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Original Article

Design and Evaluation of Unidirectional Mucoadhesive Buccal Tablets of Diclofenac Sodium Using Different Polymers

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ABSTRACT

Introduction: A mucoadhesive buccal drug delivery system is one of the novel methods to formulate the diclofenac sodium for increased bioavailability and bypass the hepatic first-pass metabolism, which would suppress the formation of peptic ulcers. The current focus of this research is to develop a mucoadhesive buccal tablet of diclofenac sodium and to evaluate its *in vitro* drug release profiles. **Aim:** The aim of this study is the design and evaluation of a unidirectional mucoadhesive buccal tablet of Diclofenac Sodium using different polymers. **Materials and Methods:** Mucoadhesive Diclofenac Sodium buccal tablets were prepared by direct compression method. Polymers used were Hydroxy Propyl Methyl Cellulose, Methyl Cellulose, Sodium Carboxy Methyl Cellulose, Carbopol, Sodium alginate and Ethyl Cellulose used as an impermeable backing layer. Ethyl Cellulose helps with the unidirectional drug release of the buccal tablet. The evaluation parameters and mucoadhesive strength evaluations, along with *in vitro* assessments, were conducted to analyse the performance of the formulations. **Results:** The formulation f4 was chosen as the best formulation based on the results. All physicochemical parameters were in compliant with the Indian Pharmacopeia. *In vitro* drug release from the buccal tablet was 63.36% at the 5th hour. The swelling index of the tablet was 65% at 30 min. The adhesion time was more than 6 hr. Surface pH is suitable for oral pH. f4 follows the mixed-order release of both first order and non-fickian (n<0.89). The Carbopol-containing tablet showed a peak force of 0.108 N and a positive work of adhesion of 0.145 N.sec, indicating stronger mucoadhesion compared to the normal tablet, which had a peak force of 0.0508 N and a negative work of adhesion of -0.241 N.sec. **Conclusion:** These findings led to the development of a product that could help to prevent the first pass effect of Diclofenac Sodium and to enhance its bioavailability.

Keywords: Buccal tablet, Mucoadhesive, Adhesion time, Swelling index, Carbopol, Surface pH.

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INTRODUCTION

The oral route of administration is the most convenient, widely used and preferred route for drug delivery for systemic action. In oral administration, many therapeutic agents undergo GI degradation. This results in low bioavailability and shorter therapeutic activity. To overcome these disadvantages, a mucoadhesive drug delivery could be used as a better alternative.[1] Mucoadhesive drug delivery systems are a type of drug delivery system that makes use of the bio adhesion property of certain polymers which become adhesive upon hydration to target a drug to a specific region of the body for an extended period of time.

Mucoadhesion drug delivery systems form attachments between an artificial material and a biological substrate. Mucoadhesion is defined as the polymer attached to the mucin layer of a mucosal tissue.[2] Buccal administration offers rapid absorption of diclofenac sodium through the mucosal membrane, also provides quicker onset of action compared to oral delivery. The mucoadhesive property ensures that the tablet remains in the buccal region and providing sustained and localised drug release directly into the blood stream and bypass first pass metabolism. This formulation is particularly beneficial for patients who require continuous pain relief but may have difficulties with swallowing conventional tablets or risk of GI irritation from oral NSAID. This type of dosage form is specially designed to adhere to the mucosal surface, thus increasing retention of the drug at the site of application. This helps in providing a controlled rate of drug release for better therapeutic efficacy. The absorption of drugs into the oral mucosa is mainly via passive diffusion into the lipoidal membrane. The buccal route has been found to be more suitable for the drug delivery of pharmaceutical agents using mucoadhesive polymers. This is due to the relatively static

