**RESEARCH ARTICLE**

# Isolation and Characterization of Disintegrant Property of *Dioscorea alata* Starch Based Emulgel Formulations

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**ABSTRACT**

The present study aimed to isolate and characterize starch extracted from *Dioscorea alata* (purple yam) tubers and evaluate its potential as a disintegrant in an emulgel formulation using diclofenac as model drug. Starch was extracted using a wet extraction method, and its physicochemical properties, including micromeritics were performed as per standard procedures the starch was found to have excellent. Five starch-based Pickering emulgel was formulated using soy oil, Tween 80, deionized water, Carbopol 934, and starch isolated from the rhizomes of *Dioscorea alata* as an adjuvant. The isolated starch was incorporated at varying concentrations to assess its impact on emulgel characteristics. Formulations exhibited high spreadability (11.54–15.15 g·cm/s), with increased viscosity observed in those containing 5% and 7.5% starch compared to lower concentrations. Microscopic analysis revealed smaller globule sizes in starch-based emulgels relative to starch-free counterparts. Rheological studies showed that apparent viscosity decreased with rising temperature and increased with rising pH. *In vitro* release studies confirmed a marked disintegrant property of starch at both pH 5.5 and 7.2, with significantly enhanced drug release from starch-containing formulations. These findings highlight the potential of *Dioscorea alata* starch as a functional excipient in emulgel systems for topical and rectal drug delivery.

**Keyword:** Dioscorea starch, emulgel, disintegrant, viscosity, globule size

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## INTRODUCTION

For a number of years, natural starches have been used in industries for development of traditional and novel oral and topical drug delivery systems. It has been traditionally used as diluent, binder and disintegrant in oral formulations while base and stabilizer for powders, pastes and microsponge based topical drug delivery systems[1]. Emulgel formulations incorporate the two properties of emulsion and gel, which has resulted in the attention of pharmaceutical and cosmetic researchers, as these formulations have the opportunity for either controlled or targeted delivery of active ingredients[2]. Disintegrants can greatly affect the bioavailability and release profile of active ingredients in the formulations, which administers a drug, and facilitates the effective release of the drug in topical and transdermal therapies. Disintegrants facilitate the disaggregation and dispersive concentration of emulsions and gels as they come in interaction with physiological fluids[3].

*Dioscorea alata* (water yam), is an edible or tuberous plant with several pharmacological properties and could serve as a form of natural excipient in pharmaceutical formulation. *Dioscorea alata* starch has gained attention among the range of starches in consideration of certain physicochemical properties; high amylose, swelling capacity and gel-forming ability, making it a potential disintegrate in emulgel formulations. Furthermore, using *Dioscorea alata* starch as a natural polymer can be advantageous for pharmaceutical formulation due to its high biocompatibility, biodegradability, and lower toxicity levels compared to synthetics. The use of Dioscorea in the development of new products or modifications too can develop products for sustainable and patient-friendly line[4,5]. The goal of this study is to isolate and characterize the disintegrant properties of *Dioscorea alata* starch, while also evaluating its utility in emulgel systems. This study aims to provide an exhaustive characterization of the starch's physical and chemical properties including swelling index, particle size, solubility, and its ability to allow the disintegration of active pharmaceutical ingredients (APIs) from emulgel systems. In this manuscript, the method of preparing *Dioscorea alata* starch based emulgel formulations, their performance in comparison to emulgel systems using synthetic disintegrants will also be assessed[6-8].

This study hopes to contribute to the development of the topical drug delivery field using *Dioscorea alata* starch, through emulgel formulations that increases drug release properties, stability, and patient compliance. Overall, this study hopes to provide more information on formulation approaches and therapeutic aspects of *Dioscorea alata* starch based emulgel systems.

## MATERIAL AND METHODS

*Materials*

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The procurement of authenticated Dioscorea rhizome was done from the West Bengal Medicinal Plant Board. Throughout the whole study, the analytical grade materials were used which were procured from Loba Chemie and SRL Labs. The various solutions were prepared by using distilled water.

