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FORMULATION AND EVALUATION OF ETODOLAC-LOADED ETHOSOMAL GEL FOR DEEPER DERMAL DELIVERY IN THE MANAGEMENT OF CHRONIC INFLAMMATION

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ABSTRACT

Etodolac is a non-steroidal anti-inflammatory drug widely used in the treatment of pain and inflammation. Oral administration of Etodolac is often associated with gastrointestinal side effects and first-pass metabolism, while conventional topical formulations may show limited skin penetration.The present study aimed to formulate and evaluate an Etodolac-loaded ethosomal gel for enhanced topical drug delivery and sustained drug release.Etodolac-loaded Ethosomes were prepared by the cold method using ethanol, soya lecithin, propylene glycol, and distilled water. Nine formulations (F1–F9) were developed by varying the concentrations of lecithin and propylene glycol. The prepared ethosomes were evaluated for encapsulation efficiency and in vitro drug release. The optimized formulation was further characterised for particle size, polydispersity index (PDI), and zeta potential, and then incorporated into a Carbopol 940 gel base. The resulting ethosomal gel was evaluated for pH, spreadability, viscosity, drug content, and skin irritation. Drug release kinetics were analysed using zero-order, first-order, Higuchi, and Korsmeyer–Peppas models. Diffusion studies for both the prepared Etodolac ethosomal gel and the marketed Proxym (Etodolac) gelwere compared. Among all formulations, F9 was found to be the optimized formulation, showing the highest encapsulation efficiency of 95.72 ± 0.28% and maximum cumulative drug release of 96.67% at 12 h. The optimized formulation exhibited a particle size of 328.1 nm, PDI of 0.507, and zeta potential of -40.0 mV, indicating nanosized vesicles with good physical stability. The ethosomal gel showed satisfactory physicochemical properties, with pH 6.0, spreadability 6.65 g·cm/sec, drug content 99.52%, viscosity 48,750 ± 320 cps, and no signs of skin irritation. Release kinetic analysis revealed that the optimized formulation best followed zero-order kinetics.Drug diffusion from prepared Etodolac ethosomal gel found as 96.4%, and that of marketed preparation found as 82.6%. The developed Etodolac-loaded ethosomal gel demonstrated satisfactory formulation characteristics, high drug encapsulation, nanosized vesicle formation, good stability, and sustained drug release. The study suggests that ethosomal gel is a promising topical delivery system for Etodolac, with potential to improve therapeutic efficacy and better release from the marketed preparation.

Keywords: *Etodolac, Ethosomes, Topical gel, Vesicular drug delivery, Encapsulation efficiency, Sustained release.*

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INTRODUCTION

Topical drug delivery systems have gained considerable attention due to their ability to provide localised therapeutic action, reduce systemic side effects, and improve patient compliance. Among various vesicular carriers, Ethosomes have emerged as a promising approach for enhancing dermal and transdermal drug delivery [1,2]. Ethosomes are soft, malleable vesicles mainly composed of phospholipids, a high concentration of ethanol, and water. The presence of ethanol imparts flexibility to the lipid bilayer and enhances penetration through the stratum corneum, thereby improving drug delivery into deeper layers of the skin. Etodolac is a non-steroidal anti-inflammatory drug (NSAID) possessing significant analgesic and anti-inflammatory activity. Although effective, the oral administration of Etodolac is associated with gastrointestinal irritation and hepatic first-pass metabolism [3]. Topical administration offers an attractive alternative for localized therapy; however, conventional topical formulations often show inadequate skin penetration and limited drug retention at the target site [4].

Incorporation of Etodolac into an ethosomal system may enhance skin permeation, improve drug retention, and provide sustained drug release. [5,6] Therefore, the present work aimed to formulate Etodolac-loaded Ethosomes, optimise the formulation composition, incorporate the optimised dispersion into a Carbopol gel base, and evaluate its physicochemical characteristics, in vitro drug release, and comparative performance with a marketed conventional gel.

MATERIALS AND METHODOLOGY

Materials

Etodolac and soya lecithin were purchased from Yarrow Chem Products, Mumbai. Propylene glycol was procured from Research Lab Fine Chem Industries, Mumbai. Carbopol 940, glycerin, and triethanolamine (TEA) were obtained from Loba Chemie Pvt. Ltd., Mumbai. All chemicals used were of analytical grade. A Hi-Media diffusion cell membrane with a molecular weight cut-off (MWCO) of 12–14 kDa was used for diffusion studies.

