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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.

I. INTRODUCTION

Oral drug delivery remains the most preferred and convenient route for administering medications due to its ease of administration and patient compliance[1]. However, the effectiveness of oral drugs is often limited by their solubility and bioavailability. According to the Biopharmaceutics Classification System (BCS), drugs are categorized into four classes based on their solubility and permeability. BCS Class 2 drugs, characterized by low solubility and high permeability, pose significant challenges in achieving optimal therapeutic levels due to their poor solubility in aqueous environments.[2,3]

Diflunisal, a non-steroidal anti-inflammatory drug (NSAID), belongs to the BCS Class 2 category. Despite its efficacy in treating pain and inflammation, Diflunisal's clinical application is hampered by its limited solubility, which leads to inadequate absorption and low bioavailability when administered orally. To overcome these limitations, enhancing the solubility and dissolution rate of Diflunisal is crucial.[4]

One effective strategy to improve the solubility of poorly soluble drugs is the formulation of solid dispersions. Solid dispersions involve dispersing the drug in a carrier matrix, which can enhance the drug's wettability and reduce its particle size, leading to improved solubility and dissolution rates. Various carriers have been explored for this purpose, with Gelucire 50/13 showing promise due to its amphiphilic nature and ability to enhance the solubility of hydrophobic drugs.[5]

This study aims to enhance the solubility of Diflunisal by preparing solid dispersions using Gelucire 50/13 as a carrier. The primary objectives include the identification of Diflunisal and determination of its maximum absorbance wavelength (λmax), assessment of its saturation solubility in different media, and the preparation and characterization

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of solid dispersions through various analytical techniques. The solid dispersions are expected to improve the solubility and dissolution rate of Diflunisal, thereby enhancing its bioavailability.[6]

The preparation of solid dispersions will be performed using the kneading method, a widely used technique due to its simplicity and effectiveness. The prepared solid dispersions will be characterized using Fourier Transform Infrared Spectroscopy (FTIR) to investigate any potential chemical interactions between the drug and the carrier. Differential Scanning Calorimetry (DSC) and Powder X-ray Diffraction (PXRD) analyses will be conducted to assess the crystallinity of Diflunisal in the solid dispersions. Scanning Electron Microscopy (SEM) will provide insights into the surface morphology and particle distribution of the solid dispersions.[7]

In addition to these characterization techniques, in vitro dissolution studies will be performed to evaluate the dissolution profile of Diflunisal from the solid dispersions compared to the pure drug. The results of these studies will provide a comprehensive understanding of the impact of solid dispersion formulation on the solubility and bioavailability of Diflunisal.[8]

Through this research, we aim to demonstrate that solid dispersion with Gelucire 50/13 is a viable approach for enhancing the solubility and therapeutic efficacy of BCS Class 2 drugs like Diflunisal. This study has the potential to contribute significantly to the field of pharmaceutical sciences by providing an effective solution to the solubility challenges associated with poorly soluble drugs.[9]

II. MATERIALS AND METHOD

Identification of drug and determination of λmax

To identify a drug, such as Diflunisal, and determine its λmax, first, a pure sample of the drug is obtained and prepared, either as a fine powder or in solution. The UV-Visible spectrophotometer is set up, and a suitable solvent is selected for the drug's solubility, which in the case of Diflunisal, could be organic solvents like methanol or ethanol. Blank solutions are prepared using the selected solvent to calibrate the instrument. Then, a series of Diflunisal solutions with varying concentrations are prepared and measured against the blank to obtain absorbance readings at different wavelengths within the UV-Visible range. A graph of absorbance versus wavelength is plotted, and the wavelength (λmax) corresponding to the maximum absorbance is determined. This λmax serves as a characteristic parameter for identifying Diflunisal.[10]

