

RESEARCH ARTICLE

UTILIZING POLYETHYLENE GLYCOL TO IMPROVE THE SOLUBILITY AND DISSOLUTION RATE OF CLARITHROMYCIN BY THE SOLID DISPERSION METHOD

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Abstract

Clarithromycin (CAL), a poorly water-soluble agent, is a novel broad-spectrum macrolide antibiotic utilised in various infections. The current study aimed to enhance its solubility and dissolution rate by formulating solid dispersions with different polyethylene glycols (PEG). These solid dispersions were synthesised via the solvent evaporation technique at varying drug-to-PEG 4000 and 6000 ratios. The dissolving investigation of the prepared solid dispersions revealed that the value of the greatest cumulative release of the solid dispersion formula clarithromycin-PEG4000 ratio (1:1) (CALPEG4000) (1.1) was 99.49%; nevertheless, the dissolution efficacy (DE) was rich at a significant level (88.4) with a ratio (1:9). The Fourier transform infrared spectroscopy (FTIR) spectra revealed that there was no interaction between the medication and PEG when physically combined, indicating that the formulation's components are highly compatible. Pure CAL has a melting point of 228. In contrast, when combined with polymers PEG4000 and 6000, the melting point drops to around 214 and 219, respectively, according to the differential scanning calorimetry (DSC) test. Finally, the use of hydrophilic carriers, such as PEG, dramatically improved the dissolution rate and solubility of CAL.

Keywords: Clarithromycin; PEG; Solid dispersion; Solubility; Dissolution rate; Kinetic.

1. Introduction

The most practical technique is to provide medications orally. Drug molecules must be adequately absorbed via the intestinal tract and enter the systemic circulation in order to reach their target. [1]. The majority of drugs being discovered exhibit poor aqueous solubility and are classified as BCS Class II drugs. The limited solubility of class II drugs leads to poor dissolution rate and lower bioavailability. One of the most promising methods to enhance the dissolution rate is the delivery of drugs in the form of amorphous solid dispersion by using efficient hydrophilic carriers. Carriers, including polyethylene glycol (PEG), poloxamer, different Eudragit grades, gelucire, and polyvinylpyrrolidone, have a propensity to form molecular complexes with a variety of drug substances owing to their strong hydrophilic nature [2].

Improving a drug's solubility may lead to increased bioavailability. Drug delivery methods that improve solubility allow for the testing and development of poorly soluble drug candidates, as well as the improvement of current medications' effectiveness by lowering dose, cost,

adverse effects, and/or variability. Clarithromycin (CAL) (Fig. 1) is a semi-synthetic macrolide antibiotic that suppresses bacterial protein synthesis by attaching to the bacterial 50s ribosomal subunit [3]. Clarithromycin is classified as a class II compound in the Biopharmaceutics Classification System (BCS), characterised by low solubility that leads to dissolution rate-limited absorption and diminished oral bioavailability. It undergoes extensive metabolism via CYP3A to form 14-hydroxyClarithromycin and N-desmethyl Clarithromycin, displaying nonlinear pharmacokinetics, as evidenced by decreased clearance with escalating doses [4 & 5]. CAL has a molecular weight of 747.95 Dalton, a pKa value of 8.99, a half-life of ~4 h, is soluble in acetonitrile, ethanol, and acetone, slightly soluble in methanol, and poorly soluble in water (0.33 mg/L) [6].

This study intends to improve the solubility and dissolution rate of CAL by solid dispersion utilising PEG. The analysis encompasses physicochemical characteristics, including Fourier transform infrared spectroscopy (FTIR), differential scanning calorimetry (DSC), dissolution profiles, and release kinetics models, based on the existing release mechanism of CAL from the formulation.

