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Formulation and Characterization of Solid Dispersion for Enhancing the Solubility of BCS Class 2 Drugs

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Abstract: BCS Class 2 drugs, such as Diflunisal, often exhibit poor solubility, leading to reduced bioavailability and therapeutic efficacy. This study focuses on enhancing the solubility of Diflunisal by formulating solid dispersions using Gelucire 50/13 as a carrier. Diflunisal was identified, and its maximum absorbance wavelength (λmax) was determined using a UV-Visible spectrophotometer. The saturation solubility of Diflunisal was assessed in various solvents, including distilled water and phosphate buffers of different pH levels. Solid dispersions were prepared in different ratios using the kneading method and characterized through Fourier Transform Infrared Spectroscopy (FTIR), Differential Scanning Calorimetry (DSC), Powder X-ray Diffraction (PXRD), and Scanning Electron Microscopy (SEM). In vitro dissolution studies were conducted using a USP dissolution apparatus. The results showed a significant increase in Diflunisal solubility with the solid dispersion formulation, particularly at a 1:4 drug-to-carrier ratio, indicating enhanced wettability and possible amorphization of the drug. The FTIR spectra confirmed no chemical interaction between Diflunisal and Gelucire 50/13, while DSC and PXRD analyses suggested reduced crystallinity. SEM images revealed improved particle morphology and distribution. These findings suggest that solid dispersion with Gelucire 50/13 is a promising approach to enhance the solubility and bioavailability of Diflunisal.

Keywords: Solid dispersion, Diflunisal, BCS Class 2, solubility enhancement, Gelucire 50/13, UV-Visible spectrophotometer, FTIR spectroscopy, dissolution study.

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