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# Effect of Polymer Morphology on the Structure–Rheology–Swelling Behavior of a Naproxen Sodium–PVP K30 Hot-Melt Extruded Solid Dispersion

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*polyvinylpyrrolidone (PVP K30), naproxen sodium, hot-melt extrusion, polymer morphology, drug delivery, solid dispersion*

**ABSTRACT**

This study investigates the influence of polymer morphology on the performance of drug-loaded delivery systems prepared by hot-melt extrusion (HME). Polyvinylpyrrolidone (PVP K30) was used as a polymer carrier, with naproxen sodium as a model drug, glycerol as a plasticizer, and butylated hydroxytoluene (BHT) as an antioxidant stabilizer. Extrusion was conducted at 150 °C using a twin-screw extruder at 50 rpm, and a shear rate of 17 $s^{-1}$. The formulation consisted of 62.1% PVP K30, 28% naproxen sodium, 9.5% glycerol, and 0.4% BHT. X-ray diffraction (XRD) analysis showed that pure PVP K30 exhibited a broad diffuse halo at 2θ ≈ 17-20°, confirming its amorphous nature. After drug incorporation, the system retained this amorphous halo with a slight shift toward higher angles (~18°), indicating changes in intermolecular arrangement due to interactions between the polymer and additives, without the appearance of distinct crystalline peaks. Differential scanning calorimetry (DSC) revealed a glass transition temperature (Tg) reduction from 169.49 °C to 163.17 °C after extrusion, indicating increased chain mobility, followed by a significant increase to 167.13 °C in the drug-loaded system, suggesting strong intermolecular interactions and an antiplasticization effect. Rheological analysis demonstrated shear-thinning behavior with reduced viscosity, improving processability. scanning electron microscope (SEM) confirmed homogeneous drug dispersion without visible phase separation. Swelling studies showed high and unstable swelling for pure PVP (107.5 ± 24.6% after 1 h) with structural disintegration, while the drug-loaded system exhibited lower and more stable swelling (21.1 ± 2.7% after 1 h and 26.2 ± 4.5% after 4 h), indicating improved structural integrity and controlled water uptake.

## 1. INTRODUCTION

Polymer drug delivery systems have garnered significant attention in recent decades due to their potential to improve drug solubility, stability, and therapeutic efficacy. Since the 1980s, advances in polymer science and pharmaceutical engineering have contributed to the development of innovative drug delivery strategies, enhancing bioavailability and improving patient adherence to treatment [1]. These systems are generally non-invasive, easy to administer, and suitable for a wide range of patient groups, making them very attractive alternatives to traditional drug dosage forms [2]. An efficient drug delivery system requires a set of essential properties, including biocompatibility, chemical stability and inertness, non-toxicity, mechanical durability, and high drug-containing capacity. Polymers are key to achieving these properties and are widely used in various drug delivery systems such as solid dispersants, hydrogels, nanoparticles, micelles, and polymer-drug complexes. These polymer systems are particularly important when dealing with poorly soluble drugs in water, as enhancing solubility and controlling the drug release mechanism are crucial for maximizing therapeutic efficacy [3]. Among synthetic polymers, polyvinylpyrrolidone (PVP) is one of the most important carriers used in pharmaceutical formulations. This polymer is non-ionic and water-soluble, exhibiting excellent biocompatibility and high thermal stability, along with the ability to interact with a wide range of drug molecules. The functional lactam group in the PVP structure contributes to the formation of hydrogen bonds with active ingredients, promoting homogeneous molecular dispersion of the drug and limiting its crystallinity. These properties give PVP effective drug stabilization in its amorphous state, leading to improved solubility and dissolution rate. PVP K30 is widely used in solid dispersion systems and fusion-based manufacturing techniques due to its medium molecular weight and favorable processing behavior [4]. Polymer morphology refers to the internal structural arrangement of polymer chains, including phase distribution, degree of crystallinity, and molecular organization. This structural arrangement plays a crucial role in drug delivery systems, as it directly influences drug dispersion uniformity, physical stability, molecular mobility, and ultimately the drug release behavior. Polymer morphology plays a pivotal role in determining the efficiency of PVP-based drug delivery systems. The internal structure of the polymer matrix influences drug distribution, molecular kinetics, and release

rate. Homogeneous morphologies typically offer better performance in terms of stability and release rate, while phase separation or partial crystallinity may reduce efficacy. In PVP-containing formulations, morphology is shaped by the polymer-drug compatibility, processing conditions, and the presence of additives such as plasticizers or stabilizers. Therefore, understanding the relationship between manufacturing parameters, polymer morphology, rheological properties, and functional properties is essential for optimizing drug delivery systems. Hot-melt extrusion (HME) is a fundamental tool in the fabrication of polymer-based drug delivery systems due to its solvent-free, continuous, and scalable nature. While originally developed for polymer processing, it has been successfully adapted for pharmaceutical applications, particularly for the production of solid amorphous dispersants. During extrusion, controlled temperatures and shear forces precisely mix the drug and polymer, enhancing molecular interactions and ensuring uniform drug distribution. This technique has proven effective in increasing the solubility and bioavailability of poorly soluble drugs [5, 6]. Twin-screw extrusion systems are preferred in pharmaceutical applications over HME due to their high mixing efficiency, flexible screw configuration, and ability to precisely control thermal and mechanical conditions. These properties are particularly important when processing PVP, as excessive temperatures or shear forces can compromise polymer stability. Furthermore, the use of plasticizers such as glycerol improves melt processing by reducing viscosity and increasing polymer chain mobility, thus promoting uniform morphology and consistent product quality [7]. Numerous studies have demonstrated the effectiveness of PVP as a polymer carrier in HME solid dispersions for poorly soluble drugs. PVP-based formulations have exhibited improved dissolution rates, better physical stability, and higher drug loading capacity compared to many other polymers. Furthermore, PVP exhibits good miscibility with a wide range of drugs, enabling the development of flexible and efficient drug delivery systems [8]. However, despite extensive research, the impact of polymer morphology on the performance efficiency of PVP-based systems remains an important area requiring further investigation [9]. Therefore, a clear understanding of how processing-induced morphological variations affect drug dispersion and functional performance remains limited. Based on these considerations, the current study focuses on developing PVP K30-based polymer matrices for drug delivery using hot melt extrusion, with particular emphasis on the role of polymer morphology in enhancing solubility and functionality. By employing specific compositional ratios and controlled extrusion conditions, this study aims to establish clear structure–property relationships to support the rational design of efficient PVP-based drug delivery systems.

## 2. EXPERIMENTAL PART

### 2.1 Material

The materials used in this work are PVP K30, Naproxen sodium (NS), glycerol, and butylhydroxytoluene (BHT). These components were selected for their well- established safety and widespread use in medical and pharmaceutical applications. The specifications of the materials are summarized in Table 1.

