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Research Article

Formulation and Evaluation of Amoxicillin Microspheres for Sustained Drug Delivery

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ABSTRACT

Bacterial pneumonia remains a major global health concern, causing significant morbidity and mortality, particularly among children, elderly individuals, and immunocompromised patients. Amoxicillin is a broad-spectrum β-lactam antibiotic commonly used for the treatment of respiratory tract infections; however, its short biological half-life, rapid elimination, and frequent dosing requirements may limit therapeutic effectiveness. The present study aimed to formulate and evaluate amoxicillin-loaded microspheres as a sustained-release drug delivery system to enhance therapeutic efficacy and improve patient compliance. Microspheres were prepared using the solvent evaporation technique with Hydroxypropyl Methylcellulose (HPMC) as the polymer and Polyvinyl Alcohol (PVA) as the emulsifying agent. Five formulations (F1–F5) were developed by varying the polymer concentration while maintaining a constant drug concentration. The prepared microspheres were evaluated for physical appearance, pH, drug content, entrapment efficiency, and percentage yield. The microspheres exhibited a white color, spherical shape, smooth texture, and odorless nature, indicating acceptable physical characteristics. The pH values ranged from 6.8 ± 0.1 to 7.2 ± 0.2, demonstrating formulation stability and compatibility. Drug content increased from 86 ± 0.6% to 94 ± 0.3%, while entrapment efficiency improved from 80 ± 0.5% to 91 ± 0.3% with increasing polymer concentration. Percentage yield also increased from 88 ± 0.4% to 94 ± 0.3%. Among all formulations, F5 exhibited the highest drug content, entrapment efficiency, and percentage yield, indicating superior formulation performance. The study concludes that amoxicillin microspheres prepared by the solvent evaporation method provide a promising sustained-release delivery system for effective management of bacterial pneumonia and may improve therapeutic outcomes by maintaining prolonged drug release.

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INTRODUCTION

Bacterial pneumonia is one of the most important infectious diseases affecting the respiratory system and is still a major cause of morbidity and mortality worldwide, especially in children, the elderly, immunocompromised patients and those with chronic illnesses. This is when pathogenic bacteria infect the lung parenchyma. This leads to inflammation and the build-up of fluid or pus in the alveoli, inhibiting normal gaseous exchange and respiratory function[1]. Among the bacterial pathogens associated with pneumonia, the most common causative organisms are Streptococcus pneumoniae, Staphylococcus aureus, Haemophilus influenzae and Klebsiella pneumoniae. Streptococcus pneumoniae is the most frequently isolated pathogen worldwide[2]. Pneumonia continues to be a major global public health challenge, despite the remarkable progress in antimicrobial therapy, vaccination and supportive healthcare. The disease affects all age groups however children under five years of age and elderly people are at particularly high risk of severe illness and death[3]. Clinically, bacterial pneumonia is usually associated with fever, productive cough, chest pain, dyspnoea, chills, leucocytosis, and purulent sputum production. In severe cases, the disease can progress rapidly to respiratory failure, sepsis, bacteraemia, pleural effusion and acute respiratory distress syndrome (ARDS) resulting in higher hospitalisation and mortality rates. The pathogenesis of bacterial pneumonia involves complex interactions between invading pathogens and the host immune response. Following bacterial invasion of the lower respiratory tract, inflammatory cells such as neutrophils, lymphocytes, and monocytes migrate to the lungs and release cytokines, proteolytic enzymes, and oxygen radicals that contribute to pulmonary inflammation and tissue injury[4]. Typical bacterial pneumonia is often associated with leucocytosis, neutrophilia, and bacteraemia, reflecting an intense inflammatory response within the lung tissues. Bacterial pneumonia may occur either as a primary infection or as a secondary complication following viral respiratory infections such as influenza. Viral infections damage the respiratory epithelium and weaken host immune defences, thereby increasing susceptibility to secondary bacterial invasion. Studies have shown that post-influenza bacterial pneumonia significantly contributes to hospitalization and death during both seasonal and pandemic influenza outbreaks. The interaction between viral infections and bacterial pathogens increases the severity of lung injury and may lead to complications such as respiratory failure and ARDS. In addition, immunocompromised individuals, particularly patients infected with the Human Immunodeficiency Virus (HIV), are at significantly greater risk of developing recurrent and severe bacterial pneumonia[5]. Studies have demonstrated that bacterial pneumonia occurs more frequently in HIV-positive individuals than in HIV-negative populations, especially among patients with reduced CD4 lymphocyte counts and injection-drug users. Factors such as smoking, malnutrition, weakened immunity, poor vaccination coverage, and inadequate healthcare access further increase susceptibility to severe pneumonia and adverse clinical outcomes. Early diagnosis and prompt treatment of bacterial pneumonia are essential for reducing disease severity and preventing complications. However, differentiating bacterial pneumonia from viral or atypical pneumonia remains difficult because many clinical signs, laboratory findings, and radiological.