Pre-formulation Studies

Determination of λmax of Etodolac

The maximum absorption wavelength (λmax) of Etodolac was determined using a UV–Visible spectrophotometer (Model UV-1800, Shimadzu). A suitable dilution of the drug was prepared using phosphate buffer (pH 7.4). The solution was scanned in the wavelength range of 200–400 nm, and the wavelength showing maximum absorbance was recorded as the λmax[7].

Construction of Calibration Curve

A standard calibration curve of Etodolac was prepared by preparing drug solutions in phosphate buffer (pH 7.4) at concentrations of 5, 10, 15, 20, and 25 µg/mL. The absorbance of each solution was measured at 224 nm using a UV–Visible spectrophotometer. A calibration curve was constructed by plotting concentration versus absorbance [8].

Drug–Excipient Compatibility Studies

Drug–excipient compatibility studies were performed using Fourier Transform Infrared (FTIR) spectroscopy (Model Alpha 11, Bruker). The spectra of the pure drug, individual excipients, and the physical mixture of drug with excipients were recorded and compared to identify any possible chemical interactions [9,10].

Preparation of Etodolac Ethosomes

Etodolac-loaded Ethosomes were prepared using the cold method. Ethanol was taken in a clean beaker, and Etodolac was dissolved under continuous stirring. Soya lecithin was then added to the ethanolic solution, followed by propylene glycol with continuous stirring. The required volume of distilled water was added slowly while stirring, and the mixture was stirred for 30 minutes to obtain the ethosomal suspension. The prepared suspension was stored under refrigerated conditions (Table 1).A full factorial design was employed to optimise the formulation variables. A total of nine formulations (F1–F9) were prepared by varying the concentrations of lecithin and propylene glycol while keeping the drug and ethanol concentrations constant. The formulations were evaluated to identify the optimisedbatch [11,12].

Table 1. Composition of Etodolac-Loaded Ethosomes

Formulation Code	Ethanol (mL)	Etodolac (mg)	Lecithin (% w/v)	Propylene Glycol (% v/v)	Distilled Water (Q.S) (mL)
F1	30	500	1	20	100
F2	30	500	1	30	100
F3	30	500	1	40	100
F4	30	500	2	20	100
F5	30	500	2	30	100
F6	30	500	2	40	100
F7	30	500	3	20	100
F8	30	500	3	30	100
F9	30	500	3	40	100

Preparation of Etodolac Ethosomal Gel

Etodolac ethosomal gel was prepared using the optimised ethosomal formulation (F9). Initially, an empty gel base was prepared using Carbopol 940. Carbopol 940 was slowly dispersed in distilled water with continuous stirring and allowed to hydrate for 30 minutes. Glycerin was added and mixed uniformly. The final volume was adjusted with distilled water. Triethanolamine (TEA) was added dropwise to adjust the pH to 6.0. The gel base was allowed to stand overnight to remove entrapped air. After cooling the gel base to room temperature (20–25°C), the ethosomal suspension was chilled to 4–8°C and gradually incorporated into the gel base with gentle stirring (Table 2). The final pH of the gel was checked again and adjusted to 6.0 using TEA. The prepared gel was stored in a wide-mouthed container under refrigerated conditions (4–8°C) [13].

Table 2. Composition of Empty Gel Base (100 g)

S. No	Ingredient	Category	Amount (g)
1	Carbopol 940	Gelling agent	2
2	Glycerin	Humectant	8
3	Water	Solvent	90
	Total		**100 g**

Evaluation of Etodolac Ethosomes

Encapsulation Efficiency

The ethosomal dispersion was centrifuged at 15,000 rpm for 45 minutes at 4°C to separate free drug from vesicles. The supernatant containing the unentrapped drug was collected and analysed using a UV–Visible spectrophotometer at 224 nm. Encapsulation efficiency was calculated by comparing the total drug content with the amount of free drug present in the supernatant.