**Table 1.** Specifications of the materials used

| Properties | PVP K30 | Glycerol | BHT | NS |
|---|---|---|---|---|
| Molecular formula | $(C_6H_9NO)_n$ | $C_3H_8O_3$ | $C_{15}H_{24}O$ | $C_{14}H_{13}O_3.Na$ |
| Molecular weight (g/mol) | ~40,000(avg) | 92.09 g/mol | 220.35 | 252.25 |
| Melting point (°C) | 160 °C | 18 °C | 69-73 °C | 250 °C |
| pH | 3.0 - 5.0 | 5.5-7.5(aqueous solution) | 6-7 | 7-8 |
| K-value (Viscosity grade) | 29.0 - 32.0 (K-value) | - | - | - |
| Dynamic viscosity | - | 1.5-1.8 Pa·s | Not applicable (solid) | Not applicable (solid) |
| Solubility in water | Freely soluble in water, in ethanol, and in methanol, very slightly soluble in acetone. | Miscible | Insoluble in water, but soluble in organic solvents | Soluble in water |
| Color | White | Colorless | White to pale yellow | White |
| Shape | Powder | Liquid | Granules | Powder |

PVP: polyvinylpyrrolidone, BHT: Butylhydroxytoluene, NS: Naproxen Sodium

### 2.2 Sample preparation

During sample preparation, the polymer was vacuum-dried at 50 °C for 4-6 hours. The pure polymer was then extruded using hot melt extrusion technology to determine the optimal conditions. Extrusion was carried out using a co-rotating twin-screw extruder (Model SLJ-30, Donghui Powder Processing Equipment Co., China) equipped with 30 mm diameter screws and a variable screw speed range of 0-300 rpm, with a main motor power of 4 kW and heating capacity of 3 kW. The material was fed through a standard hopper, and extrusion was performed under controlled temperature conditions (150 °C) at a screw speed of 50 rpm. The extrudates were collected manually and allowed to cool at ambient conditions. This process produced homogeneous, good-looking polymer sheets without any signs of burning or thermal decomposition, indicating that the selected extrusion parameters and temperature were suitable for a formulation containing PVP K30, naproxen sodium, glycerol, and BHT at 150 °C and 50 rpm. Table 2 shows the composition and functional role of the material. Due to material and time constraints, additional control groups were not included. The observed morphological changes are reasonably attributed to the interaction between PVP and naproxen sodium, while glycerol

acted solely as a plasticizer at the low concentration used. These observations are consistent with previous studies on PVP-based hot-melt extruded systems [10, 11]. The shear rate in the extrusion process was estimated based on screw rotation using standard approximations. The angular velocity (ω) was calculated using:

$$\omega = 2\pi N / 60 \quad (1)$$

where, $N$ is the screw speed (rpm).

The shear rate ($\dot{\gamma}$) was then estimated using:

$$\dot{\gamma} = \omega R / H \quad (2)$$

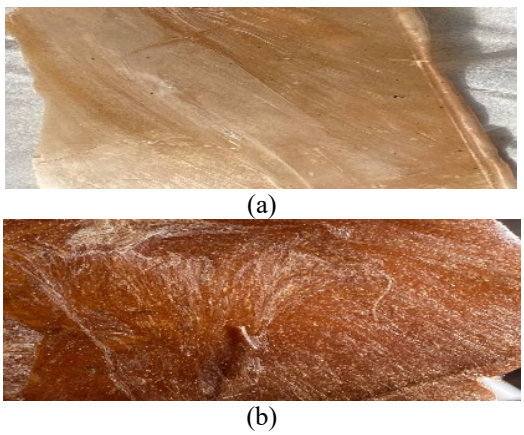
where, $R$ is the screw radius, and $H$ is the channel depth.

The calculated value (~17 $s^{-1}$) represents the shear conditions within the screw channel during extrusion. This measurement reflects the deformation caused by the screw's movement and rotation when the material is subjected to shear forces during its passage inside the screw. The shear rate increases with higher screw rotational speeds. It is important to regulate this parameter to ensure the quality and required properties of the final product. The two samples are shown in Figure 1.

**Table 2.** Composition and functional role of the prepared samples

| Material | Role in Formulation | Ratio (%) of (PVP K30/ NS/Glycerol/BHT) | Weight (g) |
|---|---|---|---|
| Polymer | Matrix | 62.1% | 55.89 |
| NS | Active Pharmaceutical ingredient (API) | 28% | 25.2 |
| Glycerol | Plasticizer | 9.5% | 8.55 |
| BHT | Antioxidant /Thermal stabilizer | 0.4% | 0.36 |

PVP: polyvinylpyrrolidone, NS: Naproxen sodium, BHT: Butylhydroxytoluene



(a)

(b)

**Figure 1.** Samples after the extrusion process for (a) Pure PVP K30, (b) PVP K30/NS/glycerol/BHT

PVP: polyvinylpyrrolidone, NS: Naproxen sodium, BHT: Butylhydroxytoluene

## 2.3 Characterization

2.3.1 Hot-melt extrusion

HME twin screw from EAST SUN Chinese brand DONGHUI, model SLJ30A, is used to mix, melt, and extrude the composites at a certain temperature and speed according to (ISO9001), with a co-rotation, partially intermeshing screw.

2.3.2 X-ray diffraction test

An XRD-6000 X-ray diffraction (XRD) spectrometer made by a Japanese company was used for XRD testing [12]. This instrument is employed to determine the development of solid substances and assess their crystal structure. To record crystallinity and the degree of crystallinity, the device measures the final diffraction pattern after shining a film over the sample PVP K30 polymer, in its pure form, and when combined with Naproxen Sodium/Glycerol/BHT at 24 °C and 32% relative humidity, it was tested in film form, consistently demonstrating crystallinity. This instrument helps distinguish between a sample's crystalline and amorphous forms, although it is not a primary tool for characterizing pharmaceutical or polymer materials.

2.3.3 Differential scanning calorimetry test

The Shimadzu differential scanning calorimetry (DSC-TA60) differential scanning calorimeter was used to analyze thermal transitions (glass transition, crystallization, and melting temperature) from 25 °C to 250 °C in compliance with ISO 11357-3 and following characterization practices reported in research [13].

2.3.4 Rheology test

The capillary shear rate was evaluated using an SR20 single-bore capillary rheometer. Prior to each measurement, the polymeric material was dried and placed in the barrel. The barrels were constructed from Stellite, tungsten carbide, and hardened steel, with a die at the bottom to maintain geometric integrity. The die had a length-to-diameter ratio of 20:10, and a 15 mm-diameter piston was used to drive the polymer melt through the die at various speeds. Preheating was performed for 300 seconds to allow the polymer to soften and flow. During testing, pressure transducers (up to 500 bar) were used to monitor the pressure at the die aperture. Experiments were conducted at 190 °C, covering an apparent shear rate range of 1 to 500 $s^{-1}$, allowing the creation of viscosity curves for the polymer melt. The apparent capillary wall shear rate ($\dot{\gamma}_{cap}$) was calculated from the volumetric flow rate (Q) and die radius (R) using the Newtonian approximation:

$$\dot{\gamma}_{cap} = \frac{4Q}{\pi R^3} \quad (3)$$

where, $R$ is the die radius.

This measurement reflects the shear conditions within the capillary die and provides a benchmark for comparing the material's flow behavior under controlled conditions, distinct from the shear experienced inside the extruder screw channel [14].

2.3.5 Fourier transform infrared test

Fourier transform infrared (FTIR) spectra of the PVP K 30, in their pure forms and with the drug, were measured. The analysis was conducted using an IR Affinity-1 spectrometer, manufactured in Kyoto, Japan. The samples were mixed with KBr powder at a 1:10 mass ratio, thoroughly ground, and then placed in an FTIR sample holder. The device provides detailed structural and quantitative information about the functional groups present in biomolecules [15]. The infrared region is commonly employed to record spectra within the wavenumber

range of 400–4000 $cm^{-1}$ [16].