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and smooth surface. Various mucoadhesive polymers used in this delivery system such as natural, synthetic, semisynthetic polymers. The absorption of drugs into the oral mucosa is mainly via passive diffusion into the lipoidal membrane. The compounds with partition coefficients in the range of 40-2000 and pKa of 2-10 are considered optimal and are absorbed through the buccal mucosa. Due to its high lipophilicity, diclofenac sodium predominantly exists in its unionized form, facilitating rapid absorption through the buccal route. The unionized state enhances its permeability across the lipophilic buccal mucosa, making it an ideal candidate for buccal drug delivery systems aimed at improving absorption and bioavailability. This provides a significant advantage over conventional delivery by overcoming premature drug degradation within the gastrointestinal tract as well as active drug loss due to first-pass hepatic metabolism that may be associated with the oral route of administration. The presence of a thin mucus membrane and rapid absorption can be observed, because of the rich blood supply in this membrane. The first-pass metabolism is bypassed, because after absorption the drug is transported through the deep lingual vein and then reaches the systemic circulation via the jugular vein. Many compounds are administered by the mucoadhesive route, such as steroids, barbiturates, papain, trypsin etc. The drugs having a short biological half-life, poor solubility and permeability and being susceptible to enzyme degradation might be suitable for delivery via oral cavity.[3,4]

Diclofenac sodium is also one of the nonsteroidal anti-inflammatory drugs and it belongs to the Biopharmaceutics Classification System (BCS) Class 2, indicating poor solubility but high permeability. It is mainly used for the treatment of rheumatoid arthritis and osteoarthritis. It provides anti-inflammatory activity, because it is a competitive and irreversible inhibitor of prostaglandin synthetase. The half-life of the drug is 2 hr and it goes through hepatic first-pass metabolism, its bioavailability is 50%.[5] The log *p* value of Diclofenac sodium is 4.218. It shows that it has enough lipophilicity to pass through the buccal membrane. By seeing the above point, it is inferred that diclofenac sodium is suitable for formulating into buccal tablets. So, a mucoadhesive buccal drug delivery system is one of the novel methods to formulate the diclofenac sodium for increased bioavailability and bypasses the hepatic first-pass metabolism, which would suppress the formation of peptic ulcers. The current focus of this research is to develop a mucoadhesive buccal tablet of diclofenac sodium and to evaluate its *in vitro* drug release profiles.[3,6]

MATERIALS AND METHODS

Materials

Diclofenac Sodium and HPMC K100M were obtained from Yarrow Chem Products, Mumbai. Methyl cellulose, SCMC, Sodium alginate, Carbopol 934, PVP-K30 and ethyl cellulose were obtained from Loba Chemie Pvt. Ltd., Magnesium stearate is obtained from Himedia Laboratories Pvt. Ltd., All the ingredients are of analytical grade.

Methods

Standard graph of Diclofenac sodium in phosphate buffer pH 6.8

About 100 mg of diclofenac sodium was weighed and dissolved in 100 mL volumetric flask containing 100 mL of phosphate buffer pH 6.8 to prepare standard stock of 1000 mcg/mL. From the above, 10 mL was taken and transferred to 100 mL volumetric flask and volume was made up to 100 mL with phosphate buffer 6.8 to prepare the standard stock solution of 100 mcg/mL. Serial dilution was carried out to get a concentration of 5, 10, 15, 20, 25 mcg/mL. The absorbance of the resulting solution was determined by using a UV spectrometer at 276 nm.

Preparation of Mucoadhesive buccal tablets of Diclofenac sodium

Diclofenac sodium mucoadhesive buccal tablets were formulated by direct compression method[7] using different types of mucoadhesive polymers. All the ingredients were taken by the required quantity except Ethyl Cellulose and mixed thoroughly. By using Rotatory tablet punching machine 150 mg of the mixture was compressed. Then the upper punch of the rotatory tablet punching machine was raised manually and 50 mg of EC was added and again compressed to get a unidirectional mucoadhesive buccal tablet of Diclofenac Sodium. Details of formulations are shown in Table 1.

Evaluation of the Mucoadhesive Buccal Tablets of Diclofenac Sodium

Weight variation test

By using electronic balance, 20 tablets were individually weighed and recorded. The average weight of the 20 tablets were calculated and recorded.[7]

Hardness of the tablet

Hardness test was performed using Monsanto hardness tester for 5 tablets from each batch and the average hardness of the tablets were calculated.[7]

Thickness

The thickness of the 5 tablets were performed using vernier calliper. The average thickness of the tablet was calculated.[3]

Friability

Friability test was performed for ten tablets from each batch using Roche type Friabilator. The following formula is used to calculate the percentage of friability.[8]

$$\% \text{ Friability} = (\text{Initial Weight} - \text{Final Weight}) / (\text{Initial Weight}) \times 100$$

