ID 356

Enhancing the Solubility of Atorvastatin Calcium: A Comparative Study of Solid Dispersions with β-Cyclodextrin, Chitosan, and PEG-4000

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The poor water solubility of active pharmaceutical ingredients presents significant challenges in formulation development. Atorvastatin, classified as a Biopharmaceutical Classification System (BCS) class 2 drug, exhibits low water solubility, resulting in reduced bioavailability. To enhance its solubility, 1:1 solid dispersions of atorvastatin with Beta-cyclodextrin (β-CD), Chitosan, and PEG-4000 polymers were prepared using the kneading method. The resulting formulations were characterized using Fourier transform infrared spectroscopy (FTIR), UV absorptiometry, melting point analysis, and moisture content determination to confirm the formation of solid dispersions. The solubility of the prepared solid dispersions was then evaluated using an octanol/water system, with the aqueous layer varied between distilled water and buffer solutions ranging from pH 2 to pH 10 at room temperature (25°C). Absorption values of the solid dispersions were measured at 243 nm using a UV-VIS spectrophotometer to quantify the solubilized content. The solubility analysis revealed that the presence of β-CD, Chitosan, and PEG-4000 in the solid dispersion formulations significantly improved the solubility of atorvastatin compared to its pure form. Specifically, the solubility of atorvastatin calcium-PEG 4000 in distilled water increased by 91.11%, while the solubility of atorvastatin calcium-Chitosan and atorvastatin calcium-β-CD increased by 50.18% and 3.37%, respectively. Furthermore, the study found that the solubility of atorvastatin calcium in buffer solutions with physiological pH was significantly higher in the atorvastatin calcium-PEG 4000 form compared to the β-CD and Chitosan forms. PEG-4000 was identified as the most effective polymer for enhancing the solubility of atorvastatin calcium via the solid dispersion technique.

Keywords: *atorvastatin calcium, solid dispersion, kneading method, PEG-4000, beta-cyclodextrin, chitosan*