2.3.6 Morphological characterization

Scanning electron microscopy

A VEGA 3 SBU analytical scanning electron microscope (SEM) was used to analyze the pure PVP K30 sample that was extruded, as well as the sample containing sodium naproxen, glycerol, and BHT dispersed within the extruded PVP K30 matrix. The sample was broken into small pieces for examination at 500× magnification, with a 50 µm scale.

Optical microscopy

By using an optical microscope, the surface morphology of the samples was examined, and the images were captured at 200× magnification.

Digital microscopy

The samples were also photographed at 1600× magnification with a scale bar of 0.50179 mm using a digital microscope.

2.3.7 Density

The high-precision density tester, with a digital accuracy of ± 0.0001 $g/cm^3$, was based on ASTM D-792 and manufactured by Matsu Haku, China. The density (ρ) of the sample was determined using Archimedes' principle according to Eq. (4), which accounts for the sample's weight in air ($W_a$) and its apparent weight in distilled water at 25 °C ($W_l$). The density of water ($\rho_L$) at this temperature is 0.997 $g/cm^3$. No additional temperature correction was needed, as the measurements were conducted at room temperature [17].

$$\rho(g/cm^3) = \frac{W_a}{W_a - W_l} \times \rho_L \quad (4)$$

2.3.8 Water-swelling capacity

After being submerged in 50 mL of distilled water at room temperature for one to four hours, the swelling capacity of samples of pure PVP K30 and PVP K30/Naproxen Sodium/Glycerol/BHT was tested. Prior to and following immersion, the samples' weight was determined using the swelling law according to Eq. (5), which states:

$$\text{Swelling ratio } (\%) = \frac{W_t - W_0}{W_0} \times 100\% \quad (5)$$

where, $W_t$ = Weight of sample after immersion in water at time $t$, $W_0$ = Weight of the sample before water immersion.

## 3. RESULTS AND DISCUSSION

### 3.1 X-ray diffraction analysis

XRD patterns of pure PVP K30 and its solid dispersion with NS/Glycerol/BHT are presented in Figure 2. The diffraction pattern of Pure PVP K30 exhibits a broad diffuse halo centered at 2θ ≈ 17–20°, with no sharp Bragg peaks, confirming its amorphous nature and absence of long-range crystalline order. This behavior arises from the irregular packing of polymer chains and the lack of a periodic lattice arrangement, which is typical for amorphous polymers such as PVP. Upon incorporation of Naproxen sodium into the polymer matrix, the XRD pattern retains the broad halo feature, indicating that the system remains predominantly amorphous. However, a slight shift in the halo position toward higher diffraction angles (~18°) is observed, which suggests modifications in the intermolecular arrangement within the system. This shift can be attributed to enhanced molecular interactions between the drug and the polymer chains, as well as the plasticizing effect of glycerol, which alters chain mobility and packing density. The absence of distinct crystalline peaks corresponding to Naproxen sodium indicates that no detectable long-range crystalline domains of the drug are present. This may suggest that the drug is either molecularly dispersed within the polymer matrix or exists in a disordered amorphous form. Additionally, the presence of additives such as glycerol and BHT may contribute to increased free volume and reduced intermolecular cohesion, further inhibiting crystallization.

Overall, the structural features observed in the XRD patterns indicate a homogeneous amorphous system with possible molecular-level interactions between components. However, further characterization techniques such as DSC are required to conclusively determine the physical state of the drug and the extent of miscibility within the system.

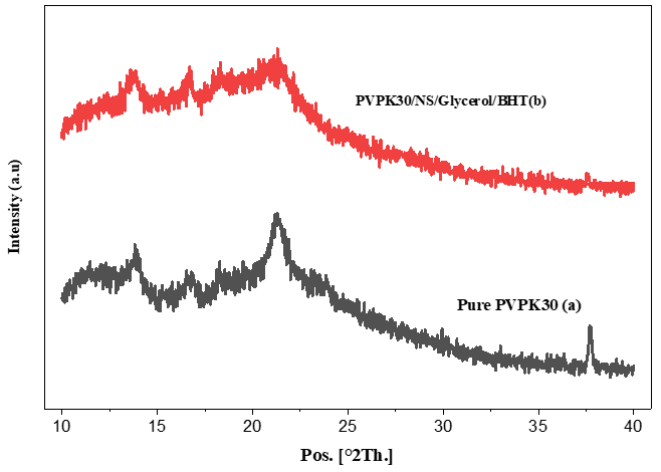



**Figure 2.** Powder X-ray diffraction (XRD) patterns of (a) pure PVP K30, (b) PVP K30/NS/Glycerol/BHT
PVP: polyvinylpyrrolidone, NS: Naproxen sodium, BHT: Butylhydroxytoluene

### 3.2 Differential scanning calorimetry analysis

Any material's glass transition (Tg) is influenced by a number of variables, such as molecular weight, chemical composition, three-dimensional structure, degree of cross-linking, free volume, and intermolecular interactions. The balance between the polymer's loss of elastic energy and the rise in free energy brought on by the drug's breakdown within the polymer determines how Tg changes when a high molecular weight polymer is exposed to tiny molecules, such as a drug. Tg is typically lowered when tiny molecules are added because they allow the polymer chains more mobility. The medication is referred to as a plasticizer, and this process is called plasticization. Strong interactions between the medication and the polymer, however, represent an exception to this rule. In some situations, the mixture's Tg may be greater than the Tg of each component separately. A larger Tg results from the reduction of the polymer's free space. Antiplasticization is the term for this phenomenon. The change in the drug's melting endotherm or Tg determines the drug's miscibility with polymers. According to the Gordon–Taylor

equation, if the drug and polymer are miscible, the mixture will exhibit a single Tg that depends on the relative proportions of the components and lies between the Tgs of the pure components. The Gordon–Taylor (GT) equation can be used to predict the Tg of the mixtures (Eq. (6)) [18].

$$T_{g,\text{mix}} = \frac{w_1 T_{g1} + K w_2 T_{g2}}{w_1 + K w_2} \quad K = \frac{T_{g1}\rho_1}{T_{g2}\rho_2} \qquad (6)$$

where,

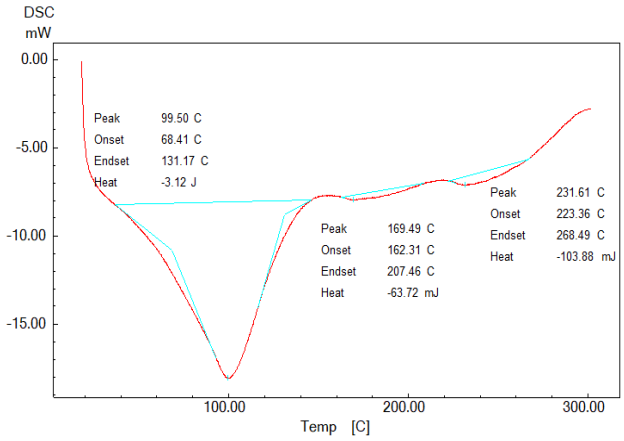
$T_{g,mix}$ is the glass transition temperature of the mixture (°C).
$T_{g1}$ is the glass transition temperature of the polymer (°C).
$T_{g2}$ is the glass transition temperature of the drug (°C).
$w_1$ is the weight fraction of the polymer (dimensionless).
$w_2$ is the weight fraction of the drug (dimensionless).
K is the Gordon-Taylor constant, calculated as:

$$K = \frac{T_{g1}\rho_1}{T_{g2}\rho_2}$$

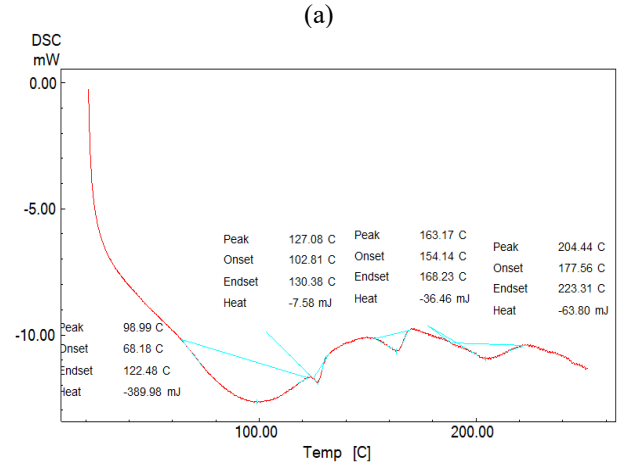
where,

$\rho_1$ is the density of the polymer (g/cm$^3$)
$\rho_2$ is the density of the drug (g/cm$^3$) [18].