Saturation solubility study of drug

Saturation solubility study of selected drug was determined in distilled water, acetate buffer pH 1.2, phosphate buffer pH 6.8 and phosphate buffer pH 7.4. Extra amount of drug was added to 10 ml study fluid in a glass vial. Samples were shaken on rotary shaker at constant speed at 25 °C±2 °C for 48 h. The resultant saturated solutions was then filtered using whatman filter paper no 1. Filtrates sample ware then estimated spectrophotometrically after suitable dilution. [11]

Phase solubility study

In order to predict the effect carrier on the solubilization of drug, the phase solubility study of drug was carried out. Excess amount of drug were added to 10 ml glass vial containing 0.25%, 0.50%, 0.75%, 1% and 2% aqueous solution of carriers and shaken on rotary shaker for 48 h at a controlled temperature at 25 °C±2 °C. The solutions were filtered using no 1 whatman filter paper. Filtrate were analyzed by UV-spectrophotometer in order to determine the concentration of the dissolved drug. [12]

Preparation of physical mixture

A physical mixture of Diflunisal with Gelucire 50/13 in different ratio (1:1, 1:2, 1:3, 1:4, 1:5) and denoted as DPM 1 to DPM 5 respectively was prepared by mixing of drug and carrier using mortar and pestle. This mixture was then passed through sieve no 40 and store in desiccators.[13]

Preparation of solid dispersion

Solid dispersion of diflunisal with Gelucire 50/13 in different weight ratio (1:1, 1:2, 1:3, 1:4, 1:5 and denoted as DSD 1 to DSD 5 respectively, was prepared by kneading method.

A mixture of drug and carrier was placed in a mortar and was kneaded thoroughly with water and methanol (1:1) for 20 min.

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The kneaded mixtures were then dried in an oven at 40 °C until it reached the uniform weight and then pulverized and screened through 80-mesh and stored in desiccator for further study[14]

Table 1: Preparation of solid dispersion

Formulation Code	Composition Ratio	Method
DPM1	1:1	Physical Mixture
DPM2	1:2	Physical Mixture
DPM3	1:3	Physical Mixture
DPM4	1:4	Physical Mixture
DPM5	1:5	Physical Mixture
DSD1	1:1	Solid Dispersion
DSD2	1:2	Solid Dispersion
DSD3	1:3	Solid Dispersion
DSD4	1:4	Solid Dispersion
DSD5	1:5	Solid Dispersion

Characterization of solid dispersion

Determination of saturation solubility of PMs and SDs The saturation solubility of physical mixture and solid dispersion was determined in distilled water using shake flask method. Excess quantities of sample were added in 25 ml of distilled water and phosphate buffer in conical flask and shaken for 24 h at room temperature on rotary flask shaker. After shaking resultant samples containing undissolved solid suspended in the test medium were centrifuged at 10,000 rpm for 5 min, the clear supernatants obtained were filtered through whatman filter paper. Filtered sample ware analyzed by spectrophotometer at 263.5 nm after dilution.[15]

Determination of percent yield of solid dispersion

The percent yield of diflunisal solid dispersions was determined by using the following formula:

Determination of drug content

Diflunisal solid dispersion equivalent to 10 mg of drug was accurately weighed and dissolved in methanol (100 ml). The solution was filtered after vigorous shaken. The drug content was analyzed at 263.5 nm against blank by UV spectrometer after appropriate dilution. [16]

Fourier transform infra-red spectroscopy

Compatibility studies of diflunisal with carrier were performed using FTIR spectroscopy (Shimadzu FTIR-8700). Spectrum of pure drug, physical mixture and solid dispersion was recorded over the frequency range of 400 to 2000 cm-1 at 4 cm resolution. Differential scanning calorimetry The thermal analysis was carried out using Shimadzu Thermal analyzer DT 40 (Japan). The samples were placed in sealed aluminum pans and heated at a rate of 10 °C per min in the temperature range of 20-300 °C under a nitrogen flow rate of 40 ml/min.[17]

Powder X-ray diffraction

X-ray powder diffraction patterns of drug, carrier and solid dispersion was recorded on an X-ray powder diffraction system (Rigaku, Mini Flex 600). The scanning was done over range of 5° to 60°. The position and intensities of diffraction peaks were considered for the comparison of crystallinity. [18]