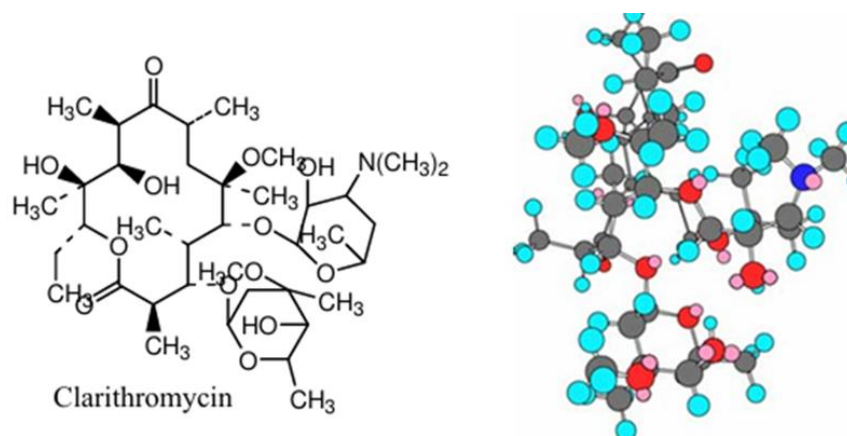


Fig. 1: Molecular formulae for clarithromycin [3]

2. Materials and Methods

2.1. Materials

CAL, PEG 4000, and PEG 6000 were purchased from Global Pharma, Sana'a, Yemen. Acetone, disodium hydrogen phosphate, and potassium dihydrogen orthophosphate were purchased from Merck, USA. Analytical-grade chemical reagents were all utilized.

2.2. Formulation of Clarithromycin Solid Dispersion

The solvent evaporation approach was used to achieve drug-polymer ratios of 1:1, 1:3, 1:5, 1:7, and 1:9. A total of 50 mg of the drug was dissolved in 5 mL of acetone, after which the polymer was added and dissolved at 50 °C with continuous mixing on a hot plate to produce a clear solution. The solvent was then allowed to evaporate. The resulting solid dispersions were collected, sieved, and stored in desiccators.[7] [8].

2.3. Analysis of clarithromycin

CAL was analysed at 210nm using a UV spectrophotometer. The standard curve for the determination of the drug was constructed by dissolving it in acetone (stock1) and phosphate buffer pH = 6.8 in a concentration range of 0.5 to 9 µg/mL. In this concentration range, good linearity was observed ($R^2 = 0.9997$). The graph obeyed Beer-Lambert's law in the selected concentration range.

2.4. Characterization of clarithromycin preparations.

Two approaches were used to characterise raw and mixed CAL - PEG. This study employed (FTIR), (DSC), drug content determination, dissolution experiments, dissolution efficacy (DE), kinetic investigations, and stability studies.

2.5. Fourier transform infrared spectroscopy (FTIR)

A Perkin-Elmer spectrophotometer was used to capture (FTIR) data between 400 and 4000 cm^{-1} . The backdrop for the sample readings was potassium bromide (KBr). 3 mg of each sample was spread out and mixed with a KBr matrix, and DRIFTS was used to quantify the infrared spectrum in a reflectance cell. The vertical axis shows the transmittance (percent), while the horizontal axis shows the wavenumber (cm^{-1}) [9].

2.6. Differential Scanning Calorimetry (DSC).

The DSC thermograms in this study were recorded with a DSC instrument. Samples (3-5 mg) were weighed and sealed using aluminium crimped cells with pierced lids. Each sample was heated from 25°C to 250°C at a thermal rate of 10°C per minute and a nitrogen gas purge rate of 35 mL/min. The temperatures at the start of each thermal episode were documented. In this study, the heat flow direction of an endothermic event was recorded down the y-axis, while an exothermic event was recorded up the y-axis.

2.7. Dissolution studies

In vitro release investigations of solid dispersions were conducted in a USP Apparatus 2 at 50 rpm in 900 mL of phosphate buffer (pH = 6.0) maintained at 37.0 ± 0.5 °C (USP 2007). The dissolution studies utilised 50 mg of pure drug, along with an equivalent volume of each sample formulation. Aliquots of 10 mL were withdrawn and replenished with matching amounts of fresh medium at designated time intervals between 5 and 240 minutes. The resulting samples were filtered via Whatman filter paper and spectrophotometrically measured at 210 nm to determine the amount of dissolved medication. [9].

