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# Kinetic and thermodynamics analysis: effect of eudragit polymer as drug release controller in electrospun nanofibers

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## Abstract

The purpose of the present study was investigating kinetic and thermodynamic analysis using eudragit (EUD) polymer as controller to drug release mebendazole. nanofibers containing various proportions of EUD polymer, that were prepared with electrospinning technique. In this study, the amount of drug mebendazole release was investigated using nanofibers containing EUD at concentrations 50, 250, 500 ppm as controller at 0 -312 time by a Spectrophotometry (UV) method Measured. For every Nanofiber at 25 °C, 31 °C, 37 °C, and 43 °C, drug release studies were performed for 72 h. The nanofibers of EUD 500ppm, EUD 250 ppm and EUD 50ppm had the highest resistance to drug release, respectively. The results showed that EUD plays a very good role in controlling drug release at the nanofiber. Experimental data were done fitted better with the Sahlin-Peppas model. Kinetic studies have shown that due to the hydrophilic nature of EUD, both diffusion and swelling mechanisms contribute to the drug release process. Thermodynamic analysis showed that drug release leading to increased disorder ($\Delta S<0$) is also an endothermic process ($\Delta H>0$) and at all controlling concentrations is not spontaneous ($\Delta G>0$). As the amount of the controller increases, activation energy increases.

**Keywords:** Drug release; thermodynamics; kinetic; electrospinning; eudragit; mebendazole.

## Introduction

Electrospinning is a process for the production of nanofibers and micro-fibers from solutions of polymeric, ceramic, and composite materials. In the electrospinning method, a high voltage power supply is used to generate electrical charge in the soluble or polymeric melt flow. This device can control various properties of nanofibers including porosity, shape, diameter, thickness, arrangement and knotting ability. The flexibility of the machine is high and the process is easy and affordable. The most important use of electrospinning is in drug release [1-4]. Controlled release is a technique by which active chemicals are administered at an appropriate time and at a controlled speed to create the desired effect available to the target organ [5-7]. In this study, EUD was

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used to control the release of mebendazole. Poly(meth)acrylates are known as the trade name EUD. EUD is hydrophilic and protects the actives sensitive to gastric fluid. The ability of EUD to merge with different polymers enables it to achieve the desired drug release profile by releasing the drug at the desired place and at the proper time [8]. EUD polymer has a wide range of applications in drug release based on its properties. The use of polymer in the treatment of intestinal, ophthalmic, vaginal and transdermal diseases are some of its applications in drug delivery systems [9-13]. EUD is naturally hydrophilic and has swelling properties in aqueous media [14]. Echinococcosis or hydatid cyst disease is one of the most important and deadly human parasitic diseases in the world [15], which is a common infectious disease between humans and animals and is of high importance in public health of both humans and animals. The disease is endemic in all Mediterranean countries [16,17]. Cysts occur mostly in the liver (75%) and in the lungs (15%), but can affect other organs such as brain, spleen, kidney and bone marrow [17-19]. There are many treatments available to eliminate this parasite, the most effective of which is surgery that is not always successful [16]. One way to treat this disease is to use mebendazole drug [19-20]. Drug delivery at the right time and place can be effective in the treatment [21]. Kinetic study of drug release and determining its mechanism is one of the most important tasks that must be done to design a predictable and repeatable drug delivery system [22]. To explain the kinetics of drug release, various models have been proposed. Each of these models relates to the amount of drug release, shown by time, and temperature [23,24]. Zero-order and first-order models are not related to biological or physicochemical phenomena. The Higuchi model (diffusion mechanism) describes the solubility of drug in solvent media based on the diffusion mechanism. This model is based on Fick's first law. Swelling of matrices and dissolution is negligible. Diffusion of solvent into the matrices, swelling of matrices as solvent enter, formation of gel, diffusion of drug and controller out of the matrices, and dissolution of fiber was considered in Korsemeyer-Peppas model (power law model) [25]. Like the aforementioned models, the Hixson-Crowell model (Erosion release mechanism), Weibull model (empirical model, life-time distribution function), Baker-Lonsdale model (Release of drug from spherical matrices), Hopfenberg model (erosion mechanism), Gompertz model (dissolution model), the Sahlin-Peppas model (contribution of each mechanism), and Sequential model (swelling mechanism) are kinetic models that each has been achieved with assumptions and limitations [22-26]. The choice of the best kinetic model depends on the research conditions and assumptions. In this study, cellulose nanofibers containing mebendazole and various amounts of EUD controller were fabricated using electrospinning technique. The release of mebendazole drug from nanofibers containing controller of EUD were investigated. Kinetic and thermodynamic studies of drug release were performed and finally equations for predicting drug release rate were obtained. It should be noted that there are no published articles on the use of EUD as a drug release controller in electrospun nanofibers containing the drug mebendazole.

