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Research Article

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Preparation of Solid Dispersion to Enhance the Dissolution Behaviour and Increase Efficacy and Activity of the Drug Substance

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ABSTRACT
Solid dispersion is a well-established technique to improve the solubility and bioavailability of poorly water-soluble drugs. This study explores the formulation and characterization of SD systems using various carriers to enhance drug dissolution rates and stability. The prepared solid dispersions demonstrate reduced crystallinity of the drug, indicating transformation into an amorphous state, which contributes to improve solubility. Physicochemical evaluations confirm the successful dispersion of the drug within the carrier matrix without significant interactions. Dissolution studies reveal a significant enhancement in the drug release profile compared to the pure crystalline drug. This research underlines the potential of solid dispersion technology as an effective and practical approach to overcome solubility limitation in pharmaceutical development.

Keywords: Miconazole Nitrate, In Vitro Release Studies, Solid Dispersion, Solvent Evaporation Method.

Introduction

Solid dispersion (SD) is a widely recognized and effective pharmaceutical technique aimed at enhancing the solubility and bioavailability of poorly water-soluble drug [1]. Since the first application in the 1960s, solid dispersion has involved dispersing a poorly soluble drug in an inert hydrophilic carrier matrix to improve dissolution rates [2]. This technique reduces drug crystallinity, promotes molecular dispersion, and increase the surface area for dissolution, thereby addressing one of the major challenges in drug formulation-poor aqueous solubility. Solid dispersion offers significant advantages over conventional formulations by improving drug absorption and therapeutic efficacy, making it a pivotal strategy in modern pharmaceutical development [3].

Method

Solid dispersion of miconazole nitrate were prepared using the solvent evaporation technique [4]. Water-soluble carriers' polyethylene glycol (PEG-6000), mannitol, and Hydroxy propyl methyl cellulose (HPMC) were used in drug-to carrier ratio of 1:1, 1:2 and 1:3. The drug and the respective carrier were accurately weighed and dissolved together in a suitable volatile solvent to form a homogenous solution. The solvent was then evaporated under the controlled condition to obtain a solid mass. The resultant solid dispersion were further dried, pulverized, and sieved to obtain uniform particle size.

The prepared solid dispersion was subjected to solubility studies, Drug content analysis, and dissolution testing to evaluate the enhancement in drug solubility and release profile. Fourier-transform infrared spectroscopy was performed to investigate potential drug-carrier interaction. Field emission gun-scanning electron microscopy (FEG-SEM) was employed to examine the surface morphology and the dispersion pattern of the drug within the carrier matrix.

Results and Discussion

The prepared solid dispersion of miconazole nitrate using PEG-6000, Mannitol and HPMC in different drug-to carrier ratios (1:1, 1:2, 1:3) were evaluated for solubility, drug content, in vitro dissolution, FTIR, and FEG-SEM analyses.

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Solubility Analysis
A significant increase in the solubility of miconazole nitrate was observed in all solid dispersion formulations compared to the pure drug, with the highest solubility recorded in the MCN-PEG-6000(1:3, 0.32 mg/ml) pre-formulation. The solubility values ranged from 0.089 mg/ml to 0.32 mg/ml, demonstrating effective enhancement due to the solid dispersion approach.

Drug Content Study
The drug content of the prepared formulations was found to be within the acceptable range, indicating uniform dispersion of miconazole nitrate in the respective carriers. The drug content values varied from 66% to 92%, supporting consistency in the solvent evaporation methodology.

Dissolution Studies
Dissolution profiles revealed that all solid dispersions achieved markedly higher drug release compared to the pure crystalline drug. The PEG-6000 in 1:3 ratio shows more drug efficiency (i.e. 47.69%) compared to the pure MCN (35.70%). The dissolution enhancement is attributed to reduced crystallinity and improved wettability of the drug in the amorphous carrier matrix.

FTIR Analysis
FTIR spectra demonstrated retention of characteristic peaks of miconazole nitrate with significant peak shifts or new peaks and the inclusion of ether peak in SD which is absent in the pure miconazole nitrate's FTIR spectra, suggesting the strong chemical interactions between the drug and the carriers. This confirmed the physical nature of the drug-carrier dispersion.

FEG-SEM Analysis
FEG-SEM studies indicated a morphological transformation of miconazole nitrate form a crystalline to an amorphous or less crystalline state in solid dispersions. A more homogenous and irregular surface pattern was observed, particularly in formulations with higher carrier ratios, supporting improved solubility and dissolution

Conclusion
These findings collectively establish that solvent evaporation is a robust method for preparing miconazole nitrate solid dispersions, with PEG-6000, mannitol and HPMC all demonstrating significant potential as solubility-enhancing carriers. The optimized pre-formulations showed superior solubility and dissolution performance, confirming their promise for further pharmaceutical development.

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