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HYDROGEL-BASED SOLID DISPERSION: DEVELOPMENT OF SUSTAINED RELEASE DRUG DELIVERY FOR ACECLOFENAC INDICATED FOR THE RELIEF OF PAIN AND INFLAMMATION

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ABSTRACT

Developing aceclofenac hydrogel-based solid dispersions enclosed in two modified gelatin capsules for long-term medication delivery was the aim of this study. Eudragit L 100 and hydroxypropyl methylcellulose acetate succinate were used to create the aceclofenac hydrogel-based solid dispersions at different drug-to-carrier ratios (1:1, 1:2, and 1:3) utilizing the solvent evaporation method. Scanning electron microscopy, differential scanning calorimetry, and percentage encapsulation efficiency (EE%) were used to characterize the formulations. In vitro drug release of 10 mg aceclofenac hydrogel-based solid dispersions was assessed using the USP Type I apparatus. Aceclofenac hydrogel-based solid dispersions, pure aceclofenac, and commercial aceclofenac tablets were examined in this study. The entrapment efficiency of solid dispersions based on eudragit was found to be substantially higher than that of those based on hydroxypropyl methylcellulose acetate succinate ($p < 0.05$). Both formulations' DSC and SEM studies showed a decrease in crystallinity as well as distinct particle sizes and shapes. Notably, redesigned gelatin capsules containing aceclofenac hydrogel-based solid dispersions showed a noticeably longer drug release profile. All things considered, modified gelatin capsules containing aceclofenac hydrogel-based solid dispersions offer a viable substitute technology for the long-term administration of aceclofenac.

Keywords: Aceclofenac, Sustained drug release, Modified gelatin capsules, Solid dispersions, Anti-inflammatory

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INTRODUCTION

The prolonged release of medications over a longer duration is made possible by sustained release drug delivery (SRDD), which improves bioavailability and makes administration easier for patients. SRDD's main objective is to increase the drug's bioavailability and efficacy in order to improve patient compliance [1]. This method works especially well for medications that need to be taken repeatedly and have short half-lives. Stable drug absorption levels in blood and plasma, uniform drug distribution, reduced side effects, enhanced patient compliance, and localized drug effects that lower dose frequency are some of the main benefits of SRDD.

The design of SRDD systems for lipophilic medicines has been the focus of recent research. However, a number of considerations, such as the drug's half-life and pharmacological effects, must be

taken into account while developing such a drug delivery system. SRDD offers consistent drug release over an extended period, minimizes side effects, and maintains favorable therapeutic drug levels in the blood, in contrast to conventional drug dosing methods, which frequently require repeated dosing and may result in issues like poor adherence, low bioavailability, instability, and toxicity [2-5]. Sustained-release drug delivery (SRDD) has been investigated in a number of research using various techniques. For example, a sustained solid dispersion of metformin was created to increase its half-life and enhance its low permeability across biological membranes. By combining methacrylate and dopamine to build a compound that is coupled with an arginine-derived material to make hydrogels, a sustained-release formulation utilizing hyaluronic acid (HA) was developed for wound

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healing. Furthermore, compared to DOX alone, poly(lactic-co-glycolic acid) microspheres containing Doxorubicin-hyaluronate (DOX-HA) micelles showed better sustained release characteristics. Additionally, by complexing plasmid DNA with a quaternary ammonium chain via electrostatic interactions and the gradual hydrolysis of ester bonds, which revealed negatively charged carboxyl groups, sustained release was accomplished [6].

Aceclofenac is a member of the class of nonsteroidal anti-inflammatory medicines (NSAIDs) and is derived from phenylacetic acid. With a water solubility of about 60 µg/mL, it is categorized as a Class II agent in biopharmaceutical classification systems and has difficulties because of its limited solubility. The drug requires several daily dosages of 100–200 mg to sustain its therapeutic impact because its biological half-life is less than 4 hours. However, gastrointestinal tract (GIT) diseases are linked to oral administration [7].

