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## ORIGINAL ARTICLE

# Effects of plasticizers and surfactants on the film forming properties of hydroxypropyl methylcellulose for the coating of diclofenac sodium tablets

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## KEYWORDS

Aqueous film coating;  
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**Abstract** Hydroxy propyl methyl cellulose (HPMC) 5cPs, an aqueous soluble polymer was employed for coating diclofenac sodium (DFS) tablets 25 mg for protecting the integrity of the drug yet rendering the drug to release at a faster rate on contact with the gastric environment. Proper optimization for the aqueous based film coating formulation was undertaken primarily employing plasticizers like polyethylene glycol (PEG) 400 and propylene glycol (PG). The defect free selected formulations were further subjected for studying the effects of surfactants like sodium lauryl sulphate (SLS) and Tween-80 along with the plasticizers. The quality of the aqueous film coats or the plasticizer efficiency in case of PEG-400 is in the order  $1.5 > 0.5 > 1.0\%$  and for PG  $1 > 4 > 3\%$  which can be stated on the basis of less incidence of major coat defects like chipping, cracking, orange peel, roughness, blistering, blooming, picking. The quality of aqueous film coat or the surfactant efficiency in case of SLS + PEG-400 is in the order  $0.3 < 0.5 < 0.1\%$  and SLS + PG is in the order  $0.5 < 0.1 < 0.3\%$ . In case of Tween-80 + PEG-400 the order is  $0.3 < 0.5 < 0.1\%$  and Tween-80 + PG is in the order  $0.3 < 0.1 < 0.5\%$ . Elegant film formation can be stated from fewer incidences of coat defects. The obtained coated tablets eventually satisfied all the normal physical parameters like thickness, weights, and weight gain, drug content, crushing strength, percent friability, disintegration time, dissolution profile and possible drug–polymer interactions. ANOVA was undertaken followed by Dunnet multiple comparison for the dissolution profile considering uncoated as the standard. The difference was considered significant at  $p \leq 0.01$ .

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## 1. Introduction

Film coating is a complex process that involves different factors. To ensure spreading and/or film forming capability plasticizers are added. The type and concentration of plasticizers can affect the film properties, as revealed by several investigations (Mortada, 1990; Siepmann et al., 2005; James, 1997). The plasticizing efficiency is measured by the lowering of the incidence of

coat defects. In this study two plasticizers namely polyethylene glycol 400 (PEG-400) and propylene glycol (PG) were selected. Aqueous film coating liquid was prepared by incorporating different concentrations of PEG-400 and PG (Mortada, 1990; Muschert et al., 2009; Abdul-Razzak and Aulton, 1984).

As the viscosity of the coating solution increases, there is greater resistance to spreading on the substrate surface and reduced tendency of the droplets to coalesce, both of which increase surface roughness. Other factors arising from an increase in solution viscosity, which may potentiate surface roughness, include the larger mean droplet size on atomization and the reduced penetration into the uncoated tablet or multiparticulate surface (Siepmann et al., 2007; Felton, 2007; Herbert et al., 1990). Variation in solution viscosity may also affect the rate and extent that a coating formulation penetrates into a substrate during the application. Difference in penetration behavior may be important in determining the adhesion of the coat to the substrate (James, 1997; Hossain and Ayers, 1990; Lippold et al., 1990). Little or no penetration may lead to poor adhesion. Invariably a tablet formulation includes lubricants to improve flow properties of the granules and to overcome certain processing problems. These ingredients are hydrophobic and in fine state of subdivision, present on the surface of the tablet which may hinder penetration of the coating liquid/solution. It is therefore prudent to include surfactants of high HLB value at smaller concentration, to improve penetration and spreading properties of the coating liquid.

The objective was also to investigate the effects of surfactants on the coating uniformity and quality of the film coat. In this study two surfactants of high HLB value such as sodium lauryl sulphate (SLS) and Tween-80 were selected and incorporated at different concentrations in the coating solutions (Mortada, 1990).

