Journal of the Faculty of Medicine Baghdad
Print ISSN: 0041-9419-Online ISSN: 2410-8057
DOI: https://doi.org/10.32007/jfacmedbagdad.6622240

Open Access Research Article

Preparation and Characterization of Dutasteride Nanoparticles as Oral Fast-Dissolving Film

Rusul W. Kadhum[1] Shaimaa N. Abd-Alhameed [2]*

[1] Department of Pharmaceutics, College of Pharmacy, University of Babylon, Babylon, Iraq.
[2]Department of Pharmaceutics, College of Pharmacy, University of Baghdad, Baghdad, Iraq.

Received: Oct., 2023
Revised: Jan. 2024
Accepted: Feb. 2024
Published: Jul. 2024

Abstract

Background: Dutasteride, is a drug whose mechanism of action is inhibition of the enzyme 5-alpha reductase. It has been approved for use in the treatment of benign prostatic hyperplasia. Dutasteride has low solubility and high permeability, which classifies it as Biopharmaceutics classification system class II, according to the Biopharmaceutics Classification System. It has a water solubility of only 0.038 ng/mL and a slow dissolving rate, resulting in its exclusive availability in the market as a formulation contained within soft gelatin capsules.

Objective: The aim of this study involves two parts. First, is the enhancement of dutasteride dissolution rate, by the creation of dutasteride nanosuspension, and second is the enhancement of patient compliance by the transformation of this nanosuspension to oral fast-dissolving film, which is characterized by its fast disintegration, stability, and ease of administration.

Methods: The solvent anti/solvent precipitation method was used to formulate dutasteride nanosuspension. In addition, dutasteride nanoparticles oral fast dissolving films were prepared by using the solvent casting method.

To compare the in vitro release patterns of pure dutasteride film and selected dutasteride nanoparticles film, the statistical analysis for the dissolution investigation was conducted using the model-independent technique (employing similarity factor f2) utilizing a DD solver. The selected dutasteride nanoparticle film was supposed to be the test material, while the pure dutasteride film was supposed to serve as the reference.

Results: dutasteride nanosuspension demonstrated a high enhancement of the dissolution rate. In addition, the prepared dutasteride nanoparticles oral fast-dissolving film exhibited a further increase in the rate of dissolution and fast disintegration, and the administration is easy, all of these properties making it a promising dosage form.

Conclusion: Nanosuspension is an excellent approach for enhancing the solubility, dissolution rate, and effectiveness of drugs with limited aqueous solubility such as dutasteride. In addition, the oral fast-dissolving film can be considered a promising dosage form that will increase patient compliance due to its high dissolution rate, fast disintegration, and easy administration.

Keywords: Benign prostatic hyperplasia; Dutasteride; Oral films; Polymers; Solvent casting; Solvent antisolvent precipitation.

Introduction

5-α-Dihydrotestosterone (DHT) plays a major role in the development of benign prostatic hyperplasia (BPH) (1). It is formed by the action of the 5-alpha reductase (5AR) enzyme (2,3). Dutasteride is a drug that functions by inhibiting the enzymatic activity of 5-alpha reductase (5AR). The utilization of this treatment has received official approval for its application in the management of benign prostatic hyperplasia (BPH). Dutasteride is classified as BCS class II according to the Biopharmaceutics Classification System due to its low solubility and high permeability. As a result, it is exclusively available in the market in the form of soft gelatin capsules (4).

* *Corresponding author's:* mailto:shaimaanazar721@gmail.com

Particle size reduction is one approach that is used for the enhancement of drug solubility and dissolution rate (5,6).

Because solubility plays a pivotal role in drug effectiveness (7), its enhancement by using the nanosuspension approach will provide a solution for the formulation problems that are related to drug solubility (8). Multiple studies have been conducted to document the creation of nanosuspensions, which have been found to result in increased dissolution rates and enhanced bioavailability (9,10). The improved dissolution properties of dutasteride can be attributed to the augmentation of the surface area available for dissolution (11). The procedure for generating nanosuspensions is uncomplicated and applicable to all pharmaceuticals that demonstrate limited solubility in water (12).