features overlap. Diagnostic approaches commonly include physical examination, chest radiography, sputum culture, blood culture, white blood cell count, C-reactive protein analysis, and

molecular diagnostic techniques such as polymerase chain reaction (PCR). Nevertheless, no single diagnostic method provides complete accuracy, and limitations in pathogen detection often lead clinicians to initiate empirical antibiotic therapy before definitive identification of the causative organism. Despite advances in antimicrobial therapy, bacterial pneumonia continues to pose a major healthcare burden worldwide due to increasing antimicrobial resistance, delayed diagnosis, and limited healthcare resources in many developing regions. The emergence of multidrug-resistant bacterial strains, including methicillin-resistant *Staphylococcus aureus* (MRSA) and drug-resistant *Streptococcus pneumoniae*, has reduced the effectiveness of conventional treatment strategies and complicated disease management. Therefore, continued research on bacterial pneumonia is essential to improve understanding of its epidemiology, pathogenesis, clinical manifestations, diagnostic approaches, treatment modalities, and preventive measures. Effective management requires timely diagnosis, appropriate antibiotic therapy, vaccination, and preventive healthcare strategies. The present study aims to contribute to the existing knowledge regarding bacterial pneumonia and to explore effective approaches for its diagnosis, management, and prevention in order to reduce its associated morbidity and mortality [6].

