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Research Article

Development and Characterization of Solid Dispersion of Poorly Soluble Nabumetone Using Locust Bean Gum

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ABSTRACT

Solid dispersion (SD) technology is used to increase the solubility and dissolution rate of poorly water-soluble medications. The aim of this study was to enhance the solubility of the poorly water-soluble drug nabumetone (NBT) by utilizing locust bean gum (LBG) as a carrier in solid dispersion (SD) techniques. In the biopharmaceutical industry, Locust Bean Gum as natural polymer is gaining more attention, on the solubility enhancement of the poorly soluble drugs. Poorly soluble nabumetone was selected as an ideal candidate for solid dispersion technique using kneading method. To evaluate the impact of polymer concentration on solubility enhancement, and dissolution experiments were conducted. The solid dispersion was subjected for FTIR, XRD and *in vitro* release studies. The results demonstrated that NBT's solubility increased with higher LBG concentrations. Dissolution studies indicated that the Kneading technique is the most practical and effective method for preparing SDs to improve the solubility of NBT. The XRD results confirmed the transition of NBT from a crystalline to an amorphous form in solid dispersion. SD with highest polymer concentration shows the highest solubility, indicates the most potential for improved bioavailability and therapeutic efficacy. In conclusion, LBG shows potential as a carrier to enhance the solubility and dissolution rate of NBT.

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INTRODUCTION

In pharmaceutical formulation, solid dispersion (SD) technology is an important and developing topic. To increase the solubility and dissolution rate of poorly water-soluble medications, it entails incorporating them into a solid matrix, including polymers. Solid dispersion technique increases the rate of drug dissolution of weakly water-soluble medicines by dispersing the substance in a solid matrix. Moreover, the solid matrix in solid dispersion technique helps shield the medicine from deterioration, improving its stability [1]. A class of solid goods known as SD are made up of two or more distinct components, usually a hydrophilic matrix and a hydrophobic medication. The foundation of the SD is the dispersion of one or more active principles in a solid state that is biologically inert. This matrix can be prepared through solvent melting-solvent techniques, melt techniques, or mixing, which can modify certain physical properties like permeability, wettability, and solubility, among others, to promote hydrophilicity [2].

At the point when SD comes into contact with an aqueous media, a hydrophilic inert carrier releases the medication from the solid dispersion [3]. To improve the dissolution characteristics and bioavailability of poorly aqueous soluble drugs, a variety of hydrophilic carriers have been studied, including polyethylene glycol (PEG), polyvinylpyrrolidone (PVP), hydroxypropyl cellulose, hydroxypropylmethyl cellulose (HPMC), gums, sugar, mannitol, urea, hydroxypropylmethyl cellulose phthalate, sodium alginate, LBG, eudragits, and chitosan (Prajapati et al., 2007). Pregelatinized starch, sodium carboxymethyl cellulose, and sodium starch glycolate are examples of hydrophilic swellable polymers that are also utilized [4]. The medicine releases as tiny colloidal particles and the carrier dissolves when the SD is in contact with aqueous fluids. Due to which the dissolution rate's surface area is increased. By decreasing the size and increasing the porosity of the particles, the drug in the soluble hydrophilic

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carrier increases the rate of dissolution. Thus, it is conceivable to increase the solubility, Dissolution and decrease negative effects of these medications by optimizing their drug release profile [5]. Novel non-steroidal anti-inflammatory medication (NSAID) nabumetone (NBT) is a member of BCS class II drugs [6]. NBT is a nonacidic prodrug that undergoes metabolism to 6-methoxy-2-naphthylacetic acid (6-MNA), an active NSAID molecule [7].

The aim of the present research work is to improve the aqueous solubility of nabumetone by solid dispersion technique using kneading method.

MATERIALS AND METHODS

Materials

Nabumetone was received as a gift sample from Divi's laboratoies Limited Quality Control Department, Hyderabad, India. Locust Bean Gum purchased from Powder Pack Chem Borivali(W) Mumbai, India. Methanol (99.8%) purchased from Loba Chem Pvt. Ltd Mumbai, India. All the chemicals used in the present study were of analytical Grade.

Standard Calibration Curve of Nabumetone

Take 10 mg of drug (NBT) and dilute with phosphate buffer of pH 7 to form 100µgm/mL solution. Then 0.2, 0.4, 0.6, 0.8, 1, 1.2, 1.4, 1.6, 1.8, 2.0 mL of solution was diluted with 10 mL of phosphate Buffer to forms 2, 4, 6, 8, 10, 12, 14, 16, 18 and 20 µg /mL Concentration of Nabumetone. Check the absorbance of all these concentration under UV and plot the graph (Fig. 1).