Pure PVP K30 before extrusion exhibited a Tg of 169.49 °C (Figure 3(a)), along with a broad endothermic region attributed to moisture loss due to its hygroscopic nature. After extrusion (Figure 3(b)), the Tg decreased significantly to 163.17 °C. This reduction is attributed to increased polymer chain mobility resulting from thermomechanical processing, including chain rearrangement, reduced entanglement density, and possible plasticization due to residual moisture. This behavior reflects an increase in free volume rather than irreversible polymer degradation.




(a)

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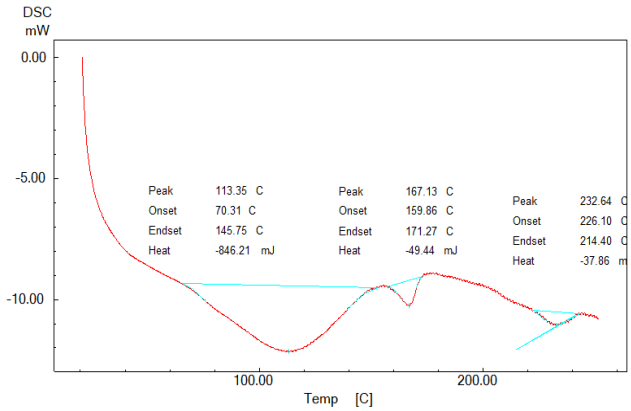



(c)

**Figure 3.** Differential scanning calorimetry (DSC) thermogram of (a) Pure PVP K30 before extrusion, (b) Pure PVP K30 after extrusion, (c) PVP K30/NS/Glycerol/BHT
PVP: polyvinylpyrrolidone, NS: Naproxen sodium, BHT: Butylhydroxytoluene

In contrast, the drug-loaded system (Figure 3(c)) exhibited a Tg of 167.13 °C. This value is significantly higher than that of extruded PVP, indicating a recovery of chain rigidity upon incorporation of naproxen sodium. This behavior cannot be explained by simple thermal history alone, but rather by the formation of strong intermolecular interactions between the drug and polymer, such as hydrogen bonding and ionic interactions. These interactions restrict segmental mobility and reduce free volume, leading to an antiplasticization effect. Importantly, while extrusion increases chain mobility, the subsequent incorporation of the drug introduces interaction-driven structural stabilization that counteracts this effect. Therefore, the increase in Tg in the drug-loaded system does not contradict the effect of shear processing, but instead reflects a transition from a mobility-dominated system to an interaction-dominated system. The absence of a melting peak for naproxen sodium (240-250 °C) confirms that the drug is molecularly dispersed within the polymer matrix, indicating the formation of a homogeneous amorphous solid dispersion (ASD). Furthermore, the experimentally observed Tg (167.13 °C) is higher than the theoretical Tg predicted by the Gordon-Taylor equation (141.5 °C), indicating a positive deviation from ideal mixing behavior. This deviation supports the presence of strong specific interactions between the drug and polymer, which are not accounted for in the Gordon–Taylor model.

### 3.3 Rheology analysis

3.3.1 Shear rate -dependent viscosity

Understanding and improving the processing behavior of polymers requires knowledge of their rheological characteristics, which directly affect material performance and production efficiency. The rheological properties of pure PVP K30 were examined, as shown in Figure 4(a), and compared with PVP K30 containing sodium naproxen, glycerol, and BHT in Figure 4(b). Both samples exhibited shear-thinning behavior, with shear rates ranging from 1 s$^{-1}$ to 500 s$^{-1}$. At a temperature of 190 °C, the first region of the curve, with viscosity values, reflects the molecular weight of the material, and the highest shear rate was initially recorded. Increasing the shear rate caused a gradual decrease in viscosity, indicating reduced resistance of the polymer to the applied forces. The free volume within the polymer matrix facilitates polymer

chain movement under force. This allows effective drug distribution during extrusion, allowing greater chain mobility and smoother drug flow. The melt was completely cohesive and homogeneous, reducing the risk of unmelted drug pools or crystals. Although the polymer's high molecular weight helps maintain structural integrity, adding sodium naproxen further decreased viscosity, maintaining heat stability during extrusion with BHT, which prevents heat damage and unwanted reactions. Lower viscosity with additives simplifies processing and promotes a uniform polymeric matrix, while preserving shear-thinning behavior and product quality. This underscores the importance of system quality in enhancing drug loading and distribution, ultimately aiding in the development of effective polymeric systems or solid formulations for drug delivery.

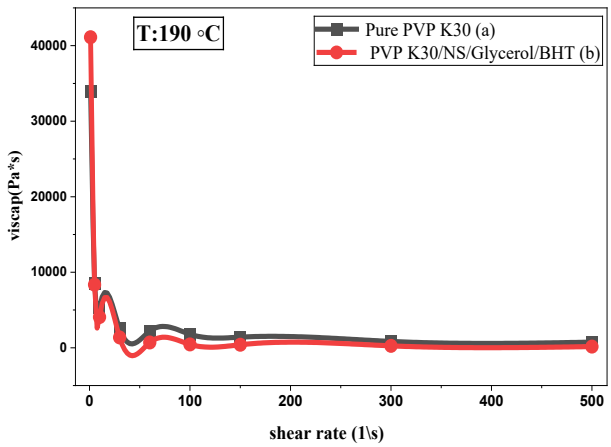



**Figure 4.** Relationship between shear rate vs. apparent viscosity for (a) Pure PVP K30, (b) PVP K30/NS/Glycerol/BHT at 190 °C
PVP: polyvinylpyrrolidone, NS: Naproxen sodium, BHT: Butylhydroxytoluene

