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Original Article

Design and characterization of Zaltoprofen film forming spray

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ABSTRACT

Zaltoprofen is one among the NSAIDs used to treat osteoarthritis and rheumatoid arthritis, as well as to reduce pain and inflammation. The present study aims to prepare Zaltoprofen film forming spray for localized analgesia and to improve patient compliance. Six formulations were prepared using different types of polymers Eudragit L100, Eudragit RLP0, and polyvinylpyrrolid (PVP) polymers, with Propylene glycol (PG) or PEG 400 serving as plastisizers. Some physicochemical properties of the resulting sprays were evaluated, including appearance, viscosity, pH, drying time, spraying angle and volume in addition to the in vitro drug release. The evaluation results revealed that formulation (F2), composed of Eudragit L100 and PG, was the most effective, demonstrating a good viscosity of 169.5 mPas and superior film-forming properties and 88.14% drug release up to 6 hours. Conversely, PVP-based formula lacked durability and PEG 400 led to drug precipitation and discoloration. With precise spray angles ranging from 16.5° to 19.3°, the Eudragit L100/PG system proved to be a superior, mechanically stable vehicle for the topical delivery of Zaltoprofen. It can be concluded that the film forming solution of Zaltoprofen mixed with polymer Eudragit L100 and plastisizer PG seems to be a good choice for the treatment of pain and inflammation.

Keywords: Zaltoprofen, Film forming spray, Eudragit L100, Anti-inflammatory effect

Introduction

The topical methods of drug delivery are targeted toward local effects, which have certain advantages such avoiding first pass metabolism, the effects of low pH and enzymes in the gastrointestinal system and the availability of a wide surface area [1]. Drugs delivered by the topical route are sometimes formulated as a dosage system such as a patch, gel, lotion, cream, ointment or spray to maximize the therapeutic efficacy or pharmacokinetics. But the danger is that patch preparations are utilized leaving drug leftovers that can be deliberately abused. Hypersensitivity, irritation and blistering are also typically related with patch preparations. Problems in the scale-up of production are also typically seen where medications are difficult to stable and can crystallize during storage [2, 3].

Other semi-solid preparations are also easily stuck to clothing during movement and can promote cross infection of wounds as it is administered with the fingers. Sprays have various advantages over other topical dose forms including ease of use, low incidence of irritation, sterility of the dosage, great coverage of the skin or wound, equal distribution of the medicine when applied and customizable dosage [4, 5].

Many advances have been made in the production of effective and efficient spray preparations during the last decades. One of them is a film forming spray (FFS), which is utilized in many industries such as agriculture, food, cosmetics and pharmaceuticals. FFS is composed of polymers, enhancers and active substances dissolved in organic solvents. Compared with other standard topical preparations, it may generate a thin, non-sticky film,

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which can increase the contact time and permeability of the drug, so as to achieve continuous drug release, and can avoid crystallization, so that more drug can be released to achieve therapeutic effect [6-9].

Film-forming sprays are considered as an emerging strategy for topical delivery of NSAIDs, providing localized therapeutic effects while reducing systemic side effects. FFS build a thin layer on the skin without irritation, improving medication residence time, penetration and prolonged release. This method reduces gastrointestinal irritation, improves patient compliance with simple, non-greasy application and lessens the danger of contamination compared to conventional semisolids making FFS a potential technique for NSAID delivery [10-12].

The spray ability of FFS depends to a large extent on kind of nozzle, size of aperture, pressure of spray applied and content of liquid. The viscoelastic, in situ gel, pH and thermal-sensitive properties of FFS should be investigated [13-15] so that one can know what to consider in the selection of polymers, solvents and other excipients.