Diclofenac sodium (DFS), a phenyl acetic derivative, is an NSAID, mainly used to treat different pain managements and inflammation in various conditions; musculoskeletal and joint disorders such as rheumatoid arthritis, osteoarthritis and ankylosing spondylitis. DFS is also effective against peri-articular disorders, soft tissue disorders and other painful conditions such as renal colic, acute gout, dysmenorrhoea, migraine, and surgical procedures. The usual dose of the drug is 75 to 150 mg orally or rectally. The terminal half-life of DFS is about 1 to 2 h. DFS at a low dose of 25 mg can also be formulated in the form of immediate release tablets as an over the counter (OTC)/non-prescription drug to counteract different pain managements. This is due to the fact that DFS is the only salt that has enough safety and pharmacovigilance data that supports  $R_X$  to OTC switch strategy (Moore, 2007; Rigato et al., 2009; Motola et al., 2001). Coating of DFS is necessary to prevent photolytic degradation and masking of its unpleasant taste.

Our present study is aimed in the preparation of a 25 mg DFS tablet and subsequent development of an optimized film coating formula after properly studying the effects of plasticizer and surfactants for the purpose of coating the tablets (Motola et al., 2001; Morkhade et al., 2008).

## 2. Materials and methods

### 2.1. Chemicals

DFS was obtained from Roland Pharmaceuticals (Ganjam, Berhampore, Orissa, India) as a gift sample. PEG-400, Propyl-

ene glycol (PG), Dicalcium phosphate, SLS and Tween-80 were purchased from LOBA Chemie, Mumbai. HPMC 5 cps and corn starch was purchased from Hi Media. Iso propyl alcohol, talc, magnesium stearate and sodium hydroxide was purchased from Merck. Titanium dioxide was purchased from Qualigens. Hydrochloric acid was purchased from SD Fine Chemicals. Fruit colors were purchased from Bush Chem. All the chemicals and solvents were of analytical grade.

### 2.2. Preparation of the tablets

DFS tablets 25 mg were prepared by the process of wet granulation in a lab-scale wet granulator (Shakti Engineering, India) (Table 1). Required quantities of corn starch were mixed with water gradually on a hot air oven until a semi-solid paste was formed. This paste was treated as a binder and gradually added to the granulator already containing the required quantities of DFS and other excipients. The granulator was operated until a proper mix was obtained. The semisolid mix was passed thorough sieve no. 10 and subjected to tray drying on a electronic tray drier (SAMS India Ltd., India). The dried granules were collected and further passed through sieve no.16. Required quantities of talc, magnesium stearate and Aerosil were added and subsequent punching of the tablets with 10 mm biconcave punches on a 16-station rotary punching device (Cadmach, India) (Table 2).

### 2.3. Procedure for the preparation of film coating liquid involving plasticizers

In a 500 ml clean beaker about 125 ml of purified water was measured and the weighed amount of polymer HPMC 5 cps was added and allowed to soak overnight. Next morning it was stirred using a magnetic stirrer (Remi Motors, India) for 5–7 min to get a uniform dispersion of the polymer solution. Other ingredients such as plasticizer, opacifier, coloring agent were added gradually in required quantities (Table 4). The simultaneous evaluations are reported (Table 5). The selected formulations F3 and F4 were further tried for the effect of two surfactants namely SLS and Tween-80 and all the ingredients were added gradually in required quantities (Table 6). The simultaneous evaluations are reported (Table 7).

### 2.4. Preliminary coating procedure

Two hundred tablets of DFS were loaded on a lab-scale pan coater (SAMS Ltd., India) previously cleaned, dedusted. The coating liquid was filled into the spray gun with pneumatic pump attachment (Suguna Pneumatics, India). The pan was

**Table 1** Characterization of the granules of F3B.

Parameters	DFS granules (starch + dicalcium phosphate)
Angle of repose (°)	28 ± 1.1
Bulk density (g/mL)	0.63
Tap density (g/mL)	0.78
Carr's index	19.2 ± 0.5
Moisture content (%)	2.1 ± 1.1

All values represent mean ± SD ( $n = 3$ ).