*Extraction of Starch*

Rhizhomes of Dioscorea (IDS) were collected and washed with thoroughly with distilled water, peeled and cut in small pieces. Then rhizhomes were soaked overnight in distilled water and were grinded. The slurry obtained was kept for 48 h at room temperature in 0.1N NaOH solution. After 24 h, the obtained slurry was cleaned with distilled water several times till the floating fluid becomes clear. The obtained slurry was passed through a muslin cloth to eliminate all pulpy material and an off white suspension filtrate was procured. The suspension of starch was permitted for settling down and slowly the top layer of supernatant was decanted. Thus, the obtained sediments of deposited starch was dried till 48 h in hot air oven at 50 °C. Ultimately the dried starch was tightly filled up in airtight PET bag and its yield was calculated in percentage[9,10].

*Physicochemical Properties of Starch*

*Flow Property*

*Apparent Density (Bulk) and Tapped Density*

A 10 g quantity of the powdered sample was carefully transferred into a dry 100 mL graduated measuring cylinder to determine the bulk volume ($V_0$), recorded without applying any tapping. The cylinder was then manually tapped 100 times, after which the final volume ($V_f$) was noted. Using the ratio of the sample weight to the respective volumes, the bulk density ($\rho_b$) and tapped density ($\rho_f$) were calculated accordingly[11].

*Powder Compressibility Measure*

Hausner's ratio (HR) and Carr's compressibility index (CI) were calculated to assess the flowability and compressibility characteristics of the powder[12]. Hausner's ratio (HR) and Carr's index (CI) can be determined by,

Table 1: Composition of starch based emulgel formulations

| Ingredients | F1 | F2 | F3 | F4 | F5 |
|---|---|---|---|---|---|
| Diclofenac Sodium (%w/v) | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |
| IDS Starch (%w/v) | 1 | 2.5 | 5 | 7.5 | 0 |
| Soy Oil (%w/v) | 20 | 20 | 20 | 20 | 20 |
| Tween 80 (%w/v) | 12 | 12 | 12 | 12 | 12 |
| Carbopol 934 (%w/v) | 1 | 1 | 1 | 1 | 1 |
| Deionised Water | qs. | qs. | qs. | qs. | qs. |

Table 2: Physicochemical properties of isolated IDS starch sample

| Sample | Carr's Index (%) | Hausner's Ratio | Angle of Repose (°) | Moisture content |
|---|---|---|---|---|
| IDS Sample | 1.09 ± 0.08 | 9.49 ± 0.32 | 34.76 ± 0.18 | 4.82 ± 0.72% |

$$HR = \rho\ tapped\ /\ \rho\ bulk \quad (4)$$

$$CI = [\ \rho\ tapped\ -\ \rho\ bulk\ /\ \rho\ tapped\ ] \times 100 \quad (5)$$

*Angle of Repose*

The angle of repose (θ) of native Chapparada Avare starch (NPL) and pregelatinized starches was established by a funnel and cone procedure. The sample of powder was passed via funnel till the funnel tip touches the tip of the powder heap (h). The diameter (D) is determined by base of powder heap, r is radius of base of powder heap[13]. And the angle of repose can be established by following formula,

$\Theta = \tan^{-1}(h/r)$

*Moisture Content*

A samples of IDS starch powder (1 g) were dried in an oven (Remi RDHO50, Remi, India) a 90°C for 2 h. Moisture content was calculated as percentage loss in weight[14].

*Formulation of Pickering Emulgels*

5 formulations different concentration of IDS starch (0%, 1% w/v, 2.5% w/v, 5% w/v and 7.5%w/v) along with Tween 80, Soy oil and Carbopol was used in preparation of emulgel as mentioned in the Table 1.

