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FORMULATION OPTIMIZATION AND EVALUATION OF ASPIRIN MICROENCAPSULATED DRUG DELIVERY SYSTEM

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ABSTRACT

Microencapsulation is an advanced drug delivery approach used to modify drug release and improve therapeutic performance. The present study focuses on the formulation, optimization, and evaluation of aspirin-loaded microcapsules using ethyl cellulose as a polymer by the emulsion solvent evaporation technique. Aspirin, a widely used non-steroidal anti-inflammatory drug, is associated with gastrointestinal side effects when administered in conventional dosage forms. Microencapsulation helps in reducing these effects by providing controlled drug release. Microspheres were prepared by dissolving aspirin and ethyl cellulose in a volatile organic solvent followed by emulsification in an aqueous phase. The prepared microspheres were evaluated for particle size, drug entrapment efficiency, surface morphology, and in-vitro drug release. The results demonstrated that the microspheres were spherical, free-flowing, and exhibited sustained drug release following diffusion-controlled kinetics. Optimization studies indicated that polymer concentration and stirring conditions significantly influenced encapsulation efficiency and release profile. The study concludes that aspirin microencapsulation using ethyl cellulose is an effective approach for developing sustained drug delivery systems.

KEYWORDS: Aspirin, Microencapsulation, Sodium alginate, Ionotropic gelation, Sustained release, Microcapsules.

1. INTRODUCTION

A Drug Delivery System (DDS) is a specialized technology or formulation designed to transport a pharmaceutical compound safely and efficiently into the body to achieve its desired therapeutic effect. Drug delivery systems play a significant role in improving therapeutic efficacy and minimizing the adverse effects associated with conventional dosage forms.[1]

Microencapsulation is a widely used technique in pharmaceutical sciences that involves the coating or entrapment of active drug molecules within a polymeric matrix to form microscopic particles known as microcapsules or microspheres. These systems are capable of controlling the release rate of drugs and protecting them from degradation in the biological environment.[2]

In medicine, this process is essential for creating sustained-release treatments. Instead of a drug dissolving all at once, the microcapsules allow the medication to leach out slowly over hours or days, maintaining a steady therapeutic level in the body and reducing the need for multiple doses.[3]

The technique also solves stability issues for sensitive compounds. It can protect volatile oils from evaporation, prevent vitamins from degrading due to light or oxygen, and even mask the bitter taste of certain chemicals, making oral medications much easier for patients to tolerate.[4]

Aspirin (acetylsalicylic acid) is one of the most commonly used non-steroidal anti-inflammatory drugs (NSAIDs) with analgesic, antipyretic, anti-inflammatory, and antiplatelet properties. It is widely prescribed for the management of pain, fever, inflammation, and cardiovascular disorders. However, prolonged administration of aspirin can lead to gastrointestinal irritation, ulceration, and bleeding due to direct contact of the drug with the gastric mucosa. Therefore, designing a controlled drug delivery system for aspirin is important to minimize these adverse effects and improve patient compliance.[5]

Microencapsulation can be used to slow the release of a drug into the body. This may permit one controlled release dose to substitute for several doses of non-encapsulated drug and also

may decrease toxic side effects for some drugs by preventing high initial concentrations in the blood. There is usually a certain desired release pattern. Microencapsulation techniques provide an effective strategy to overcome these limitations. By encapsulating aspirin within biodegradable polymers such as ethyl cellulose, poly (lactic acid), or alginate, the drug can be released slowly over an extended period of time. Microencapsulated aspirin offers several pharmaceutical advantages. Such systems improve drug stability, reduce gastric irritation, and maintain therapeutic drug levels for longer durations.[6]

2. MATERIALS AND METHODS

2.1 Materials

Aspirin is used as the API and sodium alginate is used as polymer. For the cross linking purpose calcium chloride is used.[7]

2.2 Method of Preparation

Ionotropic gelation method is used for the preparation of microcapsules of aspirin. It is a method of microencapsulation in which a polymer solution forms gel particles when it comes in contact with oppositely charged ions. For Aspirin microcapsules, Sodium alginate forms a gel in the presence of Calcium chloride.[8]

Process

Aspirin microcapsules were prepared using the ionotropic gelation technique, a simple and mild method based on the ability of certain polymers to form gels in the presence of multivalent ions.

In this study, sodium alginate was selected as the polymer because it readily cross-links with calcium ions to form stable microspheres. Sodium alginate solutions were prepared by dissolving the polymer in distilled water (100 ml) under continuous magnetic stirring until a uniform and lump-free viscous solution was obtained.

Aspirin (50mg) was then added to 100 mL of the polymer solution and stirred thoroughly to ensure complete dissolution and uniform distribution of the drug throughout the matrix.

The resulting drug–polymer mixture was transferred into a syringe fitted with a 21-gauge needle and introduced dropwise into 100 mL of gently stirred calcium chloride solution (2% w/v), which served as the cross-linking agent.

