

Formulation and Evaluation of Polymeric Microspheres Loaded with Ashwagandha Extract

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Abstract: *The development of advanced drug delivery systems has significantly improved the therapeutic efficiency, stability, and bioavailability of various pharmaceutical agents. Among these systems, polymeric microspheres have gained considerable attention due to their ability to provide controlled and sustained drug release. The present study focuses on the formulation and evaluation of polymeric microspheres loaded with Ashwagandha (*Withania somnifera*) extract, a well-known medicinal herb in Ayurveda possessing multiple pharmacological activities.*

Ashwagandha is widely recognized for its adaptogenic, anti-stress, antioxidant, immunomodulatory, and neuroprotective properties. However, the direct administration of herbal extracts often faces limitations such as poor bioavailability, rapid metabolism, and reduced stability.

In this study, polymeric microspheres containing Ashwagandha extract were prepared using the emulsion solvent evaporation method. Various formulation parameters including drug-polymer ratio, stirring speed, and solvent system were optimized to achieve desirable microsphere characteristics. The prepared microspheres were evaluated for particle size, surface morphology, drug entrapment efficiency, in-vitro drug release profile, and stability studies.

The results indicated that the formulated microspheres exhibited uniform particle size distribution, high entrapment efficiency, and sustained drug release behavior over an extended period. The controlled release pattern suggests that the polymer matrix effectively regulates the release of Ashwagandha extract, thereby enhancing its therapeutic effectiveness and reducing dosing frequency.

Keywords: Ashwagandha, Polymeric Microspheres, Controlled Drug Delivery, *Withania somnifera*, Sustained Release, Herbal Drug Delivery, PLGA, Chitosan

I. INTRODUCTION

Drug delivery systems play a crucial role in pharmaceutical science by improving the therapeutic effectiveness of drugs while minimizing their side effects. Conventional dosage forms often suffer from limitations such as rapid drug release, poor bioavailability, and frequent dosing requirements. To overcome these challenges, advanced drug delivery approaches such as polymeric microspheres have been developed, which allow controlled and sustained release of active pharmaceutical ingredients.

Polymeric microspheres are small spherical particles ranging from 1 to 1000 micrometers in size, in which a drug is either encapsulated within or adsorbed onto a polymer matrix. These systems are widely used to improve drug stability, enhance absorption, and provide targeted delivery. The use of biodegradable and biocompatible polymers such as PLGA, chitosan, and alginate makes microspheres safe and effective for pharmaceutical applications.

Ashwagandha (*Withania somnifera*) is one of the most important medicinal plants in Ayurveda and is widely known as an adaptogenic herb. It is traditionally used for reducing stress, improving memory, enhancing immunity, and promoting overall health. The major bioactive compounds in Ashwagandha, such as withanolides, contribute to its pharmacological activities.

However, direct administration of Ashwagandha extract may lead to degradation of active components and inconsistent therapeutic effects. To address these issues, the present study focuses on the formulation and evaluation of polymeric



microspheres loaded with Ashwagandha extract. This approach aims to enhance the stability, bioavailability, and sustained release of the herbal drug, thereby improving its therapeutic efficiency.

II. HISTORY OF MICROSPHERES AND ASHWAGANDHA

The history of microspheres and herbal medicines reflects the continuous evolution of pharmaceutical science from conventional dosage forms to advanced drug delivery systems. This development was driven by the need to overcome limitations such as poor drug stability, rapid elimination, low bioavailability, and frequent dosing associated with traditional formulations.

Over the years, both polymer science and herbal medicine research have contributed significantly to the emergence of microsphere-based drug delivery systems, which are now widely used in modern pharmacy.

A. Historical Background of Ashwagandha

Ashwagandha (*Withania somnifera*) has a deep-rooted history in Ayurvedic medicine dating back more than 3000 years. It is classified as a “Rasayana” herb in Ayurveda, referring to rejuvenating substances that promote longevity, vitality, and overall well-being.

Ancient Ayurvedic texts such as the *Charaka Samhita* and *Sushruta Samhita* describe Ashwagandha as a powerful herb used to treat stress, fatigue, inflammation, and neurological disorders.



Figure 3.3: Botanical and medicinal overview of Ashwagandha

III. AIM AND OBJECTIVES

A. Aim

The present research work on “Formulation and Evaluation of Polymeric Microspheres Loaded with Ashwagandha Extract” is designed to develop an advanced herbal drug delivery system that can overcome the limitations associated with conventional herbal formulations.

Ashwagandha (*Withania somnifera*), although highly effective as an Ayurvedic adaptogenic herb, suffers from poor bioavailability, rapid metabolic degradation, and inconsistent therapeutic response when administered in traditional



dosage forms. Therefore, encapsulating its extract into polymeric microspheres provides a promising approach to improve its pharmacological efficiency.

The study integrates principles of pharmaceutics, polymer science, and herbal drug technology to design a controlled and sustained release formulation.

B. Objectives

1) Extraction of Ashwagandha

To obtain a standardized crude extract of Ashwagandha using suitable extraction techniques such as solvent extraction or maceration, ensuring maximum recovery of active phytoconstituents like withanolides.

