

Pharmaceutical Development and Validation of a Technology for Obtaining Gel Compositions with Phytosubstances from *Limonium gmelinii* Plants

Dariya Kassymova

PhD candidate, Al-Farabi Kazakh National University, Kazakhstan, Galiya Zhussupova, Professor, Al-Farabi Kazakh National University, Kazakhstan

Problem Statement: Plants of the genus *Limonium gmelinii*, recognized as a pharmacopoeial raw material, are promising for medical use due to their availability, ease of harvesting, and valuable biological activity. Developing new herbal medicinal products is challenging due to variable chemical composition from genetic, ecological, and seasonal factors. This study aimed to develop and validate a pharmaceutical technology for gel formulations using phytosubstances (API) from *L. gmelinii*, following ICH Q8 guidelines. Methodology: Compatibility was studied using IR spectral analysis. Gels were tested for pH, organoleptic properties, colloidal and thermal stability, homogeneity, rheological behavior (0.01-150 s⁻¹). Release kinetics were studied in vitro using a Franz diffusion cell. The technological scheme for producing gels was developed to produce laboratory batches of 1 kg each (figure 1). Results: Compatibility of excipients and APIs was confirmed through IR spectral analysis and visual evaluation. No physical changes were observed after 30 days of storing API solutions with excipients. All gel samples exhibited acceptable pH, transparency, homogeneity, and remained stable during phase separation tests. The 1.0% carbomer and the 10.0% propylene glycol concentration was found to be optimal based on release kinetics and rheological characteristics. Validation tests showed Cp and Pp values significantly exceeding 1.33, indicating high process capability, although Cpk and Ppk values were negative. This issue is common with herbal preparations, which often have only lower specification limits and require more data collection for stability assessment. Gel containing 7.0% API showed the best anti-inflammatory effects, outperforming Diclofenac gel, while gel with 5.0% API had comparable effectiveness, demonstrating a dose-dependent anti-inflammatory effect, with higher efficacy observed in gels made from the aerial parts compared to the roots.

Biography

Dariya Kassymova is a PhD candidate at the Department of Chemistry and Technology of Organic Substances, Natural Compounds, and Polymers at al-Farabi Kazakh National University. Her research focuses on developing and validating technological schemes for obtaining substances from *Limonium* Mill plants and preparing plant-based gels. Dariya has interned at the University of Valencia, La Sapienza University of Rome, The National Center of Expertise of Medicines and Medical Devices, and Abdi Ibrahim Global Pharm. During these internships, she gained expertise in modern methods of analysis, physicochemical analysis, and the development of medicinal products.

Dariya.kassymova@kaznu.kz

Abstract received : July 1st, 2024 | Abstract accepted : July 2nd, 2024 | Abstract published : 16-09-2024