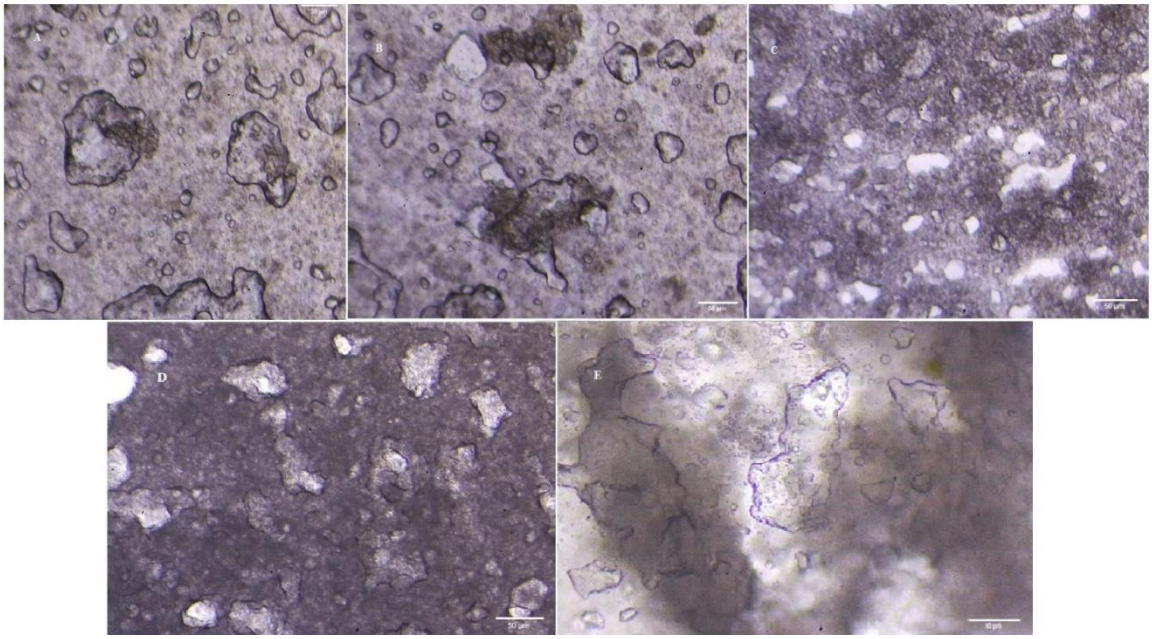


Figure 1: Microscopic observation of gels: (A) F1; (B) F2; (C) F3; (D) F4; (E) F5 (Scale bar represents 50 µm)

Table 3: Physical evaluation of the emulgel

| | F1 | F2 | F3 | F4 | F5 |
|---|---|---|---|---|---|
| Odour | Characteristic | Characteristic | Characteristic | Characteristic | Characteristic |
| Color | Opal white | Opal white | Opal white | Opal white | Block white |
| Stickiness | Non Sticky | Non Sticky | Non Sticky | Non Sticky | Partially Sticky |
| Spreadability (g.cm/s) | 15.15 | 14.32 | 12.78 | 11.54 | 11.87 |
| Stability | Shelf stable for 90 days | Shelf stable for 90 days | Shelf stable for 90 days | Shelf stable for 90 days | Shelf stable for 90 days |

Table 4: *In-vitro* drug release kinetics studies of prepared emulgel formulations in pH 7.2

| Formu-lations | First Order | Zero Order | Higuchi | Korsemayer Peppas | | Hixon-Crowell |
|---|---|---|---|---|---|---|
| | ($r^2$) | ($r^2$) | ($r^2$) | ($r^2$) | (n) | ($r^2$) |
| F1 | 0.9978 | 0.9985 | 0.9417 | 0.6427 | 0.813 | 0.9936 |
| F2 | 0.9883 | 0.9999 | 0.9015 | 0.683 | 0.836 | 0.9952 |
| F3 | 0.9824 | 0.9997 | 0.8969 | 0.6816 | 0.891 | 0.9913 |
| F4 | 0.9594 | 0.9953 | 0.8836 | 0.6761 | 0.882 | 0.9762 |
| F5 | 0.9637 | 0.9772 | 0.9604 | 0.6145 | 0.535 | 0.9732 |

Table 5: *In-vitro* drug release kinetics studies of prepared emulgel formulations in pH 5.5

| Formu-lations | First Order | Zero Order | Higuchi | Korsemayer Peppas | | Hixon-Crowell |
|---|---|---|---|---|---|---|
| | ($r^2$) | ($r^2$) | ($r^2$) | ($r^2$) | (n) | ($r^2$) |
| F1 | 0.9914 | 0.9935 | 0.9139 | 0.5135 | 0.791 | 0.9929 |
| F2 | 0.9906 | 0.9981 | 0.9099 | 0.5151 | 0.803 | 0.9951 |
| F3 | 0.9892 | 0.9986 | 0.9155 | 0.5127 | 0.852 | 0.9949 |
| F4 | 0.9852 | 0.9985 | 0.912 | 0.5146 | 0.857 | 0.9926 |
| F5 | 0.8846 | 0.9743 | 0.8957 | 0.2465 | 0.476 | 0.8943 |