2) Selection of Suitable Polymer

To identify and select appropriate biodegradable and biocompatible polymers such as PLGA, chitosan, or ethyl cellulose for microsphere formulation.

3) Formulation Development

To prepare polymeric microspheres incorporating Ashwagandha extract using techniques such as:

- Emulsion solvent evaporation method
- Ionotropic gelation method
- Spray drying technique

4) Physicochemical Evaluation

- To determine particle size distribution
- To analyze surface morphology
- To study flow properties and uniformity

5) Drug Entrapment Efficiency

To evaluate the percentage of Ashwagandha extract successfully encapsulated within the polymer matrix.

6) In-vitro Drug Release Study

To investigate the release profile of Ashwagandha from microspheres under simulated physiological conditions and determine release kinetics.

7) Stability Studies

To assess the physical and chemical stability of microspheres under different environmental conditions such as temperature and humidity.

C. Expected Outcomes

The study is expected to yield a stable, efficient, and reproducible microsphere-based drug delivery system for Ashwagandha extract. The formulation is anticipated to provide:

- Enhanced bioavailability of active phytoconstituents
- Controlled and prolonged drug release
- Improved therapeutic efficacy
- Reduced dosing frequency
- Better patient compliance



How immediate release drugs work

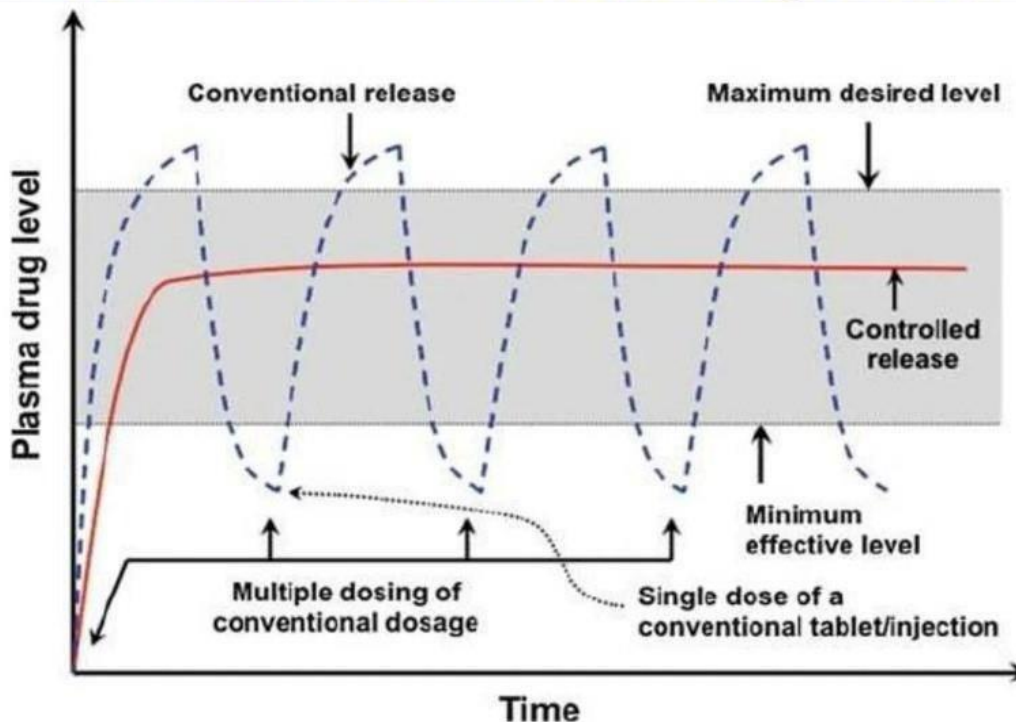


Figure 4.3 : Expected sustained release and improved bioavailability model

IV. ACTIVE COMPONENTS WITH THEIR PROPERTIES

Ashwagandha (*Withania somnifera*) is a highly valued medicinal plant in Ayurveda due to the presence of a wide range of bioactive phytochemical constituents. These active components are responsible for its pharmacological activities such as anti-inflammatory, antioxidant, immunomodulatory, stress-relieving, and neuroprotective effects.

The major active constituents belong to different chemical classes such as withanolides, alkaloids, saponins, and flavonoids.

A. Withanolides

Withanolides are the primary bioactive constituents of Ashwagandha and are responsible for most of its pharmacological activities. They are naturally occurring steroidal lactones with a C28 steroidal framework.

