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Development and Preparation of the Composition and Technology of Phytosomal Gel for the Treatment of Couperose and Study of Quality Criteria

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Abstract

Coupe rose is a widespread chronic skin problem. In the treatment of the disease, many synthetic and Phyto preparations are applied. However, the solution of the problem requires new drug delivery systems-phytosomes, which are more effective, with a reduced bioavailability and a long-term effect. Taking this into account, a scientifically based photocomposition of optimal composition was compiled from horse chestnut-ordinary hops-green tea plants, a phytoextract was obtained on its basis and the technology of obtaining a Phyto some was implemented. On the basis of phytoextract and phosphatidylcholine in a 1:1 vacuum-evaporative device (BioBase brand, 2 hours, temperature regime 40-50°C, rotation speed of the device 120 RPM) by rotor evaporation method, optimal composition Phyto some was obtained. The optimal composition of Phyto some was included in various gel bases, the optimal composition on the basis of xanthan gum (Phyto some, xanthan gum, Phenoxyethanol + Ethylhexylglycerin, Pentylene glycol, vitamin E, rose oil, distilled water) was determined. In the centrifuge of the brand "Tablet top DSC 200A-2, speed-6000 rpm " it was found that it remains stable at 6000 rpm for 10 min, pH indicator - 6.4, characteristic of good diffusion and absorbability. Ex vivo studies calculated the amount of rutin released from phytosomal gel within 24 hours and determined to be 85%. The gel "Anti coupe rose Phyto Som" developed during the studies was microbiologically pure; it was found that it has an Angio protective effect in comparison with the gel "Troxevazin" in Chinchilla rabbits.

Keywords: Phytosomes; Coupe Rose; Gel; Topical Application; *Ex Vivo*, Rapid Wear Test; Natural Stability

Introduction

Anti-coupe rose Agents for Cosmetics Market size is estimated to be USD 1.5 Billion in 2024 and is expected to reach USD 3.2 Billion by 2033 at a CAGR of 9.2% from 2026 to 2033(Figure 1). The Anti-coupe rose Agents for Cosmetics Market refers to a specific segment within the skincare and beauty industry focused on products designed to prevent or reduce the appearance of coupe rose, a condition characterized by visible capillaries and redness, especially around the face. This condition is often linked to skin sensitivities and is commonly found in individuals with fair skin. Anti-coupe rose agents are typically formulated with soothing, anti-inflammatory, and vasoconstrictive ingredients, such as plant extracts, peptides, and antioxidants, which help in alleviating the redness and promoting even skin tone. The global demand for such products has been on the rise due to increasing awareness of skin health and the growing popularity of specialized skincare regimens, as consumers increasingly seek treatments for more targeted skin concerns like coupe rose [1].

The prevalence of coupe rose, according to WHO data for 2025, is 5% of the elderly population, which is 415 million. it means that the world's population suffers from chronic skin disease. In this direction, various drugs of natural and synthetic origin are produced and applied in the elimination of the disease. However, the development of medicinal products for the development of Phyto some, a new drug delivery system with a long-term effect in solving the problem, and their loading into the gel, is considered a priority issue of Pharmaceutical Technology [2]. The emergence of Phyto some nanotechnology has potential implications in the field of drug delivery and may alter the current state of delivery of topical bioactive phytochemicals. The main problem encountered during the application of the therapeutic activity of phytochemicals to clinical conditions is their extremely low absorption rate and poor penetration through biological barriers (i.e. skin).