In Vitro Membrane Diffusion Study

Drug release from the ethosomal formulations was evaluated using a Franz diffusion cell with a dialysis membrane. The receptor compartment was filled with phosphate buffer (pH 7.4) and maintained at 37 ± 0.5°C with continuous stirring. Five millilitres of the formulation were placed in the donor compartment. Samples were withdrawn at predetermined time intervals (2, 4, 6, 8, 10, and 12 hours) and analysed at 224 nm using a UV spectrophotometer [14].

Particle Size and Polydispersity Index

Particle size and polydispersity index (PDI) were determined using a dynamic light scattering-based particle size analyser (Malvern Zetasizer). The sample was diluted with distilled water in a ratio of 1:20, and measurements were carried out at 25°C [15].

Zeta Potential

Zeta potential was measured using a Zetasizer based on electrophoretic light scattering to determine the stability of the vesicular system [16].

Evaluation of Etodolac Ethosomal Gel

The prepared Etodolac ethosomal gel was evaluated for physicochemical parameters such as pH, spreadability, viscosity, skin irritation potential, and drug content to ensure its suitability for topical application [17].

Determination of pH

The pH of the ethosomal gel was determined to ensure compatibility with skin pH and to avoid irritation upon application. Approximately 1 g of gel was accurately weighed and dispersed in 100 mL of distilled water. The dispersion was allowed to stand for 2 hours for complete equilibration. The pH was measured using a calibrated digital pH meter at room temperature (25 ± 2°C). Measurements were performed in triplicate, and the average value was recorded [18].

Spreadability Test

Spreadability was determined using the slip and drag method to evaluate the ease of application of the gel. Approximately 0.5 g of gel was placed between two glass slides. A weight of 500 g was placed over the upper slide for 5 minutes to obtain a uniform film. The time required for the upper slide to move a specified distance (6 cm) under the influence of an additional 20 g weight was recorded and spreadability was calculated.

Viscosity Measurement

The viscosity of the gel formulation was measured using a Brookfield viscometer (Model LMDV 60) to determine the consistency and suitability of the gel for topical application. The gel sample was placed in the viscometer using spindle number 64 and the measurements were recorded at room temperature.

Skin Irritation Study

The skin irritation study was conducted to evaluate the safety of the formulation for topical application. The dorsal surface of the skin was shaved 24 hours prior to the experiment. Approximately 0.5 g of the gel was applied to the test site and observed for 24–72 hours for signs of erythema, edema, or any visible skin reactions. Observations were graded according to a standard irritation scoring scale.

Drug Content Assay

The drug content of the ethosomal gel was determined to ensure uniform distribution of the drug within the formulation. Approximately 1 g of gel was accurately weighed and dissolved in 100 mL of phosphate buffer (pH 7.4). The solution was sonicated for 30 minutes to ensure complete drug extraction and filtered through Whatman filter paper. The absorbance was measured using a UV–Visible spectrophotometer at 224 nm and the drug concentration was calculated using the previously constructed calibration curve [19].

Comparative In Vitro Drug Release Study

A comparative in vitro drug release study was conducted between the optimized Etodolac ethosomal gel (F9) and a marketed Etodolac gel Proxym (5%, Emcure Pharmaceuticals Ltd.). The study was performed using a Franz diffusion cell with a dialysis membrane. The receptor compartment was filled with phosphate buffer (pH 7.4) and maintained at 37 ± 0.5°C with continuous stirring. The dialysis membrane was hydrated prior to use.A suitable quantity of gel formulation was placed in the donor compartment. Samples were withdrawn at predetermined intervals (2, 4, 6, 8, 10, and 12 hours) and replaced with fresh buffer to maintain sink conditions. The collected samples were analysed using a UV–Visible spectrophotometer at 224 nm to determine the cumulative percentage drug release [20].

RESULTS AND DISCUSSION

Determination of λmax

The UV–Visible spectroscopic analysis of Etodolac in phosphate buffer (pH 7.4) was carried out to determine the maximum absorption wavelength (λmax). The drug solution was scanned in the wavelength range of 200–400 nm. The spectrum showed a distinct absorption peak at 224 nm, which was selected as the λmax for all further analytical estimations. The sharp and well-defined peak confirms the suitability of this wavelength for quantitative determination of Etodolac.