The oral route of drug administration is widely regarded as a highly effective strategy for drug delivery. It offers several benefits, including enhanced convenience, cost-effectiveness, and ease of delivery, significantly improving patient adherence. A majority of medication forms are ingested through the oral cavity, however, after being consumed, the drugs can be broken down by enzymes and undergo a substantial reduction in effectiveness due to the first-pass effect, which occurs as they pass through the liver (13). Additionally, many pediatric and geriatric patients display hesitance in consuming solid oral preparations due to their concerns about choking (14). Recently, there has been a significant increase in both popularity and favorability of fast-dissolving drug delivery systems (15). This approach shows great potential for tackling the issue of non-compliance due to their quick disintegration and enabling self-administration without the use of water or the need for chewing (15). Two suggested forms of dosage that rapidly disintegrate in the mouth are the orally disintegrating tablet (ODT) and the orally disintegrating film (ODF). The orally fast disintegrating film, which is a thin film created using hydrophilic polymers, is formulated to disintegrate when it comes into contact with a moist surface, such as the tongue, within a few seconds. The quick disintegration can be attributed to its large surface area (16). The primary drawback of the oral fast-dissolving film is its limited ability to hold a significant amount of the drug and its restricted options for effectively masking the taste (17). The study aim is to prepare dutasteride nanosuspension and transform it into thin film formulations that provide both stability and convenient administration (18). Thin films can additionally enhance drug solubility (15).

Materials and Method

Preparation of dutasteride nanosuspension: Dutasteride nanosuspension was carried out through the solvent anti-solvent precipitation method (19). This approach included the establishment of two discrete stages. Initially, the organic phase was formed by dissolving 0.5 mg of dutasteride in 1 ml of methanol. In contrast, the formation of the aqueous phase involved the dissolution of 0.5% w/v of the stabilizer soluplus in a 10 ml solution of deionized water. The organic part was gradually introduced into the aqueous phase using a syringe, and carefully monitored at a 1 ml/min rate. The resultant mixture was subsequently subjected to mechanical agitation at a speed of 1500 revolutions per minute (rpm) and held at 37°C for duration of 30 minutes to facilitate the volatilization of the solvent.

Dutasteride nanosuspension preparation as oral fast-dissolving film: The method of solvent casting was employed to create fast-dissolving films (20), employing Polyvinyl alcohol (PVA), Hydroxypropyl methylcellulose E5 (HPMC E5), Polyvinyl pyrrolidone k30 (PVP K30), and a combination of both PVA and HPMC E5 as film-forming polymers. Each film has a surface area of 6 cm^2, which contains Dutasteride nanosuspension equivalent to 0.5 mg dutasteride, utilizing Petri dishes with a diameter of 6 cm and a surface area of 28 cm^2.

A petri dish capable of holding four films. The requisite quantity of polymers for one petri dish was dissolved in 10 ml of deionized water, this mixture was heated to 60 °C while being continuously stirred on a magnetic stirrer (1000 rpm) for 1 hour, until the polymer was fully dissolved. The mixture was then allowed to cool, and a plasticizer (glycerin) was introduced. Mannitol, serving as a cooling and sweetening agent, Vanilla serving as a flavoring agent; and cross povidone, acting as an efficient super disintegrant, were dissolved in 3 ml of deionized water. The resulting solution was subsequently combined with the polymeric solution under continuous stirring for a duration of 1 hour, resulting in the formation of a clear solution. Meanwhile, four dutasteride nanosuspension formulas were prepared with a total volume of 10 ml. These formulations were subsequently introduced into the polymer solution and were thoroughly mixed for 3 hours, ensuring uniform distribution of the drug particles inside the polymer matrix and resulting in a more homogeneous and consistent formulation. This ensures that the medicine is evenly distributed, avoiding difficulties such as dosage variability within the final oral film. The mixture was left undisturbed for a minimum of 24 hours to allow the removal of trapped air before being poured into the petri dish. The resulting homogeneous mixture was then spread onto a 6 cm^2 Petri dish, ensuring the absence of air bubbles, and subjected to drying in an oven set at 40 ºC for 24 hours. Once dried, the film was carefully detached from the Petri dish employing a sharp blade and cut into films of suitable shapes and sizes, followed by packaging in aluminum foil. These films were stored in a dry environment (21). This information is presented in the provided Table (1)