The emulgel formulation was prepared in a stepwise manner. Initially, the gel base was formed by dispersing Carbopol 934 in distilled water preheated to 80 °C, followed by cooling the dispersion to ambient temperature. The oil phase was prepared by dissolving Tween 80 in light soy oil, into which diclofenac (1% w/v), pre-dissolved in ethanol, was incorporated. The aqueous phase consisted of purified water blended with varying concentrations of starches, along with methyl paraben dissolved in propylene glycol. Both the oil and aqueous phases were individually heated to 70 ℃ and then combined by gradually adding the oil phase into the aqueous phase under continuous stirring. The resulting emulsion was allowed to cool to room temperature. Subsequently, this emulsion was blended with the gel base in a 1:1 ratio using gentle stirring to obtain the final emulgel. The pH of the formulation was then adjusted to 5.5 using triethanolamine[15,16].

*Evaluation of the Pickering Emulgels*

*Organoleptic Features*

The prepared starch based emulgel formulations were inspected visually for their appearance and consistency, while for colour was inspected using Color Grab software under normal lighting condition[17,18].

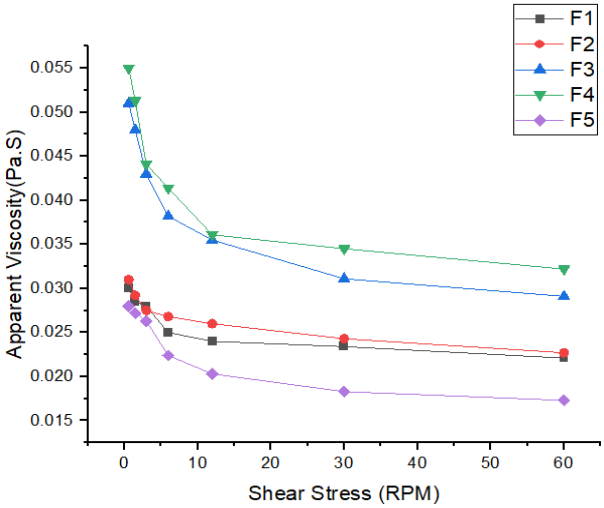


Figure 2: Apparent viscosity of the emulgel formulations

*Spreadability*

Spreadability was evaluated by placing an excess amount of the formulation between two glass slides, which were then compressed to a uniform thickness using a 1 kg weight for 5 minutes. Following this, a 50 g weight was carefully placed on the upper slide. The time taken for the upper slide to move over the lower one under the influence of the applied weight was recorded. This duration was used as an indicator of the spreadability (S) of the formulation.

(S) =M×L/T

Where M = weight tide to upper slide, L = length moved on the glass slide, T= time taken

*Microscopic Feature of the Emulgels*

The microscopic features of emulgel was observed under compound microscope fitted with 5MP camera (Quasmo C26, Quasmo, India) fitted with Future Winjoe software. The emulgel were spread on a glass slide and their photographs were taken through the software[19,20].

*Viscosity*

The viscosity of the formulated emulgel batches was measured using a Brookfield viscometer equipped with spindle number 63 (Brookfield Engineering Laboratories). The instrument was connected to a thermostatically regulated circulating water bath maintained at 25 ℃ to ensure consistent temperature conditions. The spindle was gently immersed into the emulgel, allowing it to rotate freely, and the corresponding viscosity readings were recorded[21].

*Temperature and pH Swipe*

The study was conducted in two steps, firstly all batches of emulgel formulations were stored in different temperatures (10 to 50 °C) and viscosity of each batches were measured by drum viscometer with spindle 63 (Brookfield Engineering Laboratories) with no thermostatic control attached. Secondly, a similar study involving swipe of pH (4.0 -9.0) on each batch of emulgel was performed and their viscosity was measured using drum viscometer (Brookfield Engineering Laboratories). In this case assembly was thermostatically controlled circulating water bath maintained at 25 ℃ with spindle 63 was the choice for the experiment[22,23].