## Materials and methods

Mebendazole was prepared from Modawa Company (Iran) and EUD L-30 D from Rrahavard Tamin Company (Iran) and Ethyl Cellulose and Ethanol 100% was purified from Aldrich and Merck (Germany).

Electrospun with specification A voltage of 15 kV (DW-P403-1AC high-voltage generator, Dongwen Factory, Tianjing, China) was applied to the needle and the aluminum foil. The distance from the tip of the needle to the aluminum foil was 12 cm. The rate of movement of the syringe was controlled with a syringe pump. The feed rate of the precursor solution was fixed at 0.5 mL $h^{-1}$. A dense web of fibers was collected on the aluminum foil (Figure 1). For examining the nanofibers, an SEM microscope (S-3000N, Hitachi, Japan) was used. For spectrophotometry, Hewlett-Packard 8453 diode array spectrometer was controlled by a computer. Ultrasonic devices with specification with device model MP and with device code 18128 Switzerland were prepared.

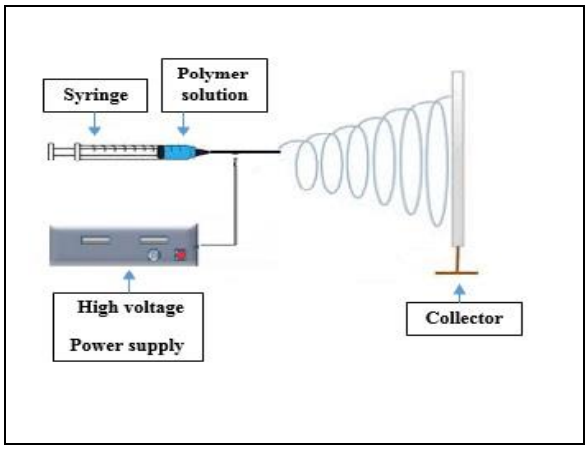


**Figure 1.** Schematic setup of electrospinning

## Experimental

*Preparation of nanofibers*

Solutions contains EUD polymer were made with three concentrations (50, 250, and 500 ppm). The difference in solutions is in the amount of the controller. Then, by placing them in an ultrasonic device and producing a uniform solution, they were transferred to the electrospinning device. The device started operating according to the following instructions (0.5 mL/h, 10 cm, 15 kV, and 300 rpm). Finally, after 6 h, good fiber was prepared.

*Scanning electron microscopy (SEM)*

In this study, The SEM image provides a magnification of up to 130000x and a resolution of about 14 nm. No nodes were found in nanofibers; the controllers were mounted on it (Figure 2).