Surface pH

Three tablets from each batch were taken for surface pH studies. Tablets were placed in beakers containing 5 mL distilled water for 2 hr. Surface pH was calculated by using an electronic pH meter.[9]

Swelling Index studies

The oral mucoadhesive tablets were precisely weighed and placed in a petri dish containing 6 mL of pH 6.8 Phosphate Buffer and maintained at 37±0.5ºC. Tablets were removed from the Petri dishes at 5, 10, 20 and 30 min. The water present on the surface of the tablet was removed and weighed.[8]

Swelling Index studies were performed by using the following formula:

$$\text{Swelling Index} = [(\text{F weight} - \text{I weight})/(\text{I weight})] \times 100$$

In vitro dissolution studies

The oral mucoadhesive tablet was tested for *in vitro* dissolution using USP type-2 dissolution apparatus with a rotating at a speed of 50 rpm. The dissolution medium, composed of phosphate buffer pH 6.8 was maintained at 37±0.5ºC. Periodically, 5 mL of sample was taken up to 5 hr and 5 mL of medium was replaced to maintain the sink condition. Finally, sample analysed by using UV spectrophotometer at 276 nm.[7]

Adhesion time of the buccal tablet

Adhesion time of the buccal tablet was carried out using USP type-2 apparatus. Goat intestinal mucosa tissue was taken for the study and was fixed to the glass slide. The tablet was placed on the mucosa tissue and put into the apparatus. Apparatus contains 500 mL of pH 6.8 phosphate buffer, which runs at 25 rpm and maintains a temperature of 37±0.5ºC. The same procedure was performed without agitation. The time taken to detach the tablets from the mucosa tissue was noted.[10]

Mucoadhesive strength using Texture analyser

The mucoadhesive strength of the buccal tablet was measured using a Texture Analyzer (Stable Micro Systems Ltd.,) with goat mucosa as the model membrane. The appropriate size of goat mucosal membrane was fixed to a stainless-steel plate accessory in the instrument. The buccal tablet was attached to the upper probe and the tablet and mucosa were brought into contact with a predetermined force for a specific duration. Then the probe was withdrawn and the parameters like peak force (adhesiveness), work of adhesion and debonding distance were recorded. These measurements allowed comparisons between mucoadhesive tablets containing Carbopol and normal tablets without Carbopol.[11]

RESULTS AND DISCUSSION

Drug Polymer Interaction

Drug polymer interaction studies play a major role in the development of safe and effective pharmaceutical products. Ranganathan V *et al.*, performed the FT-IR analysis of diclofenac sodium and drug polymer mixtures same as mentioned in the Table 1. The IR frequency peaks, and functional groups of the drug and polymer mixture were distinct and did not overlap. They concluded that there is no interaction between mixtures of drug and polymers.[7]

Weight variation test

The weight variation formulation details are cited in Table 2. All the tablets passed the weight variation test. The weight variation of tablets was within the limits of ±7.5%, as specified by the

Table 1: Composition of Mucoadhesive Buccal Tablets.

Ingredients (milligram)	F1	F2	F3	F4	F5
Diclofenac Sodium	50	50	50	50	50
Hydroxy Propyl Methyl Cellulose	50	-	-	-	-
Methyl Cellulose	-	50	-	-	-
Carbopol	-	-	-	50	-
Sodium Carboxy Methyl Cellulose	-	-	50	-	-
Sodium alginate	-	-	-	-	50
Mannitol	40	40	40	40	40
Poly Vinyl Pyrrolidine	8	8	8	8	8
Magnesium stearate	2	2	2	2	2
Ethyl cellulose	50	50	50	50	50
Total	200	200	200	200	200

Table 2: Evaluation of Post compression Parameters F1 to F5 (*n*=3).

Formulation	Thickness*(mm) ±S. D	Hardness*(kg\cm^2) ±S. D	Weight variation*(mg)±S. D	Friability*(%) ±S. D	Surface pH*±S. D
F1	2.6±0.09	4.4±0.45	201.5±8.5	0.86±0.02	7.4±0.06
F2	2.3±0.07	5±0.35	202.0±6.6	0.1±0.04	7.2±0.05
F3	2.42±0.06	4.5±0.40	199.6±7.5	0.78±0.04	8±0.02
F4	2.5±0.07	4.6±0.35	203.5±5.6	0.23±0.05	6.8±0.08
F5	2.4±0.08	4.8±0.55	202.7±8.1	0.08±0.05	7.4±0.06

mm=millimeter, kg=kilogram, cm=centimeter, mg=milligram, S.D=Standard Deviation.