Calibration Curve

A calibration curve of Etodolac was constructed using phosphate buffer (pH 7.4) in the concentration range of 5–25 µg/mL. The absorbance values obtained at 224 nm showed a linear relationship with increasing drug concentration. The calibration plot demonstrated good linearity within the selected concentration range, indicating that the method is reliable and suitable for quantitative analysis of Etodolac during formulation evaluation and drug release studies.

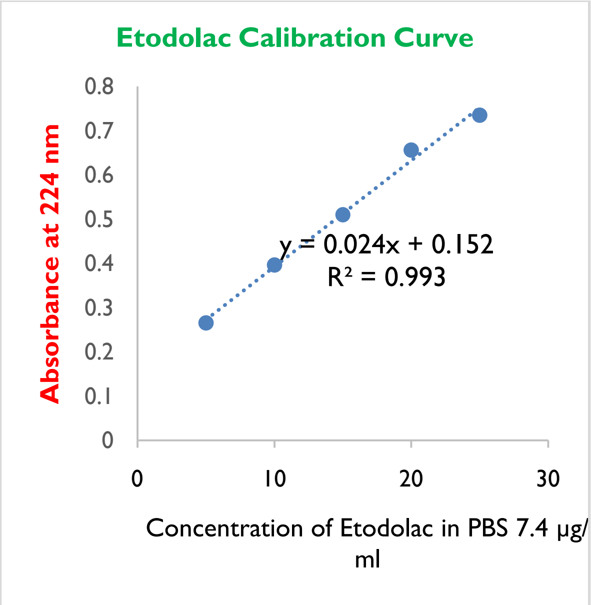

Figure 1. Calibration Curve of Etodolac in Phosphate Buffer pH 7.4

Drug–Excipient Compatibility Study

Drug–excipient compatibility studies were carried out using FTIR spectroscopy to evaluate possible interactions between Etodolac and formulation excipients. The FTIR spectra of pure Etodolac, individual excipients, and the physical mixture were compared.

The characteristic peaks corresponding to functional groups of Etodolac were observed in both the pure drug and the physical mixture without any significant shift, disappearance, or formation of new peaks. This indicates the absence of chemical interaction between Etodolac and the selected excipients. Therefore, the drug remains chemically stable and compatible with the formulation components used in the ethosomal system.

Encapsulation Efficiency

Encapsulation efficiency is an important parameter that determines the ability of vesicles to retain the drug within their structure. The encapsulation efficiency of the prepared ethosomal formulations (F1–F9) was determined and is presented in Table 3.Among all formulations, F9 exhibited the highest encapsulation efficiency of 95.72%, whereas F1 showed the lowest value of 74.32%. The increase in encapsulation efficiency from F1 to F9 can be attributed to the increasing concentration of lecithin and propylene glycol. A higher phospholipid concentration provides a larger vesicular bilayer structure capable of entrapping more drug molecules. Additionally, the presence of propylene glycol enhances vesicle stability and improves drug incorporation within the vesicular matrix.Thus, formulation F9 was considered the optimised formulation based on its superior encapsulation efficiency.

Table 3. Percentage Encapsulation Efficiency of Etodolac Ethosomes

Formulation Code	% Encapsulation Efficiency (Mean ± SD)
F1	74.32 ± 0.85
F2	78.65 ± 0.72
F3	82.14 ± 0.68
F4	85.97 ± 0.54
F5	88.43 ± 0.49
F6	90.26 ± 0.42
F7	92.18 ± 0.37
F8	94.05 ± 0.31
F9*	**95.72 ± 0.28**

In Vitro Drug Release Study

The in vitro drug release profile of Etodolac ethosomal formulations was studied using a Franz diffusion cell with phosphate buffer (pH 7.4) as the receptor medium. The cumulative percentage drug release for different formulations was evaluated over a period of 12 hours. Among the formulations tested, the optimized formulation F9 exhibited the highest cumulative drug release of 96.67% at the end of 12 hours, indicating efficient drug diffusion and sustained release behavior. The gradual and controlled release pattern observed for the ethosomal formulations may be attributed to the vesicular structure of Ethosomes, which allows controlled diffusion of the drug across the membrane.

