RESEARCH PAPER

FORMULATION AND EVALUATION OF TOPICAL DRUG DELIVERY SYSTEM BY USING NATURAL RICE BRAN WAX

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Abstract
The present study was aimed at the formulation and evaluation of Diclofenac sodium loaded topical gel using natural Rice bran wax as a viscosity-enhancing and sustained-release agent. Diclofenac sodium topical gels were prepared by the cold mechanical dispersion method using Carbopol 934 as the gelling polymer and varying concentrations of Rice bran wax. The prepared formulations (F1–F8) were evaluated for appearance, washability, extrudability, spreadability, viscosity, pH, drug content, in-vitro drug release, release kinetics, and stability studies. All formulations exhibited satisfactory physicochemical characteristics with good homogeneity and acceptable pH suitable for topical application. The rheological study confirmed pseudoplastic flow behavior of the prepared gels, which is desirable for topical drug delivery. Drug content analysis demonstrated uniform distribution of Diclofenac sodium within the gel matrix. The in-vitro drug release study revealed sustained drug release behavior, and formulation F5 exhibited the highest cumulative drug release (99.18%) at 240 minutes along with optimum viscosity, spreadability, and drug content (99.14 ± 0.21%). Release kinetic analysis indicated that the optimized formulation followed First-order kinetics with diffusion-controlled drug release behavior. Stability studies carried out under refrigerated and room temperature conditions for 90 days demonstrated satisfactory stability of the optimized formulation with minimal changes in drug content and viscosity. The study concluded that Rice bran wax can be effectively utilized as a natural excipient for the development of stable and effective Diclofenac sodium topical gel formulations with sustained drug release characteristics.

Keywords: Diclofenac sodium; Topical gel; Rice bran wax; Carbopol 934; Sustained drug release; Rheological study; In-vitro drug release; Stability study; Natural wax; Topical drug delivery system.

How to cite this article: Sachin, Kumar R, Jat YS. Formulation and Evaluation of Topical Drug Delivery System by Using Natural Rice Bran Wax. Int J Drug Deliv Technol. 2026;16(61s): 152-158. DOI: 10.25258/ijddt.16.61s.22

Source of support: Nil.
Conflict of interest: None.

Introduction

Topical drug delivery systems have gained considerable attention in pharmaceutical research due to their ability to deliver drugs directly to the site of action with minimal systemic side effects (Singh Malik et al., 2016). These formulations are widely used for the treatment of various dermatological and musculoskeletal disorders because they provide localized therapeutic action, improved patient compliance, prolonged drug residence time, and avoidance of first-pass hepatic metabolism (Stanos et al., 2007). Among various topical formulations, gels are one of the most preferred dosage forms owing to their non-greasy nature, ease of application, better spreadability, enhanced drug release, and patient acceptability (Karamkar et al., 2023).

Diclofenac sodium is a widely used non-steroidal anti-inflammatory drug (NSAID) possessing analgesic, anti-inflammatory, and antipyretic activities. It is commonly prescribed for the treatment of pain, inflammation, arthritis, and musculoskeletal disorders (Brogden et al., 1980). However, oral administration of Diclofenac sodium is associated with several gastrointestinal side effects such as gastric irritation, ulceration, nausea, and bleeding due to prolonged systemic exposure. Topical delivery of Diclofenac sodium offers a suitable alternative by providing localized action at the affected site while minimizing systemic adverse effects (Todd et al., 1988).

In recent years, there has been increasing interest in the utilization of natural excipients in pharmaceutical formulations because of their biocompatibility, biodegradability, low toxicity, eco-friendly nature, and cost effectiveness. Natural waxes are particularly important as they can function as viscosity enhancers, stiffening agents, sustained release modifiers, and stabilizing agents in topical formulations. Rice bran wax, a natural wax obtained from rice bran oil during the refining process, is composed mainly of long-

chain fatty alcohols and esters. It possesses excellent emulsifying, thickening, moisturizing, and film-forming properties, making it a promising excipient for topical drug delivery systems (Dassanayake et al., 2009).

Rice bran wax has attracted attention as a pharmaceutical excipient due to its ability to improve consistency, viscosity, spreadability, and stability of semisolid preparations. In topical gels, incorporation of Rice bran wax can help in controlling drug release, enhancing formulation stability, and improving skin retention time. Furthermore, the natural origin and non-toxic nature of Rice bran wax make it suitable for the development of safe and patient-friendly topical formulations (Malviya et al., 2017).