Formulation of Nabumetone Solid Dispersion

In this method, methanol and water is used as a solvent to wet the mixture of drug and Carrier. Drug: Carrier quantity (1:1, 1:3, 1:5) was taken to prepare the solid dispersion of Nabumetone by kneading method. Kneaded well in a glass mortar for half an hour (Table 1). The resulting paste was vacuum-dried for a full day.

Table 1: Formulation of Nabumetone

Formulation Code	Drug: Carrier Ratio	Drug (gm)	Carrier (gm)
F1	1:1	0.5	0.5
F2	1:3	0.5	1.5
F3	1:5	0.5	2.5

The powder was dried, sieved (number 60), and then kept in a desiccator for further analysis. Physical mixtures (PM) were created by meticulously combining precisely weighed quantities of locust bean gum and nabumetone in a glass mortar [8].

Characterizations of Solid Dispersion

Solubility Study

To achieve solubility mix 10 mg/mL NBT, PM, and solid dispersion with 100 mL of water. Stir with a magnetic stirrer for a full day. A 0.45 µm particle size filtering was performed on each sample. A UV-VIS Spectrophotometer (Model UV1900, Shimadzu Corporation, Japan) was used to perform spectrophotometric analysis on the top part after it had been diluted in 9 mL of ethanol. The highest wavelength absorption was found to be 332.6 nm [9,10].

FTIR

In pharmaceutical research and development, Fourier Transform Infrared (FTIR) Spectroscopy is a potent analytical method that is widely employed. It is employed in the identification and characterization of chemical compounds, the investigation of molecular interactions, and the guarantee of the uniformity and quality of pharmaceuticals [11]. FTIR offers details on a sample's molecular makeup, functional groups, and chemical bonds. The infrared intensity of light is measured in relation to its wavelength, or frequency, using FTIR spectroscopy. Certain wavelengths of infrared light are absorbed by a sample upon interaction, leading to molecular vibrations [12]. Certain functional groups and bonds within the molecule exhibit distinct absorptions. The Fourier transform is used by the FTIR spectrometer to create an interferogram, which is then used to create the final spectrum that shows absorbance (or transmittance) as a function of wavenumber (cm^{-1}) [13,14].

X-Ray Diffraction Study

Pharmaceutical research frequently uses X-ray diffraction (XRD), a potent analytical method, to characterize crystalline materials. It offers comprehensive details on the purity, phase identification, and crystalline structure of materials [15]. Because drug polymorphism can have a substantial influence on a medication's solubility, stability, and bioavailability, XRD is very helpful in this area of study [16].

Drug Content

The composition equal to 10 milligrams of NBT, PM, F1, F2, and F3 was measured and appropriately diluted using deionized water. At 332.6 nm, the absorbance was measured, and the drug content of each formulation was computed [17].

***In Vitro* Drug Release**

A 5 cm long, 25 mm wide, and 16 mm diameter dialysis bag was filled with 10 mL of water and 40 mL of phosphate buffer solution at 37 ± 1 °C and pH 7.0 ± 0.4, along with NBT, SD, and PM. At a speed of 200 revolutions per minute, the bag was spun [18]. 200 µL of the release media was taken out at predetermined intervals (5, 10, 15, 30, 60, and 120 minutes), filtered through 0.45 µm membrane pores, and examined using a UV spectrophotometer. To ensure a consistent release volume, the same volume of new phosphate buffer solution was added right away at the same temperature [19,20].

RESULT AND DISCUSSION

Standard Calibration Curve of Nabumetone

Interpreting a calibration curve involves plotting standard concentration vs. measured response, fitting a linear equation to the data, and using this equation to determine the concentration of unknown samples. A well-constructed calibration curve with a high R^2 value (0.9998) ensures reliable and accurate measurement of nabumetone concentrations (Fig. 1).