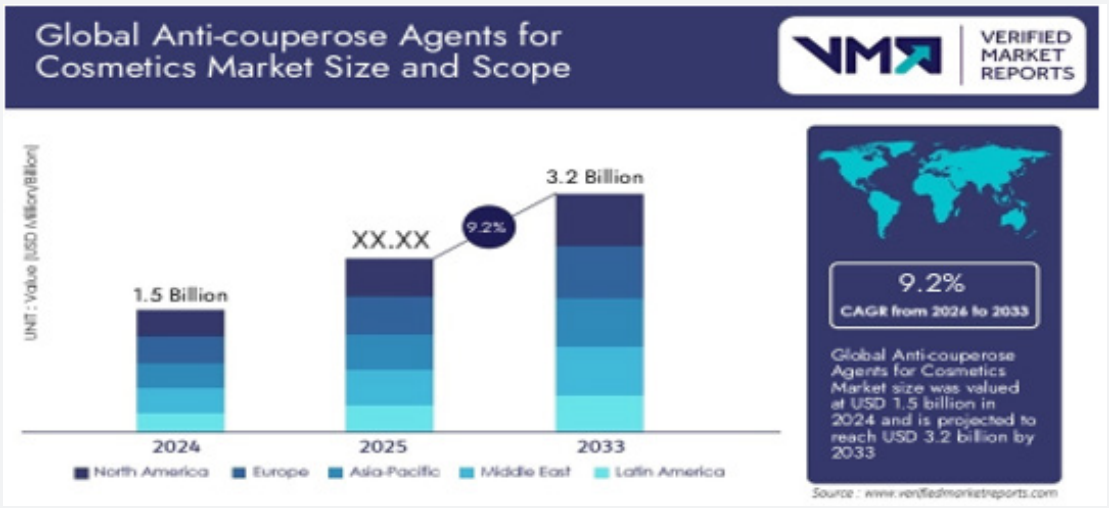

Figure 1: Global Anti-couperose Agents for Cosmetics Market Size and Scope.

Phytosomes as Lipid-based nanodducers perform an important function in enhancing the pharmacokinetic and pharmacodynamic properties of plant-based polyphenol compounds, making this nanotechnology a promising tool for the development of new topical formulations. The application of this nanoscale delivery system can strengthen the penetration of phytochemicals through biological barriers due to their unique physicochemical properties, improve their bioavailability. In this review, we provide an overview of current knowledge about the biological barriers of topical applications of phytoconstituents. With particular emphasis on phytosomes as an innovative lipid-based nano Designer, the great potential of emerging nanotechnology in delivering bioactive phytochemicals is being considered. In addition, we compared phytosomes with liposomes as the gold standard of lipid-based nanostructures for topical delivery of phytochemicals. Finally, the advantages of phytosomes in topical applications are discussed. Phytosomes, or herbosomes, are a pioneering new form of phytocresponents that are better absorbed topically and trans dermally. Phyto some is a phospholipid complex invented in 1989 by the Italian food and pharmaceutical company "Indena". The term phytosome consists of two terms, 'Phyto', denoting the plant, and 'body', similar to the cell, in which its chemical components are protected within the phospholipid double layer [3,4] It is concluded that the phytosome is a flavonoid molecule associated with at least one phosphatidylcholine molecule.

It is a hybrid molecule with high solubility in Lipid and aqueous environments. In aqueous environments, phytosomes are grouped into micelles. Phytosom is used to increase the bioavailability of the drug component, more targeted delivery, increase the effectiveness of the action and increase the therapeutic dose of the drug. A promising direction is the expansion of the range of phytosomal medicinal forms, which include not only flavonoids, but also other natural hydrophilic compounds [3].

In topical applications, phytosomes have a number of potential advantages over conventional topical formulations. Phytosomes increase the absorption and bioavailability of the skin and cause the delivery of active components of plant origin to the tissues. In addition, phytosomes improve skin functions by increasing hydration, enzyme balance and collagen structure. The high affinity of phytosomes for skin phospholipids has enhanced its effectiveness compared to conventional free compounds. As mentioned earlier, there are a number of obstacles facing topical applications of phytosomes preparation. For example, one of the most important barriers to transdermal application of phytochemicals is the stratum corneum, which is the thick outer layer of the epidermis. Bioactive molecules can pass through the SC (Stratum corneum) in various ways, intercellular or intracellular. Intercellular penetration can be achieved through sweat glands, sebaceous or hair follicles, while the intercellular lipid Matrix and corneocytes are the main pathways of intracellular penetration. It was reported that increasing the diffusion coefficient of the drug can increase the concentration of biomolecules and strengthen the division between these molecules and the SC layer, and all these factors can improve the permeability of biomolecules to SC for transdermal application.