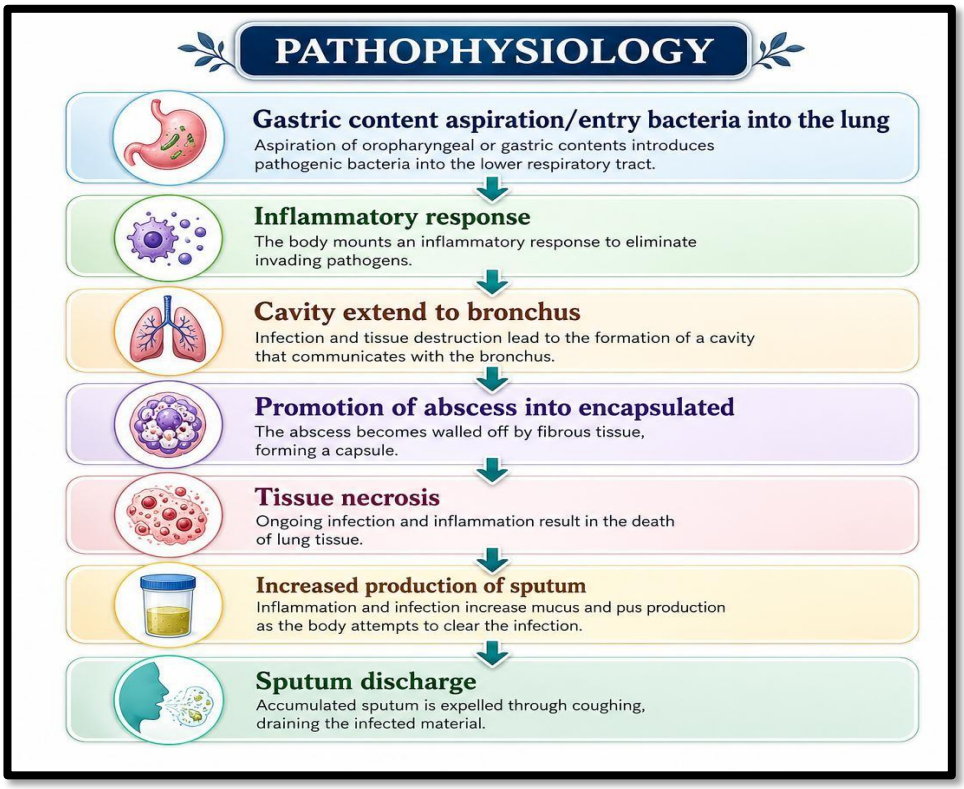


Figure: - 1 [pathophysiology of bacterial pneumonia]

Amoxicillin is a widely used broad-spectrum β-lactam antibiotic extensively employed in the treatment of various bacterial infections, particularly respiratory tract infections such as pneumonia. Pneumonia is a serious infectious disease characterized by inflammation of the alveoli and lung tissues, commonly caused by bacterial pathogens including *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Klebsiella pneumoniae*. Effective management of

pneumonia requires maintenance of adequate antibiotic concentration at the site of infection for a prolonged period. However, conventional amoxicillin therapy is often associated with several limitations such as short biological half-life, rapid elimination, frequent dosing, and reduced stability in gastric conditions, which may lead to insufficient drug concentration at the infected pulmonary site and decreased therapeutic efficacy[7].

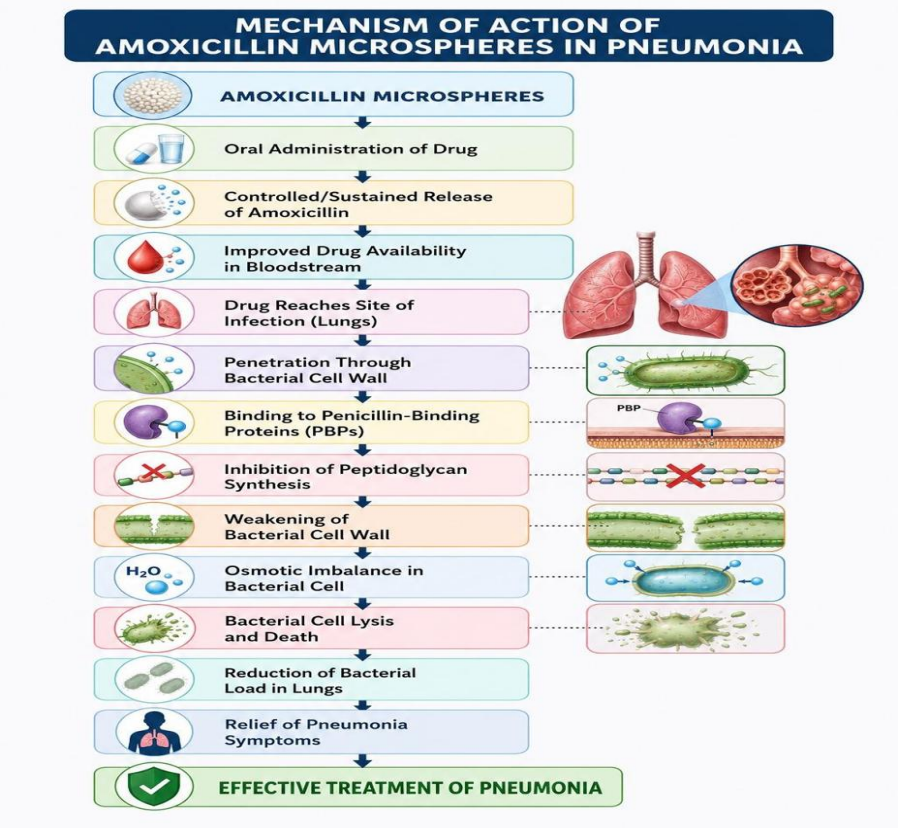
To overcome these limitations, microsphere-based drug delivery systems have gained significant attention in pharmaceutical research. Microspheres are small spherical particles composed of natural or synthetic polymers that encapsulate active pharmaceutical ingredients within a polymeric matrix. These systems are designed to provide controlled and sustained release of drugs over an extended duration. Amoxicillin-loaded microspheres are particularly advantageous because they can maintain prolonged drug release, improve bioavailability, reduce dosing frequency, and minimize fluctuations in plasma drug concentration. In addition, microspheres protect the encapsulated drug from premature degradation and enhance therapeutic effectiveness at the target site[8].