*In-vitro Release Study*

*In vitro* drug release studies were carried out using a USP Type II dissolution apparatus (LabIndia DS8000, India) equipped with pretreated cellulose membranes (Hi-Media, molecular weight cut-off <15,000 Da). Appropriately sized membranes were secured in the buffer compartments using nylon threads. The dissolution was conducted in 500 mL of phosphate-buffered saline (pH 7.4) maintained at $37 \pm 0.5$ °C, with the paddle rotating at 50 rpm. At predetermined time intervals, 5 mL samples were withdrawn and immediately replaced with an equal volume of fresh buffer to maintain sink conditions and constant volume. The collected samples were filtered and analyzed at 280 nm using a UV–Visible spectrophotometer (Shimadzu i1900, Japan). Drug concentrations were determined based on a pre-established calibration curve,

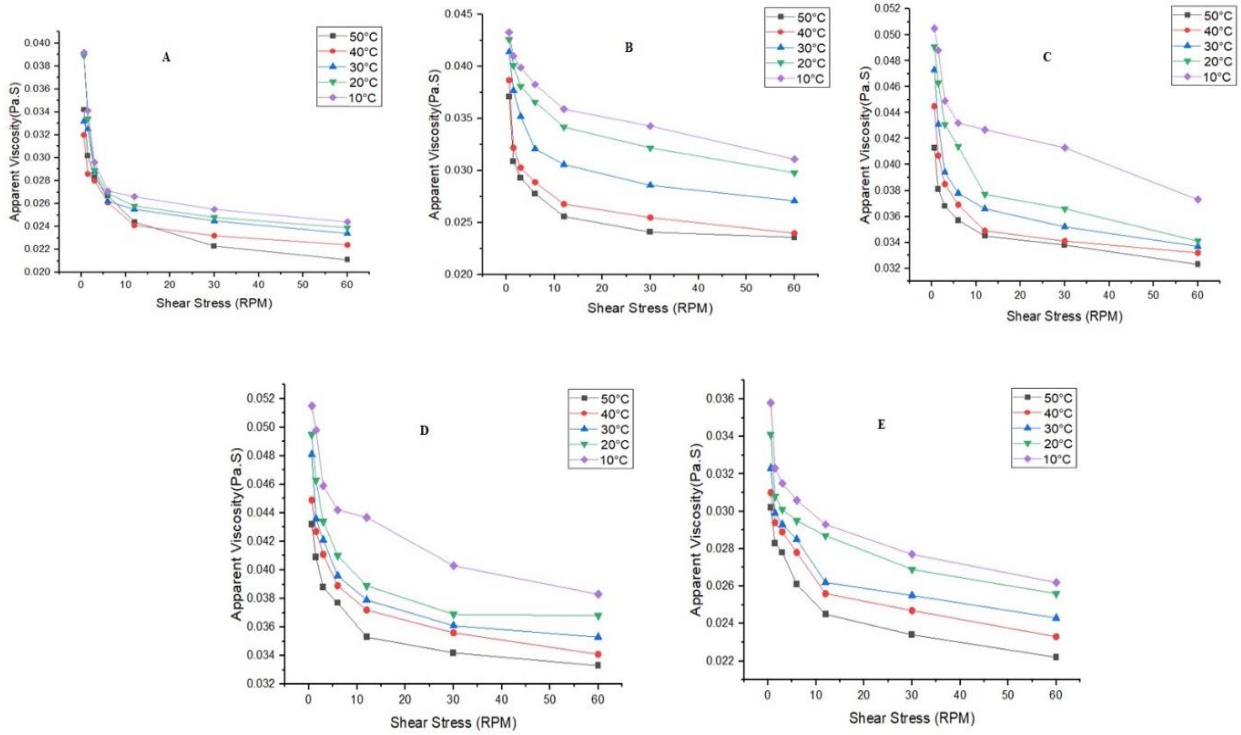


Figure 3: Temperature swipe of the emulgel formulations: (A) F1; (B) F2; (C) F3; (D) F4; (E) F5