Table 3: Swelling Index Studies of Mucoadhesive Diclofenac Sodium Tablets.

Time (min)	F1 %	F2%	F3%	F4%	F5%
5	10±0.12	50±0.21	65±0.32	23±0.25	63±0.11
10	20±0.22	65±0.24	75±0.44	45±0.4	76±0.23
20	25±0.2	76±0.25	85±0.33	54±0.2	88±0.5
30	30±0.18	85±0.31	105±0.12	65±0.2	110±0.42

%-Percentage.

Indian Pharmacopoeia. It turned out to be from 199 to 203 mg and it was consistent.

Thickness

Vernier Callipers were used to measure the thickness of the tablets after selecting them at random. Table 2 displays the average values. In all formulations, the values are essentially constant.

Hardness of the Tablet

Results are shown for all Hardness Formulations in Table 2. Monsanto Hardness tester used to determine hardness test. The reduced standard deviation results showed that all of the formulations hardness was almost uniform in their individual methods and that they have enough hardness to provide high mechanical strength.

Friability

The study findings, which are listed in Table 2, were found to be well within the permitted range (<1%) in each formulation. Formulations f1 to f5 have strong mechanical properties.

Surface pH

In order to look at potential side effects *in vivo*, the surface of buccal tablets was examined. Formulations f1, f2, f4, f5 surface pH were found to range from 6.8±0.1075 to 7.4±0.9968 in pH. The pH is almost neutral; the formulation does not irritate the mucosa. In F3 pH was found to be 8. Table 2 displays the surface pH values for all the formulations.

Swelling Index studies

Formulation f5 (Sodium alginate) has a high swelling index because it is more hydrophilic, so it swells rapidly. f3 (SCMC) has less swelling index compared to F5, due to the hydrophilicity of cellulose derivatives. f2 (MC) has less Swelling index compared to F5 due to rapid swellable of polymer, which leads to erosion. f4 (Carbopol) has less swelling index compared to f2 due to Swelling and erosion. f1 (HPMC) has less swelling index compared to other formulations due to less swelling and hydration. The swelling index values between the formulations were found to be significant (p<0.05) by one way ANOVA. The results were shown in Table 3.

In vitro dissolution studies

The drug release from f1 to f5 at 30 min was 6.8%, 30.51%, 3.44%, 4.6% and 6.8%, respectively. The drug release from f1 to f5 was 59.4%, 72.8%, 37.45%, 63.36% and 45%, respectively, after 5 hr.

f2 (Methyl Cellulose) has a high drug release rate at 5 hr, but in the 30th min, drug release was rapid because of excessive water intake that causes rapid swelling of the polymer matrix, which may cause erosion that led to the rapid release of the drug.

f4 (Carbopol) has the second-highest drug release among all the formulations, which may be due to hydration and erosion. f1 (HPMC) drug release is lower compared to f4. This may be due to gelling and slow rupture, which may result in slow release of drug. f5 (sodium alginate) has less drug release compare to f1, which due to the rapid swelling and gel layer formation over the surface of the tablet. f3 (SCMC) has the lowest drug release because water absorption leads to a tight viscous gel, which retards the drug release.

f2 > f4 > f1> f5 > f3 is the order of the drug release. The *in vitro* drug release values between the formulation were found to be significant (p<0.05) by one way ANOVA. (The results were shown in Figure 1).

Adhesion time of buccal tablet

High adhesive times will allow for more absorption. f2 (MC) has a shorter adhesion strength compared to all other formulations, which may be due to the low viscosity of polymer. f1, f3, f4 and f5 have stronger adhesion strength, which is due to the ionisation and bond formation with mucosal membrane. More adhesion strength leads to more adhesion time which leads to more drug absorption in the mucosal area.