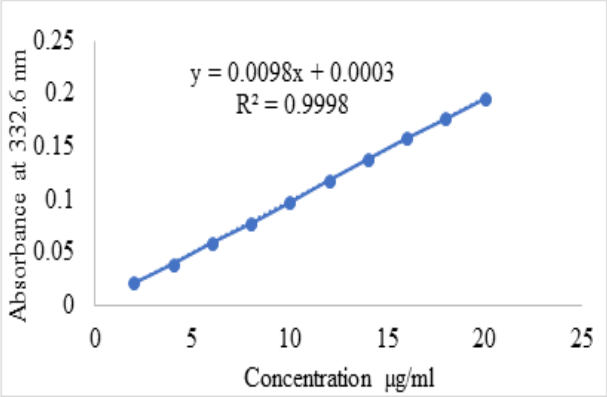

Figure 1: Calibration Curve of Nabumetone

Solubility Studies

The solubility study results clearly demonstrate the effectiveness of different formulations in enhancing the solubility of the drug. The progression from Drug (NBT) to PM, and then to F1, F2, and F3, shows a significant increase in solubility. F3, with the highest solubility, indicates the most potential for improved bioavailability and therapeutic efficacy, making it the most promising formulation among the ones studied (Fig. 2).

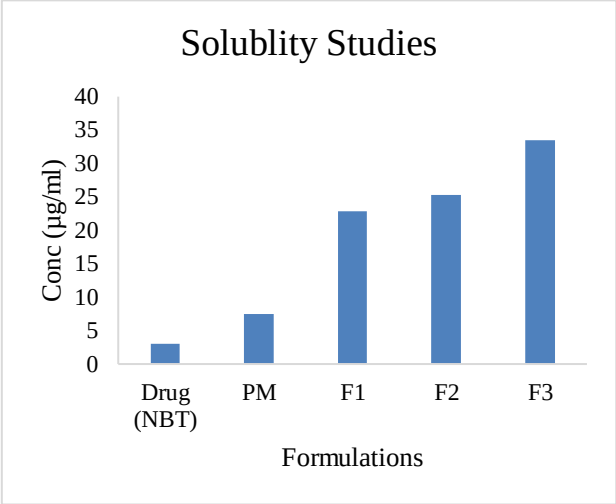

Figure 2: Solubility studies of nabumetone

FTIR study

Fig. 3 shows the FTIR spectrum of pure nabumetone drug. If the high wavenumber is corrected, this would indicate carbonyl groups, which are typical in esters and ketones found in NBT at ~1695.97 cm^{-1} which shows C=O Stretch. C=C Stretch at 1594.66 cm^{-1} represents the presence of Unsaturated bonds, indicating aromatic or alkene groups in NBT. C-H Bend at 1468.36 cm^{-1} shows Alkyl chains in the formulation. C-H Bend / C-N Stretch at 1347.90 cm^{-1} which indicates C-H deformation in alkyl chains or C-N stretching in aromatic amines. C-O Stretch at 1147.31 cm^{-1} and 1020.73 cm^{-1} shows the presence of Ethers or esters, confirming the ester group in clarithromycin. Aromatic C-H Bend at 666.48 cm^{-1} represents Aromatic rings in the structure.

Fig. 4 shows the FTIR spectrum of nabumetone solid dispersion. O-H Stretch at 3780.59 cm^{-1} shows free hydroxyl groups present, likely from excipients. N-H Stretch at 3364.16 cm^{-1} represents Secondary amine groups. C-H Stretch at 2931.04 cm^{-1} shows the presence of Aliphatic hydrocarbons present in the drug or excipients. C-H Stretch Overtone 2660.60 cm^{-1} represents Possible overtone or combination bands involving C=O stretching. C=O Stretch at 1742.97 cm^{-1} shows the presence of Carbonyl groups, characteristic of esters. C=C Stretch at 1600.71 cm^{-1} shows Unsaturated bonds, indicating aromatic or alkene groups.