Table (1): Composition of various formulations of dutasteride oral films

Ingredient	F1	F2	F3	F4	F5	F6	F7	F8	F9
Dutasteride nanosuspension	50.5	50.5	50.5	50.5	50.5	50.5	50.5	50.5	0.5
PVA (mg)	66		33		50	100	50	100	33
PVP K 30 (mg)				66					
HPMC (mg)		66	33		50		50		33
Glycerin (mg)	20	20	20	20	30	15	30	30	20
Cross povidone (mg)	7.5	7.5	7.5	7.5	10	16	10	10	7.5
Mannitol (mg)	6	6	6	6	5	12	9.5	9.5	6
Vanilla (mg)					4	6			

**Weight of film 150 mg*

**Weight of film 200 mg*

**The oral film contains pure dutasteride*

Dutasteride nanosuspension evaluation: The nanosuspension that was generated was subjected to evaluation in terms of its particle size, drug content, and entrapment efficiency (EE%). In addition, the dissolution characteristics of dutasteride nanosuspension and pure dutasteride powder were

evaluated in an in vitro study using a phosphate buffer (pH 6.8) containing 1% sodium dodecyl sulfate (SDS). A comparative analysis was conducted to evaluate the degree of similarity, as measured by the similarity factor (f2), between the release profiles of a nanosuspension formulation of dutasteride and dutasteride's pure powder, which was employed as a reference.

Measurement of drug content in dutasteride nanosuspension formula: A volumetric flask was utilized to hold 1 ml of nanosuspension formula, which was then diluted with 9 ml of methanol. The resulting mixture underwent sonication for a duration of 1 hour. The collected sample was subjected to analysis via a UV-visible spectrometer, specifically at the wavelength (λ max) where the drug in methanol displayed its highest absorbance, which was measured at 240 nm. The percentage of drug content was determined by applying a designated equation (1).

Drug content % = (detected drug content /Theoretical drug content) * 100 %…. Eq. (1) [22].

Determination of Entrapment Efficiency: The entrapment efficiency refers to the proportion of a drug or substance that is successfully incorporated within the nanoparticles. It's usually expressed as a percentage and indicates how effectively the nanoparticles entrap and hold the active ingredient. Entrapment efficiency (EE%) of the prepared dutasteride nanosuspension formula was evaluated using an Amicon ultra-4 centrifugal filter with Mwt 10 KD. A total of 4 ml of dutasteride nanosuspension was placed in the Amicon tube and centrifuged at 4000 rpm for 30 minutes. Subsequently, the concentration of concentrated dutasteride particles was assessed using UV spectrophotometry at a wavelength of 240 nm. EE% was then measured using the following equation: EE% = obtained dutasteride amount / theoretical dutasteride amount * 100 %…. Eq. (2) [23].

Evaluation of dutasteride oral fast-dissolving film

Visual appearance: The visual features of the film, including its level of transparency or semi-transparency, were evaluated using a straightforward visual inspection (24).

In vitro disintegration study: The film was placed in a small petri dish, containing 10 milliliters of deionized water. The petri dish underwent constant shaking until the film underwent complete disintegration. The period starting from the initiation of the disintegration process until the disintegration of the film is completed, is documented as the disintegration time (25, 26).

Film's thickness: The film's thickness was measured at different positions using an electronic vernier caliper. The assessment in this study aims to evaluate the uniformity of thickness across different films, as it directly impacts the accuracy of dosage administration within the film (27).

Drug content of the film: The films were solubilized in 100 ml of phosphate buffer solution with a pH value of 6.8, supplemented with 1% sodium dodecyl sulfate (SDS). Subsequently, the mixture was agitated for a duration of 30 minutes utilizing a magnetic stirrer. Subsequently, samples were obtained from the resulting solution and subjected to filtration using a syringe filter with a pore size of 0.1 µm. The absorbance of each sample was measured using a UV spectrophotometer at a wavelength of 244 nm. The quantity was determined using an equation that was derived from the calibration curve of the drug in a buffer solution with a pH of 6.8, which also contained 1% SDS (28, 29).

Weight of films: The weight variation investigations consisted of individually weighing eight films for each formula, followed by the calculation of the average weight (30,31).

Surface pH measurement: The measurement of the pH of the surface was performed by dissolving the film in 2 ml of deionized water at ambient temperature. The surface pH value was determined by placing the pH meter electrode touching the dissolved film and allowing it to remain stable for a duration of 1 minute (32).