3.3.2 Rheological model

The power-law or Ostwald de Waele model, which shows that the relationship between shear stress and shear rate (plotted on double logarithmic coordinates) for a shear-thinning fluid can frequently be approximated by a straight line over a limited range of shear rate (or stress) as given by Eq. (7) in is one of many mathematical expressions of varying complexity and form that have been proposed in the literature to model shear-thinning characteristics. An expression of the following type can be used for this portion of the flow curve [19]:

$$\tau_{yx} = k\left(\dot{\gamma}_{yx}\right)^{n} \tag{7}$$

So, the apparent viscosity for the so-called power-law (or Ostwald de Waele) fluid is thus given by Eq. (8):

$$\eta_{\text{app}} = \frac{\tau}{\dot{\gamma}} = K\dot{\gamma}^{n-1} \tag{8}$$

where, $\eta_{app}$ is apparent viscosity (Pa·s), $\tau$ is the shear stress (Pa), $\dot{\gamma}$ is the shear rate (1/s), $k$ is the fluid consistency coefficient, and the flow behavior index (n), for n < 1, the fluid exhibits shear-thinning properties, for n = 1 the fluid shows Newtonian behavior and, n > 1 the fluid shows shear-thickening behavior. which are two empirical curve-fitting parameters in these equations. The index for a shear-thinning fluid might be any number between 0 and 1. The degree of shear-thinning increases with decreasing n. The index n will be higher than unity for a shear-thickening fluid [19]. Rheology Lite for Windows software was used to analyze the flow behavior of the molten polymers using the Power-Law model to calculate the flow coefficients (n) and viscosity constant (K). The relationship between shear stress and shear rate for each sample was measured using a capillary rheometer in the range of 1-500 $s^{-1}$. Figure 5 represents pure PVP K30, and Figure 6 represents PVP K30 after the addition of sodium naproxen, glycerol, and BHT. The results for both samples showed shear-thinning behavior, meaning that the viscosity decreased with increasing shear rate. This behavior is typical in molten polymers due to the alignment of the polymer chains in the flow direction and the reduction of the material's resistance to flow, allowing for better drug distribution within the polymer matrix during extrusion. The shear stress was calculated from the pressure within the capillary die, while the shear rate was derived from the flow velocity and die shape. The data were then analyzed using the Power-Law model. n represents the flow coefficient and determines the degree of shear-thinning. All samples showed n < 1, confirming non-Newtonian behavior and indicating a decrease in viscosity with increasing shear rate. K represents the viscosity stability at a low shear rate and reflects the molten material's resistance to flow. Higher K values indicate greater resistance, while lower values facilitate extrusion.

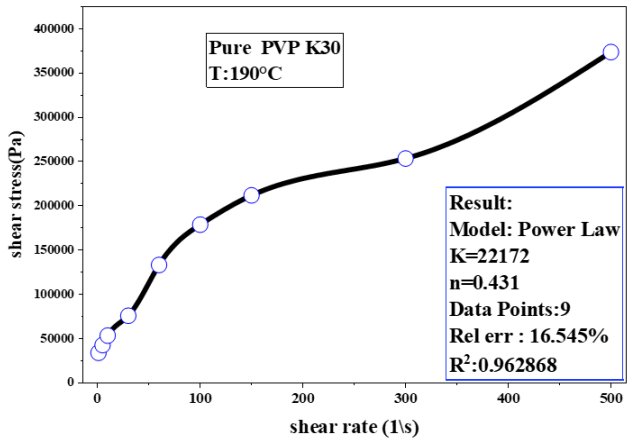



**Figure 5.** Shear rate ($s^{-1}$) vs. shear stress (Pa) of non-Newtonian flow mathematical models for composite melts using the rheology app for pure polyvinylpyrrolidone (PVP)

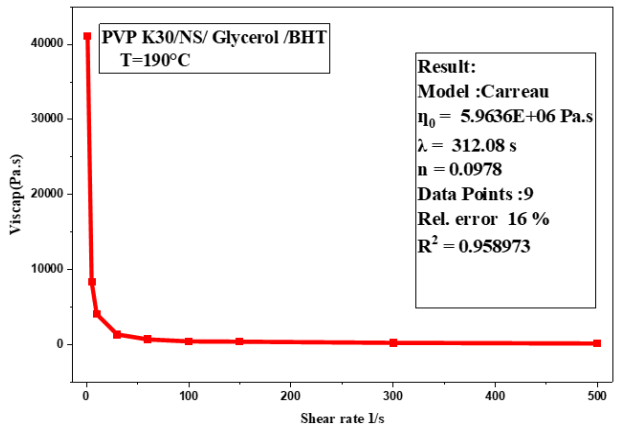



**Figure 6.** Shear rate($s^{-1}$) vs. Viscap (Pa·s) of non-Newtonian flow mathematical models for composite melts using the rheology app for PVP K30/NS/Glycerol/BHT
PVP: polyvinylpyrrolidone, NS: Naproxen sodium, BHT: Butylhydroxytoluene

The rheological behavior of neat PVP was well described by the Power Law model, showing a high coefficient of determination ($R^2 = 0.9629$), which indicates a good fit to the experimental data. The flow behavior index (n = 0.431) confirms a shear-thinning behavior, which is typical for polymeric systems due to chain orientation and gradual disentanglement under increasing shear rate. The consistency index ($K = 2.217 \times 10^4$) reflects a relatively high viscosity, suggesting a well-developed entangled polymer network in the neat PVP system. The 95% confidence intervals for the fitted parameters (n: 0.38 – 0.48, K: $1.8 \times 10^4 – 2.7 \times 10^4$) indicate acceptable parameter stability and reliability of the model fitting. This baseline rheological behavior provides an important reference for comparison with the drug-loaded formulation, where significant deviations in flow response were observed due to the presence of additional components affecting the internal structure of the system. In contrast, the rheological behavior of the drug-loaded formulation was initially analyzed using the Power Law model; however, the fitting quality was poor ($R^2 = 0.577$), indicating that this model is insufficient to describe the complex flow behavior of the system. Accordingly, the obtained parameters (n and K) were considered unreliable and excluded from further interpretation. To better capture the non-Newtonian behavior over a wide shear rate range, the data were re-evaluated using the Carreau model, which is given by Eq. (9):

$$\eta(\dot{\gamma}) = \eta_\infty + (\eta_0 - \eta_\infty)[1 + (\lambda\dot{\gamma})^2]^{\frac{n-1}{2}} \qquad (9)$$

where, $\eta(\dot{\gamma})$ represents the viscosity at a given shear rate, $\eta_0$ is the zero-shear viscosity (at very low shear rates), and $\eta\infty$ is the infinite-shear viscosity (at very high shear rates). The term $\dot{\gamma}$ denotes the shear rate, $\lambda$ is the relaxation time that controls the onset of viscosity change, and n is the flow behavior index, where $n < 1$ indicates shear-thinning behavior.

This showed a significantly improved fit ($R^2 = 0.958973$), confirming its suitability for describing the shear-dependent viscosity of the formulation. The flow behavior index (n = 0.0978) indicates a strong shear-thinning behavior, reflecting a significant reduction in viscosity with increasing shear rate. This pronounced shear-thinning response suggests the presence of a structured polymer network within the system that undergoes progressive breakdown under applied shear. Such behavior can be attributed to the combined effect of the PVP matrix, the plasticizing action of glycerol, and potential drug-polymer interactions, which collectively contribute to a highly shear-sensitive microstructure.

The fitted parameters and their 95% confidence intervals (Table 3) confirm the applicability of the Power-Law model and the Carreau model in describing the shear-thinning behavior of the studied systems within the investigated shear rate range.

