DEVELOPMENT OF THE OPTIMAL COMPOSITION AND TECHNOLOGY OF "GEPAGAL" CAPSULES BASED ON A DRY HERBAL EXTRACT

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https://doi.org/10.5281/zenodo.20587364

ARTICLE INFO

Received: 26th May 2026
Accepted: 28th May 2026
Online: 30th May 2026

KEYWORDS

dry herbal extract, biologically active supplement, capsule technology, wet granulation, Silybum marianum, Calendula officinalis, hepatoprotective agents, pharmaceutical technology.

ABSTRACT

The present study was aimed at developing the optimal composition and manufacturing technology of a biologically active supplement (BAS) in capsule form based on the dry extract "GEPAGAL." The extract was obtained from a 5:1 mixture of Silybum marianum L. seeds and Calendula officinalis L. flowers, known for their hepatoprotective properties. Preliminary investigations revealed unsatisfactory technological characteristics of the dry extract, including poor flowability, low bulk density, and an unfavorable particle size distribution, making direct encapsulation impossible. Therefore, a wet granulation method was selected to improve the technological properties of the extract.

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The aim of this study was to develop the optimal composition and manufacturing technology of "GEPAGAL" capsules based on a dry herbal extract obtained from a mixture of Silybum marianum L. seeds and Calendula officinalis L. flowers, as well as to evaluate the technological and quality characteristics of the resulting capsule formulation.

Materials and Methods: The study utilized the dry extract "GEPAGAL," prepared from a 5:1 mixture of Silybum marianum L. seeds and Calendula officinalis L. flowers. The technological properties of the extract, including particle size distribution, flowability, bulk density, angle of repose, compressibility coefficient, and residual moisture content, were determined using pharmacopeial methods. To improve the technological properties of the extract, ten capsule formulations containing various excipients such as microcrystalline cellulose, lactose monohydrate, magnesium hydrocarbonate, potato starch, calcium stearate,

and magnesium stearate were prepared by the wet granulation method. The resulting granules were evaluated for their technological characteristics, and the optimal formulation was selected. Hard gelatin capsules of different sizes were assessed to determine the most suitable capsule size for encapsulation. The final product was evaluated according to pharmacopeial requirements, including appearance, identification, average mass, mass variation, and disintegration time.

Results: Preliminary investigations revealed unsatisfactory technological characteristics of the dry extract, including poor flowability, low bulk density, and an unfavorable particle size distribution, making direct encapsulation impossible. Therefore, a wet granulation method was selected to improve the technological properties of the extract.

Ten different formulations containing various excipients were prepared and evaluated. Among the tested formulations, composition No. 4 demonstrated the most favorable technological parameters, including improved flowability (6.12×10^{-3} kg/s), bulk density (623.4 kg/m^3), and residual moisture content (4.5%). Based on the bulk density and volume calculations, size No. 1 hard gelatin capsules were selected as the most appropriate for encapsulation of the prepared mass. The final capsule formulation exhibited satisfactory technological and quality characteristics, including acceptable appearance, identity, average mass (400 ± 4.48 mg), and disintegration time (700 ± 3.15 s).

Conclusion: The obtained results confirmed the suitability of the selected composition and manufacturing technology for producing high-quality “GEPAGAL” capsules. The developed formulation demonstrated satisfactory technological properties and met the established quality requirements, indicating its potential application as a hepatoprotective biologically active supplement.

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