**Table 2** Composition of DFS tablet.

Composition	Purpose	Quantity for 1 tablet (mg)
Diclofenac sodium	API (active pharmaceutical ingredient)	25
Corn starch (paste)	Binder	55
Dicalcium phosphate	Exipients	166
Corn Starch (dried)	Disintegrant	40
Aerosil	Flow promoter	3.5
Magnesium stearate	Lubricant	7
Talc	Glidant	3.5
Total weight		300

**Table 3** The different adjusted process variables.

Process variables	Adjusted specifications
Pan design/baffling	12 feet diameter with no baffles
Rotational speed of pan	40 rpm
Spray pressure (operational)	60–70£ per square inch (p.s.i)
Bed to gun distance	1–1.5 feet
Bed temperature	30 ± 5 °C
Dry air temperature	60 ± 5 °C
Spray pattern type	Circular, occasionally elliptical
Pan load	70 gm

rotated at 40 rpm for obtaining a cascading fall of the tablets. All the parameters were previously adjusted with dummy tablets (Table 3). As the tablets rolled, the film forming liquid was sprayed intermittently allowing the solvent to evaporate. The process was continued until all the coating solution was used up (Muschert et al., 2009; Abdul-Razzak and Aulton, 1984; Siepmann et al., 2007; Bodmeier and Paeratakul, 1989).

### 2.5. Determination of different evaluatory parameters for the prepared aqueous coated tablets

The selected coated tablets were evaluated for their thickness, weights, weight gain, drug content, diametral crushing strength, percent friability, disintegration time, dissolution profile, and drug–polymer interactions.

### 2.6. Tablet weight gain

Six coated tablets were randomly selected from each batch and the weight was determined individually in an electronic balance (Sartorius, India). The average weight of 6 tablets was calculated. The difference in the average weight with respect to the average weight of the uncoated tablet gave the weight gain of the coated tablet and the percentage weight gain was calculated accordingly and reported (Table 8).

### 2.7. Film thickness measurements (Bodmeier and Paeratakul, 1989)

Six coated tablets were randomly selected from each batch and the thickness was measured individually using a slide calipers. The difference in the thickness with respect to the uncoated tablet gave the coat thickness. The cast film thickness measurement was done by using a film thickness tester (Baker dial gauge-type J17, India) by peeling off the adhering films from the substrate surface. Uniformity in thickness was measured by selecting four different zones of the cast films. The average of each formulation is noted (Table 8).

### 2.8. Disintegration test (Morkhade et al., 2008)

Disintegration tester (Campbell Electronics, India) was used to determine the resistance or disintegration time of the selected five aqueous film-coated tablets. Six tablets were randomly selected from each batch and one tablet was placed in each of the six tubes. The basket rack was positioned in a 1 l beaker of 0.1(N) HCl at 37 ± 0.5 °C. Perforated auxiliary discs were placed on the top. The instrument was operated and the time taken for a tablet to disintegrate and all the particles to pass through the no.10 USP mesh aperture was noted according to USP/NF/IP until a palpable mass remains. The average time is reported (Table 8).

### 2.9. In vitro release studies (Morkhade et al., 2008; Fulzele et al., 2002; Ghosh et al., 2007)

The release measurements were performed using 8 stage USP dissolution apparatus-1 (Disso-2000, Lab India). The dissolution parameters (one tablet; 37 ± 0.5 °C; 100 rpm; 900 ml of 0.1(N) hydrochloric acid). A single tablet from the chosen formulation was placed in the basket and 5 ml of aliquots were withdrawn at suitable intervals up to 1 h 30 min. The samples were assayed spectrophotometrically using UV–VIS double

**Table 4** Formula for film coating formulations involving plasticizers.

Ingredients	F1 (%) w/w	F2 (%) w/w	F3 (%) w/w	F4 (%) w/w	F5 (%) w/w	F6 (%) w/w
HPMC	7.5	7.5	7.5	7.5	7.5	7.5
PEG-400	0.5	1.0	1.5	–	–	–
Plasticizer (PG)	–	–	–	1	2	3
Colorants	0.6	0.6	0.6	0.6	0.6	0.6
Opacifier (titaniumdioxide)	3	3	3	3	3	3
Purified water	q.s	q.s	q.s	q.s	q.s	q.s

**Table 5** Visual observation for defects in the formulations containing plasticizers.

Defects	F1	F2	F3	F4	F5	F6
Blistering	++	–	–	–	–	–
Blooming	+++	–	–	–	++	+
Chipping	+++	+++	+	++	+++	++
Cracking	++	–	–	–	–	–
Orange peel	–	+++	–	–	–	–
Picking	–	+++	–	–	++	–
Roughness	++	+++	++	–	++	++
Splitting	+++	++	+	+	+++	+
Thickness of cast film (mm)	0.2	0.3	0.2	0.1	0.2	0.2
Weight gain (%)	25	23.64	21.62	10.13	18.24	21.62

Yes (+++), no (–), slight (++), very slight (+).