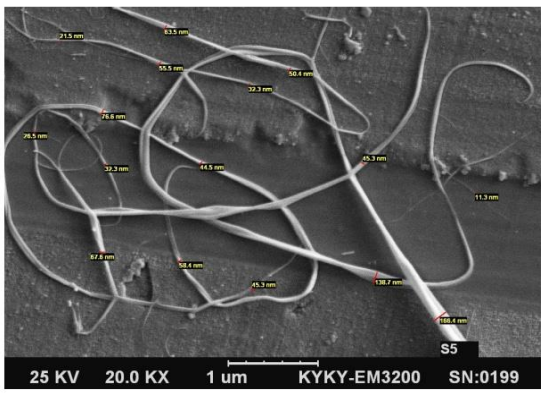


**Figure 2.** SEM image of electrospun nanofiber collected using a patterned collector

*Evaluation of the mebendazole content in the system*

Testing UV was performed at different times. To investigate the solubility of nanofibers, no drug and no controller nanofibers were placed in physiological serum. Also, no chemical interactions were observed between the compounds of EUD, mebendazole and cellulose nanofiber and no new material was added or decreased in the system.

To each nanofiber within 72 h, the absorption test was performed. The corresponding absorptions were determined in the calibration equation, which indicates the concentration of the drug released. The drug release percentage in the medium, according to the total amount of drug used in nanofibers, could be measured.

$$\text{percentage of drug release} = \frac{C_t}{C_\infty} * 10( \quad (1)$$

**Results and discussion**

After preparation of all nanofibers with electrospinning method, about 0.01 g of each nanofiber were mixed with 10 mL of physiological serum, and then placed in a Bain-marie circulatory system at 25 ˚C, 31 ˚C, 37 ˚C, and 43 °C. For each nanofiber, after 72 h, the absorption rate was measured. The drug concentration released into the medium at different temperatures were determined, based on the results of the absorption tests.