Various biodegradable and biocompatible polymers such as ethyl cellulose and poly(ε-caprolactone) have been extensively investigated for the formulation of amoxicillin microspheres due to their excellent controlled-release properties and compatibility with biological systems. Microspheres prepared using techniques such as emulsion solvent evaporation exhibit desirable characteristics including high drug entrapment efficiency, uniform particle size distribution, improved stability, and sustained drug release behaviour. These properties make amoxicillin microspheres suitable for prolonged antibacterial therapy in respiratory infections like pneumonia.

The mechanism of action of amoxicillin involves inhibition of bacterial cell wall synthesis. Amoxicillin binds irreversibly to penicillin-binding proteins (PBPs) located on the inner membrane of bacterial cell walls. These proteins are responsible for the cross-linking of peptidoglycan chains, which provide structural strength and rigidity to the bacterial cell wall. Inhibition of PBPs disrupts peptidoglycan synthesis, weakens the bacterial cell wall, and ultimately causes osmotic lysis and bacterial cell death. Since the bacterial cell wall is absent in human cells, amoxicillin exhibits selective toxicity toward bacteria[9].

In the treatment of pneumonia, the primary site of action of amoxicillin is the infected lung tissue and alveolar region where pathogenic bacteria proliferate. Sustained delivery of amoxicillin from microspheres can maintain therapeutic drug concentration at the pulmonary site for a prolonged duration, thereby enhancing antibacterial activity against respiratory pathogens. Controlled release of the drug also helps maintain concentrations above the minimum inhibitory concentration (MIC), improving bactericidal effectiveness while reducing the risk of bacterial resistance and frequent administration.

Therefore, the development of amoxicillin microspheres represents a promising approach for improving antibacterial therapy, especially in respiratory infections such as pneumonia. The present study focuses on the formulation and evaluation of amoxicillin microspheres with emphasis on sustained drug release, enhanced antibacterial activity, and improved therapeutic performance at the site of infection[10.



METHODOLOY

Physical Method

Spray drying: By dissolving Amoxicillin and a suitable polymer (such as PLGA, chitosan, or ethyl cellulose) in a suitable solvent to create a homogenous feed solution, amoxicillin microspheres are created using the spray drying method. After that, the solution is put into a spray dryer and atomized into a hot drying chamber via a nozzle. Hot air causes rapid solvent evaporation, which produces dry microspheres. After being removed from the cyclone separator, the microspheres are cooled and kept in airtight containers for additional analysis.

Fluidized bed coating: Amoxicillin -containing core particles are fluidized using a hot air stream in the fluidized bed coating technique. Using a spray nozzle, a polymer coating solution or dispersion (like ethyl cellulose, HPMC, or Eudragit) is applied to the fluidized particles. Microspheres are created when the solvent quickly evaporates and surrounds the drug particles with a uniform polymer coat. After being cooled and dried, the coated microspheres are gathered for additional analysis[13].

Coacervation-phase separation: Amoxicillin is dissolved or dispersed in a polymer solution made in an appropriate solvent in the coacervation–phase separation method. Polymer-rich droplets form around the drug particles as a result of phase separation (coacervation), which can be caused by adding a non-solvent, salt, or by altering pH or temperature. These droplets create microspheres by coating and depositing Amoxicillin . The resulting microspheres are gathered, cleaned, and dried after being solidified by cross linking or solvent removal.