Folding Endurance measurement: The measurement of Folding Endurance involved the manual folding of the film at a consistent location until it underwent rupture. The folding endurance value is ascertained by quantifying the number of times the film can be folded until it reaches the point of fracture (33).

In vitro dissolution study of the oral fast-dissolving films: The evaluation of the film's release was conducted utilizing the USP dissolution test apparatus type II. The film was immersed in a dissolution medium comprising 200 ml of a 6.8 buffer solution containing 1% SDS. The paddle was subjected to a rotational speed of 50 revolutions per minute at a temperature of 37°C (34). Samples were extracted at time intervals (1, 2, 3, 4, 5, 6, 7, 8, 9, 10, and 15 minutes) in 5 ml volumes. To maintain sink condition, the withdrawn sample was immediately replaced with 5 ml of fresh dissolution medium. Subsequently, the withdrawn sample was filtered using a 0.1 syringe filter. The measurement of absorbance for each sample was conducted utilizing a UV-visible spectrophotometer at a wavelength of 244 nm (35).

Compatibility study: The assessment of the compatibility between the dutasteride nanoparticles (NPs) and the excipients included in the formulation of the film was conducted using Fourier Transform Infrared (FTIR) analysis. To validate the absence of any interactions and ascertain the presence of characteristic peaks of the drug, a comparative analysis was conducted between the spectra of dutasteride nanoparticles (NPs) and the chosen film formulation (36).

Results

Assessment of dutasteride nanosuspensions:

The Malvern Zeta Sizer was employed to examine a sample of dutasteride nanosuspension. The analysis yielded a particle size measurement of 73.24 nm and a polydispersity index (PDI) value of 0.184. The examination of the drug content and entrapment efficiency (EE%) of the formulation of dutasteride

nanosuspension yielded a drug content of 99.58% ± 0.0121, accompanied by an EE% of 99% ± 1.41. Additionally, it was observed that the dutasteride nanosuspension exhibited complete release within a 15-minute timeframe, whereas the release of pure dutasteride powder was only 30% after duration of 1 hour.

The calculated similarity factor value is 12.37, indicating that it falls below 50. This observation indicates a notable discrepancy in the dissolution properties between the dutasteride nanosuspension that was prepared and the pure dutasteride powder (37). , as depicted in Figure (1)

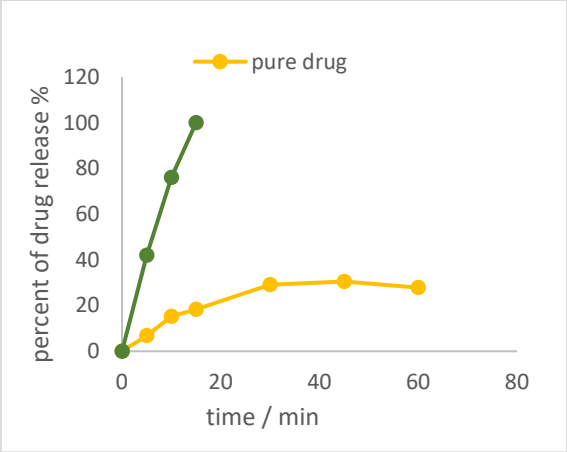

Figure (1): In vitro release of the pure dutasteride and dutasteride nanosuspension formula in 6.8 buffer with 1% SDS

General evaluation parameter of dutasteride films:

Visual appearance: The dutasteride nanoparticle films were subjected to a range of evaluations as a means of drug administration. the F1, F2, F3, and *F9 films exhibited a uniform and transparent appearance, with a smooth and consistent texture on their surfaces. However, the F5, F6, F7, and F8 films showed inconsistencies in homogeneity and clarity. Additionally, the F4 film displayed strong adhesiveness, making it impossible to separate from the Petri dish.

As depicted in Figure (2).

