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A BRIEF REVIEW ON FORMULATION AND EVALUATION OF IBUPROFEN GEL BY USING CHICLE GUM

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ABSTRACT

Prolonged oral administration of ibuprofen are used for in the treat of chronic disorders such as arthritis, including the adverse effect of peptic ulcer disease. To minimize these systemic complications, topical gel formulations of ibuprofen have been designed as an the another route of drug administration. An immediate-release ibuprofen formulation is particularly useful for transdermal systems intended for the long term management of chronic inflammatory conditions. In the current investigation, the formulated ibuprofen topical gel demonstrated a drug release study when compared with a commercially available marketed preparation.

Keywords: Ibuprofen, Gel, Chicle Gum.

1. INTRODUCTION

Non-steroidal anti-inflammatory drugs (NSAIDs) are widely prescribed for the treatment of pain and inflammation associated with various acute and chronic disorders. Among them, ibuprofen is the most frequently used agents in the management of inflammatory conditions, particularly acute and chronic arthritis. However, long term oral route administration of NSAIDs is well known to be associated with stomach complications, that's including gastric irritation and peptic ulcer disease, especially during prolonged therapy [1–3].

To reduce these adverse gastrointestinal effects, development of non-oral dosage forms of ibuprofen. Like Topical formulation drug delivery systems offer the advantage of localized drug action with reduced systemic exposure, thereby minimizing gastric toxicity while maintaining therapeutic effectiveness at the site of application. Previous research studies have demonstrated that topical ibuprofen formulations, such as 5% ibuprofen gel, can provide comparable clinical efficacy to oral ibuprofen tablets are used for the treatment of soft tissue injuries, while avoiding the stomach side effects that is commonly associated with orally administered non-selective cyclo-oxygenase inhibitors [4].

A prolonged release ibuprofen formulation with increased skin permeability may be particularly useful when incorporated into the transdermal delivery systems for the long-term management of chronic inflammatory conditions. Such systems are capable of maintaining relatively constant drug concentrations at the site of application over extended periods, thereby improving patient compliance and therapeutic outcomes.

Ibuprofen is classified as a Biopharmaceutics Classification System (BCS) class II drug, characterized by low aqueous solubility and high membrane permeability. In addition of poor solubility of ibuprofen in the aq. Phase like water, ibuprofen also show limited intrinsic permeability for the skin barrier [5]. Consequently, organic solvents such as propylene glycol are commonly employed in topical formulations to solubilize the API and simultaneously enhance dermal penetration. An alternative approach involves the use of guar gum that is natural polymers.

Guar gum is a galactomannan polysaccharide is obtained from the seeds of *Cyamopsis tetragonoloba*. That is an non-ionic, free-flowing, pale off-white powder capable of forming hydrocolloidal dispersions in aqueous media. In pharmaceutical applications, guar gum is frequently used as a binding agent and disintegrating agent in the tablet formulations. One of its major advantages over propylene glycol is its exceptionally high water-thickening ability, which is approximately 8-9 times more than that of corn starch. As a result, that's only very small quantities are required to achieve the desired viscosity in gel formulations [6,7].

In vitro study of drug release play a major role in formulation development and quality control of pharmaceutical products. These studies are very useful for evaluating batch-to-batch consistency and formulation stability, but also as rapid and cost-effective tools for predicting in vivo drug release and absorption behavior [8–10]. The current study was therefore undertaken to develop a prolonged-release ibuprofen gel using a natural polymer and to compare its in vitro release characteristics with those of a marketed ibuprofen gel, with the aim of identifying a formulation with superior drug release performance.

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2. EXPERIMENTAL

Materials

Ibuprofen powder and guar gum were generously supplied by Regal Pharmaceuticals Ltd. (Nairobi, Kenya). Propylene glycol BP and glycerol GPR (98% v/v) were procured from Sigma-Aldrich Chemie GmbH (Steinheim, Germany). The equipment used in the study included a hot water bath (Baird and Tatlock Ltd., London, UK), a top-loading balance (Sartorius AG, Goettingen, Germany), a thermometer (Brannan & Sons Ltd., Cumbria, England), an analytical balance (Shimadzu AUW ZZO D, Shimadzu Corporation, Tokyo, Japan), and a shaking water bath (GFL 1083, Gesellschaft für Labortechnik GmbH, Burgwedel, Germany). Dissolution studies parameter were performed by using an ERWEKA DT 700 dissolution machine (Erweka GmbH, Heusenstamm, Germany). UV-visible absorbance measurements analysis were obtained by using a T90+ UV/VIS spectrophotometer (Shimadzu Corporation, Tokyo, Japan). The pH of the gels was measured using a digital pH meter (WTW Microprocessor 537, WTW GmbH, Weilheim, Germany).

Preparation of gels

Approximately 3 g of ibuprofen was dissolved in 7 ml of propylene glycol by gently heating the mixture to 65 °C until a clear solution was obtained. Gel bases containing varying concentrations of guar gum was prepared by heating the guar gum of required quantity at 65 °C and dispersing it in 15-20 ml of PG that is propylene glycol under continuous stirring for 10-15 min.

The prepared ibuprofen solution was mixed into the guar gum gel base, followed by the addition of distilled water to adjust the final weight. The mixture was stirred vigorously to ensure the uniform (same) dispersion of the drug. The resulting ibuprofen gel was mixed again by using a magnetic stirrer for approximately 20 min until a homogeneous, bubble-free gel was obtained.

