to swell for a long time and release the active substance. The absence of acids (citric acid, benzoic acid, tartaric acid, etc.) in the newly proposed composition (garlic + ginger + Origanum), unlike similar floating tablets, also allowed the tablet to remain in the acidic environment of the stomach for a long time. When using a mixture of two polymers, the solubility in water in terms of water permeability depends on how quickly the acidic environment of the stomach can penetrate the tablet core to neutralize the NaHCO3 contained in it and create CO2 gas. Under these conditions, while the tablet can float for 5 minutes, it is believed that covering the surface of the tablet with a MCC + gelatin coating will extend the floating process by almost 14 minutes, gradually releasing the active substance and preventing Helicobacter pylori infection in a timely manner. In the future, its production may be proposed for the local pharmaceutical industry as a potential pharmaceutical product.

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