Zaltoprofen functions as a COX-2 inhibitor, preferentially obstructing the synthesis of prostaglandin E2 (PGE2) in areas of inflammation. Zaltoprofen is offered in the form of a crystalline powder that ranges from light yellow to white. It readily dissolves in acetone, is soluble in ethanol (99.5) and methanol, and is virtually insoluble in water. Zaltoprofen is categorized as BCS Class-II having low solubility and high permeability [16, 17]. Therefore, this present work aimed to develop a film-forming spray containing Zaltoprofen by investigating the suitable polymers as well as assessing key quality parameters to ensure optimal performance and therefore to improve patient compliance.

Materials and Methods

Materials

Zaltoprofen was acquired from Hyperchemical China, while Eudragit RLP0, Eudragit L100, and Polyvinylpyrrolid were sourced from Smara Drug Industry in Iraq. Propylene Glycol (PG) and Polyethylene Glycol 400 (PEG 400) served as plastisizing agents and supplied from college of pharmacy/ university of Baghdad. Acetone and Ethanol were obtained from BDH chemical Ltd. Pool England and were employed as the volatile solvent system.

Method of preparation

Six different formulations of film-forming solutions were prepared, as shown in **Table 1**. For each formulation, the solution was prepared by dissolving an accurately weighed quantity (0.1 g) of Zaltoprofen in a solvent mixture of Acetone (8 ml) and Ethanol (2 ml). The beaker was sealed with aluminum foil to prevent solvent evaporation and the mixture was stirring using a magnetic stirrer until the drug was completely dissolved and a clear solution was obtained. Subsequently, the designated polymer (Eudragit RLP0, Eudragit L100, or PVP, according to the formulation) was added to the solution. The system was re-sealed and stirred for 15 min at 100 rpm. Then PG or PEG-400 was added to the solution and stirred for another 15 min [18-20]. The solution was then moved into a refillable container with a plastic dip tube with an internal diameter of 2 mm.

Table 1. Formulation Composition of Zaltoprofen Film Forming Spray

Formula Code	Zaltoprofen %w/v	Eudragit RLP0 %w/v	Eudragit L100 %w/v	PVP %W/V	PG %V/V	PEG400 %V/V	Aceton+Ethanol up to (ml)
F1	1	10	-	-	3	-	10
F2	1	-	10	-	3	-	10
F3	1	-	-	10	3	-	10
F4	1	-	10	-	1	-	10
F5	1	-	10	-	-	3	10
F6	1	-	10	-	-	1	10

Evaluation

Physical appearance

The formulations were visually examined for macroscopic properties, including clarity, color, and homogeneity. This assessment aimed to detect any signs of turbidly, precipitation, or color changing [21].

pH determination

The pH of each batch was tested at room temperature (25 ±2°C) utilizing a digital pH meter that has been calibrated using common buffer solutions to guaranty skin compatibility and to minimize discomfort. All readings were carried out in duplicate after stabilization [21-23].

Film formation time

Film formation time is a significant factor for patient compliance. The drying time was determined by spraying a fixed volume of the formulation on a glass slide. A digital stop watch was used to determine the time for solvent evaporation and the formation of dry non sticky film [24, 25].

Viscosity measurement

The viscosity was measured using a rotational viscometer (spindle 1 at 30 rpm) as it is a major factor on sprayability and coverage area. [24] The test aims for a good compromise between film formation and sprayability of polymer concentration.

Spray angle

The spray angle and pattern were tested by spraying the formulation on paper at a fixed distance (l=15 cm). The radius (r) of the generated circular pattern to determine the spray angle (θ) using the following equation:

$$\theta = tan^{-1}(r/l) \quad (1)$$

The droplet distribution and coverage area were determined by looking at the spray pattern. A wider spray angle will provide a greater surface coverage which is important for uniform medication distribution [26].

Delivered volume per actuation

The volume of the formulation supplied with each actuation (Al) was calculated by weighing the spray container before (W0) and after (Wt) a single discharge. Using the density of the solution (Dn), the delivered volume was calculated according to the following equation:

$$Al = (W_0 - W_t) / Dn \quad (2)$$

This test ensures dose uniformity and consistent drug delivery upon each application [24].