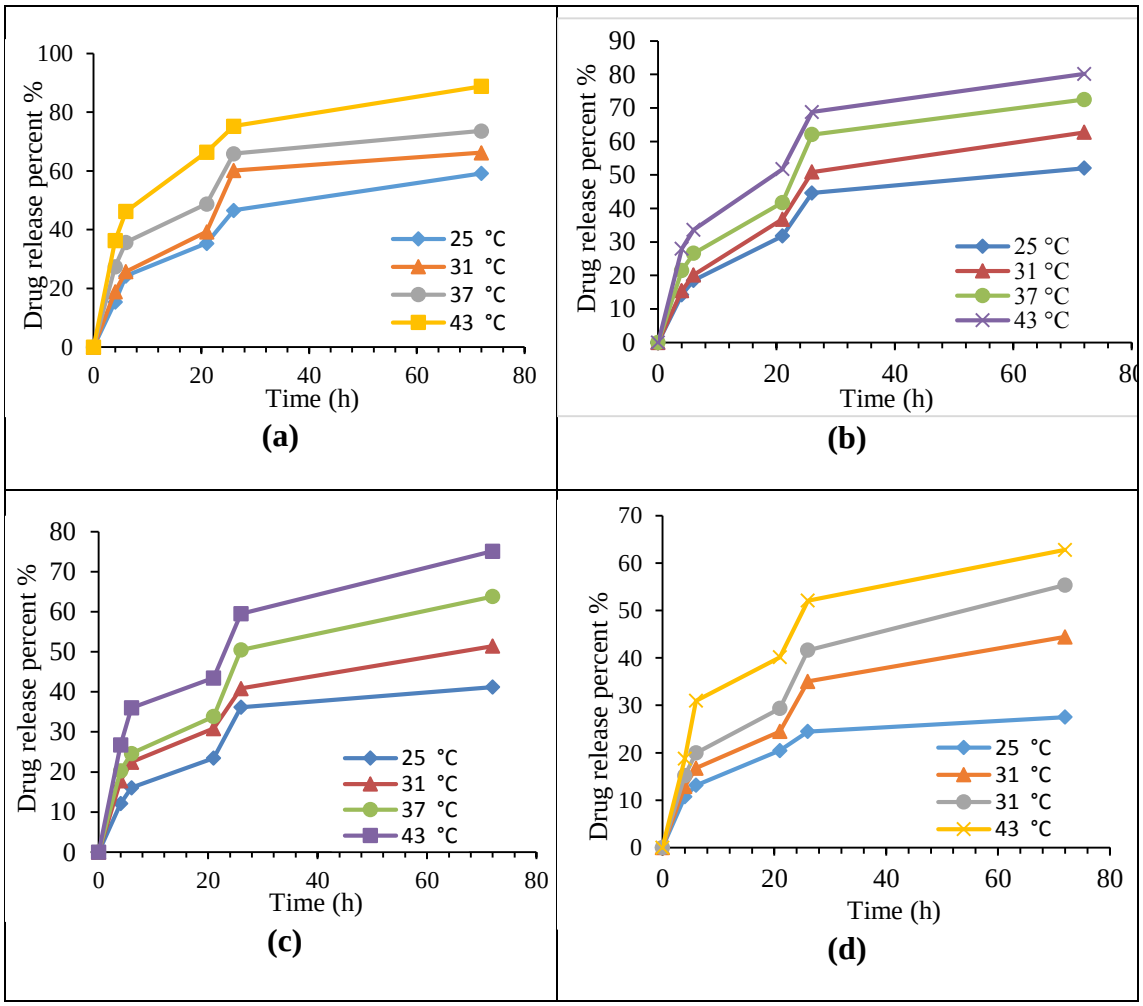


**Figure 3.** Percentage of drug release from nanofibers (a) Ethyl Cellulose, (b) EUD 50 ppm, (c) EUD 250 ppm, (d) EUD 500 ppm.

According to the diagrams, drug release in the presence of controller was harder over the certain time period, and after 72 h, the drug release percentage was decreased. In other words, as the controller concentration increased inside the nanofiber, the drug release was harder, so that the nanofibers containing 50-ppm controllers, after 55 h,and the nanofibers containing 500-ppm controllers, after 312 h, released the drug in the medium. The results showed that EUD nanofiber with three concentrations of (50, 250, 500 ppm) had (1.35, 1.07, 0.882) absorption respectively and showed the percentage of drug release (86.2%, 69.2%, 57.2%) after 312 h respectively. So, by increasing the concentration of EUD controller in nanofibers, the amount of adsorption and release drug rate decreased. It should be noted that with increases in the temperature, the amount of absorption and release rate of the drug increases (Figure 3). Due to the hydrophilic properties of EUD, the mechanisms of drug release is done by diffusion and swelling mechanism simultaneously. On this basis, a kinetic model that can describe both diffusion and swelling mechanisms should be selected for mathematical modeling. Higuchi model, Korsemeyer-Peppas model or Peppas-Sahlin model can be used in this modeling. These models are shown in Table 1.

**Table 1.** Kinetic models and their equation[22]

| **Kinetic model** | **Equation** |
|---|---|
| Higuchi | $C_t/C_\infty = K_H * t^{0.5}$ |
| Korsmeyer–Peppas | $C_t/C_\infty = K_{KP} * t^{n}$ |
| Peppas–Sahlin | $C_t/C_\infty = k_1 * t^{n} + k_2 * t^{2n}$ |

Where $K_H$, $K_{KP}$, $k_1$, $k_2$ are the constant of kinetic equations, the ‘n’ is order of equations, the‘t’ is time base on hour (hr), $C_t$ and $C_\infty$ is released drug and entire of drug in nanofiber, respectively. Kinetic constants were temperature-dependent, using to the Arrhenius equation:

$$K = K_0 \exp\left(\frac{-E_a}{R_g T}\right) \qquad (2)$$

Activation energy ($E_a$) can be obtained after obtaining kinetic constants at different temperatures. After the activation energy is obtained, the pre-exponential factor of Arrhenius equation ($K_0$) is obtained. By studying the kinetics of drug release, thermodynamic analysis of drug release is possible. Kinetic constants link to thermodynamic parameters with Eyring equation:

$$\ln\left(\frac{K}{T}\right) = \left[\ln\frac{K_b}{h} + \frac{\Delta S}{R_g}\right] - \frac{\Delta H}{R_g} \times \frac{1}{T} \qquad (3)$$

