Opinion

Selection of excipients and study of their influence on quality indicators of tablets with dry extract of clover and calendula

Volume 12 Issue 3 - 2023

Halyna Slipchenko
National university of pharmacy, Kharkiv, Ukraine

Correspondence: Halyna Slipchenko, National University of Pharmacy, Kharkiv, Ukraine, Email galinaslipchenk@ukr.net

Received: May 25, 2023 | **Published:** September 19, 2023

Introduction

Cardiovascular diseases, coronary heart disease and stroke, are the leading causes of death and one of the main factors of disability worldwide. In Ukraine, cardiovascular disease is the leading cause of mortality. Our country remains one of the world leaders in this indicator. The occurrence and course of cardiovascular and cerebrovascular diseases are closely related to the presence of risk factors, the main ones being high blood pressure, impaired lipid metabolism, overweight, unhealthy lifestyle (smoking, unhealthy diet, alcohol abuse, lack of physical activity), and environmental factors (psycho-emotional stress, harmful environment at work and at home). Some studies show that the risk of heart disease is higher among groups of people who have more than one of these risk factors (e.g., sedentary smokers). While choosing preventive herbal medicines, patients are guided by their own preferences, experience, pharmacists' advice, advertising, etc. In recent years, there has been a growing interest in doctors, pharmacists and patients to a number of original areas of medicine, in particular homeopathy and homeopathic pharmacy. We chose dry clover and calendula extract as the active ingredient.

The aim of the study

The primary objective of the master's thesis is to study the physicochemical and pharmacotechnological properties of dry clover and calendula extract, substantiate the composition and technology of tablets, and determine the effect of excipients on the quality of tablets.

To achieve this goal, it was necessary to solve the following tasks:

1) To review the literature on the prevalence of cardiovascular diseases and treatment approaches;
2) To analyze the range of drugs for the treatment of cardiovascular diseases and the development of drugs based on plant materials;
3) To study the physicochemical and pharmacotechnological properties of dry clover extract;
4) To experimentally substantiate excipients for the creation of tablets and to study the effect of excipients on the quality of the resulting tablets.

Objects of study

Dry extract of clover and calendula, physicochemical and pharmacotechnological properties. Excipients, mass for tableting, intermediates and finished dosage form - tablets.

Subject of the study

Development of tablets based on dry clover extract. Study of the technological properties of the extract, selection of excipients and the effect of excipients on the quality of tablets.

Research methods

To solve the tasks, physical, chemical and pharmacotechnological studies were used, namely:

Methods for determining fluidity, bulk density, angle of natural slope, pressability of powders and pressing force, resistance of tablets to crushing, disintegration.

Methods for determining the average weight and abrasion resistance.

Results and discussion

Clover roots, leaves and flowers are saturated with essential oils and contain a considerable number of organic acids (coumaric, salicylic, ketoglutaric), vitamins (groups A, B, C, K and E), tannins, fiber, protein, macro- and microelements (chromium, selenium, iron, phosphorus, magnesium, calcium, etc.). The green mass and flowers of clover include proteins, tannins, many flavonoids, carotenoids, as well as furfural, xanthine, tyrosine, asparagine, and other useful substances. Clover increases the level of healthy HDL cholesterol, thins the blood, and has a protective and strengthening effect on the cardiovascular system.

The choice of dosage form is of great importance in the implementation of the absorption processes of active substances, which are determined by the physicochemical, pharmaceutical and technological properties, as well as the therapeutic dose of active biologically active substances. The choice of tablet form is due to a number of advantages over other forms of solid dosage forms: precise dosage of the drug substance, the ability to vary the dosage, ease of use, full mechanization of the manufacturing process, cost-effectiveness and portability, which ensure ease of dispensing, storage and transportation.

This section highlights the research on the development of the composition and production technology of tablets for the treatment of cardiovascular diseases with dry clover extract. The components were selected, their quantitative characteristics were studied, and the

technological parameters of production were determined, taking into account the results of experimental studies of the pharmacological, technological, physical and chemical properties of dry extracts and products during production.

In order to develop and determine the optimal quantitative indicators of the composition and technological parameters and modes of preparation of tablets, the crystallographic and basic pharmacological, technological, physicochemical properties of dry clover extract and calendula were studied. The shape and particle size of the dry extract was studied by microscopy. To do this, a small amount of powder was applied to a glass slide and examined under a microscope.