Drug release

In-vitro drug release studies of Zaltoprofen film forming technology were carried out utilizing Franz diffusion cell. The cell was compartmented into a donor and a receiver compartment separated by the diffusion membrane. It was immersed in phosphate buffer pH 7.4 for 24 h. The receptor cell served as the medium for diffusion and the donor cell was exposed to the environment. Diffusion was performed in phosphate buffer pH 7.4. Diffusion experiments were constantly stirred at 50 rpm in 10 mL phosphate buffer (pH 7.4) at 37 °C. The donor compartment was filled with the film forming formulation and 0.5ml of medicine. 1 ml sample was taken hourly and was analyzed using UV spectrophotometer. After each sampling, the receptor chamber was refilled with the same volume of phosphate buffer [27-30].

Statistical analysis

The results are presented as the mean of standard deviation (SD) of triplicate models, and the significance of the observed changes was determined using one-way analysis of variance (ANOVA) at the 0.05 level of significance.

Results and Discussion

The preparation of a Zaltoprofen film-forming spray represented a significant advancement in overcoming the limitations associated with conventional topical and oral delivery systems. The limit of alcohol and acetone in topical solutions is higher than 83% and 12%, respectively, according to the US Food and Drug Administration's (US FDA) inactive ingredient guide. In order to promote quicker film development (less than 8 minutes) on skin, acetone and alcohol were used in the vehicle blend [26]. All used film former and Zaltoprofen were dissolved in vehicle blend of alcohol and acetone.

Effect of polymer type on film properties

Eudragit L100 was selected to be the optimal polymer for the Zaltoprofen spray, forming a water-insoluble, transparent, elastic, and adhesive film. Eudragit-based copolymers, these materials are essential for smart healthcare due to their pH-dependent nature, which supported targeted high drug release and improved absorption [31]. While Eudragit RLP0 is scientifically recognized for increasing bioavailability and providing sustained release for over 6 hours, it was excluded from final testing due to a technical human error during storage. Regarding the PVP formulation, although Sahane and Gaikwad [32] described film-forming systems as a promising transdermal drug delivery system, PVP failed to produce a proper peelable film in this study. Instead, it formed a very thin, tacky layer that lacked the mechanical integrity and matrix strength required for a functional film. This layer was easily removed, unlike the durable film formed by the Eudragit L100 polymer.

Effect of plastisizer type on film properties

Note that both formulations F5 and F6 using PEG 400 as a plastisizer were not able to maintain the physical integrity. They revealed a substantial flocculent precipitate and intense color shifts. This observation is in agreement with the work of Galgatte *et al*. [33] scientifically. It is known that PG has lower polarity and less hydrophilicity than PEG 400 which facilitates better interaction with the polymeric chains. The relationship is intensified, the film more flexible, but not destabilized. The non-clearance of the PEG 400 formulations may signal a possible incompatibility with the Zaltoprofen-polymer after few days of storage.

Physicochemical properties of zaltoprofen film

The results obtained from the evaluation of the formulations comprising appearance, F1,F5 and F6 exhibited an unacceptable appearance;therefore they are discarded, pH which was in the range of 2.4 – 4.3, showing somewhat acidic pH, nevertheless, did not cause any skin irritation are presented in **Table 2**.

The formulation is based on evaporation mechanism using a volatile solvent system (Acetone: Ethanol). The successful

formulations were applied to the liquid and resulted in quick volatilization of the solvents within one to three minutes, which converted the liquid to a cohesive, non-tacky film. This mechanism forms a "drug reservoir" on the skin which increases the residence time and penetration [21].

Spray angle (θ) is one of the most important characteristics for uniform drug administration and to prevent over-spraying. As per the findings of Gohil *et al*. [34], a good spray angle should be less than 85° to provide accurate application. All investigated formulations (F1, F2 and F3) attained angles from 16.5° to 19.3°. These narrow angles provide limited and regulated deposition of Zaltoprofen on the target area which is important for localized analgesic and anti-inflammatory effects. Additionally, it was found that there was no notable variation in the quantity emitted with each actuation, demonstrating the spray system's efficacy in providing a consistent amount of the formulation every actuation.