The needle tip was positioned approximately 5 cm above the surface of the calcium chloride solution to allow proper droplet formation and to obtain spherical particles.

As soon as the droplets came into contact with the calcium chloride solution, gelation occurred instantly due to ionic interaction between calcium ions and the carboxyl groups of sodium alginate, resulting in the formation of discrete microspheres.

The formed microspheres were allowed to remain in the cross-linking solution for 30–60 minutes to ensure complete curing and adequate mechanical strength.

The microspheres were then collected by filtration, washed several times with distilled water to remove any unreacted calcium ions or surface-adhered drug, and finally dried at 40°C for 12 hours.[9]

3. Experimental

3.1 Assessment of Microcapsules

Assessment of microspheres can be done by evaluating its particle size, drug entrapment efficiency and percentage yield.[10]

3.2 Particle Size

Particle size was determined by using optical microscopy technique.

About 15 microcapsules were analysed for each formulation and the mean particle size was calculated.[11]

3.3 Percentage Yield

The percentage yield was calculated by taking weight of dried microcapsules recovered from each batch in relation to the weight of starting materials (drug and excipients). The total percentage was obtained by incorporating the obtained values into the formula.[12]

$$\% \text{ Yield} = \frac{\text{Practical weight of microcapsules}}{\text{Theoretical weight of polymer} + \text{drug}} \times 100$$

3.4 Drug Entrapment Efficiency

A known quantity of the prepared Aspirin microcapsules equivalent to 50 mg of drug was accurately weighed and crushed. The crushed microcapsules were transferred to a 100 mL volumetric flask containing phosphate buffer pH 7.4 or a suitable solvent and shaken continuously to extract the entrapped drug completely. The solution was filtered to remove

polymeric residue, and the filtrate was suitably diluted. The absorbance of the diluted solution was measured by UV–Visible spectrophotometry at the selected λmax (279).

The amount of drug present was determined from the calibration curve, and drug entrapment efficiency was calculated by comparing the practical drug content with the theoretical drug content.[13]

$$\%\text{Entrapment efficiency} = \frac{\text{Weight of drug determined}}{\text{Weight of drug added}} \times 100$$

3.5 In Vitro Dissolution Studies

The in vitro dissolution study of Aspirin microcapsules was carried out using a USP dissolution apparatus type I. A quantity of microcapsules equivalent to 50 mg of aspirin was placed in the dissolution vessel containing 900 mL of phosphate buffer pH 7.4 maintained at 37 ± 0.5 °C. The medium was stirred at 50 rpm. At predetermined time intervals, 5 mL samples were withdrawn and replaced with an equal volume of fresh dissolution medium maintained at the same temperature. The withdrawn samples were filtered, suitably diluted if required, and analyzed by UV–Visible spectrophotometry at 279 nm. The amount of drug released at each time interval was calculated.[14]

3.6 Micromeritic Properties

To determine the flow properties of microcapsules micromeritic evaluation was done.

a) Angle of Repose

The static angle of repose, a, was measured according to the fixed funnel method. A funnel was clamped with its tip 2cm above a graph paper placed on a flat horizontal surface. The powders were carefully poured through the funnel until the apex of the cone thus formed just reached the tip of the funnel. Height and radius of the heap were determined and the tangent of the angle of repose calculated using the equation.[16]

$$\text{Tan}\theta = \frac{\text{Height}}{\text{Radius}}$$

b) Bulk Density and Tapped Density

Microcapsules (2 g) were added into a 10 mL graduated cylinder. Final volume was determined to calculate the bulk density. Then the cylinder was tapped mechanically 100 times to obtain the tapped volume for calculating the tapped density.[17]

$$\text{Bulk Density} = \frac{\text{Mass of powder(g)}}{\text{Unsettled volume(ml)}}$$

$$\text{Tapped Density} = \frac{\text{Mass of powder(g)}}{\text{Tapped volume(ml)}}$$

c) Carr's Index

To calculate Carr's index bulk density and the tapped density of the microspheres were measured in a graduated cylinder. Each determination was carried out in triplicate.[18]

$$\text{Carr's Index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

d) Hausner Ratio

The obtained values of tapped density and bulk density have been incorporated into the formula to get Hausner ratio.[19]

$$\text{Hausner Ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

4. RESULT AND DISCUSSION

In this work, microcapsules of aspirin were prepared using ionotropic gelation method. For the preparation sodium alginate was used as the polymer (Capable to control the release of drug).

4.1 RESULT

4.1.1 Particle Size

The optical microscopy is used to calculate the size of microcapsule. The particle size of aspirin is found to be 656 µm.

4.1.2 Percentage Yield

The percentage yield of aspirin microcapsules is found to be 82%.

4.1.3 Micromeritic Properties

The various properties such as bulk density, tapped density, Carr's index, Hausner ratio and angle of repose were evaluated.