Properties of Withanolides

- Strong adaptogenic activity
- Anti-inflammatory properties
- Anticancer potential
- Neuroprotective effects
- Immunomodulatory action



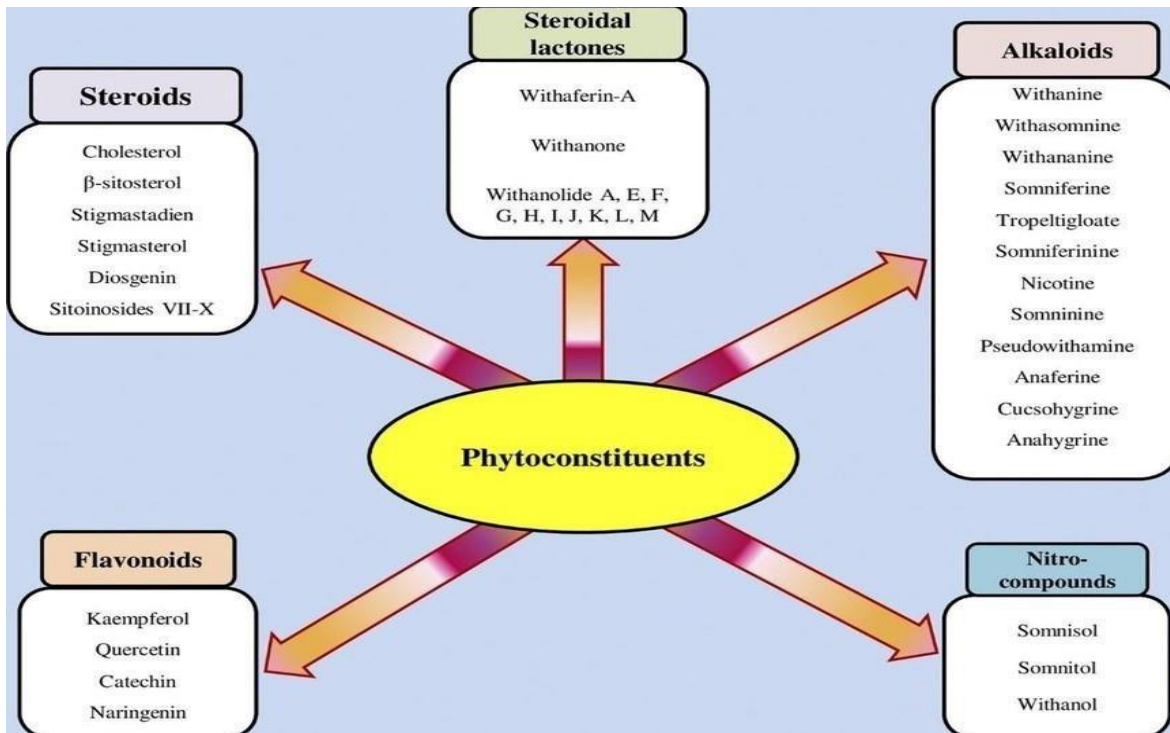


Figure 5.1: Chemical structure of Withanolides

B. Alkaloids

Alkaloids are nitrogen-containing compounds present in Ashwagandha that contribute to its pharmacological effects.

Properties of Alkaloids

- Mild sedative effect
- Nervine tonic action
- CNS modulation
- Muscle relaxant properties
- Support in anxiety reduction

These compounds help in calming the nervous system and improving mental stability, making Ashwagandha useful in stress-related disorders.