Scanning electron microscope analysis (SEM)

The surface morphology of pure diflunisal and selected solid dispersion was studied using SEM. (ZEISS, EVO 18, Germany). The samples were mounted on a sample stub with double-sided adhesive tape and coated under vacuum with gold ion using sputtering device prior to study. SEM image at different magnifications were recorded to study the morphological and surface characteristics of the solid dispersions. [19]

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In vitro dissolution study

In vitro dissolution study of pure diflunisal and solid dispersions were determined using USP dissolution test apparatus II (Paddle type) (Esico International, Mumbai). Accurately weighted preparation equivalent to 10 mg of diflunisal ware added to 900 ml of phosphate buffer pH 6.8 used as a medium of dissolution, which was maintained at 37±0.5 °C and rotation speed was selected at 50 rpm. 5 ml samples were withdrawn at time interval of 10, 20, 30, 40, 50, 60 min and the same volume was replaced with fresh media in order to maintain the sink condition. After suitable dilution, collected samples were analyzed at 263.5 nm using UV-visible spectrophotometer against the blank.[20]

III. RESULTS AND DISCUSSION

Identification of drug

Determination of λmax

The scanning of the drug solution in the UV range showed maximum absorbance at 254.5 nm and hence, the calibration curve was developed at this wavelength

Table 2: Calibration curve

Sr. No.	Concentration (µg/mL)	Peak Area
1	10	398.76
2	20	794.80
3	30	1134.33
4	40	1481.06
5	50	1873.87
6	60	2240.38

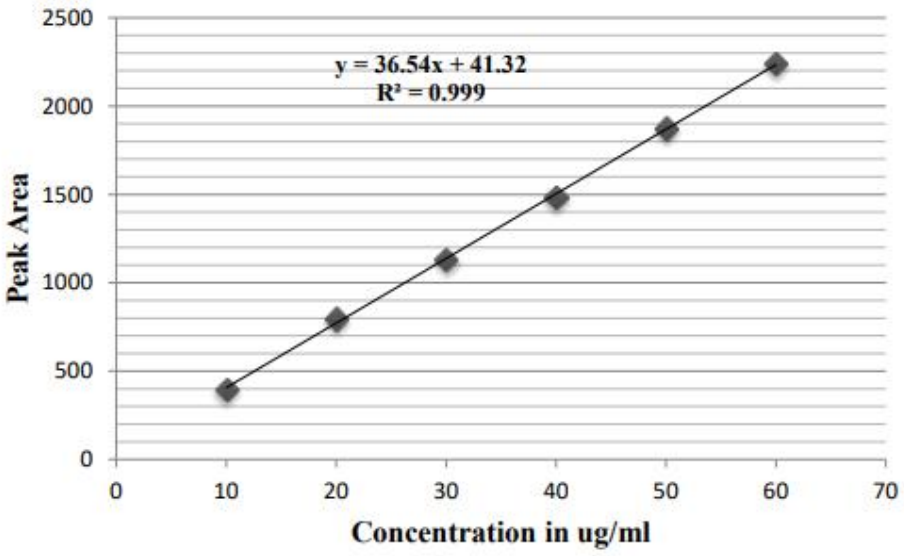

Fig 1: Calibration curve of diflunisal

Saturation solubility study of drug

Saturation solubility study indicates that diflunisal was poorly soluble in water, showing 7.347±0.003 µg/ml of solubility in distilled water. Diflunisal shown pH dependent solubility, solubility of diflunisal increases as the pH of solvent increases. Solubility of drug in acetate buffer pH1.2, phosphate buffer pH 6.8 and pH 7.4 was found to be 5.173±0.006 µg/ml, 28.507±0.012 µg/ml and 35.391±0.004 µg/ml, respectively