Solvent Evaporation: In the solvent evaporation method, Amoxicillin and a suitable polymer are

dissolved in a volatile organic solvent to form the internal phase. This solution is emulsified into an aqueous phase containing a stabilizer under continuous stirring. The organic solvent is then evaporated, leading to solidification of the polymer and formation of Amoxicillin loaded microspheres, which are collected, washed, and dried[14].

Chemical Method

Interfacial Polymerization: In the interfacial polymerization method, Amoxicillin is dissolved or dispersed in one phase (organic or aqueous), while monomers or polymers are present in the other immiscible phase. Upon emulsification, polymerization occurs at the interface of the two phases, forming a polymeric shell around the drug. This results in Amoxicillin loaded microspheres, which are then separated, washed, and dried.

In-situ Polymerization: In the in-situ polymerization method, Amoxicillin is dispersed in a monomer or polymer solution along with an initiator. Polymerization is then initiated by heat, radiation, or chemical activation, leading to the formation of polymer chains around the drug particles. As polymerization proceeds, azithromycin becomes entrapped within the polymer matrix, forming microspheres, which are subsequently collected, washed, and dried[15].

Solvent evaporation Method

The solvent evaporation method is a widely used method for the preparation of microspheres. The method is based on the principle that a polymer dissolved in a volatile organic solvent can precipitate around the drug as the solvent evaporates. In this method, the drug and the polymer are dissolved or dispersed in an organic solvent, such as dichloromethane or acetone. The organic phase is then emulsified in an aqueous phase that contains an emulsifying agent such as Polyvinyl Alcohol (PVA). The continuous stirring produces small droplets of the organic phase dispersed in the aqueous medium and an oil-in water emulsion is formed. With continued stirring the organic solvent slowly evaporates, the polymer hardens around the drug particles. This leads to the formation of solid microspheres with azithromycin encapsulated. The size and characteristics of microspheres are influenced by several factors as: Polymer concentration Agitation speed Nature of the solvent Temperature Emulsifier concentration Drug to polymer ratio The solvent evaporation method is preferred as it produces uniform microspheres with high entrapment efficiency and controlled drug release[16].

Amoxicillin

Amoxicillin is a widely used penicillin-type antibiotic that helps treat many bacterial infections, including throat, ear, chest, urinary tract, skin, and dental infections. It works by stopping bacteria from forming protective cell walls, which kills them. Doctors prescribe it in capsules, tablets, or liquid form. It is not effective against viral infections such as colds or flu.

Polymers

Eudragit/HPMC Eudragit is a synthetic polymer for sustained and controlled drug delivery. It improves the stability of the drug and regulates its release from the microspheres.

Ethylcellulose

Ethyl cellulose is a hydrophobic polymer widely used in formulations for sustained drug release. It reduces fast drug release and increases encapsulation efficiency.

PLGA (Polylactic-co-Glycolic-Acid)

PLGA, a biodegradable and biocompatible polymer, is widely used in sophisticated drug delivery systems. It is released slowly and is safely biodegradable in the body.

Organic Solvents

Organic solvents such as dichloromethane and acetone dissolve both the polymer and drug to form the internal phase. Their volatile nature enables rapid evaporation during microsphere formation.

Polyvinyl Alcohol (PVA)

PVA acts as an emulsifying and stabilizing agent. It prevents aggregation of droplets and helps in the formation of stable and uniform microspheres[18].

Evaluation parameter

Physical Appearance:

Visually inspect the microspheres for colour, odour, shape and texture. Colour, odour, shape and texture check.

Ensure uniformity and acceptability.