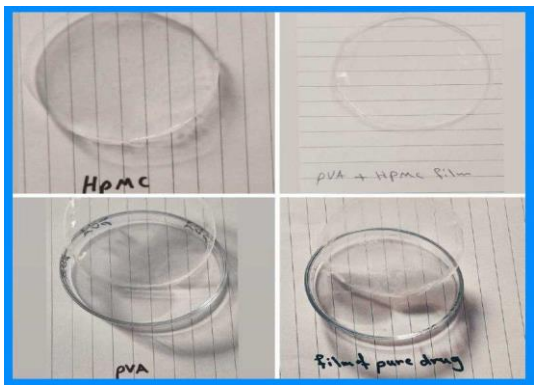

Figure (2): Film formulas containing HPMC E5 (F2), PVA(F1), a combination of HPMC E5 and PVA (F3), and film of pure dutasteride (*F9)

In vitro disintegration study: Analysis of in vitro disintegration revealed the following film disintegration times: 29 ± 1 second for (F1), 30 ±1.2 seconds for (F2), 28 ± 1.7 seconds for (F3), and 53 ± 1.4 seconds for a pure drug film (*F9), whereas the disintegration time of other films exceeded 30 seconds. They were consequently eliminated from the other examination.

Thickness of films: Within each formulation, the thickness of the films was consistent between 0.13 and 0.18 mm. All of the films fall within the acceptable thickness limit (less than 0.3 mm) for oral films (38). Extremely low standard deviation (SD) values illustrate the reproducibility of the method and the uniformity of film thickness (39).

Drug content: The drug content of the film formulation was determined to be 97.2% ± 0.0007, 95% ± 0.12, 98.6% ± 0.001195, and 96.5% ± 0.011 for PVA-based film (F1), HPMC E5-based film (F2), the combination of PVA and HPMC E5-based film (F3), and ordinary film (*F9), respectively. According to the results, all formulations adhered to the British Pharmacopoeia criteria for drug content (85-115%) (40). These results indicate that the drug nanoparticles have a uniform distribution throughout the film and that the film production method is effective, resulting in a homogeneous film with a high drug content (41,42).

Weight of films: The recorded weights of the prepared films were found to be 148.3 ± 5.7, 147.3 ± 15.5, and 149 ± 4.2 for films F1, F2, and F3, respectively. The findings indicate that the mean weight of the films aligns with the weight of the initial formulation.

Surface PH measurement: The pH values of the films ranged from 6.5 to 6.8. The pH range of these films aligns with that of the oral mucosa, and none of the films cause any mouth irritation, making them appropriate for utilization (43).

Folding Endurance measurement: As indicated in Table 2, all of the films exhibit a folding capacity that exceeds 300.

Table (2): Physicochemical characteristics of the selected dutasteride oral films after preparation

F. Code	Weight of film (mg)	Film thickness (mm)	Folding endurance	Drug content	surface pH	In vitro DT (sec)
F1	148.3 ± 5.7	0.147 ± 0.0194	> 300	97.2% ± 0.0007	6.5± 0.07	29 ± 1
F2	147.3 ± 15.5	0.150 ± 0.014	> 300	95% ± 0.12	6.8 ± 0.05	30 ± 1.2
F3	149 ± 4.2	0.143 ± 0.0171	> 300	98.6%± 0.0011	6.6 ± 0.02	28 ± 1.7

In vitro dissolution study of the films: The assessment of the dissolution of dutasteride nanoparticle film formulations and the pure dutasteride film was conducted using the USP dissolution test apparatus type II. The dissolution medium employed in the experiment consisted of 200 milliliters of phosphate buffer solution with a pH value of 6.8, supplemented

with 1% sodium dodecyl sulfate (SDS). According to the data presented in Figure (3), it can be observed that the film composed of PVA and HPMC E5 (referred to as F3) exhibited a complete release of its contents in an in vitro setting within 2 minutes. On the other hand, the film composed solely of PVA (F1) achieved complete release after duration of 5 minutes. The film containing HPMC E5 (F2) exhibited a release rate of 73% after 15 minutes, whereas the pure dutasteride film (*F9) demonstrated a release rate of only 28% during the same time frame. The study involved a comparison of the release patterns of films containing F1, F2, and F3, as well as a pure dutasteride film (*F9) that served as a reference.

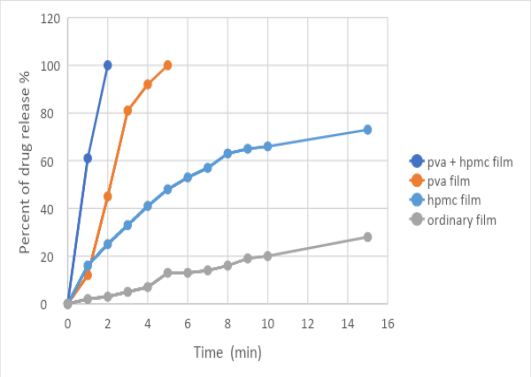

Figure (3): In vitro dissolution of the pure dutasteride oral film and dutasteride NPs films in phosphate buffer pH 6.8 containing 1% SDS

The similarity factor f2 was utilized for this purpose. According to the data provided in Table 3, the obtained similarity factor value was determined to be below 50.