Table 4. Percentage Drug Release of Etodolac Ethosomes

Time (h)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)	F6 (%)	F7 (%)	F8 (%)	F9 (%)
2	29.10	25.40	30.00	32.67	30.67	44.83	65.00	73.00	78.63
4	35.80	38.20	33.00	43.33	35.50	53.75	70.30	74.47	81.50
6	49.60	44.20	46.67	56.00	44.17	67.17	75.33	77.15	83.83
8	55.80	61.17	53.83	61.67	50.83	72.03	81.33	81.67	86.50
10	61.80	64.07	68.47	69.33	58.63	78.53	83.50	84.63	91.97
12	70.43	72.13	73.33	77.67	70.00	84.67	91.83	88.83	96.67

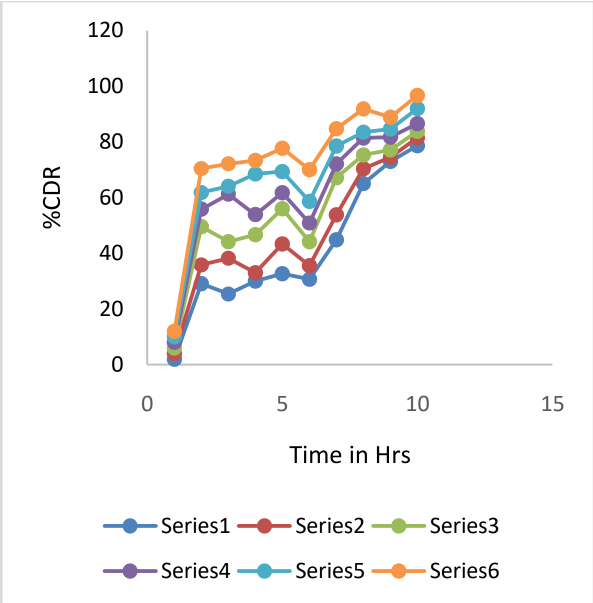

Figure 2. Percentage Drug Release of Etodolac Ethosomes

Particle Size, Polydispersity Index, and Zeta Potential

The particle size, polydispersity index (PDI), and zeta potential of the optimized formulation (F9) were analyzed using a Malvern Zetasizer.The optimized ethosomal formulation showed an average particle size of 328.1 nm, which is suitable for enhanced dermal penetration. Smaller vesicle size facilitates better permeation through the stratum corneum and deeper skin layers.The PDI value of 0.507 indicates a moderately uniform distribution of vesicles within the formulation. The zeta potential value of −40 mV suggests good electrostatic stability of the vesicles, preventing aggregation and ensuring long-term stability of the formulation.Drug release kinetic analysis revealed that the optimized formulation followed zero-order release kinetics, indicating a controlled and sustained drug release from the ethosomal matrix.

Table 5. Key Evaluation Parameters of Optimised Formulation (F9)

Parameter	Result	Significance
Encapsulation Efficiency	95.72%	High drug loading
Particle Size	328.1 nm	Enhanced skin penetration
PDI	0.507	Uniform particle distribution
Zeta Potential	−40 mV	Good vesicle stability
Drug Release (12 h)	96.67%	Sustained drug release

Physicochemical Evaluation of Etodolac Ethosomal Gel

The optimized ethosomal formulation (F9) was incorporated into a Carbopol gel base and evaluated for various physicochemical parameters.The pH of the gel formulation was found to be 6.0 ± 0.15, which falls within the normal physiological skin pH range (5.5–7.0), indicating that the formulation is suitable for topical application without causing irritation.The formulation demonstrated good spreadability (6.65 ± 0.45 g·cm/s), which ensures easy application and uniform distribution over the skin surface. The viscosity value of 48,750 ± 320 cps indicates appropriate gel consistency, which helps in maintaining the formulation at the site of application for an extended period. The drug content of 99.52% confirms uniform drug distribution throughout the gel matrix. The skin irritation study showed no signs of erythema or edema, indicating that the formulation is safe and non-irritant for topical use.