Autonomic Nervous System Balance

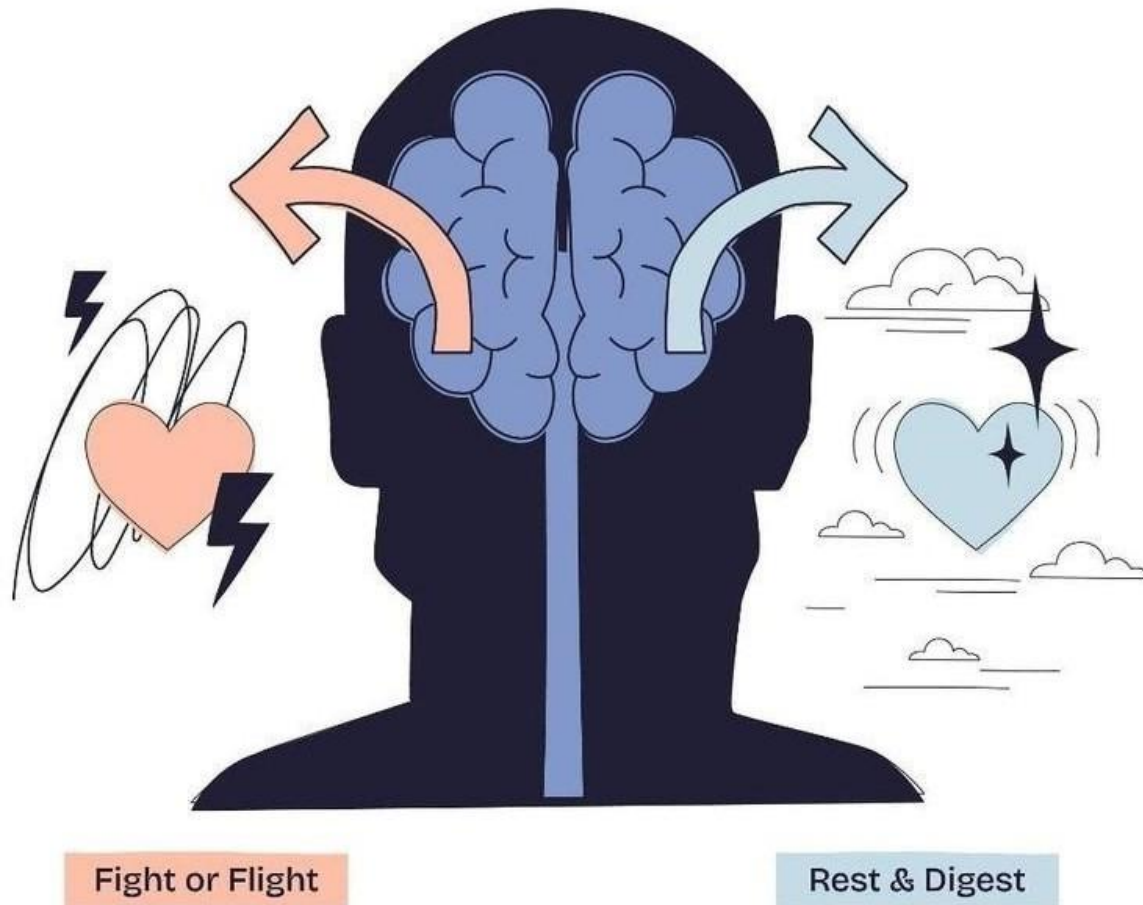


Figure 5.2: Alkaloid molecular structures and CNS action

V. MATERIALS AND METHODS

A. Materials Used

The materials selected for this study were chosen based on their compatibility, safety, biodegradability, and efficiency in drug delivery applications.

The primary active ingredient used was Ashwagandha extract, known for its adaptogenic and therapeutic properties. Biodegradable polymers such as PLGA, chitosan, or ethyl cellulose were used as matrix-forming agents for microsphere preparation.



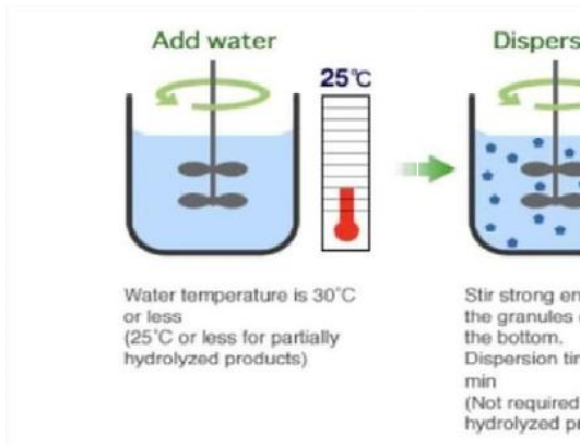


Figure 6.1: Raw materials and laboratory chemicals

B. Instruments and Equipment Used

The following instruments were used:

- Rotary evaporator
- Centrifuge
- UV-Visible spectrophotometer
- SEM (Scanning Electron Microscope)





Figure 6.2: Microsphere preparation (emulsion solvent evaporation method)

C. Preparation of Ashwagandha Extract

Dried roots of Ashwagandha were cleaned properly to remove impurities and dried under controlled conditions. After drying, the roots were powdered using a mechanical grinder.

The powdered material was subjected to solvent extraction using maceration or Soxhlet extraction methods. In maceration, the powder was soaked in a suitable solvent such as ethanol-water mixture for 24–72 hours with occasional shaking to ensure maximum extraction of phytoconstituents.

After extraction, the mixture was filtered using filter paper to remove solid residues. The filtrate obtained was concentrated using a rotary evaporator under reduced pressure to remove excess solvent and obtain a semi-solid extract. The final extract was stored in airtight containers under refrigeration conditions to maintain stability.





Ashwagandha Root Extract



Ashwagandha Root Powder

Figure 6.3: Ashwagandha extraction

D. Formulation of Polymeric Microspheres

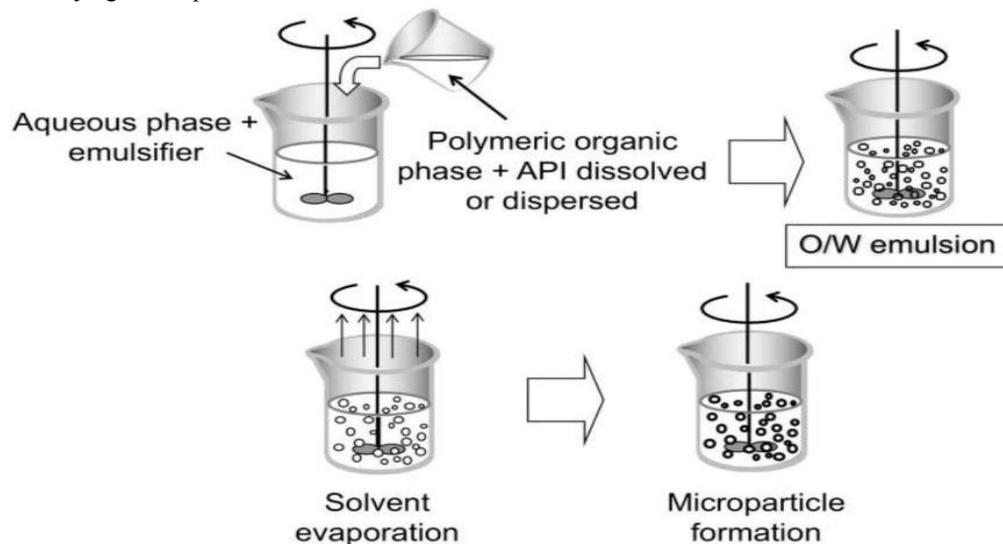
The polymeric microspheres were prepared using the emulsion solvent evaporation technique.