**Table 6** Formula for film coating involving plasticizers and surfactants.

Ingredients	F3A	F3B	F3C	F4A	F4B	F4C	F3D	F3E	F3F	F4D	F4E	F4F
	(%) w/w	(%) w/w	(%) w/w	(%) w/w	(%) w/w	(%) w/w	(%) w/w	(%) w/w	(%) w/w	(%) w/w	(%) w/w	(%) w/w
HPMC	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5
PEG-400	1.5	1.5	1.5	–	–	–	1.5	1.5	1.5	–	–	–
Plasticizer (PG)	–	–	–	1.0	1.0	1.0	–	–	–	1.0	1.0	1.0
Opacifier (titanium dioxide)	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Surfactants (SLS)	0.1	0.3	0.5	0.1	0.3	0.5	–	–	–	–	–	–
Tween-80	–	–	–	–	–	–	0.1	0.3	0.5	0.1	0.3	0.5
Colorants	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Purified water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

**Table 7** Visual observation for defects in the formulations containing plasticizers and surfactants.

Defects	F3A	F3B	F3C	F4A	F4B	F4C	F3D	F3E	F3F	F4D	F4E	F4F
Blistering	+++	–	–	+++	–	–	–	–	–	–	–	–
Blooming	–	–	++	++	–	–	+++	+	–	++	++	++
Chipping	+++	–	–	+++	–	++	–	+++	++	++	–	++
Cracking	–	–	–	–	–	–	–	–	–	–	–	+++
Orange peel	–	–	–	+++	+++	–	+++	–	–	–	–	++
Picking	–	–	–	–	+++	–	–	–	–	–	–	–
Roughness	++	–	++	++	+++	–	+++	++	–	–	–	+++
Splitting	++	–	+++	–	–	++	–	+++	++	++	–	+++
Thickness of cast film (mm)	0.33	0.23	0.30	0.30	0.40	0.30	0.33	0.23	0.10	0.10	0.10	0.30
Weight gain (%)	23.64	21.62	25.15	22.63	18.24	23.64	18.24	22.63	23.64	20.13	22.63	25.10

Yes (+++), no (–), slight (++), very slight (+).

**Table 8** Evaluatory parameters for uncoated and selected coated tablets of DFS.

Parameters	Uncoated	F3B	F4E	F4	F3	F4C
Thickness (mm)	5.5	5.7	5.7	5.6	5.7	5.8
Cast film thickness	–	0.2	0.21	0.15	0.2	0.33
Weights (mg)	300.0	340.0	342.5	340.5	345.0	350.0
Diametral hardness (kg/cm <sup>2</sup> )	4.8	5.2	5.3	5.1	5.4	5.4
Friability (%)	0.34	0.03	0.10	0.08	0.06	0.04
Disintegration time	2 min 20 s	2 min 30 s	3 min 2 s	2 min 40 s	2 min 55 s	3 min 10 s
Weight gain (%)	0	13.33	14.16	13.5	15.0	16.66
Assay (%)	98.24	98.74	98.16	95.85	97.66	94.92

beam spectrophotometer (Elico, India) at 276 nm. The data for percent drug release was fitted for zero order equation. The

percent of drug release was determined as a function of time (Fig. 2).

### 2.10. Statistical analysis

The significance of difference between the dissolution of different studied formulations considering uncoated formulation as the standard was evaluated using the analysis of variance (ANOVA) followed by Dunnett multiple comparison test. The difference was considered significant at  $p \leq 0.01$ . These statistical calculation were performed using Graph pad Instant computer program (September 11, 2003; Graph Pad Software, San Diego, CA).