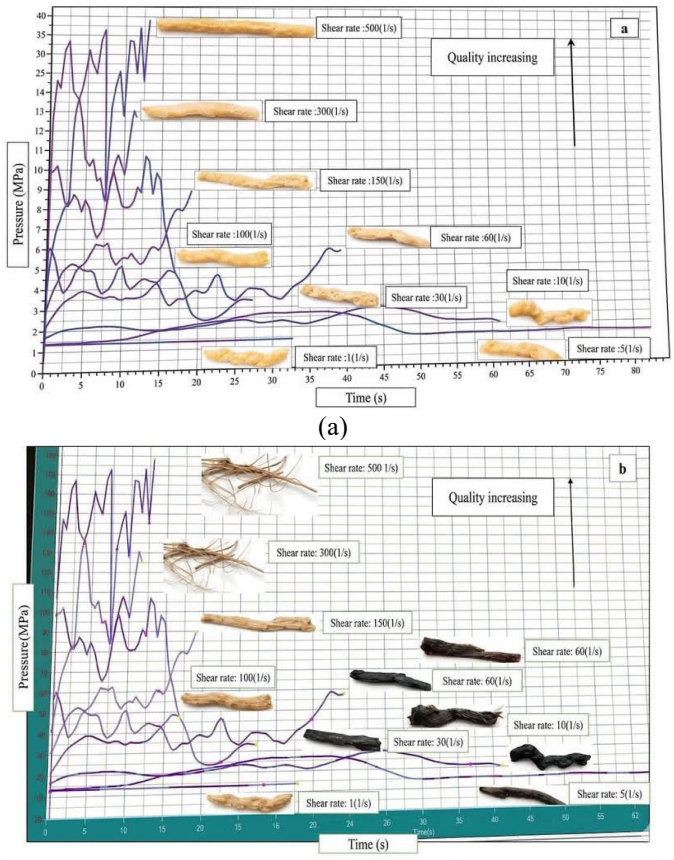



**Figure 7.** Surface quality of (a) Pure PVP K30, (b) PVP K30/NS/Glycerol/BHT, which is melt extruded in a capillary rheometer die with different shear rates at 190 °C
NS: Naproxen sodium, BHT: Butylhydroxytoluene

**Table 3.** Fitting parameters with 95% confidence intervals

| Sample | n | K | $R^2$ | CI (n) 95% | CI (K) 95% |
|---|---|---|---|---|---|
| Pure PVP K30 at 190 °C | 0.431 | 22172 | 0.962868 | 0.38-0.48 | (1.8-2.7) × $10^4$ |
| PVP K30/NS/Glycerol/BHT at 190 °C | 0.0978 | - | 0.958973 | 0.029-0.180 | - |

PVP: polyvinylpyrrolidone, NS: Naproxen sodium, BHT: Butylhydroxytoluene

3.3.3 Surface quality

The results of extruding PVP K30 polymer in its pure state and when extruded with naproxen sodium, glycerol, and BHT using a capillary at 190 °C showed that the morphology and surface quality are directly affected by shear rate and viscosity reduction, as shown in Figure 7(a) for pure PVP K30 and Figure 7(b) for PVP K30/NS/Glycerol/BHT. At low shear rates, irregular surfaces with obvious deformations were observed, resulting from poor polymer chain alignment and high viscosity 33950 Pa·s in its pure state at 1 $s^{-1}$ (Figure 7(a)) and 41125 Pa·s at 1 $s^{-1}$ when mixed with the additives (Figure 7(b)) and flow instability, but when the shear rate and pressure went up, the surface quality got a lot better, becoming smoother and more even with a visible elongation in the direction of the flow. This is attributed to improved polymer chain alignment and smoother material flow resulting from the apparent viscosity reduction due to shear thinning. These results indicate that controlling the shear rate and the applied pressure during extrusion is a key factor in achieving high surface quality and improved flow stability within the capillary.

### 3.4 Fourier transform infrared analysis

The purpose of the FTIR test was to investigate possible chemical interactions and compatibility between PVP K30 and

the components of the additives (NS, glycerol, and BHT), both in the pure condition and after blending. Figure 8(a-b) represents the FTIR spectroscopy of pure PVP K30 and PVP K30/Naproxen Sodium/Glycerol/BHT. The absorption bands of the C = O group were most visible in the IR spectrum of PVP K30 in Figure 8(a), at 1650-1620 $cm^{-1}$. The carbonyl (C = O) group is considered one of the characteristic features of the tertiary amide in the N-vinylpyrrolidone unit in PVP K30. The preservation of this band after the addition of naproxen sodium, with a slight shift to the range of 1650-1600 $cm^{-1}$ without disappearance, indicates that no chemical interaction has occurred; rather, the interaction is physical in nature. This behavior confirms the compatibility between the polymer and the active pharmaceutical ingredient, with each component retaining its original functional groups and without the formation of new bands attributable to chemical reactions. The FTIR spectrum of pure PVP K30 polymer shows a broadband within the 3400-3200 $cm^{-1}$ range, which is due to the stretching vibrations of the hydroxyl groups (O-H) of the absorbed water. In addition, absorption bands in the range of 2950-2850 $cm^{-1}$ are attributed to the stretching vibrations of aliphatic C–H bonds, along with bands observed in the 1290-1100 $cm^{-1}$ region associated with C-N and C-O stretching vibrations. The presence of C-C vibration bands in the region of 900-600 $cm^{-1}$ indicates the integrity of the polymeric carbon backbone and confirms that no structural degradation or chemical interaction occurred during processing. The FTIR spectrum of the sample containing naproxen sodium is shown in Figure 8(b), which shows characteristic peaks belonging to the ionized carboxyl group ($COO^-$). A band in the 1550-1600 $cm^{-1}$ region is attributed to the asymmetric elongation vibration, and another at 1400–1450 $cm^{-1}$ represents the symmetric elongation of this group. Additional peaks associated with the aromatic ring are observed in the 1600-1500 $cm^{-1}$ region, in addition to peaks at 1260-1240 $cm^{-1}$ and 1250-1050 $cm^{-1}$ belonging to the C-O vibrations of the drug's characteristic methoxy group. It is noted that these peaks persist without disappearing, with slight overlap or shifts occurring as a result of the polymer's presence, indicating that sodium naproxen retains its chemical structure and no chemical reaction occurs, suggesting that the reaction is limited to physical interactions within the polymer matrix. All the above peaks showed that the spectrum retained the same basic peaks with slight shifts and a relative decrease in the intensity of some beams, after the addition of naproxen sodium, glycerol and BHT without the appearance of new peaks, indicating the physical interaction, which confirms the good compatibility between the polymer and the active ingredient and the retention of each component of its chemical structure, which is consistent with what was reported in the scientific literature about PVP systems that enhance drug stability and improve their solubility [20, 21]. In addition, FTIR analysis was also performed on capillary-extruded samples processed at 190°C to further evaluate the effect of processing conditions on the chemical stability of the system. Figure 8(c-d) represents the FTIR spectra of PVP samples extruded at 190 °C, whether pure or loaded (PVP K30/NS/Glycerol/BHT), indicating that no significant thermal or chemical decomposition occurred under the processing conditions. The characteristic peaks, particularly the carbonyl (C = O) peak in the range (1650-1750 $cm^{-1}$), retained their positions without the appearance of new peaks indicative of decomposition products. Furthermore, the slight changes in the intensity and width of some peaks, particularly in the region (3200-3500 $cm^{-1}$), can be explained by intermolecular interactions such as hydrogen bonding and plasticization effects resulting from the addition of glycerol and the drug, rather than as a result of the breakdown of the polymer chains. These results are consistent with those reported in the study by Loría-Bastarrachea et al. [22], which showed that the actual thermal decomposition of PVP begins at much higher temperatures (~ 668 K, i.e., approximately 395 °C), and occurs primarily via depolymerization to the monomer. Consequently, it can be concluded that curing at 190 °C did not lead to chemical decomposition, but caused only physical changes and rearrangements within the polymer matrix.