Based on the mucoadhesive time results, formulation 4 was selected for evaluating mucoadhesive strength using a texture analyser with a goat mucosal membrane. The mucoadhesive tablet containing Carbopol exhibited stronger adhesive properties, with a peak force of 0.108 N, a positive work of adhesion of 0.145 N.sec and a debonding distance of 3.636 mm, shown in Figure 2. The normal tablet, lacking Carbopol, displayed a peak force of 0.0508 N, a negative work of adhesion of -0.241 N.sec and a debonding distance of 2.016 mm, shown in Figure 3. These findings, shown in Table 4, suggest that the Carbopol-containing tablet will adhere more effectively and remain in contact with the mucosal surface for a longer period, which may contribute to extended mucoadhesive time and sustained drug release.

Drug release kinetics

The % *in vitro* drug release data was exposed to zero order, first order and Korsmeyer Peppas to determine the release mechanism of drugs and drug release kinetics. The formulation with the highest r^2 value is the best-fit model. Among all formulations, f4 was found to be the best formulation based on release. The zero-order r^2 value is 0.9545. The first-order r^2 value is 0.9791 and the Korsmeyer Peppas r^2 value is 0.6531. The n value is less than 0.89. This tells us that the f4 follows non-fickian diffusion and first-order release.

Non-Fickian diffusion and first-order release in the buccal tablet ensure a more controlled and sustained drug release compared to conventional tablets. This mechanism prolongs the therapeutic effect and improves drug availability over time, whereas normal tablets typically result in an initial burst release, leading to a rapid but short-lived effect. The buccal tablet's-controlled release profile thus offers a more consistent drug concentration, minimizing fluctuations and enhancing overall therapeutic efficacy.

Comparison of Release Kinetics Between Normal and Buccal Tablet Formulations

The normal tablet formulation exhibited distinct release kinetics compared to the buccal adhesive tablet (F4). While the buccal

Table 4: Comparison of Mucoadhesive Properties between Tablet Formulations with and without Carbopol.

Parameter	Mucoadhesive tablet with carbopol	Normal tablet without carbopol
Peak force (Adhesiveness)	0.108 N	0.0508 N
Work of adhesion	0.145 N.sec	-0.241 N.sec
Debonding distance	3.636 mm	2.016 mm

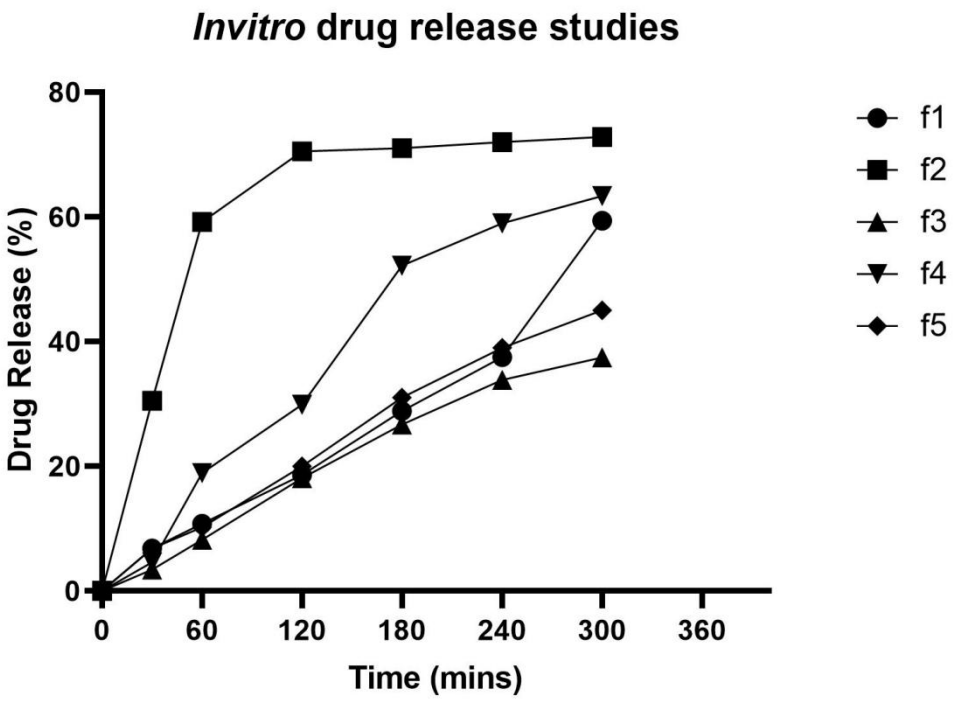

Figure 1: *In vitro* Drug Release of Mucoadhesive Buccal Tablets of Diclofenac Sodium.