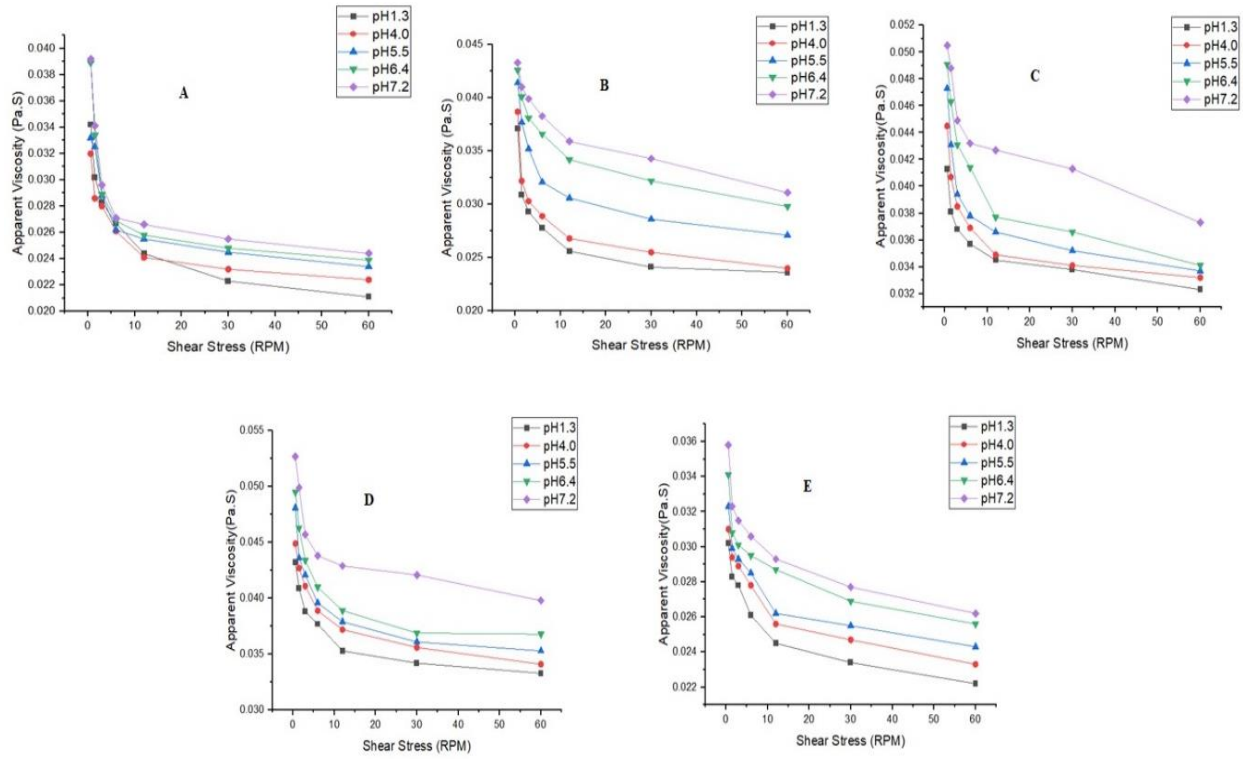


Figure 4: pH swipe of the emulgel formulations: (A) F1; (B) F2; (C) F3; (D) F4; (E) F5

and the release profiles of various emulgel formulations were plotted as drug concentration versus time[24].

*Drug Release Kinetics*

The *in vitro* drug release data from the Pickering emulgel formulations were analyzed using various mathematical models to determine the release kinetics. These included zero-order, first-order, Higuchi, Hixson–Crowell, and Korsmeyer–Peppas models. The model that exhibited the highest correlation coefficient ($r^2$) was considered to best describe the drug release behavior[25].

*Statistical Analysis*

The values are expressed as the mean ± standard error of the mean.

## RESULTS AND DISCUSSIONS

*% Yield of Starches*

The yield of the starch was determined to be 18.23± 0.61% which is well within the range of yield mentioned by Ezeocha and Okafor in 2016[26].