### 2.11. Fourier transform infrared spectra (FT-IR) (Ghosh et al., 2007; Wang et al., 2008)

Infrared spectra of the pure drug, uncoated DFS tablets and HPMC coated DFS tablets dispersed in KBr were recorded on a FT-IR spectrophotometer (Model-FT-IR 8400S, SHIMADZU, Japan). The disc method was employed to study the possible interactions between the drug and the selected polymer HPMC (5cPs). KBr (IR Grade) discs in a proportion of 1:100:sample:KBr, were prepared from the samples and eventually analyzed over a range of 400–4000  $\text{cm}^{-1}$ . Transmittance ( $T$ ) spectra were recorded and displayed in an overlay mode (Fig. 1).

### 2.12. Scanning electron microscopy

Tablet samples (F3B) were removed from dissolution apparatus at predetermined time intervals (0, 30 min, 1 h) and films were scrapped off by sectioning transversally from the concave face of the tablet. The specimen was then placed on a sample holder so as to present surface and cross sectional view of the tablet to the microscope. Samples were coated with gold

and visualized under scanning electron microscope (SEM) (JEOL, JSM 840A, Japan) (Fig. 3).

## 3. Results and discussion

The tablets were prepared in an environment free from organic solvents. From the results it can be stated that plasticizers like PEG-400 at 1.5% and PG at 1% have a significant effect on the film forming property of HPMC. The films formed with HPMC + PEG400 (1.5%) were free from major defects like cracking, orange peel, and picking with good gloss and very slight chipping and splitting occasionally (Mortada, 1990; James, 1997; Hossain and Ayers, 1990). In regard to HPMC + PG (1%) the resultant films were free from defects such as roughness, picking, orange peel and cracking, having good gloss and slight chipping. Uniformity in tablet weight gain and thickness of the film coat data obtained from cast film measurements are supportive for elegant film formation. The quality of aqueous film coat or the plasticizer efficiency in case of PEG-400 is in the order  $1.5 > 0.5 > 1.0\%$  and for PG  $1 > 4 > 3\%$ . This preliminary study infers that plasticizer significantly influences the quality of aqueous film coats. The best formulations (F3 and F4) are selected for further trials. Two surfactants of high HLB value namely SLS and Tween-80 were tried for bringing uniformity in the spreading efficiency on the substrate surface. It was found out that among the six formulations containing SLS, F3B (HPMC + PEG 1.5% + SLS 0.3%) yielded the most satisfactory result. The films were found to be free from blistering, blooming, chipping, cracking, picking, orange peel, roughness, splitting with uniform color distribution and good glossy appearance. On the other hand with the six formulations of Tween-80, F4E (HPMC + PG1.0% + Tween-80 0.3%) yielded the most satisfactory