Table (3): Similarity factor $f_2$values for the dissolution profiles of the oral films containing dutasteride nanoparticles as compared to the oral film containing dutasteride in pure form

Formula name	f_2
F1	8.79
F2	22.03
F3	6.53

Based on the aforementioned findings, encompassing disintegration time, drug content, and release profile, the formulation denoted as F3, which incorporates both PVA and HPMC E5 polymers, was chosen as the favored option, as depicted in Table (4).

Table (4): The characteristics of optimized dutasteride nanoparticle oral film.

Parameter	F3
Weight	149± 4.2
Drug content	98.6%± 0.0011
drug release %	100%
In vitro disintegration time	28 ± 1.7
pH of surface	6.6 ± 0.02
Thickness	0.143 ± 0.017
Folding endurance	>300

The comparative analysis of the in vitro dissolution performance of the optimal dutasteride nanoparticles oral film (F3) was conducted to evaluate the impact of the film component on drug release, as depicted in Figure (4). This assessment involved comparing the results with those obtained from the prepared dutasteride nanosuspension formula.

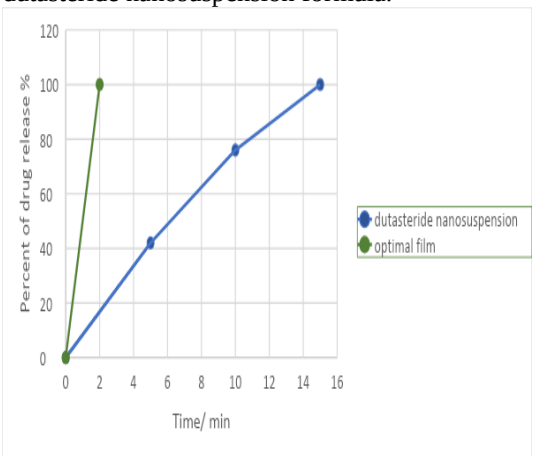

Figure (4): In vitro dissolution of dutasteride nanosuspension formula and optimal film (F3) in phosphate buffer pH 6.8 with 1% SDS

Compatibility study: There was no observed interaction between dutasteride nanoparticles (NPs) and the selected excipients for the film formulation, as evidenced by Figures (5) and (6). The Fourier Transform Infrared (FTIR) spectrum of the optimized film formulation (F3), depicted in Figure (7), exhibits prominent peaks corresponding to the drug (44).