The transdermal permeability of active products can be increased if the active substances have lipophilic and low molecular weight.4,5 Most of the widely studied phytocard compounds are polyphenols, which, due to their hydrophilic nature, have poor bioavailability and lipid solubility and limit their activity in vivo. The phospholipid parts of phytosomes have a high affinity for tightly binding several flavonoid compounds. There are several plant extracts, such as Hawthorn, grape seed, green tea, milk thistle and ginseng, which are more effective when loaded into phytosomes, or even more effective when transported

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in liposomal form. Formation of phytosome nanoparticles of polyphenol-based phytochemicals enhances the application of standard plant materials, increasing their stability, since the phospholipid molecules of phytosomes interact with active phytochemicals. In addition, the phytosomes-plant complex has a higher affinity for the phospholipid part of the skin, which can improve the lipid solubility of the topical preparation [4-8].

Many studies have reported better anti-inflammatory activity of phytosome on pure plant extract. A study was carried out on the absorption of the rutin phytosome into the skin and it was found that rutin phytosomes are better able to penetrate the stratum corneum with a high permeability capacity than free rutin. Maintaining this high amount of routine will make it possible to slowly pass through the living dermis and have a long-term anti-inflammatory effect. In the study of carrageenan-induced inflammation in rats, inflammation was significantly inhibited by the test group rutin phytosome compared to the standard diclofenac gel. Since Rutin-phytosomes are lipophilic, it has been found that the drug is located in the epidermal-dermal region, where it is slowly released to have a long-term anti-inflammatory effect. In another study, lausone phytosome gel therapy for 4 hours in rat paw edema caused by carrageenan showed significant anti-inflammatory effects compared to plant Lauson gel. [9-11]. Taking into account the above, we set ourselves the goal of developing a phytosomal gel from plant components, the composition of which is rich in rutin, for the treatment of cuprosis, which remains a problem to this day.

Materials and methods

Green tea *(Camellia sinensis)*; common yeast *(Humulus lupulus)*, common horse chestnut *(Aesculus hippocastanum)* was chosen as objects of study. At the same time, lecithin, Xanthan gum, Carbopol, Na-KMC, pentylene glycol, glycerin, essential oil of Rose, Phenoxyethanol+ Ethylhexylglycerin were used.

Discussion of Results

Inclusion of Phyto some in gel and study of quality criteria

For the first time in our previous work, we prepared an extract and Phyto some of optimal composition from the proposed Phyto composition and studied the quality criteria [12,13]. In our current work, the preparation of a gel based on the same Phyto some has been set as a goal. For this purpose, several gel bases (carbopol, xanthan gum, sodium-CMC) were selected. The composition of the gels is given in (Table 1).

Table 1: Phytosome-containing gel formula.

Components	Quantity		
	I	II	III
Active Ingredients (Extracts Of Green Tea, Horse Chestnut, Hops)	3	3	3
Lecitin	1-2	1-2	1.0-2.0
Xantan gum	-	-	0.6
Carbopol	0,5	-	
Sodium-KMS	-	0,7	-
Sodium hydroxide	10	-	-
Glycerin	1,5	2,0	3
Pentilenglycol	1,5	3,0	2
Phenoxyethanol + Ethylhexylglycerin	1	0,5	0.8
Essential oil of Rose (Lavender)	0,05	0,05	0,05
Distilled Water	100 q.s.	100 q.s.	100 q.s.

When the colloidal stability of the prepared gels was studied, it became a xanthan gum-containing gel with better stability. In the other 2 gel models, a violation of the structure was observed. Therefore, we carried out the next studies precisely on the composition of the 3rd composition. After that, the rheological properties of the prepared gel were studied. For this purpose, a graph of the viscosity of the gel at different temperature modes, the viscosity of graph of the dependence of the sliding voltage, the construction of the hysteresis loop was carried out (Table 2, Figures 2 & 3). As can be seen from the table and figure, as the temperature regime increases, a decrease in the viscosity of the gel is observed. This also indicates that the optimal temperature range for phytosomal gels is: +4°C – +8°C (refrigeration conditions) or +20°C – +25°C (dry, cool, away from sunlight). Temperatures above + 30°C can lead to degradation of phytosomes and a decrease in the viscosity of the gel. In general, if the phytosome-containing gel is stored in the refrigerator (4-8°C), its stability increases, but a slightly firmer consistency may be observed when

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applied. At 30°C and above, there is a risk that phytosomes will come out of the capsule, the phospholipid bonds will weaken and the viscosity will decrease. Thus, for the preservation of the phytosomal structure and stable viscosity, it is advisable to store it in the range of 20-25°C, in a sun-free and dry environment.