*Physicochemical Properties*

Evaluations of micromeritic properties of native IDS starch are present in Table 2. The starch sample was found to be having excellent flow property with Carr's Index below 1.1 % and Hausner's Ratio below 10. However, the angle of repose (34.76±0.18º) was found to be in the good flow range (31-35º). The higher angle of repose may be attributed to the higher moisture content in the native starch (4.82±0.72%), which creates cohesive force among the starch particle thereby restricting the total flow. The higher moisture content may also indicate higher water holding capacity which further can be utilized in formulation of sustained release in oral or topical forms[27].

*Evaluation of Pickering Emulgel*

All the emulgel formulations were found to pearl white color in appearance with characteristic smell and was non sticky in nature. The spread-ability decreased from 15.15 g.cm/s to 11.54g.cm/s with the increase in the amount of starch from F1 to F5 with the least amount found in F4. All formulations were found to be shelf stable for more than 90 days in closed containers indicating highly stable formulation[28].

Microscopic evaluation of the emulgel serves as a vital technique for confirming the formation of a starch-stabilized emulsion within the gel matrix, as indicated by the presence of irregularly distributed internal phase globules. This observation validates the effectiveness of the preparation method employed. Furthermore, globule size plays a significant role in predicting the long-term physical stability of the formulation. Any variation in globule diameter can signal potential instability, such as coalescence or phase separation.

Microscopic analysis was carried out to assess the globule size distribution of the emulgel formulations. Panels A–D in Figure 1 illustrate the average globule diameters of starch-containing formulations, which ranged from 45.13 ± 0.21 µm to 54.88 ± 0.43 µm. In contrast, panel E shows a starch-free formulation with a considerably larger mean globule diameter of 75.36 ± 0.88 µm. These results suggest that starch effectively adsorbs at the oil–water interface, forming a robust interfacial film that prevents coalescence, thereby producing smaller and more stable droplets. Modified starches may further enhance this stabilization due to their tailored hydrophobic–hydrophilic balance[29].

Viscosities of the four-starch based emulgel formulations are shown in Fig 2, the results showed that the emulgel formulations prepared using higher percentage of starch (F3 and F4) have shown higher viscosity as compared to lower starch-based formulation (F1 and F2) and no starch formulation F5. This is in line to the opinion of Singh et al., additive accumulation strengthen the viscous nature of emulsion. Migration of other long chain stabilizers into glucan bonds in amylose and amylopectin increases the molecular weight of the additives thereby increases the viscosity value. Fig.4. show the rheogram starch based emulgel containing carbopol soy oil and Tween 80. As represented in the figure, all the prepared emulgel exhibited a shear- thinning behavior as the viscosity decreased by increasing the shear rate[30].

The viscosity study of optimized formulations at different temperature (10°C, 20°C, 30°C,40°C, 50°C) and pH (pH 1.5, 4.0, 5.5, 6.8, and 7.4) conditions. The rheological property showed that with increasing temperature there is a slight decrease in viscosity for each F1-F5 formulation and can be well observable in F3 and F4 with maximum amount of decrease in viscosity as observable in Fig. 3[31]. The viscosity of emulgel typically decreases with increasing temperature due to increased thermal movement of starch

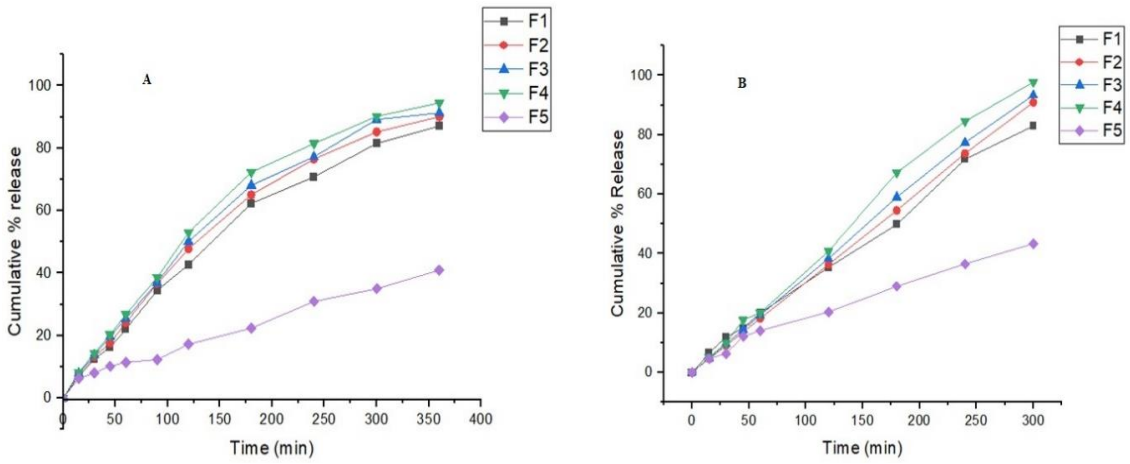


Figure 5: *In vitro* drug release studies of the emulgel formulations: (A) in pH 7.2; (B) in pH 5.5