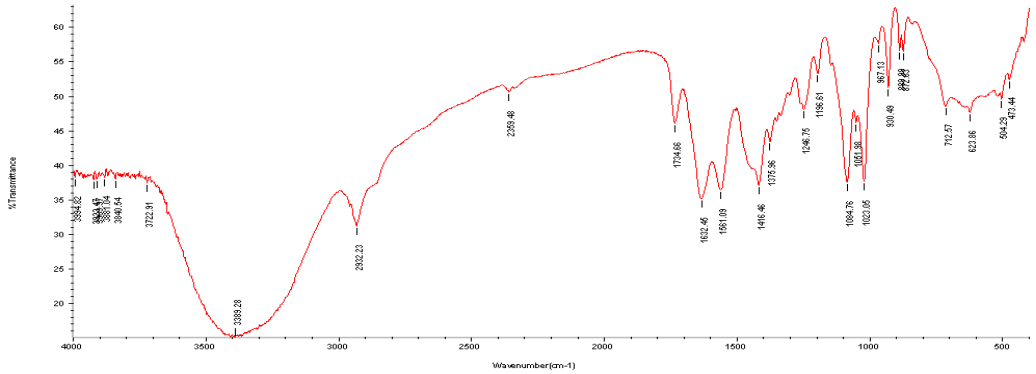

Figure (5): FTIR spectrum of dutasteride nanoparticles

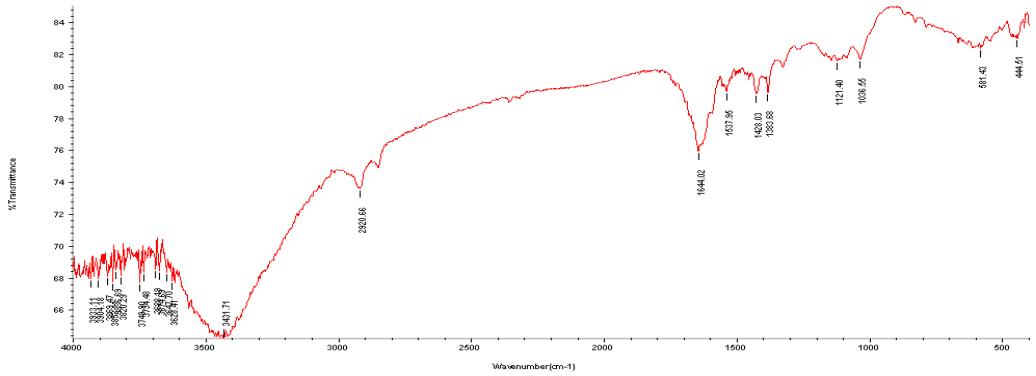

Figure (6): FTIR spectrum of the selected film formulation (F3)

Discussion

The impact of the concentrations of polymers on the films' appearance: The experimental findings indicate that the F5, F6, F7, and F8 films exhibited a lack of homogeneity and clarity. Moreover, it was observed that as the polymer concentration increased, the thickness of the films also increased, leading to a decrease in transparency (45).

The impact of polymer concentration on the disintegration time of the films: The longer than 30-second disintegration time of F5, F6, F7, and F8 films can be explained by the fact that a greater polymer concentration results in the formation of a thicker gel upon contact with the medium (46).

The impact of a plasticizer on the folding endurance of the films: All of the manufactured films have folding endurance values greater than 300, which is indicative of success (46). By decreasing the glass transition temperature, glycerin acts as a plasticizer. The film's flexibility is increased by the decrease in its glass transition temperature, which in turn increases its folding endurance (47).

The impact of polymer type on the release of dutasteride np from the resulting films: Films made with hydroxypropyl methylcellulose (HPMC) and polyvinyl alcohol (PVA)(F3), showed the desired degree of flexibility and ease of peeling, as found by Bhikshapathi et al. A large amount of water can be absorbed by these polymer systems, causing them to gel. Drug molecules are released from the film via diffusion after the film expands in response to the penetration of a dissolution medium or biological fluid (48,49). As shown in F1, a higher concentration of the hydrophilic polymer PVA causes a more rapid and extensive swelling process, which contributes to the film's quicker release (50). HPMC's retardant properties cause HPMC-based film (F2) to have a slow-release profile. Its high viscosity causes a thicker, swollen gel layer to form, which in turn increases the time it takes for drug molecules to diffuse out of the gel (51,52).

The effectiveness of the dutasteride nanosuspension formulation in terms of in vitro dissolution was compared to that of the chosen dutasteride np oral fast-dissolving film (F3). Figure 4 shows that the dissolution properties are significantly different. Thin films have the potential to further enhance drug solubility, as has been demonstrated (53).

Conclusion

The present study has successfully showcased the ability to produce a dependable, swiftly disintegrating film composed of dutasteride nanoparticles through the utilization of a solvent-casting technique and the incorporation of diverse polymers. This approach aims to improve patient compliance, drug dissolution, and the extent to which the drug is absorbed and available for use in the body. Shorter disintegration and faster dissolution times were observed in formulations utilizing the combination of polyvinyl alcohol (PVA) and hydroxypropyl methylcellulose E5 (HPMC E5) as the film-forming polymer (F3). The drug delivery system described herein exhibits substantial potential for various patient populations, with a particular emphasis on individuals encountering challenges related to swallowing, such as geriatric patients. Therefore, it can be deduced that dutasteride oral fast-dissolving films (OFDFs), with their exceptional patient compliance and numerous advantages, present innovative and promising opportunities for the future.