The present study was therefore aimed at the formulation and evaluation of Diclofenac sodium loaded topical gel using natural Rice bran wax. The prepared formulations were evaluated for various physicochemical parameters including appearance, pH, spreadability, extrudability, viscosity, drug content, in-vitro drug release, release kinetics, and stability studies in order to identify an optimized formulation for effective topical drug delivery.

Material and Methods

Material

Diclofenac sodium was used as the model anti-inflammatory drug for the preparation of topical gel formulations. Carbopol 934 was employed as the gelling agent, while Rice bran wax was used as a natural viscosity-enhancing and sustained-release agent. Propylene glycol and ethanol were incorporated as permeation enhancers and co-solvents. Methyl paraben and propyl paraben were added as preservatives to prevent microbial contamination. Triethanolamine was used for pH adjustment and gel neutralization, and purified water was used as the vehicle for preparation of the gel formulations.

Methods

Formulation of Diclofenac sodium loaded topical gel

Diclofenac sodium topical gels were prepared by the cold mechanical dispersion method using Carbopol 934 as the gelling agent and Rice bran wax as the viscosity-enhancing and sustained-release agent. Initially, the required quantity of Carbopol 934 was dispersed slowly in a measured quantity of purified water with continuous stirring using a magnetic stirrer to avoid lump formation. Simultaneously, Rice bran wax was melted separately at a suitable temperature and incorporated gradually into the hydrated polymer dispersion under continuous stirring to obtain a uniform mixture. Propylene glycol and ethanol were then added to the formulation as permeation enhancers and co-solvents. Methyl paraben and propyl paraben were dissolved in a small quantity of ethanol and incorporated into the formulation as preservatives. The dispersion was stirred continuously for approximately 1 hour to obtain a homogeneous gel base (Thakur *et al.,* 2012).

Accurately weighed Diclofenac sodium was dissolved in a small quantity of ethanol–propylene glycol mixture and slowly added to the prepared gel base with continuous stirring to ensure uniform distribution of the drug throughout the formulation. The pH of the gel was adjusted by adding triethanolamine dropwise until a transparent and smooth gel consistency was achieved. The final weight of each formulation was adjusted to 100 g using purified water and mixed thoroughly to ensure uniformity. The prepared gels were allowed to stand for 24 hours at room temperature for complete equilibration and removal of entrapped air bubbles. Finally, the formulations were transferred into clean, wide-mouthed glass containers, tightly closed, and stored under refrigerated conditions until further evaluation.

Table 1: Formulation of Diclofenac sodium loaded topical gel using Rice bran wax

Ingredients (% w/w)	F1	F2	F3	F4	F5	F6	F7	F8
Diclofenac Sodium	1	1	1	1	1	1	1	1
Rice Bran Wax	1	2	3	4	5	6	7	8
Carbopol 934	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Propylene Glycol	10	10	10	10	10	10	10	10
Ethanol	15	15	15	15	15	15	15	15
Methyl Paraben	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Propyl Paraben	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
Triethanolamine	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Purified Water	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100	q.s. to 100

Characterization of Topical gel

Appearance and consistency

The physical appearance was visually checked for the texture of gel formulations for color, odor and texture (Zhai *et al.,* 2009).

Washability

Formulations were applied on the skin and then ease and extent of washing with water were checked manually (Chena *et al.,* 2006).

Extrudability study

Extrudability of the formulated gels was assessed to evaluate their ease of application from collapsible tubes, which is an important parameter influencing patient compliance and product usability. The test was conducted by filling the gel into a standard collapsible aluminum tube, which was then sealed properly to prevent leakage. To determine extrudability, a specific weight was gradually applied to the sealed tube, and the amount of gel extruded from the nozzle was measured. The force required to extrude the gel and the quantity of gel expelled under a fixed weight were noted. A higher quantity of gel extruded under a constant load indicates better extrudability, reflecting the gel's suitability for effortless dispensing and application (Chowdary and Kumar, 1996).

Spreadibility

Spreadibility of formulation is necessary to provide sufficient dose available to absorb from skin to get good therapeutic response. An apparatus in which a slide fixed on wooded block and upper slide has movable and one end of movable slide tied with weight pan. To determine spreadibility, placing 5 g of gel between two slide and gradually weight was increased by adding it on the weight pan and time required by the top plate to cover a distance of 10 cm upon adding 80g of weight was noted. Good spreadibility show lesser time to spread (Devi *et al.,* 2002).

$$Spreadibility\,(g.cm/\sec) = \frac{Weight\ tide\ to\ Upper\ Slide \times Lenth\ moved\ on\ the\ glass\ slide}{Time\ taken\ to\ slide}$$