molecules and the breaking of intermolecular forces, such as hydrogen bonds, within the gel structure. An opposite trend was observed for pH ranges with increasing pH, the viscosity tends to increase with higher rate. This may be due to the effect of pH on emulgel viscosity depends on the gelling agent (Carbopol 934) used. For most common gelling agents including Carbopol, increasing pH (making it more alkaline, typically towards pH 6-7) causes the polymer chains to uncoil due to electrostatic repulsion, leading to increased viscosity[32].

*In-vitro Dissolution Studies*

The release profile of the active pharmaceutical ingredient from the emulgel formulations was found to be influenced by the concentration of starch. At pH 5.5, the drug release followed the order: F5 < F1 < F2 < F3 < F4, with respective release percentages after 3 hours recorded as 43.34%, 82.98%, 90.90%, 93.33%, and 97.74%. A similar trend was observed at pH 7.4, where the corresponding drug release values were 40.94%, 87.08%, 90.08%, 91.28%, and 94.48%. The gradual increase in drug diffusion across the membrane is attributed to higher concentrations of Pickering starch, which likely creates a microporous, mosaic-like structure on the dispersed phase interface. This microstructure facilitates enhanced drug permeation from the emulgel matrix. These findings suggest that increasing starch content positively influences drug diffusion, whereas excessive polymer concentration may hinder membrane permeation due to increased matrix viscosity. The cumulative drug release profiles for all formulations are illustrated in Figure 5A and 5B, where the cumulative percentage drug release is plotted against time[33].

*Drug Release Kinetics*

The drug release kinetics of the five starch-based emulgel formulations at pH 7.2 and pH 5.5 were analyzed using various mathematical models, and the results are summarized in Tables 4 and 5. The model best describing the release behavior was identified based on the highest regression coefficient ($r^2$) value, with values closer to 1 indicating a better fit. Among the applied models, the zero-order model consistently showed the highest $r^2$ values at both pH conditions, suggesting that the drug release followed zero-order kinetics. Additionally, the release exponent (n) obtained from the Korsmeyer–Peppas model was greater than 0.8 for formulations F1 to F4 at both pH 7.2 and pH 5.5, indicating that the drug release was controlled by a combination of diffusion and polymer matrix erosion. In contrast, formulation F5 exhibited lower n values under both conditions, implying a less complex release mechanism. These observations support the conclusion that the drug release from the formulations was governed by non-Fickian, anomalous transport mechanisms[34].

## CONCLUSION

In this study, an emulgel was developed using soy oil, Tween 80, deionized water, and the gelling agent Carbopol 934, along with starch isolated from the rhizomes of *Dioscorea alata* as an adjuvant. The starch exhibited excellent flow properties, and the starch-based Pickering emulgels formulated with varying concentrations of starch showed spreadability values ranging from 11.54 to 15.15 g·cm/s, indicating that the formulations were highly spreadable. The viscosity of formulations containing 5% and 7.5% starch was significantly higher compared to those containing 0%, 1%, and 2.5% starch. Microscopic analysis revealed smaller globule sizes in the starch-based formulations compared to those without starch. Temperature and pH variation studies showed contrasting results: the highest apparent viscosity was observed at the lowest temperature, with a decreasing trend at higher temperatures. In contrast, the pH study showed the lowest apparent viscosity under acidic conditions, with an increasing trend toward basic pH. The *in vitro* release study demonstrated a distinct disintegrant property of the starch in both pH 7.2 and 5.5 conditions, with starch-containing formulations exhibiting significantly faster drug release compared to the starch-free emulgel, suggesting its potential utility in both topical and rectal formulations.

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