Abbreviations	Meaning
BPH	Benign Prostatic Hyperplasia
BCS	Biopharmaceutical Classification System
ODF	Oral disintegrating film
OFDF	Oral fast-dissolving film
EE%	Entrapment Efficiency
PDI	Polydispersity index
FTIR	Fourier transform infrared spectroscopy
SD	Standard deviation
DT	Disintegration time
NPS	Nanoparticles
UV	Ultraviolet
USP	United states pharmacopeia
pH	Is a numeric scale that is used to determine the acidity or basicity of an aqueous solution.
f_2	Similarity factor
cm	Centimeter
cm^2	Square centimeter
ml	Milliliter
nm	Nanometer
mg	Milligram
Min.	Minute
rpm	Revolution per minute
PVA	Polyvinyl alcohol
PVP k30	Polyvinyl pyrrolidone k30
HPMC E5	Hydroxypropyl methylcellulose E5
SDS	Sodium dodecyl sulfate

Acknowledgment
I want to express my sincere appreciation to the College of Pharmacy at the University of Baghdad for their invaluable support in facilitating this research effort.

Ethics Statements
In vitro study, no ethical statements are required.

Conflicts of Interest: None
Funding: None

Author Contribution
The authors confirm their contribution to the paper as follows: data collection, analysis and interpretation of results, and draft manuscript preparation: Rusul Wahhab Kadhum. Shaimaa N Abd-Alhammid reviewed the results and approved the final version of the manuscript.

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How to cite this Article:

Kadhum RW, Abd-Alhammid SN. Preparation and Characterization of Dutasteride Nanoparticles as Oral Fast-Dissolving Film. J Fac Med Baghdad [Internet]. 2024 Jul. 1 [Available from: https://iqjmc.uobaghdad.edu.iq/index.php/19JFacMedBaghdad36/article/view/2240

تحضير وتوصيف جسيمات الدوتاستيرايد النانوية كأفلام ذات ذوبان سريع عن طريق الفم

رسل وهاب كاظم[1]، شيماء نزار عبد الحميد[2]
[1]فرع الصيدلانيات، كلية الصيدلة، جامعة بابل، بابل، العراق.
[2]فرع الصيدلانيات، كلية الصيدلة، جامعة بغداد، بغداد، العراق.

الخلاصة
الخلفية :دوتاستيرايد هو مثبط لانزيم 5-الفا ريداكتيز. تمت الموافقة عليه لعلاج تضخم البروستات الحميد. تم وذلك لقلة ذوبانتيته في الماء. يتوفر الدوتاستيرايد في السوق فقط على شكلBCSتصنيفه كفئة ثانية من نظام
كبسولات جيلاتينية ناعمة .
الهدف: هدفنا من هذه الدراسة هو لغرضين الأول زيادة معدل الذوبان للدوتاستيرايد عن طريق تحضير معلق نانوي من الدوتاستيرايد، الثاني هو زيادة التزام المريض بالعلاج وذلك من خلال تحويل المعلق النانوي الى أفلام فموية تتميز بانها سريعة الذوبان، سريعة التفتت، وسهلة الاستخدام.
الطرق :استخدمت تقنية ترسيب المذيب والمضاد للمذيب في تخضير المعلق النانوي للدوتاستيرايد. بالنسبة لإنتاج الأفلام الفموية ذات الذوبان السريع، فقد تم استخدام طريقة صب المذيب .
النتائج :المعلق النانوي للدوتاستيرايد الذي تم الحصول عليه أدى إلى زيادة معدل الذوبان. إضافة الى ذلك،
الفلم الفموي سريع الذوبان الذي يحتوي على جزيئات الدوتاستيرايد النانوية أظهر زيادة اكثرفي سرعة الذوبان والتفتت وأيضا سهولة الاستخدام، كل هذه الصفات جعلته شكل دوائي واعد.
الاستنتاج: المعلق النانوي هو وسيلة ممتازة لتحسين ذوبانية، سرعة الذوبان وفعالية الدواء الذي يمتلك ذوبانيه محدودة في الماء مثل الدوتاستيرايد، بالإضافة الى ذلك فان الأفلام الفموية سريعة الذوبان يمكن اعتبارها كشكل دوائي واعد الذي سيحسن من التزام المريض بالعلاج بسبب تحسينه للذوبانية، لسرعة الذوبان وسهولة استخدامه .
الكلمات المفتاحية: تضخم البروستات الحميد، دوتاستيرايد، أفلام سريعة الذوبان، بوليمرات، صب المذيب، ترسيب المذيب والمضاد للمذيب.