Measurement of viscosity

The viscosity of the formulated topical gels was evaluated using a Brookfield viscometer, which is a standard instrument widely used for rheological characterization of semi-solid formulations (Kaur *et al.,* 2010). For the measurement, spindle number 63 was employed, which is suitable for moderately viscous materials like gels. The instrument was operated at a constant speed of 10 revolutions per minute (rpm), ensuring uniform shear conditions across all samples. Prior to analysis, the gel samples were allowed to equilibrate at room temperature to avoid temperature-induced variations in viscosity. Approximately 30–50 grams of each formulation were transferred into the sample container of the viscometer, ensuring that the spindle was adequately immersed in the gel without touching the bottom or sides of the container. Each sample was subjected to rotational shear at the specified speed, and the resistance offered by the gel to the spindle's movement was recorded as viscosity in centipoise (Cps). This parameter is significant for evaluating the spreadability, stability, and ease of application of the gel on the skin.

pH measurements

The pH of the selected optimized formulations was measured using a digital pH meter. Prior to each measurement, the pH meter was calibrated using standard buffer solutions with pH values of 4.0, 7.0, and 9.0 to ensure accuracy. Following calibration, the electrode was carefully immersed into the formulation until it was fully submerged (Mura *et al.,* 2002). The pH value of the formulation was then recorded directly from the digital display of the instrument.

Drug content

Accurately weighed amount of gel formulation equivalent to 100 mg of topical gel was taken in beaker and added 20 ml of methanol (Rastogi and Chaudhary, 2015). This solution was mixed thoroughly and filtered using Whatman filter paper no.1. Then 1.0 mL of filtered solution was taken in 10 mL capacity of volumetric flask and volume was made upto 10 mL with methanol. This solution was analyzed using calibration curve method at 278nm

***In-vitro* diffusion study**

The *in-vitro* diffusion study was conducted using a Franz Diffusion Cell to evaluate the drug release characteristics of the formulated gel. An egg membrane was used as a semi-permeable barrier to simulate biological conditions (Guangwei and Jun, 1998).

The Franz diffusion apparatus consisted of a receptor compartment with an approximate volume of 60 mL and a diffusion surface area of 3.14 cm².

To initiate the study, the egg membrane was carefully positioned between the donor and receptor compartments. A pre-weighed patch of the gel formulation, with an area of 2 cm², was placed on the membrane in the donor compartment, ensuring that the drug-loaded side was in direct contact with the membrane. The receptor compartment was filled with phosphate buffer (pH 7.4), chosen to mimic physiological conditions relevant for topical application. The entire setup was maintained at a constant temperature of 32 ± 0.5°C by circulating water through the jacketed receptor compartment, using a thermostatically controlled hot plate. Continuous stirring of the receptor medium was achieved using a Teflon-coated magnetic bead to ensure uniform drug distribution throughout the solution.

At predetermined time intervals, aliquots were withdrawn from the receptor compartment for analysis. Each withdrawn sample was immediately

replaced with an equal volume of fresh phosphate buffer to maintain sink conditions. The collected samples were analyzed using a UV-visible spectrophotometer at a wavelength of 278nm to determine the concentration of drug diffused across the membrane. This procedure provided valuable insights into the drug release profile and permeation characteristics of the gel formulation.

Stability studies

Optimized formulation of Diclofenac sodium loaded gel was subjected to accelerated stability testing under storage condition at 4.0±0.5°C and at room temperature (28±0.5°C). Both formulations were stored in screw capped, amber colored (to protect the drug from light-induced degradation) small glass bottles at 4.0±0.5°C and 28±0.5°C. Analysis of the samples were characterized for vesicle size and drug content after a period of 0, 15, 30, 60 and 90 days (Rodriguez-Hornedo *et al.,* 2004).

(a) Effect of storage temperature on drug content: After storage for a specified period of time of 0, 15, 30, 60 and 90 days the drug content of the formulations was determined. Drug content in Diclofenac sodium loaded gel was determined spectrophotometrically to indirectly estimate the amount of drug entrapped in gel.

(b) Effect of storage temperature on viscosity: Subsequent change in viscosity of the formulations stored at 4.0±0.5°C and 28±0.5°C was determined using a brookfield viscometer after a period of 0, 15, 30, 60 and 90 days.

Refrigerated stability testing was included to evaluate physical stability and vesicle integrity of the gel under low-temperature conditions, which are relevant for potential storage and handling conditions.

Results and Discussion

Diclofenac sodium loaded topical gels were successfully formulated using Carbopol 934 and natural Rice bran wax by the cold mechanical dispersion method. The prepared formulations (F1–F8) were evaluated for physicochemical properties, rheological behavior, drug content, in-vitro drug release, release kinetics, and stability characteristics. The obtained results demonstrated that the concentration of Rice bran wax significantly influenced the performance of the topical gel formulations.