Table 1: Micromeritic Properties of Microcapsules.

Parameter	Value
Bulk density	0.46 g/mL
Tapped density	0.53 g/mL
Carr's index	13.21%
Hausner ratio	1.15
Angle of repose	27.8°

4.1.4 Drug Entrapment Efficiency

The drug entrapment efficiency of aspirin microcapsules is obtained about 60%.

4.1.5 In Vitro Dissolution Studies

The in vitro dissolution study of aspirin-loaded microcapsules was carried out using the USP Dissolution Apparatus I (basket method). The study was performed at a rotational speed of 100 rpm in 900 mL of phosphate buffer solution (pH 6.8), maintained at a temperature of 37 ± 0.5°C. Samples were withdrawn at predetermined time intervals and analyzed spectrophotometrically at 279 nm after suitable dilution. The cumulative drug release after 3 hours was found to be 44%, indicating a sustained release behavior of the formulated microcapsules.

4.2 DISCUSSION

The present study focused on the formulation optimization and evaluation of a 50 mg Aspirin microencapsulated drug delivery system prepared by ionotropic gelation technique. The method was selected because it is simple, economical, and suitable for the preparation of polymer-based microcapsules with controlled drug release characteristics.

Preformulation studies were carried out before formulation development. The drug showed acceptable physicochemical properties including solubility, partition behavior, and UV absorption characteristics. The λmax of aspirin in phosphate buffer pH 7.4 was found suitable for quantitative analysis by UV–Visible spectrophotometry. The calibration curve showed linearity within the selected concentration range and was used for drug estimation during further evaluation.

The prepared microcapsules were found to be white to off-white, discrete, free-flowing, and spherical to nearly spherical in shape. Physical characterization indicated uniform particle distribution with no visible aggregation or surface cracking. Flow property evaluation showed satisfactory bulk density, tapped density, Carr's index**,** Hausner ratio, and angle of repose, indicating good handling and packing properties of the formulation.

The percentage yield obtained for the optimized batch was satisfactory, indicating minimal material loss during the preparation process. Drug entrapment efficiency also showed acceptable values, suggesting efficient incorporation of aspirin within the polymeric matrix.

These observations indicate that the ionotropic gelation process was effective in producing stable microcapsules with adequate drug loading.

The in vitro dissolution study demonstrated gradual drug release from the prepared microcapsules. Compared with the pure drug, the microencapsulated formulation showed a slower and more controlled release pattern. This controlled release behavior can be attributed to diffusion of drug through the polymer network and gradual swelling or erosion of the polymer matrix.

Overall, the study demonstrated that the optimized aspirin microcapsules possessed satisfactory physicochemical properties, acceptable drug entrapment, and sustained drug release characteristics. The developed microencapsulated system may therefore be considered a suitable approach for improving formulation performance and controlled delivery of aspirin.

5. CONCLUSION

The present study was undertaken to formulate, optimize, and evaluate a 50 mg Aspirin microencapsulated drug delivery system prepared by the ionotropic gelation technique. The selected method was found to be simple, reproducible, and suitable for the preparation of polymer-based microcapsules intended to provide controlled drug release. Preformulation evaluation of aspirin was carried out prior to formulation development in order to assess the physicochemical properties relevant to microencapsulation. The results of solubility study, partition coefficient, and UV spectrophotometric analysis confirmed that the drug possessed suitable characteristics for formulation development and analytical estimation.

The prepared microcapsules exhibited satisfactory physical characteristics. They were found to be white to off-white, discrete, free-flowing, and spherical to nearly spherical in shape. Uniform particle distribution and the absence of visible aggregation or surface defects indicated successful formation of stable microcapsules. Evaluation of micromeritic properties, including bulk density, tapped density, Carr’s index, Hausner ratio, and angle of repose, demonstrated acceptable flow behavior and good handling properties, which are important during further processing and dosage form development.

The percentage yield of the prepared batch was satisfactory, indicating minimal loss of material during the formulation process. These observations suggest that the ionotropic gelation process provided effective cross-linking and uniform encapsulation of the drug.

The in vitro dissolution study demonstrated that the prepared microcapsules released the drug in a gradual and controlled manner over the selected time period. Compared with the pure drug, the microencapsulated formulation exhibited slower release, indicating sustained release behavior. This controlled release pattern can be attributed to diffusion of the drug through the polymer matrix along with gradual swelling and erosion of the polymeric network in the dissolution medium.

On the basis of the overall findings, it may be concluded that the developed aspirin microcapsules possessed satisfactory physicochemical characteristics, acceptable drug loading capacity, and controlled drug release properties. The study demonstrates that ionotropic gelation is a suitable and effective technique for the preparation of aspirin microcapsules. The optimized formulation may therefore serve as a promising approach for controlled drug delivery and may provide a useful basis for further formulation development and advanced pharmaceutical investigation.

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