Table 2: The result of the change in viscosity of the gel made with xanthan gum depending on the temperature.

Temperature (°C)	Viscosity (mPa·s)
4	5200
10	4800
20	4300
25	4100
30	3600
37	3100
45	2600

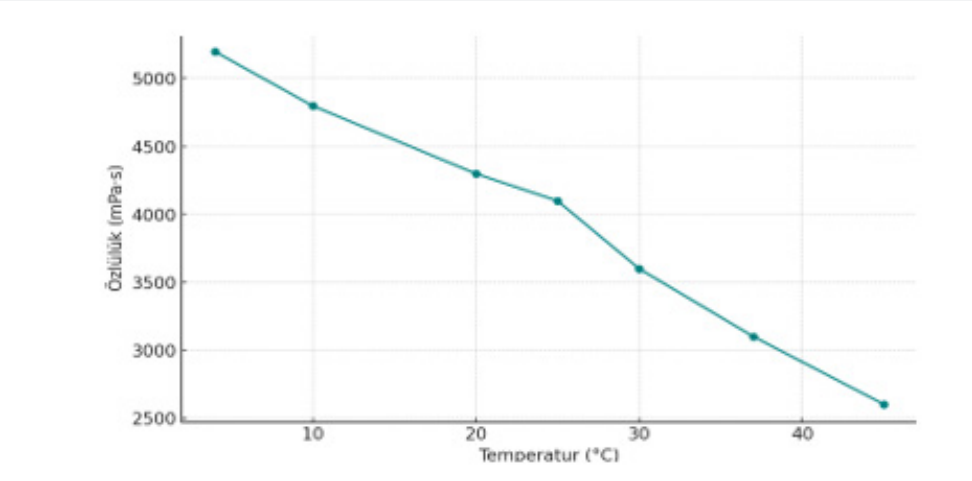

Figure 2: Change in viscosity of phytosomal gel at different temperature modes.

Ex vivo studies of phytosomal gel

The following stages were performed to assess how effectively the active substances passed through the membrane using the *Ex vivo* egg membrane:

a) Preparation of the egg membrane: separating the outer shell of the egg, we use only the

membrane (i.e., egg shell membrane, ESM). Using the upper layer of the membrane, Phyto some or other extracts to be treated are placed on it.

b) Use of Phyto some gel: the Phyto some-containing gel is rubbed into the egg membrane (1 g)

closed in a test bottle and placed in a chemical beaker with a saline solution inside. The process is performed by adjusting the temperature regime at 37°C in the device with a magnetic mixer. In this case, Phyto some enter the lipid structures of the membrane, releasing biologically active substances. Every 1 hour, 10ml of the solution passed to dialysate is taken and analyzed. The same amount of new solution is added to the experimental glass.

c) Measurement of the permeability of active substances: In order to measure the passage of

active substances through the membrane, appropriate analytical methods are used, for example: UV-Vis Spectrophotometry: by measuring the absorbance of the active substance, its quantity and speed of passage can be determined. HPLC (High-Performance Liquid Chromatography): used to analyze the passage of active substances specifically to the membrane. Fluorescent marking: by adding fluorescent markings to the active ingredients, the permeability can be traced at the microscopic level. Weight-volume method. It is used to analyze the passage of active substances into the membrane.

d) Evaluation of results: conduction velocity: to assess the rate of passage of active substances

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through the egg membrane. Depth of penetration of the skin: up to which layers of the skin are Phytosomes able to penetrate. Toxicological data: by analyzing the amount and rate of release of active substances of Phytosomes, information about the safe dose and effectiveness is obtained.

e) Application of coupe rose in the treatment of facial skin: Phytosomes can be effective in the

treatment of coupe rose (condition of the skin in which there is red, vasodilation), one of the main problems of facial skin. Active ingredients, such as flavonoids, can reduce coupe rose symptoms by strengthening blood vessels and improving blood circulation. Along with this, phytosomes penetrate deep into the skin, helping to increase microcirculation, and also ensure the effect of active substances on the muscles.

Conclusion: This method shows the ability of phytosomes to pass through different layers of the skin, releasing active substances deeper. Experiments on the Ex vivo egg membrane are useful to show how effective these types of systems are, as well as further increase the potential to be applied to treat the skin. A deeper study of this technology and its future use in the field of coupe rose treatment on facial skin can lead to significant developments in dermatology and cosmetology (Table 3).