Table 6. Physicochemical Evaluation of Optimized Etodolac Ethosomal Gel (F9)

Parameter	Result	Inference
pH	6.0 ± 0.15	Compatible with skin pH
Spreadability	6.65 ± 0.45 g·cm/s	Excellent spreadability
Viscosity	48,750 ± 320 cps	Suitable dermal consistency
Drug Content	99.52%	Uniform drug distribution
Skin Irritation Score	0	Non-irritant

Comparative in Vitro Drug Release Study

A comparative in vitro drug release study was performed between the optimized Etodolac ethosomal gel (F9) and a marketed Etodolac gel (Proxym®, 5%, Emcure Pharmaceuticals Ltd.).The results showed that the ethosomal gel exhibited significantly higher drug release at all time intervals compared to the marketed formulation. The optimized ethosomal gel showed 96.4% drug release at 12 hours, whereas the marketed gel showed 82.6% release.The enhancement factor ranged from 1.17 to 1.59, demonstrating improved drug diffusion and sustained release behavior of the ethosomal gel formulation. The improved release profile may be attributed to the nano-sized vesicular structure of ethosomes and the presence of ethanol, which enhances membrane permeability and facilitates better drug transport across the diffusion membrane.These results clearly indicate that the ethosomal gel system enhances drug release and permeation compared to conventional topical formulations, thereby improving the therapeutic potential of Etodolac for the management of chronic inflammatory conditions.

Table 7. Comparative In Vitro Cumulative % Drug Release – Ethosomal Gel vs Marketed Gel

Time (hrs)	Marketed Proxym Gel (%)	Etodolac Ethosomal Gel (%)	Enhancement Factor
2	20.5	32.6	1.59
4	34.1	48.3	1.42
6	47.6	63.7	1.34
8	59.3	78.5	1.32

10	70.8	90.1	1.27
12	82.6	96.4	1.17

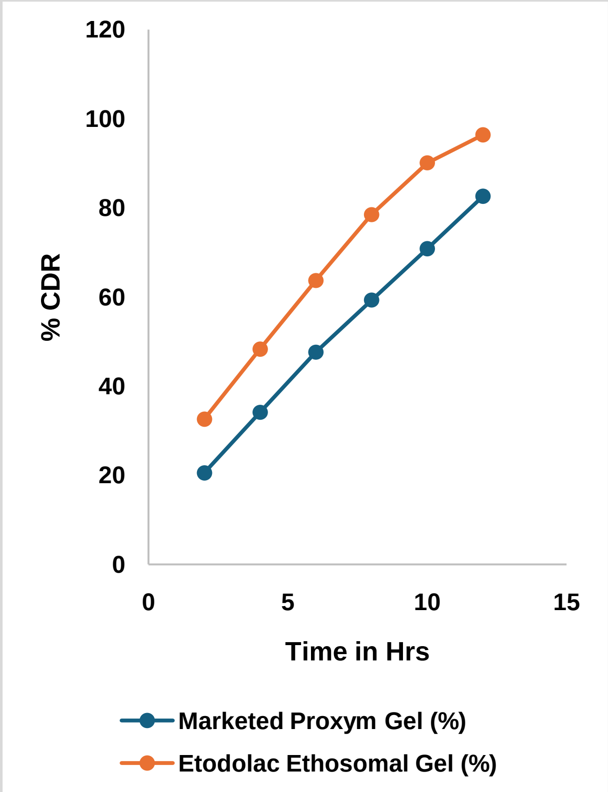

Figure 3. Comparative In Vitro Cumulative % Drug Release – Ethosomal Gel vs Marketed Gel

CONCLUSION

The present study successfully developed and evaluated an Etodolac ethosomal gel for enhanced dermal drug delivery. Among the prepared formulations, formulation F9 showed optimized vesicle characteristics and a superior drug release profile.The developed Etodolac ethosomal gel exhibited controlled drug release, improved dermal penetration, and better therapeutic potential compared to the marketed Etodolacgel. The formulation also demonstrated good physicochemical properties and was safe for topical application.Therefore, the developed Etodolac ethosomal gel may serve as a promising topical drug delivery system for the treatment of chronic inflammatory dermatological conditions such as Arthritis.

AUTHOR CONTRIBUTIONS

Shaik Muhammad Soheb carried out the experimental work, data collection, analysis of results, preparation of figures and tables, and drafting of the manuscript. A Venkata Badarinath contributed to the conceptualization of the study, supervision of the research work, review of experimental results, and final editing of the manuscript.Both authors reviewed and approved the final version of the manuscript.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this paper.

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