The cumulative released drug is the sum of the drug present in the release medium and the portion eliminated. The following formula was used (t_n = time point at n hours, C_{dr} concentration of drug, while RE_{dr} is the

elimination of drug in each sample, and V = volume of released medium) [10]:

$$RE_{dr}(t_n) = C_{dr}(t_n) \times 10ml$$

$$\text{Cumulative released drug } (t_n) = C_{dr}(t_n) \times V + RE_{dr}(t_{n-1}) + \dots + RE_{dr}(t_{0.5})$$

$$\text{Cumulative release\% } t_n = \frac{\text{Cumulative release drage } (t_n)}{C_{total \text{ drug}}} \times 100$$

DE was used to compare dissolution data. Where "y" is the percentage of drugs dissolved at time "t".

$$DE = \left[\frac{\int_0^t y \cdot dt}{y^{100}} \right] \cdot 100$$

2.8. Kinetic studies

The dissolution profiles of all samples were evaluated using Baker-Lonsdale and Korsmeyer-Peppas models to determine drug release kinetics.

2.8.1. Baker-Lonsdale model

Baker and Lonsdale (1974) developed a model based on the Higuchi model to define the release of medicines from spherical matrices using the following equation:

$$f_1 = \frac{3}{2} \left[1 - \left(1 - \frac{M_t}{M_\infty} \right)^{2/3} \right] \frac{M_t}{M_\infty} = k_t$$

The proportion of medication released at time t is calculated as M_t/M_∞ , which can be simplified to Q . This model predicts that if pharmaceuticals are released from spherical matrices by a diffusion process, the $3/2 [1 - (1 - Q)^{2/3}] - Q$ versus time plot for a drug housed in a spherical matrix will show a straight line. The release constant K is defined by the slope of the plot $3/2 [1 - (1 - Q)^{2/3}] - Q$ with respect to time. [11].

2.8.2. Korsmeyer-Peppas model

Korsmeyer et al. (1983) discovered a straightforward relationship that explained drug release from a polymer system equation.

To determine the mechanism of drug release, the Korsmeyer-Peppas model was used to the first 60% of drug release data.

$$M_t/M_\infty = kt^n, \text{ where } M_t/M_\infty$$

represents the amount of medication released at time t , k is the release rate constant, and n is the release exponent. The n value is used to distinguish various releases for matrices with a cylindrical shape. [12].

3. Results and discussion:

3.1. Fourier transform infrared spectroscopy FTIR

Pure CAL's FTIR spectrum (Figure 2) shows peaks at 1690 cm^{-1} and 1734 cm^{-1} , which correspond to the stretching vibrations of lactone and ketone carbonyl groups.

N-C bonds in amine groups stretch and vibrate, resulting in an absorption band at 1457 cm^{-1} . Peaks in the range of 2780 cm^{-1} to 3000 cm^{-1} are associated with the stretching vibration modes of alkane groups' C-C bonds. Intermolecular hydrogen interactions between hydroxyl groups are responsible for the absorption band at 3461 cm^{-1} , a rather strong peak. Stretching vibration modes were found at $1000\text{-}1200 \text{ cm}^{-1}$ for the -C-O group and $1340\text{-}1400 \text{ cm}^{-1}$ for the CH₂ group. [13]. The drug-polymer compatibility FTIR spectra are recorded. Clarithromycin was determined to be compatible with the chosen PEG utilized in the formulations since no additional peaks or color changes were seen.[14] [15].