1. **PH determination:**
   Dissolve sample In distilled water and measure pH in using digital pH meter. Check the acidity or alkalinity of the formulation.
   Important for stability and compatibility.
2. **Particle size Analysis:**
   Measure particle size in using optical microscopy. Determines size and distribution of particles.
   Affect drug release and absorption.
3. **In-Vitro drug release study:**
   Samples are withdrawn periodically from dissolution and analyzed using UV spectrometer.
   Evaluates the rate and extend of drug release over time. Helps determine sustained or controlled release.
4. **Drug Content:**
   Crush microsphere dissolve in solvent, filter and analyze drug concentration. Measure the amount of azithromycin present in the formulation.
   Ensure accurate dosage.
5. **Entrapment Efficiency:**
   Determine amount of drug entrapped inside microsphere and compare with total drug added.
   Determines the percentage of drugs successfully incorporated into the carrier system. Important in nanoparticles and microspheres.
6. **Percentage yield:**
   Weigh dried microspheres and compare with total weight of drug and polymer used. Weight of dried particles.
   % yield = weight of dried particles/total weight of drug +polymer used**X 100.

Preparation of microsphere for amoxicillin
Materials required

- **Figure2: [Chemicals]**

- Amoxicillin (Active Pharmaceutical Ingredient) Polymer (e.g., Eudragit, Ethyl Cellulose, or PLGA)
- Organic solvent (e.g., Dichloromethane or Acetone)
- Emulsifier (e.g., Polyvinyl Alcohol - PVA) Distilled water
- Magnetic stirrer
- Filter paper
- Oven or vacuum desiccator.

Step-by-Step Process:

Procedure

1. **Prepare Drug-Polymer Solution:** Dissolve a known amount of Amoxicillin and the selected polymer (e.g., Eudragit) in the organic solvent (e.g., Dichloromethane or Acetone) under stirring until a clear solution is formed.
2. **Prepare Aqueous Phase:** Prepare an aqueous solution of emulsifier (e.g., 1–2% PVA in distilled water).
3. **Emulsification**: Slowly add the drug-polymer organic solution dropwise into the aqueous phase while stirring at a constant speed (e.g., 500–1000 rpm). Continue stirring for 2–3 hours to allow the formation of an oil-in-water (O/W) emulsion and solvent evaporation.
4. **Solvent Evaporation & Microsphere Formation:** Continue stirring until the organic solvent fully evaporates, leaving solid microspheres suspended in the aqueous phase.
5. **Collection of Microspheres:** Filter the microspheres using filter paper or centrifugation. Wash microspheres several times with distilled water to remove residual emulsifier and solvent.

Figure3: [Collection of Microspheres]

6. Drying: Dry the microspheres in an oven at low temperature (e.g., 40–50°C) or in a vacuum desiccator until completely dry.

Formulation and Evaluation of microsphere for Amoxicillin

Formulation table [14,15,16]:- 1

	API (Amoxicillin) mg	Polymer (HPMC) mg	Organic solvent(Acetone) ml	Emulsifier (PVA) % w/v	Distilled water ml	Stirring time hour
F1	100	100	10	1%	100	3
F2	100	150	10	1%	100	3
F3	100	200	10	1%	100	3
F4	100	250	10	1%	100	3
F5	100	300	10	1%	100	3

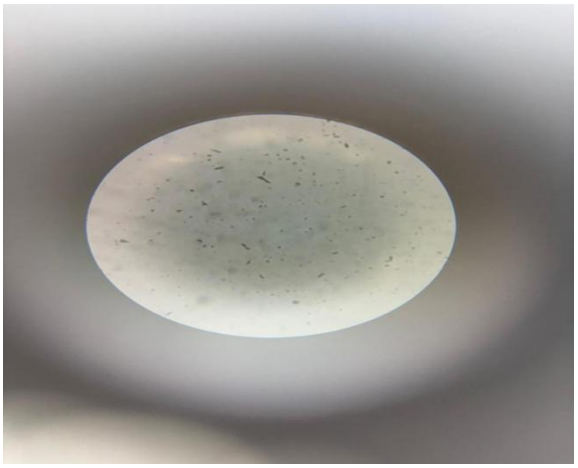


Figure4:- [formulation of microsphere in using optical microscopy]

Result

1. Physical Appearance:

Table:- 2 [physical appearance]

Test	Appearance
colour	White
odour	Odourless
Shape	Spherical
Texture	Smooth

2. PH Determination

Table:- 3 [pH determination]