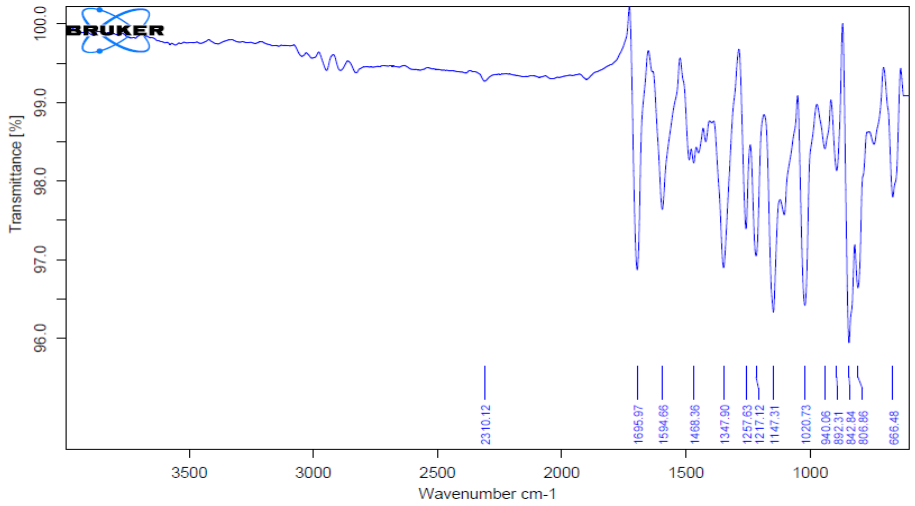

Figure 3: FTIR of Nabumetone Drug

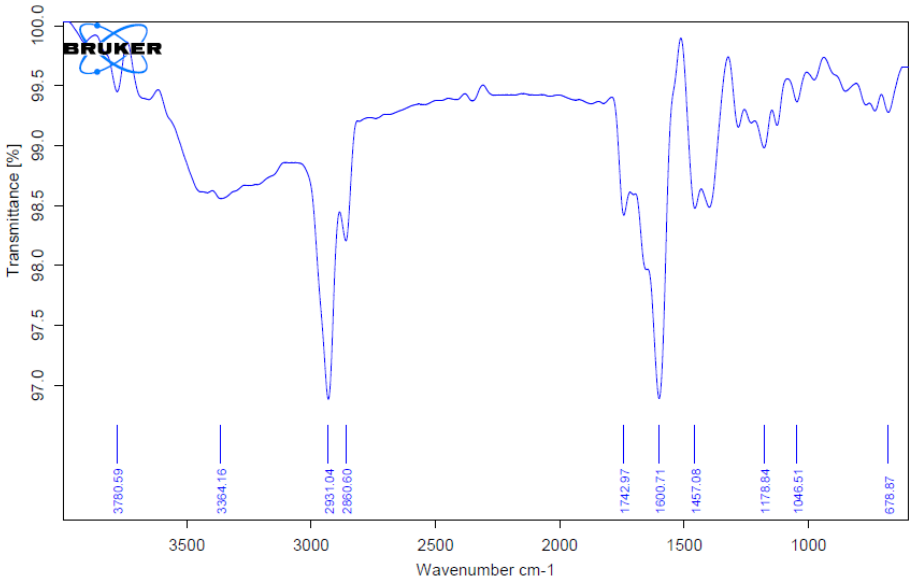

Figure 4: FTIR of nabumetone solid dispersion

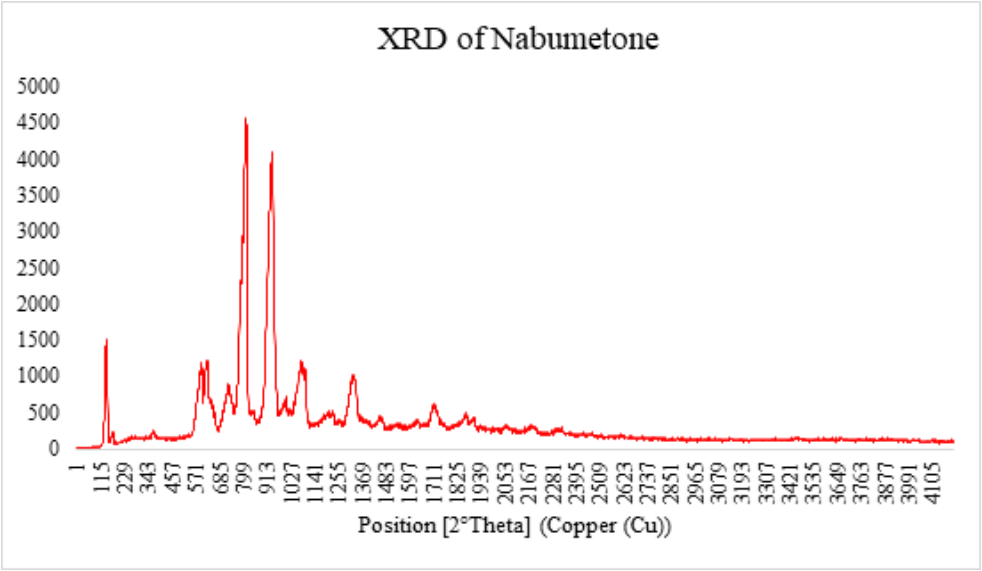

Figure 5: XRD of Nabumetone Drug

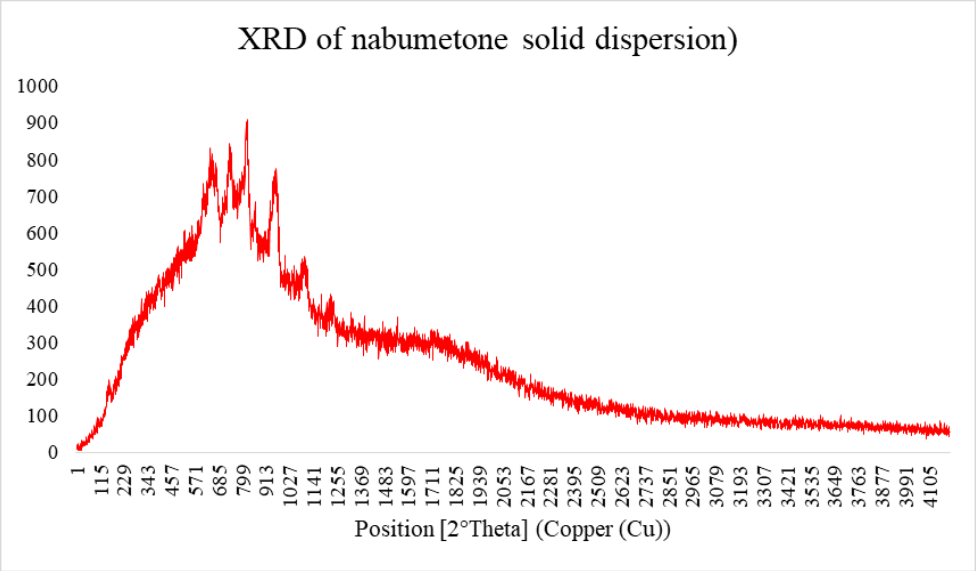

Figure 6: XRD of Solid Dispersion (F3)

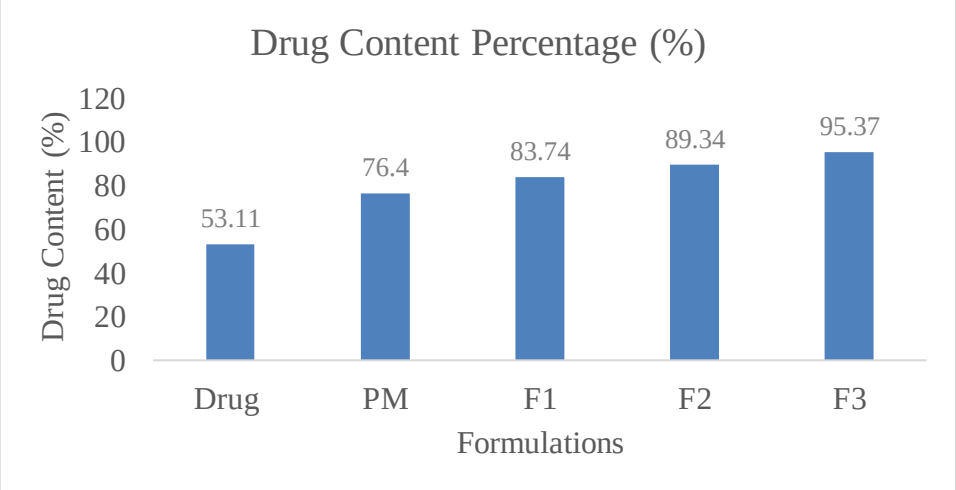

Figure 7: Percentage Drug Content

C-H Bend at 1457.08 cm^{-1} shows the presence of Alkyl chains in the formulation. C-O Stretch at 1178.84 cm^{-1} and 1046.51 cm^{-1} represents the presence of Ethers or esters, confirming the ester group. Aromatic C-H Bend at 678.87 cm^{-1} shows Aromatic rings in the structure.

XRD of nabumetone and solid dispersion

Pure NBT exhibits characteristic peaks at 2 °Theta= 124, 618, 778, and 910, according to XRD diffractograms, indicating its crystalline nature (Fig. 5). However, the XRD pattern of SD showed a drop in the amplitude of certain significant peaks and the lack of others, which indicates a decrease in the NBT crystallinity in this preparation (Fig. 6). The outcome validated the change from the crystalline to the amorphous form of NBT in the form of solid dispersion.