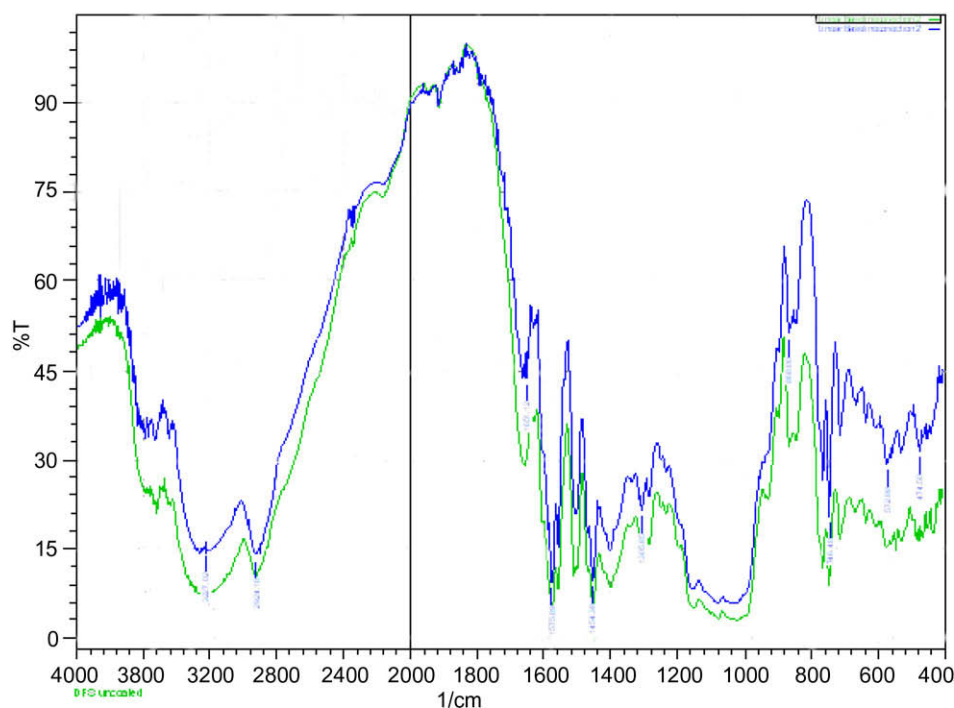
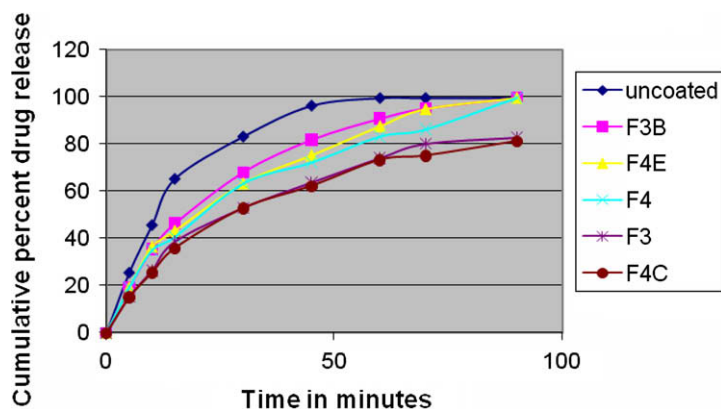
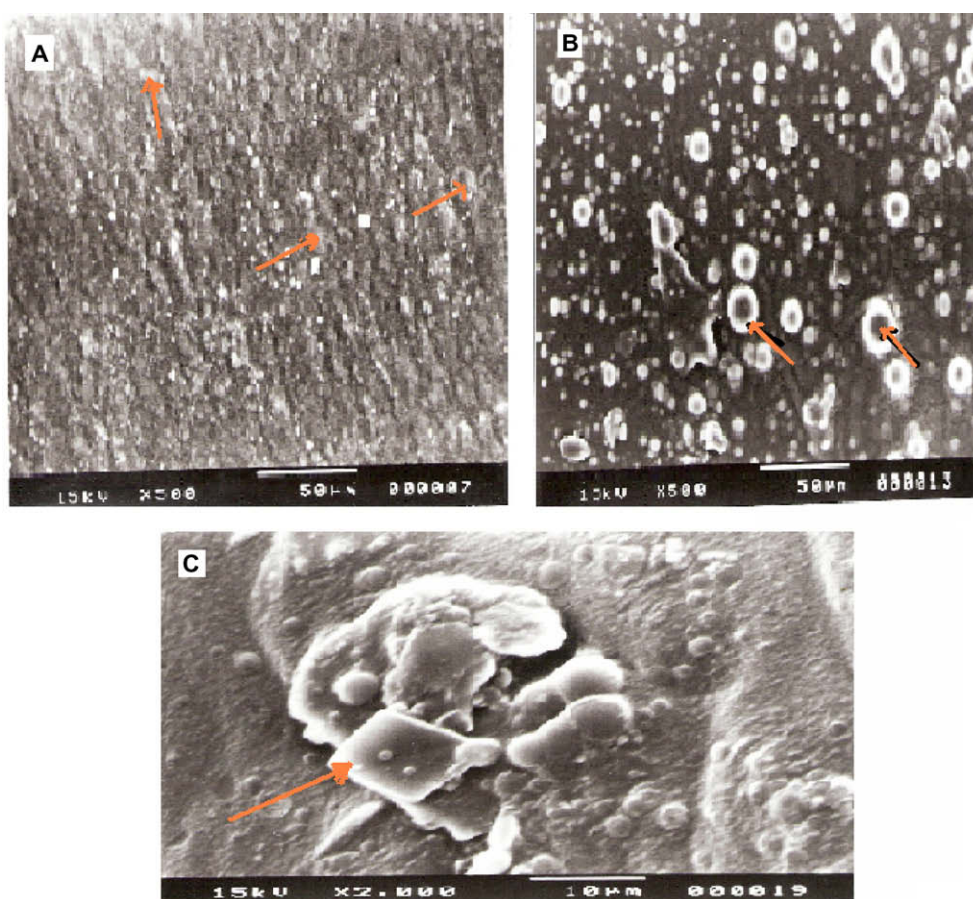