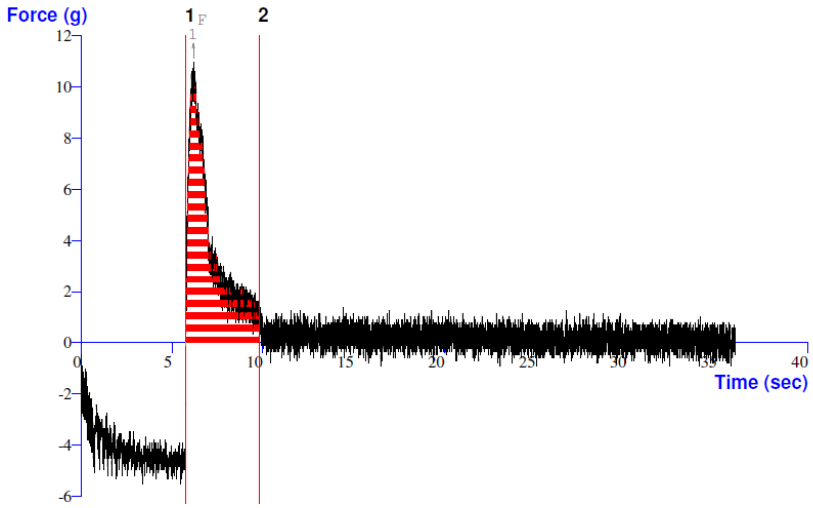

Figure 2: Mucoadhesive tablet with Carbopol.

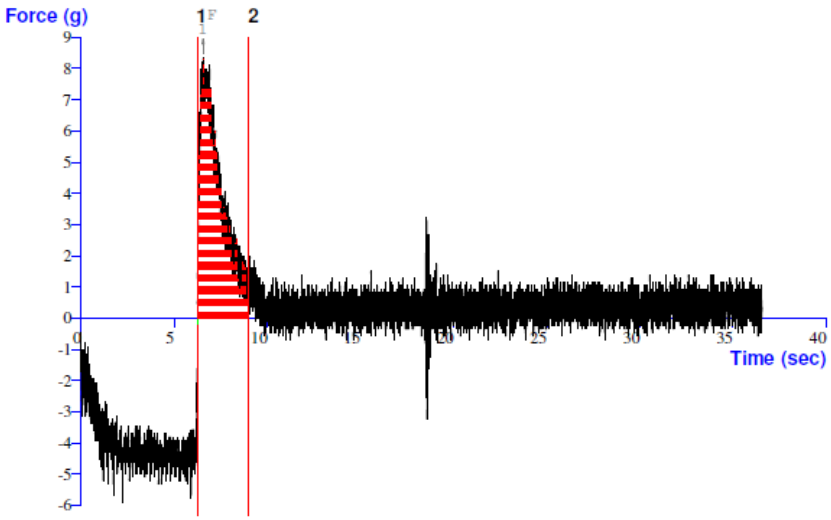

Figure 3: Normal tablet without Carbopol.

tablet followed mixed-order kinetics, combining elements of first order and sustained release, the normal tablet showed a clear first-order release pattern with an R^2 value of 0.998, indicating a faster release profile. Furthermore, the normal tablet demonstrated lower adhesive retention, limiting its ability to provide prolonged drug delivery. In contrast, the buccal adhesive tablet's sustained release profile, coupled with stronger mucoadhesive properties, ensures more gradual and extended drug delivery.

CONCLUSION

In the study, several polymers like HPMC, SCMC, MC, Carbopol, Sodium Alginate were used to formulate Diclofenac sodium buccal tablets using direct compression method. The mucoadhesive adhesion time for buccal tablets (f1, f3, f4, f5) were greater than 6 hr. Formulation f4 gave promising sustained drug release of more than 5 hr. The formulation f4 was chosen as the best formulation based on the results. Further in *vivo* studies are warranted to confirm the results.

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ABBREVIATIONS

SCMC: Sodium Carboxy Methyl Cellulose; **MC:** Methyl Cellulose; **HPMC:** Hydroxy PropylMethyl Cellulose; **nm:** Nano meter; **%:** Percentage; **UV:** Ultraviolet; **mm:** Millimeter; **kg:** Kilogram; **cm:** Centimeter; **mg:** Milligram.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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