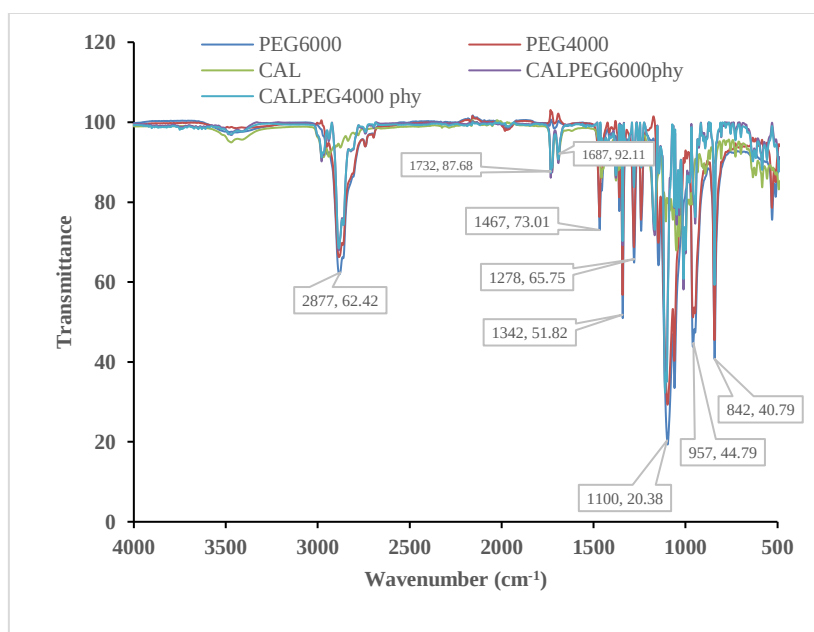


Fig. 2: Infrared spectra of the PEG4000, PEG6000, CAL, CALPEG4000phy and CALPEG6000phy.

3.2. Differential Scanning Calorimetry (DSC)

DSC is commonly used to measure heat released or absorbed; thus, this approach was applied to analyse the interaction between the drug and the polymer, as shown in Fig. 3, which illustrates the drug and PEG. According to published research, the DSC thermogram of pure CAL showed an endothermic peak at 228.5 °C, indicating the drug's melting point. This prominent peak indicated that pure CAL existed in a crystalline state [2].

Melting and high temperatures are impacted by the different molecular weights of PEGs. This framework states that molecular weight plays a significant role in increasing the melting temperature because it increases the heat of melting in tandem with molecular weight [16]. The analysis of untreated PEG 6000 and PEG 4000 shows that the endotherm begins at the CALPEG4000phy and CALPEG6000phy peaks, which shift from the CAL free base melting point (228.5 °C) to lower temperatures as a result of the physical mixture, most likely representing the melting of CALPEG4000 and CALPEG6000, respectively. The drop in the melting peaks of CAL at 214.06 °C and 219 °C, respectively, is most likely due to the formation of a new form of the drug during the solid dispersion process in the presence of PEG4000 and PEG6000. transpire at 69.3°C and 49.2°C, respectively.

In contrast, PEG4000 peaked at 64.2, while PEG6000 saw a slight decrease to 68.3. The reduction or absence of the drug's endothermic peak, which indicates the amorphous nature of the materials produced, can generally be connected to the drug's lack of crystallinity in the sample or its solubility in the polymer [17]. No distinct endothermic peak was observed at 214 and 226° in the formulas CALPEG6000 and CALPEG4000, suggesting a substantial reduction in the crystallinity of

CLA in the polymer; hence, it can be inferred that the drug exists in the amorphous state inside the formulation and is likely uniformly distributed throughout the polymer matrix [18].

3.3. In vitro dissolution:

Using different PEG ratios (1:1, 1:3, 1:5, 1:7, and 1:9), the in vitro release of CAL from formulations was investigated. The effects of PEG 4000 and 6000 on drug release characteristics are depicted in Figures 4 and 5. The drug release of the CALPEG4000 samples was greater than 70% in 90 minutes, except for CALPEG4000 1:7, which was 50%. After 4 hours, all samples reached approximately 90%. In contrast, the drug release of the CALPEG6000 formulations exceeded 70% for CALPEG6000 (1:1), whereas the other ratios were below 70%. Three CALPEG6000 samples (1:1, 1:3, and 1:7) achieve over 90% of CAL release. The amount of medication released in each sample showed a consistent upward trend as the molecular weight of PEG decreased. As a result, the CALPEG4000 samples exhibited more release than the CALPEG6000 samples. As previously mentioned, samples having low molecular weight PEG can expand well and release more drug content because they are more hydrophilic than samples containing high molecular weight PEG [19].