The selected polymer was dissolved in an organic solvent to form the internal oil phase. The Ashwagandha extract was then added and mixed thoroughly to ensure uniform distribution.

This organic phase was slowly added into an aqueous phase containing PVA under continuous stirring. The formation of an oil-in-water emulsion took place due to agitation.

As stirring continued, the organic solvent gradually evaporated, leading to the formation of solid microspheres encapsulating the drug.

Finally, the formed microspheres were collected by centrifugation, washed to remove residual surfactant, and dried using suitable drying techniques.



E. Drying and Storage of Microspheres

After preparation, the microspheres were subjected to drying to remove any remaining solvent or moisture. Drying methods such as air drying, vacuum drying, or freeze drying were used depending on the required stability and particle characteristics.

Once dried, the microspheres were carefully collected and stored in airtight containers or desiccators to protect them from moisture, light, and environmental degradation.



F. Evaluation of Microspheres

The prepared microspheres were evaluated using standard pharmaceutical tests.

1) Particle Size Analysis

Particle size analysis was performed to determine the size distribution of microspheres, which directly affects drug release behavior.

2) Surface Morphology

Surface morphology was studied using SEM to observe the shape and structure of microspheres.

3) Drug Entrapment Efficiency

Drug entrapment efficiency was calculated to determine the amount of Ashwagandha extract successfully incorporated into the polymer matrix.

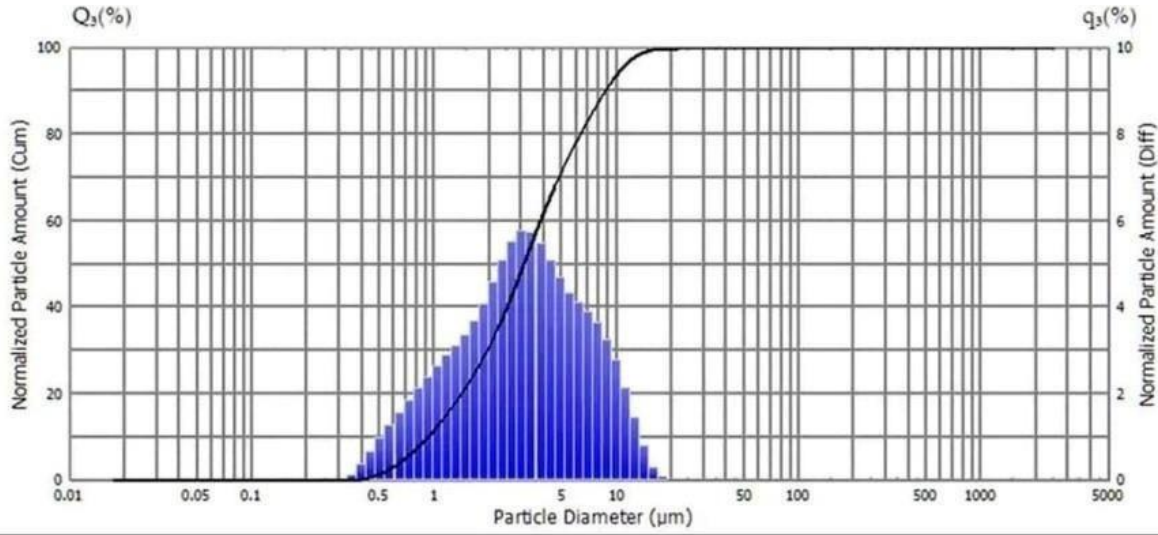
4) In-vitro Drug Release Study

In-vitro drug release studies were conducted to evaluate the release pattern under simulated physiological conditions.

5) Stability Studies

Stability studies were carried out under different temperature and humidity conditions to ensure formulation stability over time.





VII. FORMULATION OF POLYMERIC MICROSPHERES LOADED WITH ASHWAGANDHA EXTRACT

The selection of an appropriate polymer is essential for successful microsphere formulation. The polymer determines the efficiency, stability, and controlled release behavior of the final drug delivery system.

The objective of formulation is to encapsulate the herbal extract within a suitable polymer matrix so that it is protected from degradation and released in a sustained manner over a prolonged period.