Formulation	Appearance
F1	6.8+/-0.1
F2	6.9+/-0.1
F3	7.0+/-0.1
F4	7.1+/-0.1
F5	7.2+/-0.2

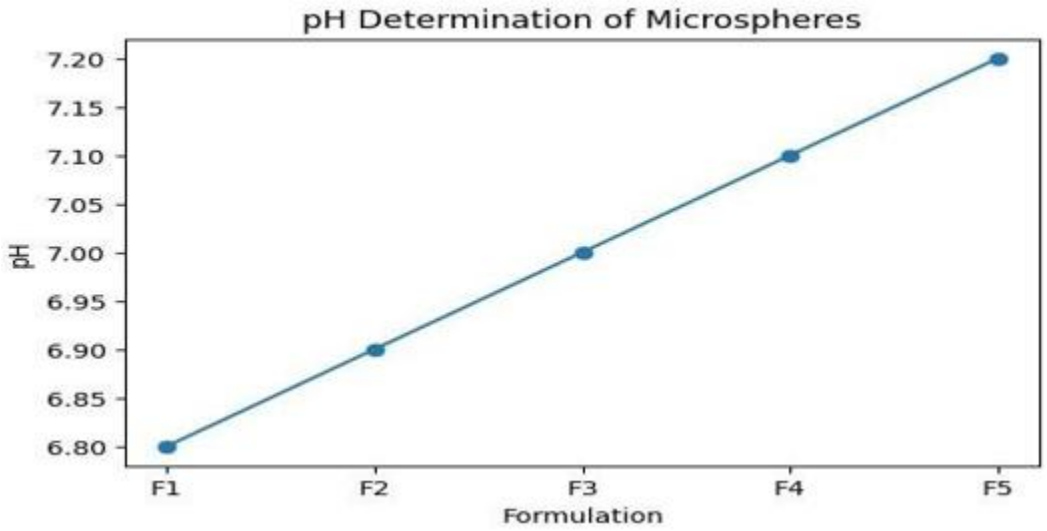


Figure5: [Graph for pH Determination of microspheres]

1. Drug content:

Table: - 4 [drug content]

Fomulation	Drug content (Mean+/-SD)
F1	86+/-0.6
F2	88+/-0.5
F3	90+/-0.4
F4	92+/-0.5
F5	94+/-0.3