Microscopy of clover extract powder and calendula powder are shown in Figure 1&2.[1-3]

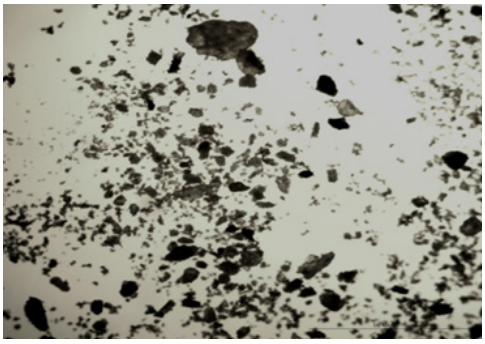

Figure 1 Micrograph of clover extract powder dry (magnification 100 times).

Figure 2 Micrograph of calendula extract dry.

Studies have shown that the powder of the dry extract is a moderate particle with a size of 500 to 1000 microns, uniform in shape.

It should be noted that the extract is hygroscopic and can agglomerate under the influence of environmental moisture, and also has a specific odor.

The next stage was the study of pharmacological, technological, physical and chemical properties: fluidity, angle of natural slope, bulk density before compaction and after compaction, compressibility, force of pressing out the pressing from the matrix, moisture content, etc. of the tested substances were carried out according to the methods described in Section 2. The results of the research are presented in Table 1&2.

Table 1 Pharmacotechnological properties of clover extract dry

Moisture content, %	1.5 ± 0.15
Flowability, c/100g	45 ± 1.14
Bulk density, g/cm^3	0.75
Natural level angle, degrees	38^o
Pressing, H	40.0 ± 1.04

Table 2 Pharmacotechnological properties of dry calendula extract

Moisture content, %	4.68 ± 0.12
Flowability, c /100g	52 ± 2.1
Bulk density, g/cm^3	0.71
Pressing, H	35.0 ± 1.13

The analysis of the pharmacotechnological properties of dry clover extract (Table 1) showed that the powder has satisfactory fluidity values (45 ± 1,14), as evidenced by the angle of natural slope. The obtained pressability needs to be adjusted as it is extremely important in the technology of tablet dosage forms.

Dry calendula extract has quite satisfactory flow characteristics (Table 2), but the resistance to pressing is unsatisfactory, which requires the introduction of excipients.

Purified water was chosen as the solvent for the dry extract. Carbomer 971 NF, Na-CMC, CMC, agar-agar, carbomer, xanthan gum, apple pectin and their combinations were used as gelling agents. Sorbic acid was used as a preservative. Experimental samples were prepared, and their structural and mechanical properties were studied. Na-CMC was chosen as a gelling agent. Flavor corrigents (fructose, sodium saccharinate, stevia extract, sucralose) and flavorings (raspberry, banana and cherry) were used to improve taste characteristics. The research allowed us to choose sucralose at a concentration of 0.15% and banana flavoring as a flavor corrigent.

Conclusion

As a result of technological studies, the shape and particle size of dry clover and calendula extract were studied. The physicochemical and pharmacotechnological properties of the substance and the kinetics of moisture absorption were studied. The results of the study made it possible to predict the possibility of using the direct pressing method in the production of tablets. Excipients were selected as the most used in direct pressing. The concentration of each component was selected experimentally and the effect of each excipient on the quality of tablets was studied.

AEROSIL® 200 Pharma was chosen as a moisture-absorbing agent in the amount of 1%. The amount of aerosil is sufficient to obtain a fluid mass. The method of obtaining tablets - direct pressing - was substantiated, the technology of their production was developed, and the corresponding technological scheme was drawn up.

Acknowledgments

None.

Conflicts of Interest

None.

References

1. Brodowska KM. Natural flavonoids: classification, potential role, and application of flavonoid analogues. *European Journal of Biological Research.* 2017;7(2):108–123.
2. Sahoo N, Manchikanti P, Dey S. Herbal drugs: Standards and regulation. *Fitoterapia.* 2010;81(6):462–471.
3. Kukhtenko OS, Simonyan LS, Hladukh YeV. Market research of medicinal products which are used in cardiological diseases treatment. Current issues in pharmacy and medicine: science and practice. 2017;2.