### 3.5 Morphological analysis

3.5.1 Scanning electron microscopy

SEM photomicrographs were obtained at 500× magnification for the PVP K30 polymer after HME. Figure 9(a) shows a relatively smooth and homogeneous surface with some cracks, likely resulting from the flow of molten polymer during extrusion. The sample loaded with sodium naproxen (Figure 9(b)) exhibited a wavy surface following the direction of polymer flow, with no visible particles or crystalline features. No phase separation was observed, indicating a uniform distribution of the drug within the polymer matrix. These observations are consistent with the DSC results showing a single Tg, XRD indicating the absence of crystalline peaks, and FTIR confirming only physical interactions.

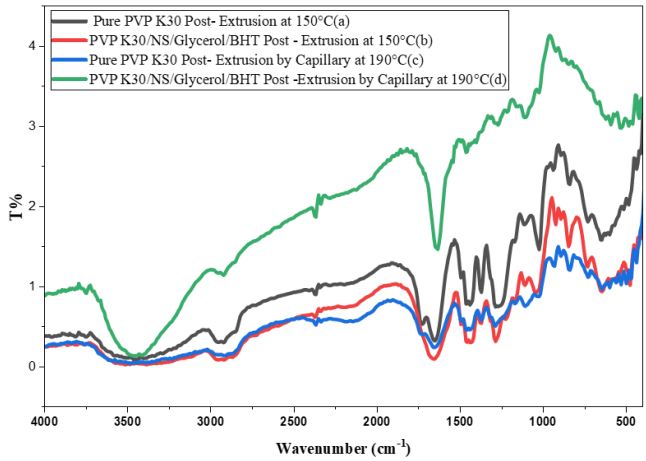


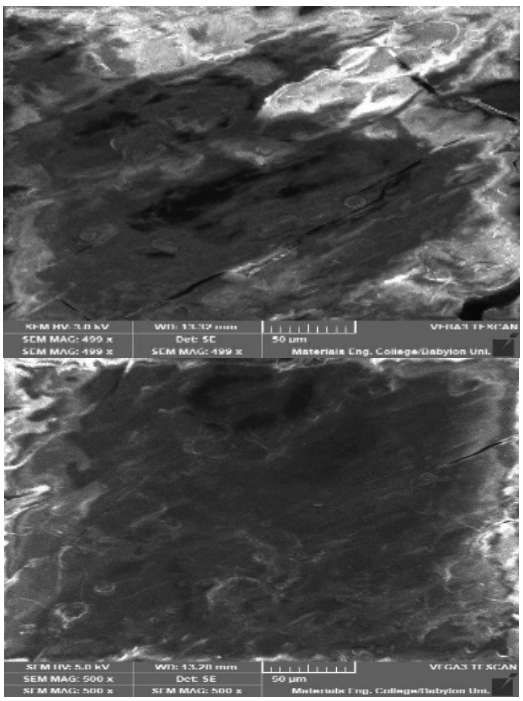

**Figure 8.** FTIR spectra for (a) Pure PVP K30 post-extrusion at 150 °C, (b) PVP K30/NS/Glycerol/BHT post-extrusion at 150 °C, (c) Pure PVP K30 post-extrusion by capillary at 190 °C, (d) PVP K30/NS/Glycerol/BHT post-extrusion by capillary at 190 °C

PVP: polyvinylpyrrolidone, NS: Naproxen sodium, BHT: Butylhydroxytoluene

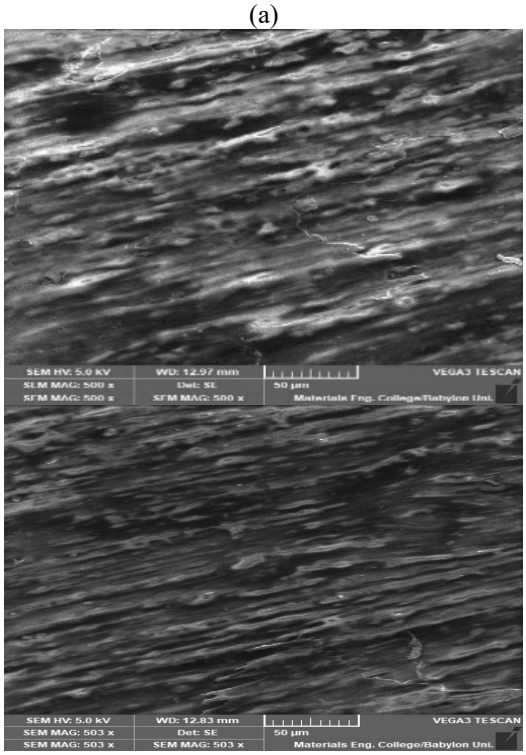
3.5.2 Optical and digital microscopy

Figure 10(a) shows optical images of the pure PVP K30 polymer, which exhibited small, variable particle sizes. The addition of sodium naproxen, glycerol, and BHT, as shown in Figure 10(b), resulted in a surface with a homogeneous distribution of these components. Particle size was analyzed using Image Software to assess uniformity and compatibility within the polymer matrix. The particles were observed to be very small, without agglomeration, suggesting good miscibility and distribution within the PVP K30 polymer. Figure 11 shows digital microscope images at 1600 ×

magnification of (a) pure PVP K30 polymer and (b) the polymer mixture with sodium naproxen, glycerol, and BHT. The pure polymer exhibited a relatively smooth and homogeneous surface. In contrast, the modified mixture showed increased surface roughness, some agglomerates, and irregularities in distribution, reflecting the incorporation of glycerol, sodium naproxen, and BHT into the polymer matrix. The observed changes are consistent with the role of glycerol as a plasticizer, which can increase the spacing between polymer chains and affect the surface morphology.




(a)




(b)

**Figure 9.** Scanning electron microscope (SEM) photomicrographs of (a) Pure PVP K30(500X), (b) PVP K30/Naproxen sodium/Glycerol/BHT (500×)
NS: Naproxen sodium, BHT: Butylhydroxytoluene

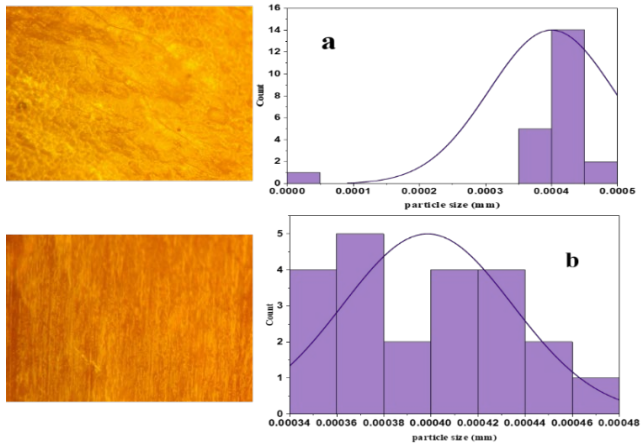
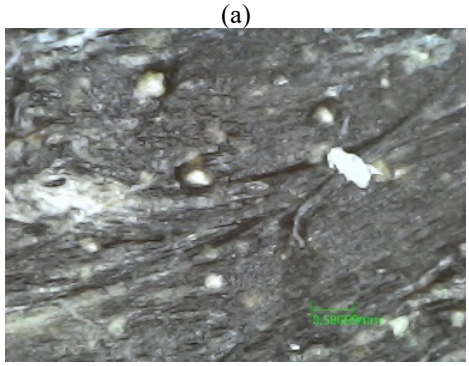