Three different ibuprofen gel formulations were prepare by varying the concentration of guar gum. The gels were pour into high-density polyethylene (HDPE) containers and stored under appropriate conditions until further evaluation.

3. CHARACTERIZATION STUDY

Homogeneity

The prepared gels was examined visually after the 48-50 hrs. of storage to assess their physical appearance and to confirm the absence of visible aggregates or phase separation.

Texture

Texture evaluation was performed by gently applying a small quantity of gel onto intact skin and assessing smoothness, spreadability, and the absence of grittiness.

Surface pH

The surface pH of the formulated gels was estimated by directly immersing the electrode of ph into a small quantity of gel. The same procedure are used for a marketed ibuprofen gel to allow comparison.

Drug Content

An accurately weighed amount of the formulated gel equivalent to 5 to 6 mg of ibuprofen was sent to a 100 ml glass volumetric flask that containing 80 ml of buffer solution that's pH is 7.4pH. The flask was sealed and placed in a mechanically agitated water bath maintained at 37 °C for 2 h to ensure the complete drug extraction. Volume was then adjusted to 99.5 ml using phosphate buffer.

From this solution, a 20 ml sample was given and diluted with 100 ml of distilled water. The absorbance of solution was measured at 222 nm using 7.4 pH of phosphate buffer as the blank. The content of ibuprofen (µg/ml) was from a previously prepared calibration curve, and the contant of drug was expressed as a percentage.

In Vitro Release Studies

The in vitro release behavior of ibuprofen from the formulated gel and the marketed gel was evaluated by using a modified dissolution apparatus II. The 7.4 pH of phosphate buffer served as the release medium. Prior to the experiment, the paper was cellulose acetate soaked in the buffer solution to 2 hrs.

One gram of the formulated gel (equivalent to 262 mg ibuprofen) and one gram of the marketed gel (equivalent to 5 mg ibuprofen) were individually spread onto separate microscopic glass slides. The layer of gel was completely covered with cellulose acetate paper, and the edges of the seprated by using adhesive tape to prevent the leakage.

The prepared slides were suspended in the 900 ml ofbuffer solution (phosphate buffer) of maintain at 37 ± 0.5 °C. and the paddles are starting to rotate at the 50 rpm. Samples (20 ml) were withdrawn at 15, 30, and 45 min, at 1 h, and

subsequently at hourly intervals up to 5 h. After each sampling, The withdrawn volume was replaced with an same volume of newly fresh prepared phosphate buffer to maintain sink conditions.

The absorbance of the collected aliquots were measured at 222 nm. Release studies were conducted in triplicate for both the formulated and marketed gels. The percentage of drug released was calculated on the based of measured concentrations and expressed as a function of the initial drug loading in each gel sample. Further analysed of the circulate analysis report by using DDSolver software (Version 1.0, 2010) to evaluate various kinetic release models [11].

4. RESULT AND DISCUSSION

Both the formulated gels and the marketed product exhibited good physical homogeneity, with no visible lumps or phase separation observed. The surface pH of the formulated gels (F1, F2, and F3) ranged between 6.25 and 6.40, that is lower than the marketed gel (pH 8.17). Despite this difference, the value of pH of the formulated gels were considered acceptable, as both ibuprofen and guar gum are stable within this range. Moreover, the pH of the formulated gels was closer to normal skin pH (approximately 5.5), which may reduce the likelihood of skin irritation upon topical application.

That means the drug amount of ibuprofen in the formulated gels was evaluated to be 83.2% with the standard deviation of 2%, indicating the satisfactory drug evenly distribution for the main aim of this current study. This is anticipated that improved content uniformity approaching 99% achieving result by useing of a high speed homogenizer during preparation, that was not present during the study time.

The in vitro result was checked a 5 h period demonstrated that all three formulated gels exhibited a higher cumulative percentage of ibuprofen release match to the marketed gel, as illustrated in Figure 1. The enhanced release from the formulated gels suggests that therapeutic drug levels could be achieved more rapidly while still maintaining a sustained release pattern. Additionally, the high water-thickening capacity of guar gum allows effective gel formation at relatively low polymer concentrations, offering an economic advantage in terms of reduced formulation costs.

To further characterize the release mechanism, the experimental release data were examine by using different kinetic models, like the Korsmeyer–Peppas [17,18], Higuchi [19], and Weibull [20] models [12–16]. The coefficient of determination (r^2) was used as the primary criterion for selecting the most appropriate model. An r^2 value greater than 0.99 was considered indicative of a good fit.

Among the evaluated models, the Korsmeyer–Peppas model showed the highest r^2 values and therefore provided the best description of ibuprofen release from hydrophilic gels. The model parameters optimized through this report are shown in table no. 2, confirming that the release of ibuprofen from the developed gels followed Korsmeyer–Peppas kinetics.

5. CONCLUSION

The current study was successfully demonstrated the formulation of a prolonged-release ibuprofen gel intended for dermatological application using the natural polymer guar gum. The formulated gels exhibited acceptable physical characteristics, including good homogeneity and a smooth, uniform texture. The In vitro studies was demonstrated the developed formulations provided a drug release profile when the compared with the marketed ibuprofen gel. These analysis findings suggest that the guar gum based ibuprofen gels may serve as a promising alternative for the management of inflammatory conditions through topical application, offering potential benefits in both localized therapy and systemic delivery following percutaneous absorption.

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