$K$ is a kinetic equation constant, $K_b$ is the Boltzman constant, $h$ is the plank constant, $R_g$ is the universal gas constant and T is the temperature. $\Delta S$ and $\Delta H$ is entropy and enthalpy change of drug released process, respectively. After the enthalpy and entropy of the process are obtained, Gibbs free energy is obtained:

$$\Delta G = \Delta H - T \times \Delta S \qquad (4)$$

Curve fitting of kinetic models was performed by least squares method using the MATLAB 2016b. The drug release experimental data were fitted along with the respective equations and parameters. The percentage of the drug released was considered as a function of time. In the current study, with obtaining a kinetic model to describe the process of drug release with regard to laboratory data in a better and more predictable way and determine the infiltration (penetration) and swelling mechanisms that play an important role in the process of drug release. The least squares method (LSM) was employed to obtain the corresponding parameters. According to the $R^2$ adjusted, RMSE, and SSE parameters, the Sahlin model accurately fit the data and the model parameters were physically conceptualized in Table 2.

This model encompasses both release mechanisms including diffusion and swelling. $K_1$ is the diffusion coefficient and $k_2$ is the coefficient of the swelling mechanism, each of which has a physical meaning. The current study results showed $k_2 < k_1$ , which indicated the greater influence of infiltration (penetration) than swelling in the process of drug release through the fiber prepared by the electrospinning technique as the temperature increased.

**Table 2.** Adjustment of the kinetic model to the experimental data

| Release controller | Kinetic Model | Equation | Constants | | Adjusted R^2 | RMSE |
|---|---|---|---|---|---|---|
| **EUD 50 ppm 25 °C** | korsmeyer-peppas | $K_{kp}t^n$ | | $K_{kp}$ = 0.107 | 0.9434 | 0.0462 |
| | peppas-sahlin | $k_1t^n+k_2t^{2n}$ | $k_1$ = 0.0684 | $k_2$=-0.002241 | 0.956 | $k_1$ = 0.0684 |
| | higuchi | $K_Ht^{0.5}$ | | $K_H$ = 0.06945 | 0.9189 | 0.0553 |
| **EUD 50 ppm 31 °C** | korsmeyer-peppas | $K_{kp}t^n$ | | $K_{kp}$= 0.134 | 0.8907 | 0.0806 |
| | peppas-sahlin | $k_1t^n+k_2t^{2n}$ | $k_1$= 0.07286 | $k_2$ = -0.00207 | 0.9064 | $k_1$= 0.07286 |
| | higuchi | $K_Ht^{0.5}$ | | $K_H$ = 0.08542 | 0.8745 | 0.864 |
| **EUD 50 ppm 37 °C** | korsmeyer-peppas | $K_{kp}t^n$ | | $K_{kp}$ = 0.14 | 0.9402 | 0.0659 |
| | peppas-sahlin | $k_1t^n+k_2t^{2n}$ | $k_1$= 0.09115 | $k_2$ = -0.00284 | 0.9448 | $k_1$= 0.09115 |
| | higuchi | $K_Ht^{0.5}$ | | $K_H$ = 0.09545 | 0.9254 | 0.0736 |
| **EUD 50 ppm 43 °C** | korsmeyer-peppas | $K_{kp}t^n$ | | $K_{kp}$= 0.2253 | 0.9514 | 0.0635 |
| | peppas-sahlin | $k_1t^n+k_2t^{2n}$ | $k_1$ = 0.1912 | $k_2$ = -0.01095 | 0.9448 | $k_1$ = 0.1912 |
| | higuchi | $K_Ht^{0.5}$ | | $K_H$ = 0.1109 | 0.8441 | 0.114 |
| **EUD 250 ppm** | korsmeyer-peppas | $K_{kp}t^n$ | | $K_{KP}$ = 0.0828 | 0.9274 | 0.0415 |