The influence of polymers on drug release profiles is characterized by Mean Dissolution Time (MDT) and (DE) in 4h for the formulation CALPEG6000 (1:5) exhibited an MDT of 41.22 minutes and a DE4h of 88.68%, whereas CALPEG4000 (1:9) demonstrated an MDT of 38.84 minutes and a DE4h of 88.84%. indicating an inverse relationship between release rate and MDT. The MDT value reached a maximum of 94 minutes for the CALPEG4000 (1:7) formulation and 75.19 minutes for CALPEG6000 (1:3), Table 1.

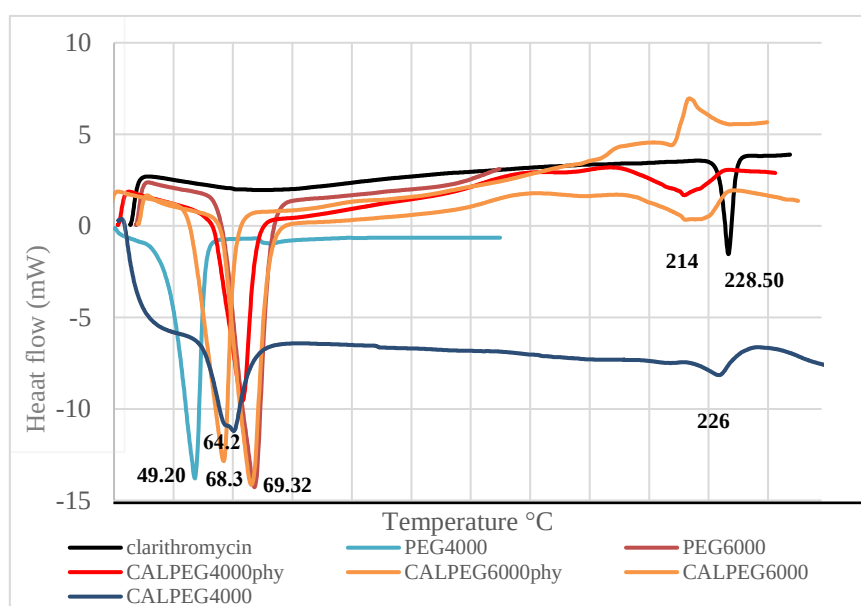


Fig. 3: represented the DSC for CAL, PEG 4000, PEG 6000, CALPEG4000, and CALPEG6000

Table 1: Dissolution efficiency and mean dissolution time of CALPEG4000 and 6000.

Formulation	CALPEG4000					CALPEG6000				
Ratio	1:1	1:3	1:5	1:7	1:9	1:1	1:3	1:5	1:7	1:9
DE	81.64	84.40	80.59	72.22	88.40	83.82	78.14	88.68	79.87	87.14
MDT	61.30	53.53	65.67	94.56	38.84	55.05	75.19	41.22	69.21	50.94

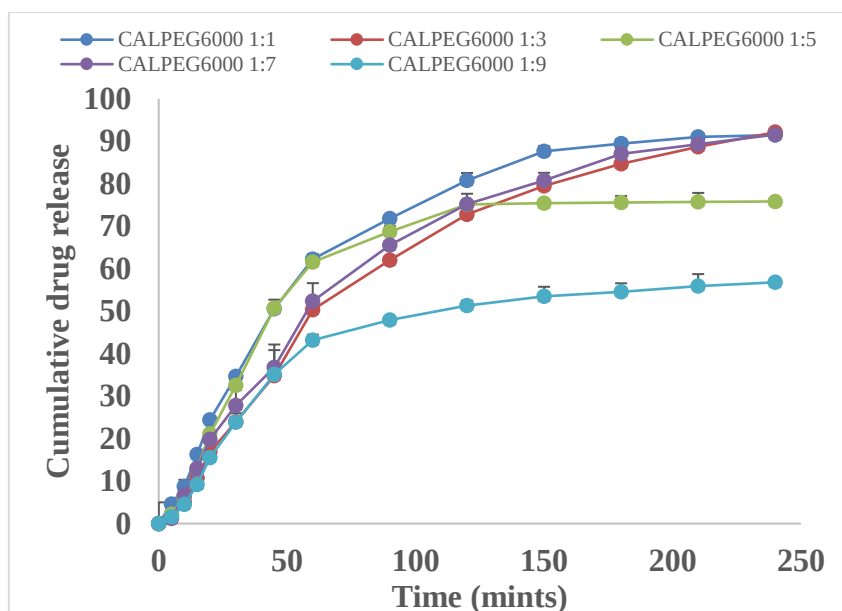


Fig. 4: Dissolution profiles of the clarithromycin-loaded PEG 4000 of 1:1, 1:3, 1:5, 1:7, 1:9 drug-to-polymer ratios. Data represent the mean value of 3 replications $\pm$ SD (n=3).