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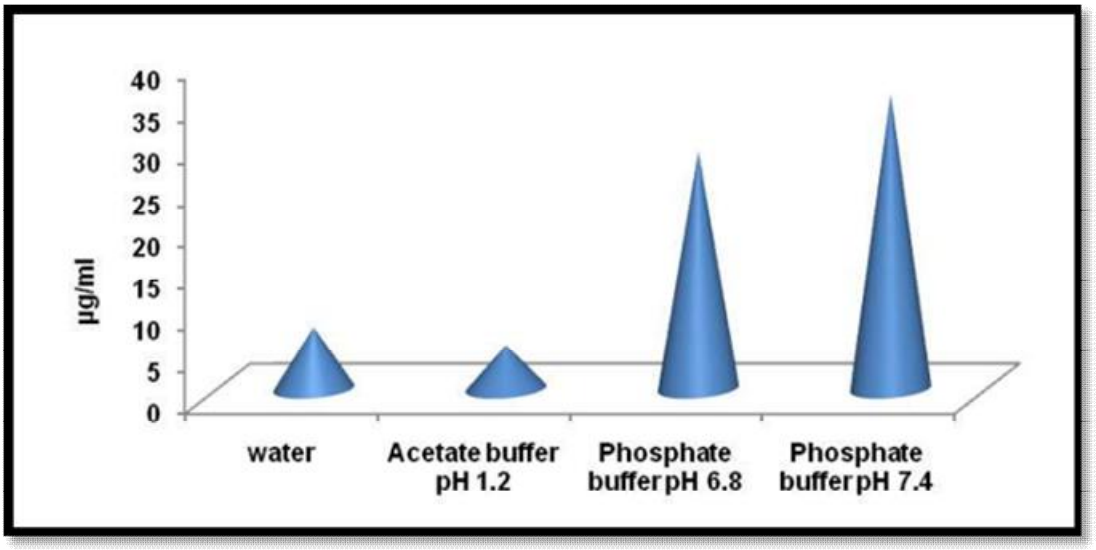

Fig 2: Saturation solubility study of drug

Phase solubility study

In order to determine the possible solubilizing effect of Gelucire 50/13 on drug solubility, phase solubility study of diflunisal was studied using an increasing concentration of carrier. A linear increase in the solubility of drug was seen with an increasing concentration of hydrophilic carriers in water. The solubility of diflunisal at 0.25, 0.5, 0.75, 1 and 2% aqueous solution of Gelucire 50/13 was found to be 16.89±2.13, 21.30±1.26, 27.18±0.94, 32.32±3.21, 48.49±1.86 µg/ml, respectively. Increased solubility may be due solubilization effect of Gelucire 50/13 that increased the wettability of the drug. At 2% w/v concentration of carrier, the aqueous solubility of diflunisal was increased by 6.6 fold, indicating good affinity between drug and polymer. The phase-solubility diagram investigated for Gelucire 50/13 in distilled water was linear giving AL type solubility curve.