| | | | | | | |
|---|---|---|---|---|---|---|
| **25 °C** | peppas-sahlin | $k_1t^n+k_2t^{2n}$ | $k_1 = 0.05387$ | $k_2 = -0.00175$ | 0.9292 | $k_1 = 0.05387$ |
| | higuchi | $K_Ht^{0.5}$ | | $K_H = 0.05468$ | 0.9099 | 0.0462 |
| **EUD 250 ppm 31 °C** | korsmeyer-peppas | $K_{kp}t^n$ | | $K_{KP} = 0.1151$ | 0.9542 | 0.0391 |
| | peppas-sahlin | $k_1t^n+k_2t^{2n}$ | $k_1 = 0.1052$ | $k_2 = -0.00422$ | 0.9409 | $k_1 = 0.1052$ |
| | higuchi | $K_Ht^{0.5}$ | | $K_H = 0.06784$ | 0.9073 | 0.0556 |
| **EUD 250 ppm 37 °C** | korsmeyer-peppas | $K_{kp}t^n$ | | $K_{KP} = 0.1205$ | 0.9573 | 0.0468 |
| | peppas-sahlin | $k_1t^n+k_2t^{2n}$ | $k_1 = 0.1093$ | $k_2 = -0.00344$ | 0.9447 | $k_1 = 0.1093$ |
| | higuchi | $K_Ht^{0.5}$ | | $K_H = 0.08176$ | 0.9387 | 0.0561 |
| **EUD 250 ppm 43 °C** | korsmeyer-peppas | $K_{kp}t^n$ | | $K_{KP} = 0.2053$ | 0.9508 | 0.053 |
| | peppas-sahlin | $k_1t^n+k_2t^{2n}$ | $k_1 = 0.1743$ | $k_2 = 0.01119$ | 0.9449 | $k_1 = 0.1743$ |
| | higuchi | $K_Ht^{0.5}$ | | $K_H = 0.09343$ | 0.8069 | 0.105 |
| **EUD 500 ppm 25 °C** | korsmeyer-peppas | $K_{kp}t^n$ | | $K_{kp} = 0.0859$ | 0.9646 | 0.0191 |
| | peppas-sahlin | $k_1t^n+k_2t^{2n}$ | $k_1 = 0.05582$ | $k_2 = -0.00281$ | 0.9903 | $k_1 = 0.05582$ |
| | higuchi | $K_Ht^{0.5}$ | | $K_H = 0.0392$ | 0.8449 | 0.04 |
| **EUD 500 ppm 31 °C** | korsmeyer-peppas | $K_{kp}t^n$ | | $K_{KP} = 0.08325$ | 0.9437 | 0.0387 |
| | peppas-sahlin | $k_1t^n+k_2t^{2n}$ | $k_1 = 0.05974$ | $k_2 = -0.00196$ | 0.9395 | $k_1 = 0.05974$ |
| | higuchi | $K_Ht^{0.5}$ | | $K_H = 0.05773$ | 0.931 | 0.0428 |
| **EUD 500 ppm 37 °C** | korsmeyer-peppas | $K_{kp}t^n$ | | $K_{KP} = 0.09071$ | 0.9712 | 0.0334 |
| | peppas-sahlin | $k_1t^n+k_2t^{2n}$ | $k_1 = 0.07769$ | $k_2 = -0.00221$ | 0.9646 | $k_1 = 0.07769$ |
| | higuchi | $K_Ht^{0.5}$ | | $K_H = 0.06942$ | 0.965 | 0.0369 |
| **EUD 500 ppm 43 °C** | korsmeyer-peppas | $K_{kp}t^n$ | | $K_{KP} = 0.1247$ | 0.9755 | 0.0341 |
| | peppas-sahlin | $k_1t^n+k_2t^{2n}$ | $k_1 = 0.1246$ | $k_2 = -0.000213$ | 0.9674 | $k_1 = 0.1246$ |
| | higuchi | $K_Ht^{0.5}$ | | $K_H = 0.0802$ | 0.9437 | 0.0517 |