Drug Content

The % drug content in the formulations directly impacts their release profiles. Formulations with higher drug content (F1, F2, F3) demonstrate faster and more extensive drug release, making them more suitable for applications requiring quick drug availability. F3, with the highest drug content, proves to be the most efficient formulation for rapid drug release (Fig. 7).

In Vitro Drug Release

The data represents the percentage of drug released from various formulations (Drug, PM, F1, F2, F3) over different time intervals (5, 10, 15, 30, 60, 120 minutes). Drug (NBT) shows the slowest release. PM shows an initial rapid release followed by a more gradual increase. F1, F2, and F3 formulations show significantly higher and faster drug release compared to Drug (34.64%)

and PM (46.16%). Among these, F3 has the highest release rate 93.33%, followed by F2 (88.88%) and F1 (84.73%) in 120 minutes. The data suggest that F1, F2, and F3 could be more effective for applications requiring rapid drug release (Fig. 8).

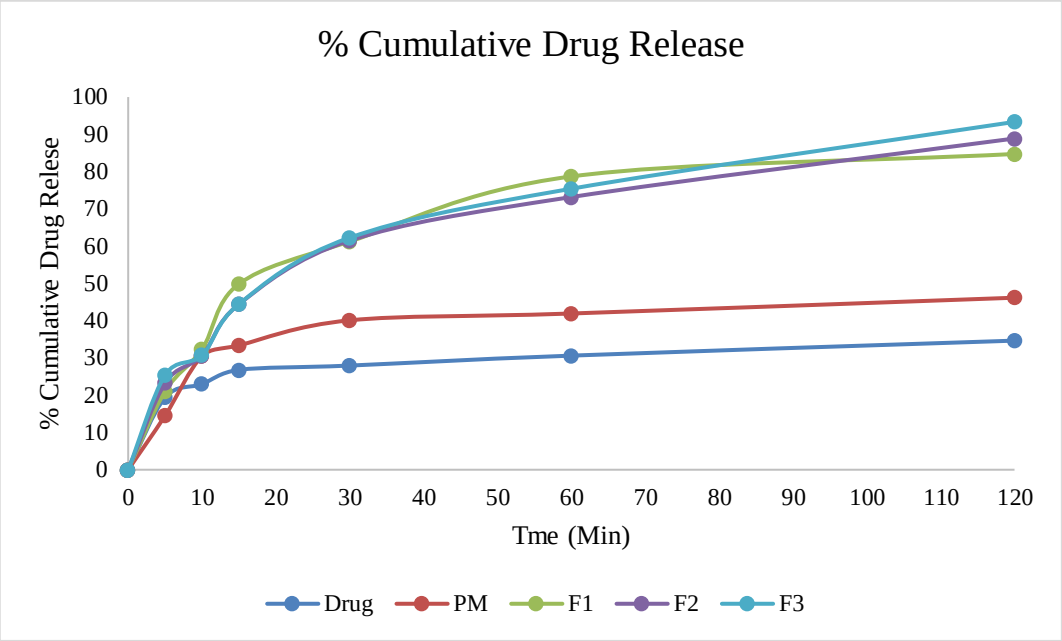

Figure 8: % Cumulative Drug Release

CONCLUSION

The study on the solid dispersion of nabumetone using locust bean gum as a carrier for solubility enhancement demonstrates promising results. The application of locust bean gum significantly improved the solubility and dissolution rate of nabumetone, which is a critical factor for enhancing its bioavailability. This enhancement can be attributed to the amorphization of nabumetone and the effective dispersion of the drug within the polymer matrix. In conclusion, locust bean gum proves to be a viable carrier for the preparation of solid dispersions aimed at improving the solubility and dissolution profile of nabumetone. This approach can potentially lead to better therapeutic efficacy and patient compliance.

ABBREVIATIONS

NBT	Nabumetone
SD	Solid Dispersion
FTIR	Fourier Transform Infrared
XRD	X-Ray Diffraction
PEG	Polyethylene Glycol
PVP	Polyvinyl Pyrrolidone
HPMC	Hydroxypropyl methylcellulose
LBG	Locust Bean Gum
NSAID	Non-Steroidal Anti-inflammatory Drug
PM	Physical Mixture

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CONFLICT OF INTEREST

The authors do not have any conflict of interest.

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