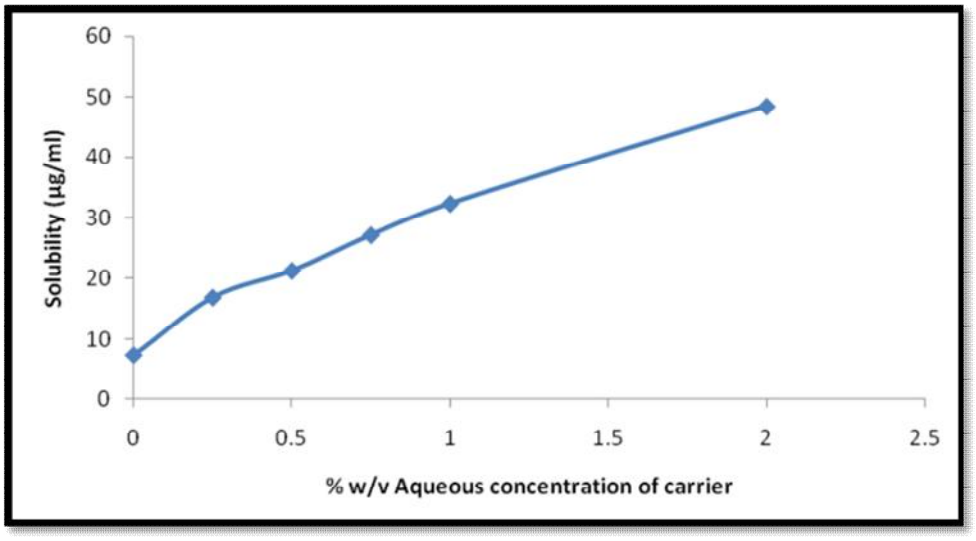

Fig 3: Phase solubility study

Phase solubility study with gelucire 50/13

Saturation solubility study of solid dispersion and physical mixture

The solubility of diflunisal physical mixture and solid dispersion was determined in distilled water and phosphate buffer 6.8. Prepared physical mixture showed improved solubility as compare to pure drug in both solvent. Solubility study of

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solid dispersion showed multi-fold increase in solubility of the drug when compare with pure and physical mixture of drug. It was observed that solubility of the drug increases with increase in carrier concentration up to 1:4 ratio, but after that no significant increase in drug solubility was observed by increasing the carrier ratio. Solid dispersion DSD4 (1:4 ratio) showed maximum solubility of the drug, giving 8.23 fold increase in water solubility of diflunisal. Higheralue of solubility was shown by all SD formulations, this may be due to conversion of drug in amorphous form or by the increased wet ability of drug by hydrophilic carrier . All SD formulations showed higher solubility of the drug in phosphate buffer solution than distilled water.

Solubility analysis of diflunisal-gelucire 50/13 physical mixture and solid dispersion

To analyze the solubility data of diflunisal-gelucire 50/13 physical mixture and solid dispersion, let's break down the results:

Formulation Code: This indicates the different formulations tested, with "DPM" representing the physical mixture and "DSD" representing the solid dispersion.

Solubility in Distilled Water (µg/ml): This column shows the solubility of the formulations in distilled water.

Solubility in Phosphate Buffer pH 6.8 (µg/ml): This column shows the solubility of the formulations in phosphate buffer at pH 6.8.

Table 3: Solubility analysis

Formulation Code	Distilled Water (µg/ml)	Phosphate Buffer pH 6.8 (µg/ml)
DPM1	19.41±1.30	91.43±1.16
DPM2	22.12±1.41	108.86±0.46
DPM3	25.61±0.84	124.42±0.62
DPM4	28.58±1.14	140.32±1.21
DPM5	31.41±0.81	154.52±1.63
DSD1	32.14±0.94	153.93±0.66
DSD2	40.25±0.47	173.89±0.41
DSD3	48.74±0.81	210.95±0.56
DSD4	60.46±1.63	250.86±1.24
DSD5	62.24±1.24	258.64±0.12

Solubility in Distilled Water:

For both physical mixtures (DPM) and solid dispersions (DSD), there is a general trend of increasing solubility with increasing formulation code. This suggests that as the composition changes or the ratio of diflunisal to Gelucire 50/13 varies, the solubility in distilled water tends to increase.

The solubility values for solid dispersions (DSD) are consistently higher compared to physical mixtures (DPM), indicating that the solid dispersion formulation enhances the solubility of diflunisal in distilled water more effectively than the physical mixture.

Solubility in Phosphate Buffer pH 6.8:

Similar to solubility in distilled water, there is a trend of increasing solubility with increasing formulation code for both physical mixtures (DPM) and solid dispersions (DSD).

Again, the solubility values for solid dispersions (DSD) are consistently higher compared to physical mixtures (DPM), indicating that the solid dispersion formulation enhances the solubility of diflunisal in phosphate buffer at pH 6.8 more effectively.