Viscosity is another critical factor as it determines both atomization quality and spray retention on the skin. All formulations exhibited a slightly low viscosity, a property that describes as ideal for Eudragit-based systems to ensure a fine mist during pumping that stabilizes quickly upon contact.

Formulation F2 (L100 + 3% PG) and F4 (L100+1% PG) identified as the optimal system, with the viscosity of (169.5 mPas and 174.4 mPas, respectively) providing the perfect balance between ease of spraying and skin adhesion. In contrary, the PVP formulation (F3) showed a much lower viscosity of 82.4 mPas, making the liquid too thin and "runny" to form a stable, protective film.

In vitro drug release

The dissolution profile was done for Zaltoprofen film forming spray formulas (F2, F3, and F4) because they provide the optimum parameters. The order of drug release was found: F3>F2>F4 as shown in **Figure 1**. From the *in vitro* release data, it can be concluded that F2 that contain Eudragit L100 polymer and 3% PG plastisizer and gave the best release in comparison with other formulas because Eudragit L100 is the most commonly used pH-dependent polymers, Eudragit L dissolve above pH 6 with the formation of polymeric salts [35].

Table 2. Physicochemical Properties of Zaltoprofen Film Forming Spray

Formula Code	Apperance	pH	Drying Time (min.)	Spray angle	Volume of spraying(ml)	Viscosity (mPas)
F1	Initially clear, developed turbidity after 2 weeks.	3.6 ±0.3	1:42±0.070	16.5^0 ±0.075	0.1±0.001	195.6±0.82
F2	Clear	2.9±0.2	3:06±0.072	16.7^0 ±0.074	0.18±0.12	169.5±0.82
F3	Slightly turbid	4.3±0.6	2:11±0.071	17.6^0 ±0.077	0.16±0.13	82.4± 0.4
F4	Clear	2.4±0.3	2:30±0.073	19.3^0 ±0.077	0.19±0.001	174.4±0.52
F5	Initially clear, developed heavy flocculent yellowish-white precipitates after 2weeks	3.8±0.4	-	-	-	-
F6	Color changed from pale yellow to orange-amber with turbidity after 2weeks.	3.2±0.2	-	-	-	-

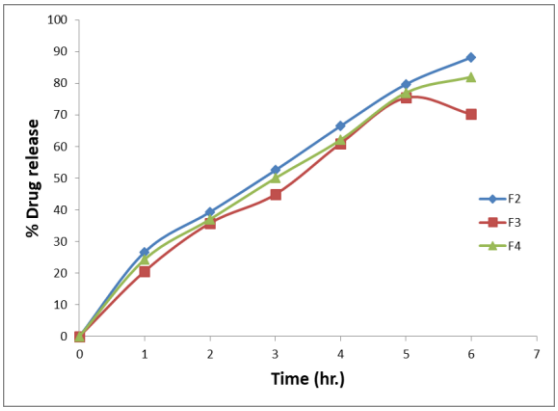

Figure 1. *In vitro* release of Zaltoprofen film forming spray.

Conclusion

A polymeric solution that forms films of Zaltoprofen was prepared and evaluated in order to select the best formula. Among all formulation F2 (Eudragit L100 with PG) was identified as the optimized formulation . It maintained its clarity, proper viscosity and a practical film-forming time, as well as providing an efficient spray pattern for localized Zaltoprofen delivery and better drug release up to 6 hr. The film forming solution developed was successful in improving patient's compliance. Thus this novel dosage form will improve bioavailability and can be alternative to the conventional topical treatment.

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Ethics statement: The Research Ethics Committee of the University of Baghdad College of Pharmacy formally approved the study

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