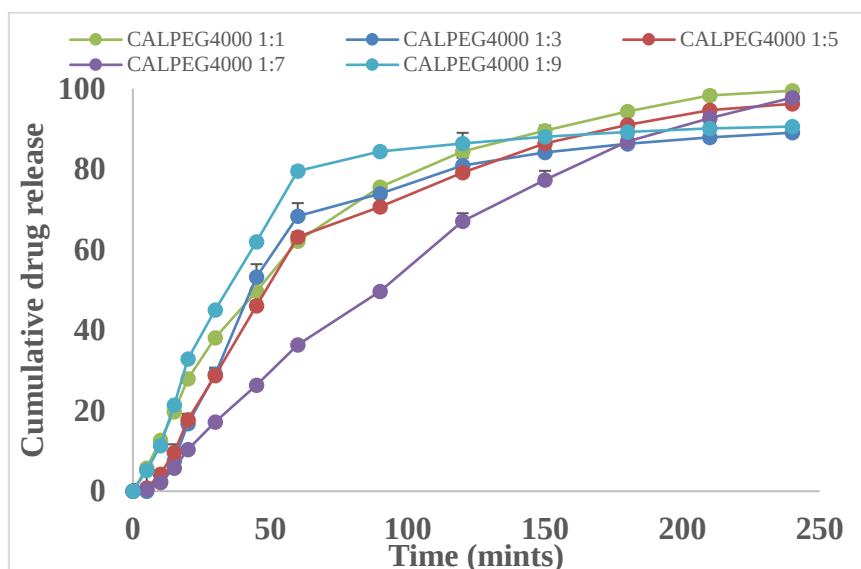


Fig. 5: Dissolution profiles of the clarithromycin-loaded PEG 6000 of 1:1, 1:3, 1:5, 1:7, 1:9 drug-to-polymer ratios. Data represent the mean value of 3 replications $\pm$ SD (n=3).

Table 2: represents the factors of the Korsmeyer-Peppas mathematical release model.

Drug -PEG	CALPEG4000					CALPEG6000				
Ratio	1:1	1:3	1:5	1:7	1:9	1:1	1:3	1:5	1:7	1:9
n	0.95	2.7	1.7	1.5	1.1	1.08	1.19	1.37	1.43	0.85
K	0.01	2.04	0.07	0.06	0.08	0.08	0.03	0.02	0.09	0.08
R ²	0.99	0.94	0.98	0.97	0.99	0.99	0.98	0.99	0.96	0.93

Table 3: represents the results of the Baker-Lonsdale drug-release model.

Drug -PEG	CALPEG4000					CALPEG6000				
Ratio	1:1	1:3	1:5	1:7	1:9	1:1	1:3	1:5	1:7	1:9
Baker-Lansdale equation										
a	0.02	0.001	0.02	0.04	0.02	0.004	0.02	0.012	0.004	0.02
b	0.002	0.001	0.001	0.001	0.001	0.001	0.001	0.0007	0.0003	0.001
R ²	0.998	0.96	0.997	0.97	0.92	0.98	0.997	0.91	0.95	0.997
t ^(1/2)	27.1	43.0	32.6	33.6	41	38	40	69	157	32.6

3.4. Kinetics Studies

Tables 2 and 3 present the results of the kinetic models used to assess dissolution data. Korsmeyer-Peppas mathematical release model was employed in this study to show the precise mechanisms of drug release from the proposed dispersion formulation. The values of (n) can be used to calculate various release mechanisms. For cylindrical tablets, if $n \leq 0.45$, the medication will be released via Fickian diffusion (Case I transport). Anomaly or non-Fickian release (diffusion and polymer relaxation), Case II transport (polymer degradation and zero-order kinetics), and Super Case II transport (polymer erosion) are denoted by n values of " < 0.89 ," " $= 0.89$," and " > 0.89 ," respectively[20] [21]. The result shows a Super Case II transport mechanism (n value > 0.89); thus, the polymer is relaxing by erosion (Table 3). This expression refers to stresses and state transitions in hydrophilic polymers that expand in biological fluids or water. Polymer dissociation and erosion are also present.