Overall, the data suggests that the solid dispersion formulation of diflunisal-gelucire 50/13 has superior solubility properties compared to the physical mixture, both in distilled water and phosphate buffer at pH 6.8. This could be attributed to the improved dispersion of diflunisal in the solid dispersion formulation, leading to increased surface area and better interaction with the dissolution medium.

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Fourier transform infrared spectroscopy

Comparing the Fourier transform infrared (FTIR) spectra of pure diflunisal and its solid dispersion (SD) with Gelucire 50/13 can provide insights into the molecular interactions between diflunisal and the excipient. Here's a general outline of what you might observe:

Pure Diflunisal IR Spectrum:

Diflunisal is expected to exhibit characteristic peaks corresponding to its functional groups.

Common peaks in the IR spectrum of diflunisal include:

A strong peak around 1690-1710 cm^-1 corresponding to the carbonyl (C=O) stretch in the carboxylic acid moiety.

Peaks in the region of 1600-1650 cm^-1 corresponding to the aromatic ring vibrations.

Peaks in the fingerprint region (below 1500 cm^-1) that can help identify specific functional groups.

Diflunisal Solid Dispersion with Gelucire 50/13 IR Spectrum:

In the IR spectrum of the solid dispersion, you might observe shifts or changes in the peaks compared to pure diflunisal.

Interaction between diflunisal and Gelucire 50/13 may lead to new peaks, disappearance of some peaks, or changes in peak intensities.

Look for any shifts or broadening in the carbonyl (C=O) stretch peak, which could indicate interaction with Gelucire 50/13.

Changes in the aromatic ring vibrations or other functional groups of diflunisal may also indicate interaction with the excipient.

Interpretation:

The FTIR spectra can provide information about the molecular interactions between diflunisal and Gelucire 50/13 in the solid dispersion.

Peaks shifting or broadening could suggest hydrogen bonding or other types of interactions between diflunisal and the excipient.

The absence or reduction of certain peaks may indicate changes in the molecular environment of diflunisal due to its dispersion in Gelucire 50/13.

In summary, FTIR spectroscopy can be a valuable tool for characterizing the molecular interactions and changes in solid dispersions compared to the pure drug, providing insights into the formulation and potential mechanisms for improved solubility and bioavailability.

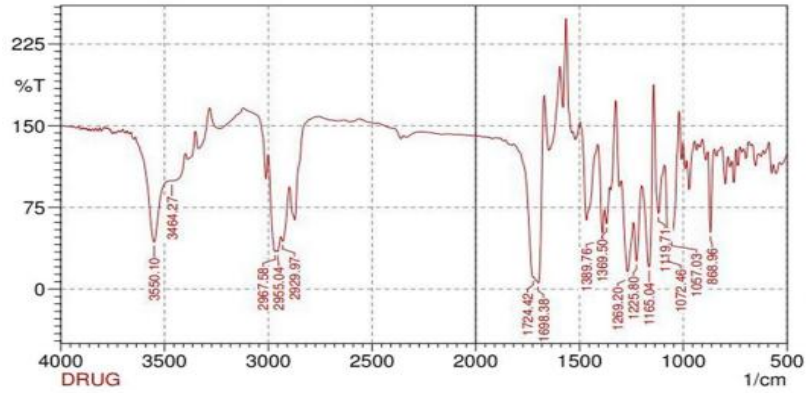

Fig 4: IR spectra of pure diflunisal

SEM image of pure diflunisal (A and B) and selected diflunisal gelucire SD (DSD4) (C and D) at different magnification

When examining scanning electron microscopy (SEM) images of pure diflunisal and its solid dispersion (SD) with Gelucire 50/13, differences in particle morphology, size, and distribution can provide valuable insights into the formulation.