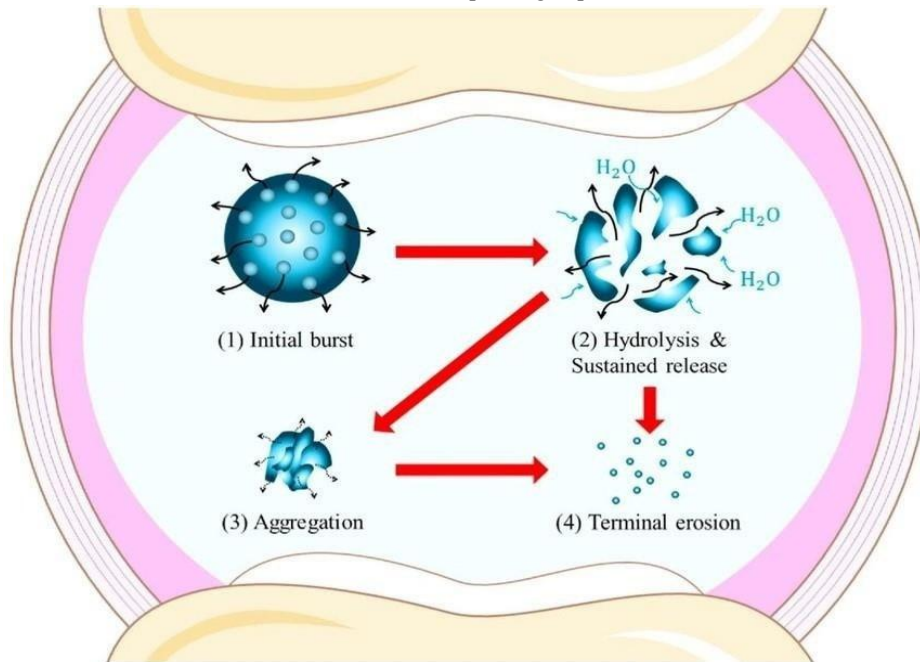


Figure 7.1: Polymer structures used in microsphere formulation



The polymer acts as the carrier matrix that controls drug entrapment and release behavior. Biodegradable and biocompatible polymers such as PLGA, chitosan, or ethyl cellulose are considered suitable due to their safety profile and controlled degradation properties inside the body.

Properties of Ideal Polymer

- Biocompatible and non-toxic
- Biodegradable in physiological conditions
- Capable of controlled drug release
- Stable during formulation process
- Compatible with herbal extracts

A. Drug–Polymer Compatibility

Drug–polymer compatibility studies help in preventing instability, degradation, or interaction between the drug and polymer.

Compatibility is generally assessed using:

- FTIR (Fourier Transform Infrared Spectroscopy)
- DSC (Differential Scanning Calorimetry)

These studies ensure that there is no significant chemical interaction affecting therapeutic activity.

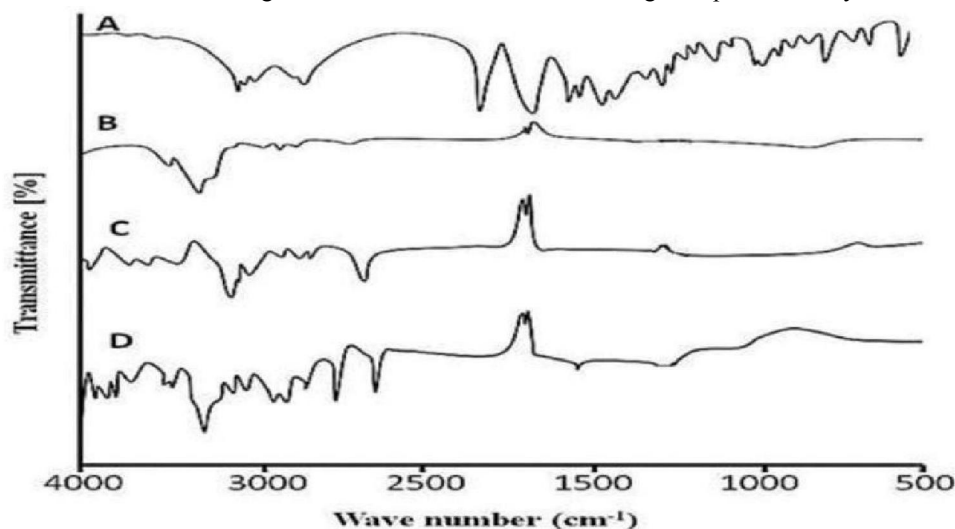


Figure 7.2: Emulsion solvent evaporation technique

B. Method of Preparation (Emulsion Solvent Evaporation Technique)

The emulsion solvent evaporation method is widely used for preparation of polymeric microspheres due to its simplicity and efficiency in drug encapsulation.

Procedure

1. Dissolve polymer in organic solvent such as dichloromethane or acetone.
2. Add Ashwagandha extract to polymer solution.
3. Add organic phase into aqueous phase under stirring.
4. Formation of oil-in-water emulsion occurs.
5. Solvent evaporation results in microsphere formation.
6. Microspheres are collected, washed, and dried.



VII. MECHANISM OF ACTION

The mechanism of action of polymeric microspheres loaded with Ashwagandha extract is based on controlled and sustained drug release.