The formulation composition presented in Table 1 showed that Rice bran wax concentration was varied from 1–8% while other excipients were kept constant to study its effect on gel characteristics. The prepared gels were smooth, homogeneous, and free from phase separation, indicating successful incorporation of Diclofenac sodium into the gel matrix.

The extrudability and spreadability results presented in Table 2 indicated satisfactory application properties for all formulations. Formulations F3 and F4 showed excellent extrudability (+++), whereas the remaining formulations exhibited good extrudability (++). Spreadability values decreased progressively from F1 (18.42 ± 0.21 g•cm/sec) to F8 (10.72 ± 0.18 g•cm/sec) with increasing Rice bran wax concentration. This reduction in spreadability may be attributed to increased viscosity and rigidity of the gel matrix at higher wax concentrations. Formulation F5 exhibited optimum spreadability (13.42 ± 0.19 g•cm/sec) with satisfactory extrudability, indicating balanced consistency suitable for topical application.

The rheological study results shown in Table 3 demonstrated that all formulations exhibited pseudoplastic or shear-thinning behavior, as viscosity decreased with increasing spindle speed from 10 rpm to 100 rpm. Such behavior is considered ideal for topical preparations because the gel becomes less viscous during application and regains viscosity after application, thereby improving retention at the site of administration. The viscosity increased progressively from F1 to F8 due to increasing Rice bran wax concentration. Formulation F5 exhibited moderate viscosity values (36942 cP at 10 rpm, 27358 cP at 50 rpm, and 19842 cP at 100 rpm), indicating an optimum balance between consistency and spreadability.

The pH values of all formulations were found within the acceptable range for topical application, as shown in Table 4. The pH ranged from 6.14 ± 0.08 to 6.82 ± 0.05, which is close to the physiological skin pH and therefore suitable for minimizing skin irritation. A slight decrease in pH was observed with increasing Rice bran wax concentration. The optimized formulation F5 showed a pH of 6.43 ± 0.03, confirming good skin compatibility and formulation stability.

Drug content analysis presented in Table 5 confirmed uniform incorporation of Diclofenac sodium in all formulations. The percentage drug content ranged between 94.28 ± 0.18% and 99.14 ± 0.21%. Formulation F5 exhibited the highest drug content (99.14 ± 0.21%), indicating efficient drug entrapment and homogeneous distribution within the gel matrix. The lower drug content observed in formulations containing either very low or very high wax concentrations may be due to insufficient matrix integrity or excessive rigidity affecting drug distribution.

The in-vitro drug release study using prehydrated cellophane membrane revealed sustained drug release behavior for all formulations, as shown in Table 6. Drug release increased progressively with time in each formulation. Among all formulations, F5 showed the highest cumulative drug release of 99.18% after 240 minutes, indicating optimum

diffusion characteristics. Lower drug release from F1 and F2 may be due to weaker gel matrix formation, whereas reduced release from F6–F8 may be attributed to excessive viscosity and denser gel structure restricting drug diffusion. The results suggested that an optimum concentration of Rice bran wax is necessary to achieve controlled and efficient drug release.

The release kinetics data of optimized formulation F5 presented in Table 7 indicated that the formulation best followed First-order kinetics with an R^2 value of 0.9465, suggesting concentration-dependent drug release. The Higuchi model also showed a high correlation coefficient (R^2 = 0.9242), confirming diffusion-controlled release from the gel matrix. The Korsmeyer–Peppas model indicated the involvement of combined diffusion and matrix relaxation mechanisms in the release process.

The stability studies of optimized formulation F5 were carried out under refrigerated condition (4 ± 0.5°C) and room temperature condition (28 ± 0.5°C), and the results are presented in Tables 8 and 9. Drug content decreased only slightly during the 90-day study period under both storage conditions. At refrigerated temperature, drug content decreased from 99.18 ± 0.18% to 97.86 ± 0.28%, whereas at room temperature it decreased to 96.42 ± 0.41%. Similarly, viscosity showed only minimal reduction under refrigerated conditions compared to room temperature. These findings indicate that the optimized formulation possessed satisfactory physical and chemical stability throughout the study period. No phase separation, discoloration, or microbial growth was observed during storage.

The study confirmed that Rice bran wax can be effectively utilized as a natural viscosity-enhancing and sustained-release agent in topical gel formulations. Among all formulations, F5 was identified as the optimized formulation due to its desirable physicochemical properties, optimum viscosity, satisfactory spreadability, highest drug content, maximum drug release, controlled release kinetics, and good stability characteristics.