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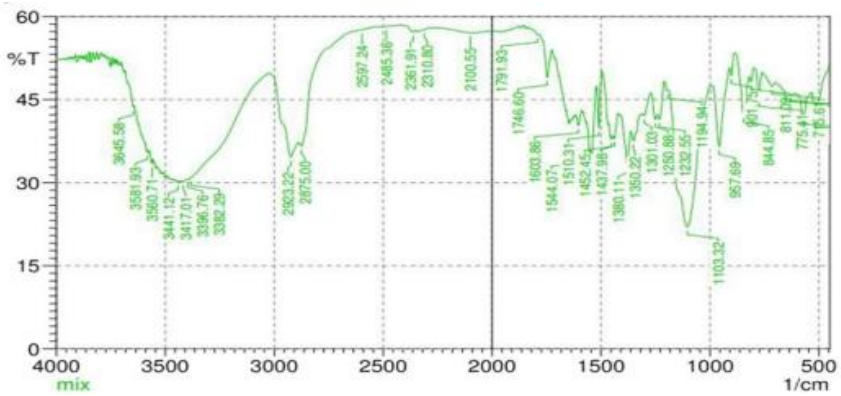

Fig 5: IR spectra of diflunisal and its SD with Gelucire 50/13

SEM Images of Pure Diflunisal (A and B):

In these images, you would expect to see individual diflunisal crystals or particles.

The morphology might vary, depending on factors such as crystallinity, polymorphism, and particle size distribution.

At lower magnification (A), you might observe the overall particle distribution and aggregation patterns.

Higher magnification (B) would reveal finer details of individual particle surfaces, such as shape, roughness, and any surface features.

SEM Images of Diflunisal Gelucire SD (DSD4) (C and D):

The solid dispersion formulation with Gelucire 50/13 is expected to show differences compared to pure diflunisal.

You may observe changes in particle morphology, aggregation, or dispersion due to the presence of the excipient.

At lower magnification (C), you might observe the overall morphology of the solid dispersion particles, including their size distribution and aggregation behavior.

Higher magnification (D) would provide more detailed information about the surface morphology and any interactions between diflunisal and Gelucire 50/13, such as coating or encapsulation.

Interpretation:

Differences in particle morphology and distribution between pure diflunisal and its solid dispersion can indicate the effectiveness of the formulation in modifying the drug's physical properties.

Uniform dispersion of diflunisal within the excipient matrix, as seen in the SEM images of the solid dispersion, can contribute to improved solubility and dissolution properties.

Observing any coating or encapsulation of diflunisal particles by Gelucire 50/13 can provide insights into the mechanisms of drug release and bioavailability enhancement.

In summary, SEM imaging allows for the visualization of particle characteristics and interactions in diflunisal solid dispersions, providing valuable information for understanding the formulation's performance and potential mechanisms of action.

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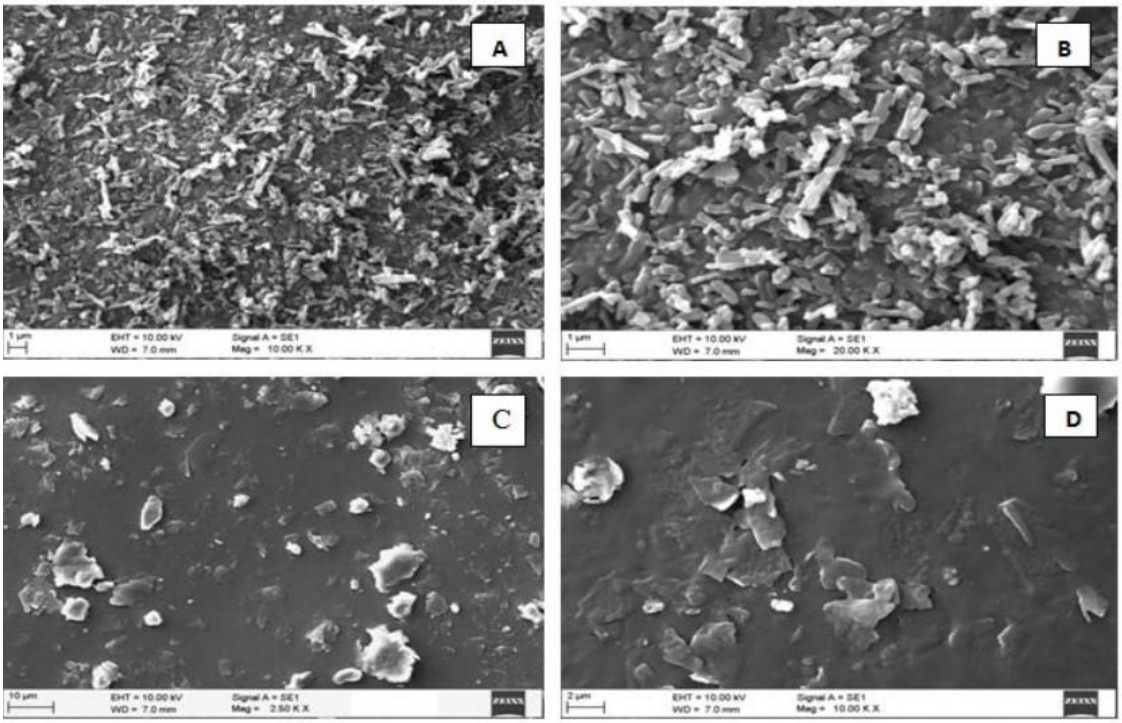