A. Drug Release Mechanism

Drug release occurs through:

- Diffusion
- Polymer degradation
- Erosion mechanisms

Initially, a small amount of surface drug is released rapidly, known as burst release. Subsequently, entrapped drug is released slowly from the polymer matrix.

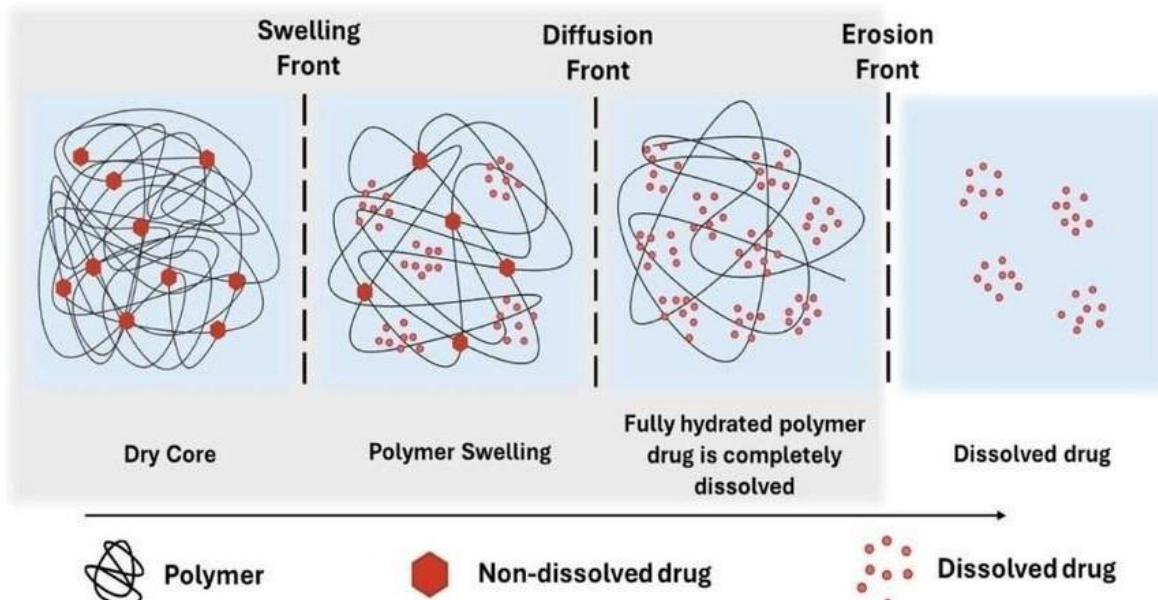


Figure 8.1: Drug release mechanism (diffusion + erosion)

B. Polymer Degradation Mechanism

Biodegradable polymers such as PLGA undergo hydrolysis in the biological environment, resulting in degradation of polymer chains into smaller fragments.

As degradation progresses, pores are formed within the microsphere structure, allowing gradual release of Ashwagandha extract.



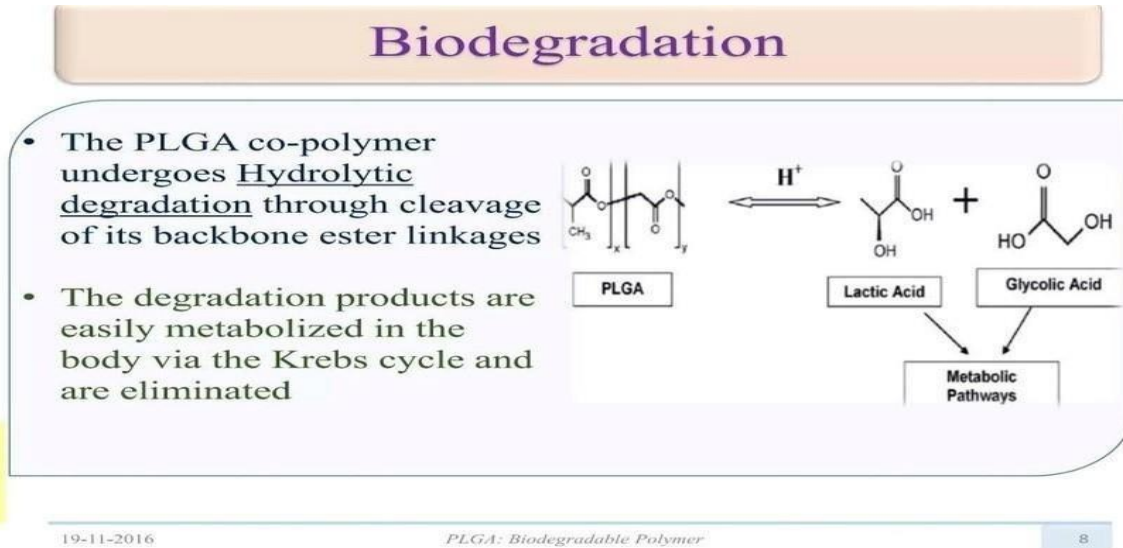


Figure 8.2: Polymer degradation process in Microspheres

C. Controlled Release Behavior

The release pattern generally shows:

1. Initial burst release
2. Sustained release phase
3. Final slow release phase

This provides immediate and prolonged therapeutic effects.