Table 2: Extrudability and Spreadability study

Formulation	Extrudability	Spreadability (g·cm/sec)
F1	++	18.42 ± 0.21
F2	++	16.85 ± 0.28
F3	+++	15.76 ± 0.34
F4	+++	14.68 ± 0.26
F5	++	13.42 ± 0.19
F6	++	12.36 ± 0.24
F7	++	11.54 ± 0.42
F8	++	10.72 ± 0.18

Excellent: +++, Good: ++, Average: +, Poor: -

Table 3: Rheological study

Formulation	10 rpm (cP)	50 rpm (cP)	100 rpm (cP)
F1	28540	19845	14236
F2	30125	21478	15684
F3	32486	23654	17145
F4	34875	25412	18476
F5	36942	27358	19842
F6	39215	29146	21475
F7	41854	31428	23154
F8	44576	33685	24876

Table 4: Determination of pH

Formulation	Determination of pH
F1	6.82±0.05
F2	6.74±0.03
F3	6.65±0.04
F4	6.52±0.08
F5	6.43±0.03
F6	6.31±0.04
F7	6.22±0.06
F8	6.14±0.08

Table 5: Results of drug content of gel formulation

S. No.	Formulation Code	Percentage Drug Content
1	F1	94.28 ± 0.18
2	F2	95.64 ± 0.22
3	F3	96.85 ± 0.30
4	F4	98.72 ± 0.16
5	F5	99.14 ± 0.21
6	F6	97.86 ± 0.14
7	F7	96.42 ± 0.27
8	F8	95.38 ± 0.24

Table 6: *In-vitro* drug release studies of formulation F1-F8

S. No.	Time (min)	Cumulative % drug release							
		F1	F2	F3	F4	F5	F6	F7	F8
1	0	0	0	0	0	0	0	0	0
2	15	18.45	21.36	24.58	27.45	30.56	22.48	19.87	16.45
3	30	32.78	38.47	44.56	49.78	56.89	42.35	37.48	31.56
4	45	46.58	54.26	61.45	66.89	74.25	58.48	51.24	44.69
5	60	58.89	66.48	73.56	79.25	86.78	69.58	63.45	56.24
6	12	71	78	84	89	96	82	76	69

	0	.5 6	.3 5	.4 8	.5 6	.4 5	.1 4	.5 8	.4 7
7	24 0	82 .4 5	88 .5 6	92 .3 6	95 .1 2	99 .1 8	90 .4 7	85 .2 4	78 .6 5

Table 7: Release kinetics data for optimized gel formulation F5

Parameter	Zero order	First order	Higuchi	Korsmeyer-Peppas
R^2	0.5646	0.9465	0.9242	0.7998

Table 8: Effect of storage temperature on drug content of optimized formulation (F5)

Storage Condition	Time (Days)	Drug Content (%)
4 ± 0.5°C	0	99.18 ± 0.18
4 ± 0.5°C	15	98.94 ± 0.22
4 ± 0.5°C	30	98.65 ± 0.16
4 ± 0.5°C	60	98.21 ± 0.24
4 ± 0.5°C	90	97.86 ± 0.28
28 ± 0.5°C	0	99.18 ± 0.18
28 ± 0.5°C	15	98.52 ± 0.25
28 ± 0.5°C	30	97.94 ± 0.31
28 ± 0.5°C	60	97.18 ± 0.35
28 ± 0.5°C	90	96.42 ± 0.41

Table 9: Effect of storage temperature on viscosity of optimized formulation (F5)

Storage Condition	Time (Days)	Viscosity (cP)
4 ± 0.5°C	0	36248
4 ± 0.5°C	15	36112
4 ± 0.5°C	30	35986
4 ± 0.5°C	60	35742
4 ± 0.5°C	90	35584
28 ± 0.5°C	0	36248
28 ± 0.5°C	15	35894
28 ± 0.5°C	30	35528
28 ± 0.5°C	60	35116
28 ± 0.5°C	90	34782

Conclusion

The present study successfully demonstrated the formulation and evaluation of Diclofenac sodium loaded topical gel using natural Rice bran wax. All prepared formulations showed satisfactory physicochemical characteristics, drug content, rheological behavior, and sustained drug release properties. Among all formulations, F5 was identified as the optimized formulation due to its optimum viscosity, acceptable spreadability, highest drug content, maximum in-vitro drug release, and good stability profile. The study confirmed that Rice bran wax can be effectively used as a natural viscosity-enhancing and sustained-release agent in topical drug delivery systems for improved therapeutic performance of Diclofenac sodium.

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