Research has concentrated on creating answers to aceclofenac physicochemical problems. In order to increase aceclofenac water solubility, prolong its residence duration, and boost its bioavailability, this study investigated solid dispersions of the drug that were then enclosed in modified gelatin capsules (MGCs). In particular, the solvent evaporation method was used to create aceclofenac hydrogel-based solid dispersions (ADS), which were then encapsulated in two different kinds of modified gelatin capsules for extended and sustained drug delivery [8–10].

MATERIAL AND METHOD

Materials

Aceclofenac (SIZA International (Pvt) Ltd), Eudragit® L100 powder, Hydroxypropyl methylcellulose acetate succinate, Cremophor® RH 40 (Sigma Aldrich, Germany). All chemicals were of analytical grade.

Formulation of Aceclofenac-hydrogel Solid Dispersion

Aceclofenac hydrogel-based solid dispersions (ASD) were prepared using the solvent evaporation technique with Eudragit® L 100 (EF1 – EF5) and hydroxypropyl methylcellulose acetate succinate (HF-1 – HF-5) in 98% methanol at various drug-carrier ratios (1:1, 1:2, 2:1, 1:3, and 3:1) [11]. Each formulation contained 10 mg of the drug, which was added to a 250 mL beaker and dispersed in 30 mL of methanol. The formulation was mixed with one carrier (either EF or HF), and 0.5 mL of Cremophor® RH 40 was incorporated. The beaker was placed on a magnetic stirrer set to 800 rpm without heat and stirred for about 60 minutes to achieve a uniform solution and enhance solvent evaporation. The resulting solid dispersions (SDs) were air-dried, weighed, pulverized in a mortar, and sieved using sieve no. 60. This procedure was repeated with

different ratios and the other carrier. The SDs were stored in airtight containers and kept in desiccators until further use.

Encapsulation Efficiency (EE %) and Drug Loading Capacity

A sample of 10 mg from the ADS was transferred to a calibrated beaker and dispersed in 1 mL of methanol and phosphate buffer (pH 7.4) up to the 10 mL mark. The mixture was then separated using a centrifuge for 30 minutes at 6000 rpm. The supernatant was analyzed with a spectrophotometer at 290 nm. A blank sample was prepared using 10 mL of methanol and phosphate buffer in a 1:9 ratio. All samples were analyzed in triplicate. The loading capacity (LC) indicates the proportion of the encapsulated Aceclofenac formulation relative to the total quantity of the carrier, along with the theoretical quantity of Aceclofenac contained in the solid dispersions [12, 13].

Micromeritics Properties of Solid Dispersions

Samples (10 g) were placed in a measuring cylinder, and the bulk volume (V1) was recorded. The samples were then subjected to 100 taps, after which the tapped volume (V2) was recorded. The bulk and tapped densities, Hausner's ratio, and Carr's index were calculated using the appropriate equations [14].

A clean glass funnel was clamped to a retort stand at a height of 5 cm from the tip of the funnel to the horizontal base. The funnel orifice was opened, and the flow rate and angle of repose (θ) were measured in triplicate using the designated equation. In this context, w represents the weight of the powder, t is the flow time in seconds, h is the height of the powder heap, and d is the diameter of the formed powder heap.

Scanning Electron Microscopy (SEM)

The morphological properties of selected solid dispersions (SDs) were evaluated using a scanning electron microscope. Samples were freeze-fractured in the SEM holder at 50 °C. Surface morphology was assessed at 15 kV, and images were captured using an integrated digital camera, then transferred and recorded [15–17].

XRD Studies

For comparison purposes, the physical mixture was analyzed alongside drug samples using powder X-ray diffraction (XRD). XRD analysis was performed to characterize the pure drug and its formulations. XRD diffractograms were obtained in the temperature range of 5.0 to 51°C at an angle of 2 θ to analyze the amorphous and crystalline nature of aceclofenac [18].