D. Mechanism of Therapeutic Action of Ashwagandha

Once released from the microspheres, active compounds such as withanolides interact with biological systems to produce therapeutic effects.

These compounds:

- Regulate stress hormones such as cortisol
- Modulate neurotransmitter activity
- Enhance antioxidant defense
- Reduce inflammation
- Support immune system function



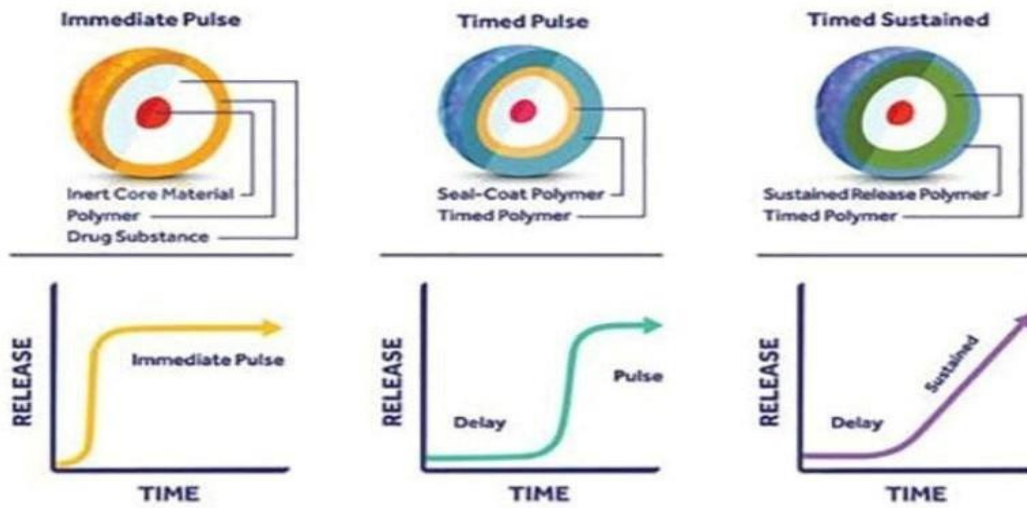


Figure 8.3: Controlled release profile (three-phase)

VIII. RESULTS AND DISCUSSION

A. Particle Size Analysis

Particle size is a crucial parameter influencing drug release rate, bioavailability, and stability.

The prepared microspheres showed:

- Uniform particle size distribution
- Acceptable microscale range
- Controlled release behavior

Increasing polymer concentration resulted in larger particle size due to increased viscosity.

B. Drug Entrapment Efficiency

Drug entrapment efficiency indicates the percentage of Ashwagandha extract successfully encapsulated within the polymer matrix.

Good entrapment efficiency was achieved due to:

- Proper polymer selection
- Optimized emulsification conditions

Higher polymer concentration improved entrapment efficiency by providing a stronger matrix for drug retention.

C. In-vitro Drug Release Study

The release profile showed a biphasic pattern:

- Initial burst release
- Sustained release phase

The burst release was attributed to surface drug molecules, whereas sustained release occurred due to gradual diffusion and polymer degradation.

D. Surface Morphology Study (SEM Analysis)

SEM analysis revealed:

- Mostly spherical microspheres



- Smooth surface morphology
- Presence of pores and irregularities

These characteristics confirmed successful encapsulation and controlled diffusion behavior.

E. Stability Study

Stability studies showed:

- No significant change in appearance
- Stable drug content
- Consistent release profile

The polymeric system effectively protected Ashwagandha extract from environmental degradation.

F. Overall Discussion

The findings suggest that polymeric microspheres are an efficient carrier system for Ashwagandha extract.

The formulation successfully achieved:

- Controlled drug release
- Improved entrapment efficiency
- Stable physicochemical properties
- Enhanced therapeutic performance

Compared to conventional dosage forms, the microsphere system maintains consistent drug concentration, reduces dosing frequency, and improves patient compliance.

IX. CONCLUSION

The present study on “Formulation and Evaluation of Polymeric Microspheres Loaded with Ashwagandha Extract” successfully demonstrated the development of an efficient and stable controlled drug delivery system using a biodegradable polymer matrix.

The polymeric microspheres were successfully formulated using the emulsion solvent evaporation method. The prepared microspheres showed desirable physicochemical characteristics including uniform particle size distribution, good surface morphology, and high drug entrapment efficiency.

The in-vitro drug release studies confirmed a biphasic release pattern consisting of an initial burst release followed by sustained and controlled release. This behavior ensures immediate therapeutic action along with prolonged drug availability.

Stability studies further confirmed that the microspheres were stable under different environmental conditions, indicating that the polymer effectively protected the Ashwagandha extract from degradation.

Overall, the study concludes that polymeric microspheres loaded with Ashwagandha extract represent a promising approach for improving herbal drug delivery systems by providing:

- Controlled release
- Improved bioavailability
- Reduced dosing frequency
- Enhanced patient compliance

Therefore, this system can be considered a potential platform for future herbal drug delivery applications.

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