The kinetic study showed that most of the formulations followed the Baker-Lonsdale drug-release model, where the R² values are between 0.95 and 0.997. The Baker-Lonsdale model was based on the Higuchi model. The Higuchi model is based on three theories. First, the initial drug concentration in the polymer is much higher than the drug's solubility. Second, because the drug particles are much smaller than the system's thickness, they are contained inside the created particles and do not have any drug on the surface. Third, drug diffusivity remains unchanged. The release is made possible by the pores in the matrix. This concept supports the porous system because hydrophilic polymers easily dissolve and release through the pores[22] [23].

Conclusion

The study's objective was to increase the rate of dissolution of the class II CAL by the solid dispersion method with a hydrophilic carrier (PEG). The study's findings demonstrated that the drug's physicochemical characteristics were improved by the synthesis of CLAPEG. It was shown that the solubility of CLA particles in formulation may be effectively influenced by the kind of polymers and their ratio. The time for solubility and drug release from the formulations was considerably reduced for four hours when different molecular weights of PEG were applied with raw CAL. According to the in vitro dissolving study, CALPEG4000 1:1 released the highest percentage of clarithromycin—nearly 99% in about 4 hours—with a DE of almost 81%. Since CLA is a weakly soluble medication, the solid dispersion approach may be a useful strategy for improving its solubility.

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مقالة بحثية

استخدام البولي إيثيلين جلايكول لتحسين ذوبانية ومعدل انحلال الكلاريثروميسين باستخدام طريقة التشتت الصلب

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المُلخَص

يُعد كلاريثروميسين (CAL) -وهو عقار ضعيف الذوبان في الماء- مضاداً حيوياً جديداً واسع الطيف من فئة الماكروليدات يُستخدم لعلاج حالات عدوى متنوعة. هدفت الدراسة الحالية إلى تحسين ذوبانية العقار ومعدل انحلاله من خلال تحضير تشتتات صلبة باستخدام أنواع مختلفة من البولي إيثيلين جليكول (PEG). وقد تم تحضير هذه التشتتات الصلبة باستخدام تقنية تبخير المذيب بنسب متفاوتة بين العقار وكل من PEG 4000 و PEG 6000. وأظهرت دراسة الانحلال أن أعلى قيمة للتحرر التراكمي سُجلت لصيغة التشتت الصلب المكونة من كلاريثروميسين و PEG 4000 بنسبة (1:1) حيث بلغت 99.49%؛ ومع ذلك، لوحظت كفاءة انحلال (DE) عالية ومهمة (بمعدل 88.4) عند استخدام نسبة (1:9). وكشفت أطياف مطيافية الأشعة تحت الحمراء بتحويل فورية (FTIR) عدم وجود أي تفاعل كيميائي بين الدواء و PEG عند المزج الفيزيائي، مما يشير إلى توافق عالٍ بين مكونات الصيغة. تبلغ درجة انصهار عقار CAL النقي 228 درجة مئوية، في حين تنخفض هذه الدرجة إلى حوالي 214 و 219 درجة مئوية عند دمجها مع بوليمرات PEG 4000 و PEG 6000 على التوالي، وذلك وفقاً لاختبار قياس السرعات الحرارية بالمسح التفاضلي (DSC). وأخيراً، أدى استخدام حوامل محبة للماء (مثل PEG) إلى تحسين ملحوظ في معدل الانحلال وذوبانية عقار CAL.

الكلمات المفتاحية: كلاريثروميسين؛ بولي إيثيلين جلايكول؛ التشتت الصلب؛ الذوبانية؛ معدل الذوبان؛ الحركية.

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