In vitro Drug Release study of ADS

The in vitro release of aceclofenac from aceclofenac hydrogel-based solid dispersions (ADS) encapsulated in modified gelatin capsules (MGCs) was conducted using a slightly modified method. The ADS selected for this test were optimized based on the highest

percentage of encapsulation efficiency (% EE) from batches. A total of 10 mg of AC in ADS was transferred into the MGCs, which were chosen for their favorable swelling index and poor aqueous dispersibility. Each encapsulated ASD was immersed in a beaker containing 900 mL of simulated gastric fluid (SGF; pH 1.2) for 2 hours, followed by immersion in simulated intestinal fluid (SIF; pH 7.4) until the experiment concluded. At intervals of 2, 4, 6, and 12 hours, 5 mL aliquots were withdrawn from each medium, and the percentage of AC released was measured spectrophotometrically at 290 nm. The percentage of AC released was calculated and averaged for each time point.

Statistical Analysis

Data were analyzed using GraphPad InStat Demo (USA). Results are expressed as mean $\pm$ SD (n = 3) and compared using one-way analysis of variance (ANOVA). Differences between means were assessed using a two-tailed Student's t-test, with P < 0.05 considered statistically significant.

RESULTS AND DISCUSSION

Entrapment Efficiency, Loading Capacity, and Yield

The highest encapsulation efficiencies were achieved in formulations EF-5 and HF-4, which were prepared using Eudragit® L 100 in a 3:1 ratio and hydroxypropyl methylcellulose acetate succinate in a 1:3 ratio, respectively. The ADS exhibited % yields ranging from 76% to 92% for EF and 69% to 82% for HF (Table 1). Formulation EF-5, with its higher percentage yield, demonstrated enhanced encapsulation efficiency and loading capacity. Both EF and HF solid dispersions displayed favorable flow characteristics [19].

Morphological Characteristics

The morphology of the ASD, as determined by scanning electron microscopy (SEM). The photomicrographs revealed a mixture of various discrete, irregular particle sizes and shapes, along with some aggregated particles [20].

Table 1: Yield, encapsulation efficiency, and flow properties.

Batch	Encapsulation efficiency (%)	Loading capacity (%)	Yield (%)	Angle of repose (°)	Bulk density (g/mL)	Tapped density (g/mL)	Hausner's index	Compressibility index (%)
EF-1	88 $\pm$ 0.23	27 $\pm$ 0.17	76.24	21 $\pm$ 0.10	0.5 $\pm$ 0.03	0.75 $\pm$ 0.12	1.77	51
EF-2	84 $\pm$ 0.43	22 $\pm$ 0.32	79.46	29 $\pm$ 0.12	0.5 $\pm$ 0.02	0.75 $\pm$ 0.17	1.73	31
EF-3	80 $\pm$ 0.42	23 $\pm$ 0.28	84.71	20 $\pm$ 0.15	0.6 $\pm$ 0.02	0.65 $\pm$ 0.25	1.35	22
EF-4	65 $\pm$ 0.36	19 $\pm$ 0.16	89.32	21 $\pm$ 0.21	0.6 $\pm$ 0.17	0.75 $\pm$ 0.14	1.30	27
EF-5	94 $\pm$ 0.21	21 $\pm$ 0.18	92.31	27 $\pm$ 0.26	0.5 $\pm$ 0.15	0.65 $\pm$ 0.18	1.49	39
HF-1	82 $\pm$ 0.16	33 $\pm$ 0.29	69.54	19 $\pm$ 0.01	0.6 $\pm$ 0.17	0.65 $\pm$ 0.21	1.39	34
HF-2	74 $\pm$ 0.19	26 $\pm$ 0.13	77.41	23 $\pm$ 0.04	0.6 $\pm$ 0.14	0.75 $\pm$ 0.16	1.19	18
HF-3	82 $\pm$ 0.21	30 $\pm$ 0.12	71.18	18 $\pm$ 0.24	0.4 $\pm$ 0.24	0.65 $\pm$ 0.26	1.45	33
HF-4	93 $\pm$ 0.25	34 $\pm$ 0.11	82.27	19 $\pm$ 0.17	0.5 $\pm$ 0.17	0.65 $\pm$ 0.11	1.42	37
HF-5	71 $\pm$ 0.28	22 $\pm$ 0.26	70.05	24 $\pm$ 0.13	0.5 $\pm$ 0.11	0.65 $\pm$ 0.02	1.58	44