According to the accepted model, the kinetic constants of each nanofiber were extracted. Accordingly, kinetic constants were temperature-dependent, and according to the Arrhenius law $K=Ke^{-Ea/(RT)}$, the activation energy was extracted, and using the Arrhenius equation, the corresponding values of enthalpy and entropy changes were calculated. Then, using the equation $\Delta G^0=\Delta H^0-T\Delta S^0$, the Gibbs free energy was calculated. The results are presented in Table 3. The current study analyzed the drug release kinetics at various temperatures and employed the thermodynamic method for its

evaluation. Therefore, the amount of activation energy reflects the amount of drug released into the environment. By this way, the value of Ea was high, and drug transfer from the nanofiber contains controller to the dissolution medium required more energy Ea (EUD 500ppm)> Ea (EUD 250ppm)> Ea (EUD 50ppm). As Figure 3 shows, EUD can play a considerable role to control the release of the drug mebendazol to treat hydatid cyst by electrospinning technique. In other words, this process increased more concentrations of the controller Ea, and drug release process decreased [23].

**Table 3.** Activation energy and thermodynamic parameters of release drug from nanofiber containing 50, 250, 500 ppm of EUD

| System | Temperature (°C) | Gibbs Free Energy (ΔG) [kJ/mol] | Enthalpy ΔH [kJ/mol] | Entropy ΔS [kJ/mol.K] | Activation Energy Ea[kJ/mol] |
|---|---|---|---|---|---|
| **EUD 50 ppm** | 25 | 80.04927723 | 40.2954638 | -0.133334944 | 42.84703 |
| | 31 | 80.8492869 | | | |
| | 37 | 81.64929656 | | | |
| | 43 | 82.44930622 | | | |
| **EUD 250 ppm** | 25 | 80.02194533 | 44.0500662 | -0.120650274 | 46.60246 |
| | 31 | 80.74584698 | | | |
| | 37 | 81.46974862 | | | |
| | 43 | 82.19365026 | | | |
| **EUD 500 ppm** | 25 | 80.42699685 | 32.1269588 | -0.161999121 | 50.67853 |
| | 31 | 81.39899157 | | | |
| | 37 | 82.3709863 | | | |
| | 43 | 83.34298103 | | | |

However, between the EUD nano fibers, nanofiber at the concentration of 500 ppm showed higher Ea, which yielded a lower drug release. The Eyring equation was used to calculate other thermodynamic parameters. Here, the most important point was that the relationship between changes in thermodynamic parameters and drug release behavior were influenced by the concentration of the used polymer in nanofiber, as well as the environment temperature. Behavior changes in these components of nanofibers can affect the enthalpy. Furthermore, the calculated ΔH showed that the above nanofibers presented release processes of an end thermic nature (ΔH>0). According to the experimental results, drug release depends on heat. Additionally, the nanofibers entropy was negative (ΔS<0), which indicates an increase in system disorder during drug release, the equilibrium between the outside drug delivery and amount side is indicative of a reduction in disorder. Also, the thermodynamic of the reaction was associated with variation in the ΔG. This ΔG variation is the most important

thermodynamic parameter that reveals the process spontaneity when the parameter value is negative. But a positive free energy was found for all nanofibers in this case (ΔG>0) which indicates that the process is non-spontaneous.

## Conclusion

The current study aimed at investigating the thermodynamic constants and controlled-release of mebendazole drug through a nanofiber prepared by the electrospinning technique with temperature variations to destroy protoscoleces or echinococcus granulosus infection. The nanofibers were prepared by different controller concentration EUD® at 50, 250, and 500 ppm. Absorption test was conducted on each nanofiber at 25 °C, 31 °C, 37 °C, and 43 °C for 72 h. The results showed that the higher the polymer concentration used inside nanofiber, the harder the mebendazole drug release used inside the nanofiber. After plotting the mathematical model of the data, enthalpy, Gibbs free energy, activation energy, and entropy amount of drug release were determined. In other words, this approach was employed to determine the kinetics of drug release.

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## Conflicts of interest

The authors declare no conflict of interest.

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