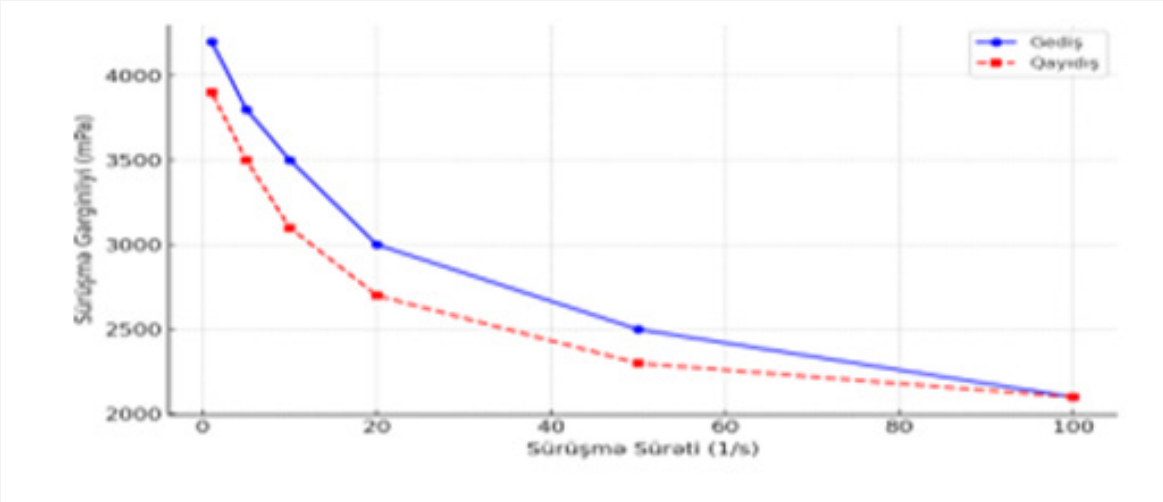

Figure 3: Image of the hysteresis loop.

Table 3 shows the amount of release within 24 hours. However, it should be noted that the complete release of the routine does not occur during this period, and the release period with new applications applied to the surface of the skin continues. The process of releasing rutin occurs with time under the influence of phytosom gel applied to the skin. The properties of products of this type are such that biologically active substances (for example, rutin) penetrate into the deep layers of the skin, but the process of complete liberation is not completed in a few hours. Thus, the rate of release of rutin and the persistence of its effect on the skin depend on various factors: on the type of skin, the structure of phytosomes, the solubility of substances and the dose administered.

The rate of release of rutin and the effect of Phytosomes: the process of release of rutin occurs gradually after application to the surface of the skin. Phytosomes help to more effectively deliver biologically active substances such as rutin to the lower layers of the skin. These substances cross the hard barriers of the skin and act on the lower layers of the skin. The process of applying it daily or applying it 1-2 times a day ensures that the routine is released over a longer period of time and that a smaller amount remains on the surface of the skin. This supports the Slow-Release process and helps protect the upper layers of the skin. Amount of rutin released in 24 hours: if within 12 hours 1191 mg of rutin is released, then within 24 hours there may be double (or more) of this amount, but at this time the process of complete release will not occur. Because phytosomes gradually release substances into the skin and the routine that has not been completely freed is released again after the next application. Taking into account the rate of release of phytosomes and rutin, approximately 24 times more rutin will be released within 2 hours. But during this time, new layers applied to the skin will provide new rutin substances, so that the time of complete release will be extended [14-16].

Structural - mechanical properties, pH indicators, colloidal stability of the prepared phytosomal gel at different temperature regimes for 6-12-18 months were determined (Tables 4-7).

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Table 3: BAS released from phytosomal gel within 24 hours (in rutin example).

Hours (s)	Liberating routine, (%)	Liberating routine, (mg)
0	0%	0 mg
1	5%	59.55 mg
2	10%	119.1 mg
3	15%	178.65 mg
4	20%	238.2 mg
5	25%	297.75 mg
6	30%	357.3 mg
7	35%	416.85 mg
8	40%	476.4 mg
9	45%	535.95 mg
10	50%	595.5 mg
11	55%	655.05 mg
12	59.55%	1191 mg
13	62%	1191 mg
14	64%	1191 mg
15	66%	1191 mg
16	68%	1191 mg
17	70%	1191 mg
18	72%	1191 mg
19	74%	1191 mg
20	76%	1191 mg
21	78%	1191 mg
22	80%	1191 mg
23	82%	1191 mg
24	85%	1191 mg

Table 4: A. Accelerated Wear Test (Accelerated Stability Test).