**Figure 10.** Optical microscopy images of (a) Pure PVP K30(200X), (b) PVP K30/NS/Glycerol/BHT (200×)
PVP: polyvinylpyrrolidone, NS: Naproxen sodium, BHT: Butylhydroxytoluene

(a)



(b)

**Figure 11.** Digital microscopy images of (a) Pure PVP K30 (1600×), (b) PVP K30/NS/Glycerol/BHT (1600×)
PVP: polyvinylpyrrolidone, NS: Naproxen sodium, BHT: Butylhydroxytoluene

### 3.6 Density

The slight decrease in density observed after the incorporation of naproxen sodium, glycerol, and BHT into the PVP-based extruded sheets can be attributed to several factors. The additives, having lower densities than the polymer matrix, partially replace the polymer volume, while glycerol acts as a plasticizer, increasing chain mobility and introducing microscopic free volume within the polymer. Additionally, the HME process can generate minor porosity due to mechanical shear and thermal expansion, particularly when additives interfere with polymer chain packing. Overall, the reduction in density from 1.1243 g/cm³ for plain PVP sheets to 1.0496 g/cm³ for loaded sheets reflects the expected structural modifications and confirms that the system maintains its integrity while accommodating the additives.

### 3.7 Water-swelling capacity

The water swelling behavior of the extruded PVP-based

sheets was evaluated using three replicates (n = 3) for both pure and drug-loaded systems, immersed in 50 mL of distilled water at ambient temperature (~25 °C). The swelling percentage was calculated at four time points (1, 2, 3, and 4 hours), and the results were expressed as mean ± standard deviation to ensure reproducibility and error analysis. As shown in Figures 12 and 13, the Pure PVP samples exhibited pronounced and irregular swelling behavior. After one hour of immersion, the swelling reached approximately 107.5%, indicating rapid water uptake due to the highly hydrophilic nature of PVP and the presence of carbonyl (C = O) groups, which strongly attract water molecules. This facilitates fast diffusion of water into the polymer matrix, increasing the intermolecular spacing and causing significant expansion. However, one of the pure PVP samples underwent structural disintegration after the first hour of immersion; therefore, measurements beyond this time point were not considered for this sample and were excluded from the subsequent analysis. The apparent fluctuations in swelling values at later time points (2-4 hours) can therefore be attributed to partial collapse, dissolution, and structural instability of the polymer network rather than true equilibrium swelling. This behavior reflects the amorphous and loosely packed structure of pure PVP, which lacks sufficient mechanical integrity to maintain dimensional stability upon prolonged exposure to water. In contrast, the drug-loaded system (PVP with sodium naproxen, glycerol, and BHT) demonstrated significantly lower and more stable swelling behavior, with values ranging from 21.1% after one hour to 26.2% after four hours. The reduced swelling can be attributed to intermolecular interactions between the drug and polymer, including hydrogen bonding and possible ionic interactions, which reduce the free volume and restrict chain mobility. Additionally, glycerol acts as a plasticizer, enhancing chain flexibility and allowing controlled water diffusion without causing rapid expansion or structural failure. Unlike pure PVP, no disintegration was observed in the loaded samples, indicating improved structural integrity and stability over time. Overall, the results indicate that pure PVP possesses a highly hydrophilic and open structure prone to excessive swelling and structural collapse, whereas the drug-loaded system exhibits a more controlled and stable swelling profile. This behavior supports the formation of a more compact and interaction-driven matrix in the presence of additives, which is advantageous for maintaining dimensional stability and achieving controlled drug release in pharmaceutical applications.

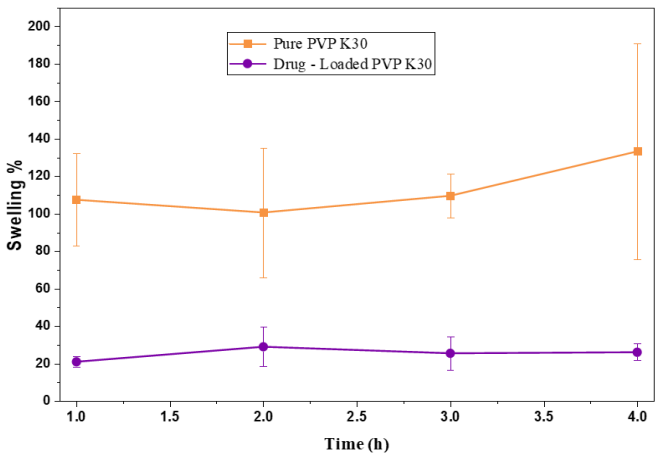



**Figure 12.** Water swelling (%) vs time for pure and drug-loaded PVP K30 (mean ± SD, n = 3)

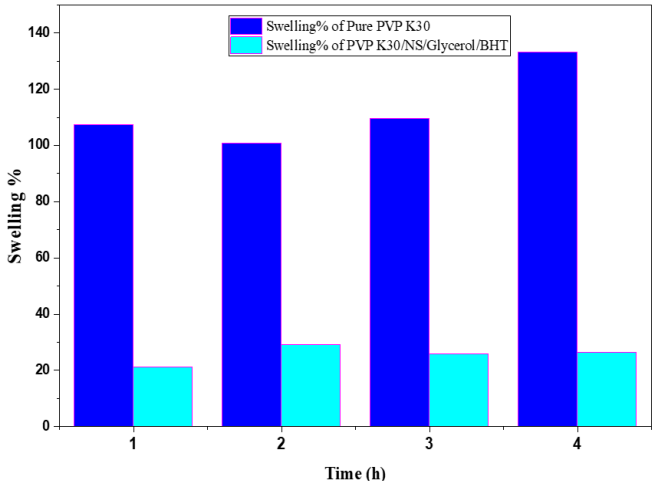



**Figure 13.** Water-swelling capacity of pure PVP, PVP K30/NS/Glycerol/BHT
NS: Naproxen sodium, BHT: Butylhydroxytoluene

## 4. LIMITATIONS OF THE STUDY

A key limitation of this study is the absence of intermediate control formulations, as the experimental design was restricted to neat PVP and the multicomponent system (PVP + NS + glycerol + BHT). This limits the ability to independently evaluate the contribution of each component. In particular, the lack of a (PVP + glycerol + BHT) control prevents clear isolation of the effect of NS, as the observed changes in thermal and physicochemical properties may result from the combined effects of polymer interaction, plasticization by glycerol, or the antioxidant effect of BHT. Therefore, the observed changes cannot be directly attributed to NS alone.

Future studies will include additional control formulations, such as (PVP + glycerol + BHT) and binary systems containing NS, to better distinguish individual and synergistic effects and provide a clearer understanding of the interaction mechanisms.

## 5. CONCLUSIONS

This study aimed to evaluate the effect of polymer morphology on the performance of PVP K30-based drug delivery systems using HME. The results showed that the pure polymer was loose with rapid swelling but exhibited instability upon prolonged water exposure. The addition of naproxen sodium, glycerol, and BHT improved polymer stability, reduced initial swelling, and enhanced flexibility, processability, and thermal stability. DSC, XRD, and FTIR analyses confirmed homogeneous drug distribution within the polymer matrix, while SEM showed no visible drug clustering or phase separation. Rheological measurements indicated improved flowability and processability during thermal extrusion without structural collapse. These findings suggest that incorporating glycerol and BHT with PVP K30 can enhance the system's handling and performance. Further studies are needed to evaluate the impact of these modifications on drug release behavior.

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