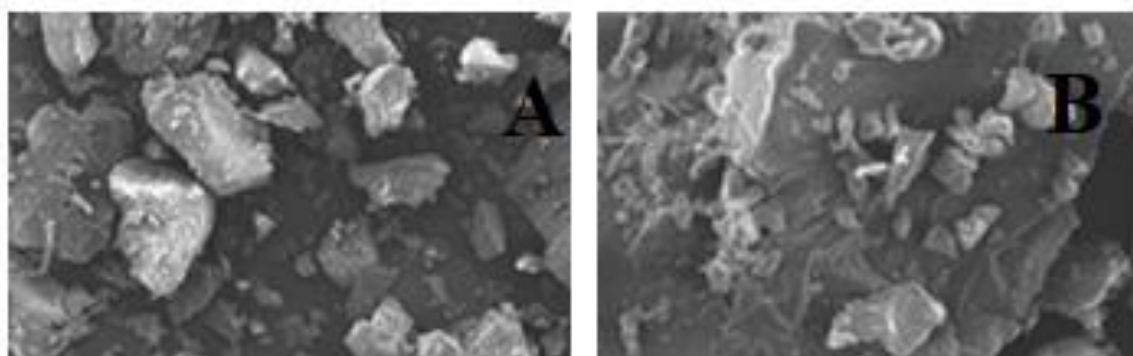


Figure 1: Scanning electron microscopy (SEM) of solid dispersion of Eudragit L 100 (A), and hydroxypropyl methylcellulose acetate succinate (B).

X-ray Diffraction Study

The powder characteristics of drug and its formulations were analyzed by XRD. The diffractograms of pure drug, solid dispersion formulations (Fig. 2). The XRD pattern of pravastatin displayed a series of distinct peaks, indicative of its crystalline nature. In contrast, the XRD pattern of the formulation exhibited fewer peaks, and these peaks had lower intensity. These results strongly suggest that pravastatin underwent a transformation from its crystalline form to a less crystalline or amorphous form. This transition contributed to an increase in dissolution and solubility, consequently enhancing the release of the drug.

In-vitro Release of Aceclofenac Hydrogel Solid Dispersions Sustained Release

In vitro AC release from solid dispersions of AC modified with gelatin capsules (MGCs) is illustrated in Figure 3. The results for the two developed MGCs indicate that AC release was negligible in simulated gastric fluid (SGF, pH 1.2). In contrast, the MGCs initiated drug release through swelling and expansion, resulting in gradual AC release in simulated intestinal fluid (SIF, pH 7.4). Batches EFSDs and HFSDs exhibited T50% (time for 50% release) at around 8 hours, and T80% at around 12 hours using MGX. No premature drug release was detected in either medium.

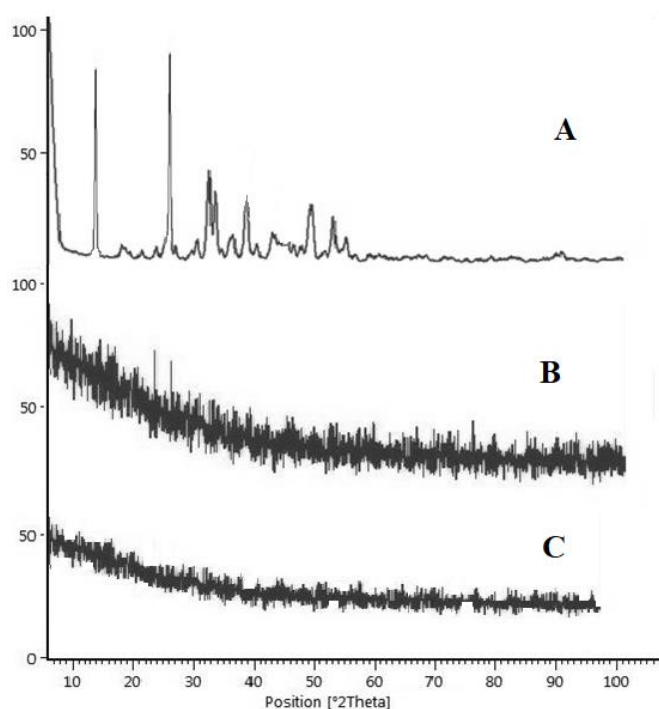


Figure 2: X-ray diffraction, Pure drug (A), solid dispersion of Eudragit L 100 (B), and solid dispersion of hydroxypropyl methylcellulose acetate succinate (C).