Figure 1 FT-IR overlay spectra of both coated and uncoated formulations of DFS.



**Figure 2** Dissolution profiles of coated and uncoated formulations of DFS in 0.1(N) HCl.



**Figure 3** Scanning Electron (SEM) photomicrographs of HPMC 5cPs coated DFS tablets (F3B) showing surface morphology after 0 h (A, 500 $\times$ ), 30 min (B, 500 $\times$ ), 30 min (C, 2000 $\times$ ) of dissolution study (in A and B, arrow indicates the formation of pores on coated surface, C indicates eruption and leaching of drug).

result. The films were found to be free from blistering, chipping, cracking, picking, orange peel, roughness, splitting with slight blooming, uniform color distribution and good glossy appearance. The quality of aqueous film coat or the surfactant efficiency in case of SLS + PEG-400 is in the order  $0.3 < 0.5 < 0.1\%$  and SLS + PG is in the order  $0.5 <$

$0.1 < 0.3\%$ . In case of Tween-80 + PEG-400 the order is  $0.3 < 0.5 < 0.1\%$  and Tween-80 + PG is in the order  $0.3 < 0.1 < 0.5\%$ . From this study it may be concluded that surfactants of high hydrophilic nature might be useful in improving the film coating liquid properties to achieve better spreading and resulting in better quality film coats.

The normal characterization of the granules like angle of repose, moisture content, and bulk density was found to be normal within the acceptable limits stated in Table 1. Evaluatory parameters of the coated tablets like thickness, weight, diametral hardness, and friability were found to be within the normal limits as stated in Table 8.

The total disintegration time of all the selected tablets was found to be within 2 min 30 s (F4B) to 3 min 30 s compared to the uncoated 2 min 20 s in 0.1(N) HCl. This suggests that there is no abnormality for the drug to disintegrate in its specified environment.

The *in vitro* release data of all formulations were fitted in zero order and the rate constants and correlation coefficient were compared to get a trend in the release pattern of the drug from the formulations. From Fig. 2 it is evident that the selected batches F4B and F4E predominantly shows a zero order profile releasing the DFS within 1 h 30 min which eventually satisfies the percentage release. The initial bursting effect of the film coats was obtained in between a time span of 5 min and leaching of the API was observed. The cumulative percent release within 5 min after examination was found out to be in the order F4B > F4E > F4 > F3 > F4C which suggests the proper functioning of the films.

From the infrared spectra Fig. 1 it is clearly evident that there were no interactions of the drug with the polymer. The main peaks in the spectrum of the drug DFS, both uncoated and coated does not show any substantial difference. The IR spectra show a peak at 746.18, which signifies the presence of N–H (rocking) functional group. A peak is also observed at 1651.12 wave number, which signifies the presence of C=C (stretch). Simultaneously a peak at 746.48 signifies the presence of C–Cl (stretch). All these peaks were observed at the fingerprint region of the FT-IR spectra. This proves the fact that there is no potential incompatibility of the drug with the polymer (HPMC 5cPs) used in the formulations. Hence, the formula for preparing DFS (25 mg) coated with HPMC 5cPs tablets can be reproduced in an industrial scale without any apprehension of possible drug–polymer interactions.

