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FORMULATION AND CHARACTERIZATION OF PROPRANOLOL HYDROGEL WITH SODIUM ALGINATE FOR THE TREATMENT OF INFANTILE HEMANGIOMA

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Abstract

This study focuses on the development and characterization of a sodium alginate hydrogel as a topical formulation for release of propranolol hydrochloride (PPL HCl). Our research indicates that local or transdermal drug administration is a viable alternative to oral administration, especially for drugs like oral propranolol, which undergoes first pass metabolism. The primary objective of this study was to formulate a product for the local delivery of propranolol hydrochloride for the treatment of infantile hemangioma, exhibiting favorable physicochemical properties. It was conducted in two phases: preformulation and formulation. In the preformulation phase, initial gel formulations were developed with different concentrations of propranolol hydrochloride (1%; 1.5%; 2%; 3%) gelled at various temperatures and stirring rates. The results demonstrated that high preparation temperatures disrupted the gel structure, whereas gradual and controlled gelation led to mechanically more stable gels. The inclusion of $CaCl_2$ in the matrix improved the mechanical properties and consistency of the hydrogels. Gel structure degradation (syneresis) was observed after the addition of propranolol hydrochloride, necessitating the use of a buffer in further formulation development. Buffer systems (NaOH and $NaHCO_3$) regulated the pH value of the medium, leading to improved mechanical properties of the gel structure while also exhibiting surfactant like effects. They did not interact with the active substance and contributed to nearly identical physicochemical characteristics in the formulation analyses. In the formulation phase, two optimized formulations were developed with 2% sodium alginate and 1% propranolol hydrochloride, where the pH value was adjusted to physiological values (6.98 and 7.04) by adding NaOH and $NaHCO_3$. The analyses demonstrated pH stability over 14 days, good spreadability, maintained texture, and аппроприате microbiological purity. Spectrophotometric analysis confirmed the presence and

stability of propranolol hydrochloride within the hydrogel matrix. Due to the observed higher absorption in the gel where NaOH was used as a buffer (pH 7.04) compared to the other with $NaHCO_3$ (pH 6.98), we concluded that this formulation potentially exhibits better stability or a different interaction of propranolol with the gel matrix depending on the pH value of the system.

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