Table 2: *In-vitro* pravastatin release at pH 1.2

pH	Time	F0	PM
1.2	30	10.15	36
	60	15.2	50.35
	90	22.4	55.44
	120	32.42	71.35
7.4	180	10.15	38
	240	15.20	54.45
	360	22.40	60.35
	720	32.42	74.45

The ability of a formulation to encapsulate a drug is a critical quality indicator, represented by the percentage entrapment efficiency (% EE). The loading capacity (LC) reflects the ratio of entrapped drug molecules to the total weight of the carrier. Previous studies have indicated that factors such as the poor aqueous solubility of the drug, the type of constituents, the synergistic effects of the components, and the formulation technique can influence the loading capacity of drug formulations. The ASD formulated with HF demonstrated higher % EE and LC at elevated carrier concentrations, in contrast to EF formulations, which aligns with earlier findings. Thus, formulations with equal or greater carrier concentrations exhibited effective drug encapsulation. However, complexes with higher drug content showed increased loading capacity.

Material density is a crucial parameter that influences flow characteristics. Bulk and tapped densities provide insights into particle packing, arrangement, and compaction profiles. A material with high bulk density typically has low porosity, resulting in reduced deformation potential. This limitation decreases the space available for restructuring during compression, leading to less intimate contact between particles. Bulk and tapped densities are utilized to predict the flow behavior and compressibility of a powder. The ASD batches exhibited favorable bulk and tapped densities, indicating good packing properties necessary for effective drug delivery, consistent with previous reports [21].

The packing volume of a powder is influenced by factors such as particle shape, particle size distribution, true density, and cohesiveness resulting from surface properties like moisture. Previous studies have indicated that an angle of repose (AOR) of $\leq 30^\circ$ signifies good flow, while an AOR of $\geq 40^\circ$ indicates poor flow. All the aceclofenac hydrogel-based solid dispersions (ASD) in this study demonstrated good flow properties, with an AOR of less than 40° . This suggests low inter-particulate cohesion, which facilitates easy encapsulation in a uniform dose [22].

The compressibility index (CI) and Hausner's ratio (HR) are used to evaluate the flowability and

consolidation characteristics of materials. A powder with an appropriate CI and HR flows at a minimum bulk density and consolidates to a maximum density when compressed. An HR of ≤ 1.25 indicates good flow, while an HR of ≥ 1.25 suggests poor flow. Additionally, a Carr's index of 5 to 16% indicates good flow, while 18 to 23% indicates fair flow [23, 24].

Consequently, dose variability is minimized. In scanning electron microscopy (SEM) images, aggregated particles may have formed due to dehydration during sample preparation in a high vacuum environment.

The release of AC from the encapsulated ASD was characterized by the swelling and expansion of the modified gelatin capsules (MGCs), which facilitated fluid penetration into the solid dispersions. Previous investigations have shown that fluid imbibition can lead to gel formation, potentially delaying drug release. Therefore, the 3-hour developed capsules effectively controlled drug release, allowing up to 80% of AC to be released over 12 hours, particularly in the lower gastrointestinal tract. The higher AC release observed is attributed to its unique design, which incorporates both a chemically modified cap and body.

CONCLUSION

This study demonstrates that the poor aqueous solubility, short residence time, and low bioavailability of conventional aceclofenac delivery can be improved using aceclofenac hydrogel-based solid dispersions (ASD) encapsulated in modified gelatin capsules, facilitating effective sustained drug release. Therefore, ASD encapsulated in MGCs represent a promising technology for achieving sustained delivery of aceclofenac.

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