Condition	Temperature	Moisture	Term
1	40°C	75% RH	6 months
2	25°C	60% RH	12 months
3	4°C (Cold Blow)	Dry conditions	1 month (optional)

Table 5: Sample for 40 months under 75°C/6% RH condition.

Months	pH	Viscosity (mPa·s)	Phytosome Size (nm)	Releasing routine from the gel (%)	Color/Odor Change	Notes
0	5.6	4100	50-80	85	not	Stable
1	5.6	4000	60-90	82	not	
2	5.5	3900	65-100	80	Slight yellowing	Partially fixed
3	5.4	3700	70-110	76	Slight odor change	Partially fixed
6	5.2	3300	90-130	70	Color and texture change	Degradation begins

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Table 6: Natural stability – Real Time Stability) - 25 months under 2°C ±60 °C and 5% RH ±18% condition.

Months	pH	Viscosity (mPa·s)	Phytosome Size (nm)	Releasing routine from the gel (%)	Organoleptics	Notes
0	5.6	4100	50-80	85	Normal	Starting month
3	5.6	4080	55-85	84	Normal	Stable
6	5.5	4050	55-90	82	Normal	Stable
9	5.5	4000	60-90	80	Slight change	Partially steady
12	5.4	3950	65-95	77	Slight yellowing	Partially steady
15	5.3	3850	70-100	74	Slight structural change	Partially steady
18	5.2	3700	75-110	70	Color changes	Degradation begins

Table 7: Test types and conditions.

Test Type	Temperature	Moisture	Term	Storage container	Following Settings
Real time	25 ± 2°C	60% RH	12 months	Amber bottle	pH, viscosity, color, odor, phytosome size, rutin release
Cold test	4 ± 2°C	Dry	6 months	Amber bottle	Same parameters
Accelerated testing	40 ± 2°C	75% RH	6 months	Plastic/PET	Same parameters

Stability test protocol (anti-Coupe rose phytosoml containing gel) Product name: Anti-coupe rose gel with Phyto some Ingredients: atshabalidi-green tea-humulus lupulus extract, lecithin, xanthan, glycerin, pentylene glycol, phenoxyethanol+Ethylhexylglycerin, rose oil, water Formula pH: 5.6 Viscosity: 5200 mPa.s (4°C), 4100 mPa.s (25°C) Phyto some size: 50-80 nm Routine release (24 hours): 85%.

In the course of research, it turned out that the gel for the treatment of coupe roses can remain stable for 4-25 months if stored in cold conditions and in a place protected from light (12°C).

Study of the Angio Protective Effect of Phytosomal Gel

Research on rabbits: a study was conducted on 10 rabbits. Artificial hyperemia was created by applying toluene to one ear of each rabbit and observation was carried out. Within thirty minutes, it was seen that the ear fell too normal.

At the second stage, hyperemia is again created in the ears of rabbits, and a commercial product "Troxevazin" gel is applied over it and monitored. A decrease is seen within 5 minutes, a normal state within 15±2 minutes.

In the third stage, hyperemia is created in the ears of rabbits and phytosomal gel is applied and monitored. A decrease was observed within 8 minutes and a completely normal state within 15 minutes

Conclusion

In this research work, the study of the technology and quality criteria of phytosomal gel, an alternative drug form for the treatment of coupe roses, was carried out by tests *in vitro*, *ex vivo*, *in vivo*. In the preparation of the gel, a gel base of natural origin, auxiliary substances were applied, which allows the Phyto some to remain stable, good bioavailability. *Ex vivo* studies found that the rutin released from the egg membrane within 24 hours was 85%, laying the foundation for a positive role in the elimination of coupe rose. Comparative experiments *in vivo* experiments with the gel" troxevazin " proved that the newly developed Phyto some-containing gel has an effective effect, or rather, a good Angio protective effect. We believe that the results of the study will be of interest to these scientific community.

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