Fig 6: SEM image of pure diflunisal (A and B) and selected diflunisal gelucire SD (DSD4) (C and D) at different magnification

Drug content and practical yield of SD formulations (DSD1 to DSD5)

Here's an analysis of the drug content and practical yield of the solid dispersion (SD) formulations (DSD1 to DSD5):

Practical Yield:

Practical yield refers to the percentage of the theoretical amount of product obtained in a synthesis or formulation process.

It indicates the efficiency of the formulation process in terms of product recovery.

In this case, the practical yield ranges from approximately 80.43% to 83.58% across the different formulations (DSD1 to DSD5).

Generally, a higher practical yield is desirable as it indicates less wastage during the manufacturing process.

Table 4: Drug content and practical yield

S. No.	Formulation code	% Practical yield	% Drug content*
1	DSD1	80.43	98.15±1.39
2	DSD2	81.27	97.26±0.38
3	DSD3	81.61	97.56±0.26
4	DSD4	83.58	98.62±1.18
5	DSD5	83.54	98.12±0.24

Drug Content:

Drug content refers to the percentage of the active pharmaceutical ingredient (API) present in the formulation.

It is a critical parameter for ensuring the consistency and potency of the final product.

The drug content is reported as a percentage with an associated standard deviation (±) to represent the variability in measurements.

Across the formulations DSD1 to DSD5, the drug content ranges from approximately 97.26% to 98.62%.

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The narrow range of drug content values and the consistency in drug content across formulations indicate uniformity and reliability in the manufacturing process.

Overall, the high practical yields and consistent drug content values suggest that the formulation process for the solid dispersion formulations (DSD1 to DSD5) is efficient and reproducible. These parameters are essential for ensuring the quality, efficacy, and consistency of the final product.

IV. CONCLUSION

The study successfully demonstrated the potential of solid dispersions to enhance the solubility and bioavailability of BCS Class II drugs, specifically Diflunisal. The use of Gelucire 50/13 as a carrier in the solid dispersion formulation resulted in significant improvements in the drug's solubility, particularly at a 1:4 drug-to-carrier ratio. Various characterization techniques, including FTIR, DSC, PXRD, and SEM, confirmed the physical and chemical stability of the formulation, as well as the reduced crystallinity and improved particle morphology of Diflunisal. The in vitro dissolution studies further supported these findings, showing a marked increase in the dissolution rate of Diflunisal when formulated as a solid dispersion with Gelucire 50/13. This enhancement is likely due to improved wettability and possible amorphization of the drug. Overall, the results suggest that solid dispersion with Gelucire 50/13 is an effective strategy to overcome the solubility challenges associated with BCS Class II drugs, potentially leading to better therapeutic efficacy and bioavailability.

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