SEM study further confirmed the proper erosion and diffusion mechanisms to be operative during drug release from the optimized batch of HPMC 5cPs coated DFS tablet (F3B). SEM photomicro-graphs of the tablets at different time intervals after the dissolution experiment showed that tablets were intact and pores had formed through the surface (Fig. 3). Photomicrographs from SEM at definite time intervals 0, 30 min, (A, B) revealed pores with increasing diameter. The photomicro-graphs also revealed formation of gelling structure (C) indicating the possibility of swelling and eroding of the tablets.

#### 4. Executive summary

In conclusion, tablet coating films made of HPMC 5cPs with the addition of PEG at 1.5% and SLS at 0.3% and films made of HPMC 5cPs with PG at 1% and Tween-80 at 0.3% could be considered as an elegant film forming formulation for solving different coating problems generally faced in an industrial scale. The film coating formulations were entirely prepared in an aqueous environment avoiding the environmental unfriendly toxic hazards accompanied with organic solvents. These optimized formulations could be further developed in an industrial scale for the purpose of coating immediate release

formulations for those drugs whose integrity needs to be protected from sunlight, oxidations, moisture, thermolability and foreign microbial attack. The concept of  $R_x$  to OTC switch strategy (Moore, 2007; Rigato et al., 2009), for the proven safest salt of diclofenac can be eventually satisfied by the use of such selected formulations for the purpose of coating.

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## تأثير المدنات والفاعلات السطحية على الخواص المكونة لفيلم الهيدروكسي بروبيل ميثيل سليولوز لتغليف أقراص الدايكلوفيناك صوديوم

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### ملخص البحث

إن هيدروكسي بروبيل ميثيل سليولوز هو بوليمر ذائب في الماء تم استخدامه لتغليف أقراص دواء دايكلوفيناك صوديوم 25 مغ لحماية سلامة الدواء مع إطلاق الدواء بمعدل أسرع عند ملامسة البيئة المعوية. إن التهيئة الصحيحة لصيغة الغلاف الفيلمي المائي تم تنفيذها بشكل مبدئي باستخدام المدنات مثل بولي إيثيلين جليكول 400 وبروبيلين جليكول. وقد أخضعت الصيغ الخالية من العيوب لمزيد من الدراسة لمعرفة تأثيرات الفاعلات السطحية مثل كبريتات لاورايل الصوديوم وتوين 80 مع المدنات. إن جودة الأغلفة الفلمية المائية أو فاعلية المدن في حالة بولي إيثيلين جليكول 400 هي بالترتيب التالي  $1.5\% < 0.5\% < 1.0\%$  وفي حالة بروبيلين جليكول  $1\% < 4\% < 3\%$  والتي يمكن ذكرها على أساس قلة معدل حدوث العيوب الكبيرة للغلاف مثل التشققات، والتششير، والخشونة، والتحبب، والتزهير، والتفتت. كما أن جودة الغلاف الفيلمي المائي أو فاعلية الفاعلات السطحية في حالة كبريتات لاورايل الصوديوم مع بولي إيثيلين جليكول 400 هي بالترتيب  $0.3\% > 0.5\% > 0.1\%$  وفي حالة كبريتات لاورايل الصوديوم مع البروبيلين جليكول هي بالترتيب  $0.3\% > 0.5\% > 0.1\%$ . أما في حالة توين 80 مع بولي إيثيلين جليكول 400 فالترتيب هو  $0.3\% > 0.5\% > 0.1\%$  وفي حالة التوين 80 مع بروبيلين جليكول فالترتيب هو  $0.3\% > 0.1\% > 0.5\%$ . ويمكن معرفة تكوين الفيلم الأنقى من معدل حدوث عيوب أقل في التغليف. إن الأقراص المغلفة التي تم الحصول عليها قد استوفت كل البارامترات الفيزيائية الطبيعية مثل السماكة، والوزن، واكتساب الوزن، ومحتوى الدواء، وقوة السحق، ونسبة الهشاشة، وزمن التفتت، ومنحنى الذوبان، والتفاعل المحتمل للدواء والبوليمر. وقد تم إجراء اختبار أنوفا الإحصائي متبوعاً باختبار دانيت للمقارنات المتعددة لمنحنى الذوبان بالمقارنة مع الأقراص غير المغلفة. وقد أعتبر الفرق معنوياً عند  $p \leq 0.05$ .

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