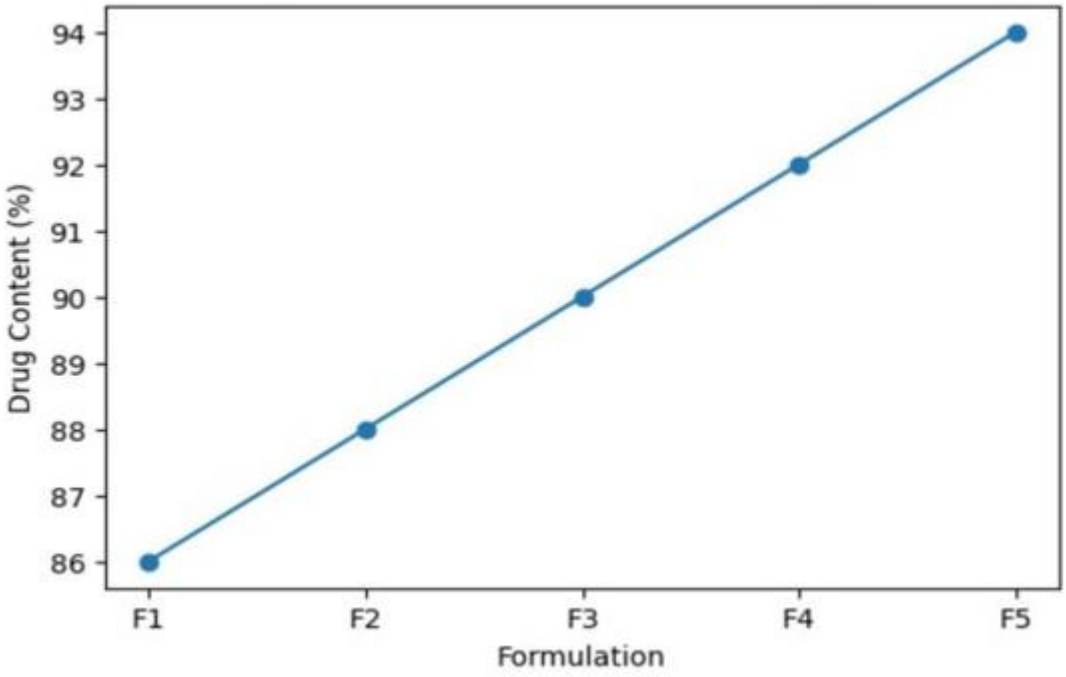


Figure6:- [Graph for drug content of Amoxicillin microspheres]

1. Entrapment efficiency:

Table:- 5 [Entrapment efficiency]

Formulation	**Entrapment efficiency (mean+/-SD)**
F1	80+/-0.5
F2	83+/-0.4
F3	86+/-0.5
F4	89+/-0.3
F5	91+/-0.3

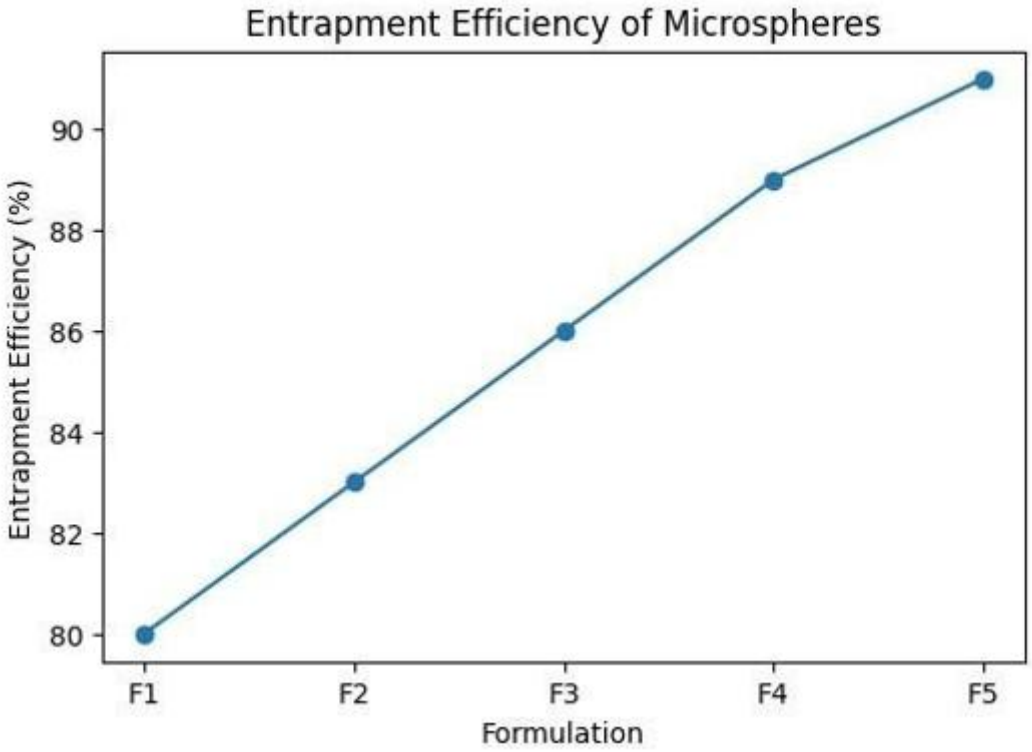


Figure7: [graph for entrapment efficiency of microsphere]

1. **Percentage Yield**

Table: - 6 [practical yield]

Formulation	Yield (Mean + SD)
F1	88+/-0.4
F2	90+/-0.5
F3	92+/-0.3
F4	93.14+/-0.2
F5	94+/-0.3

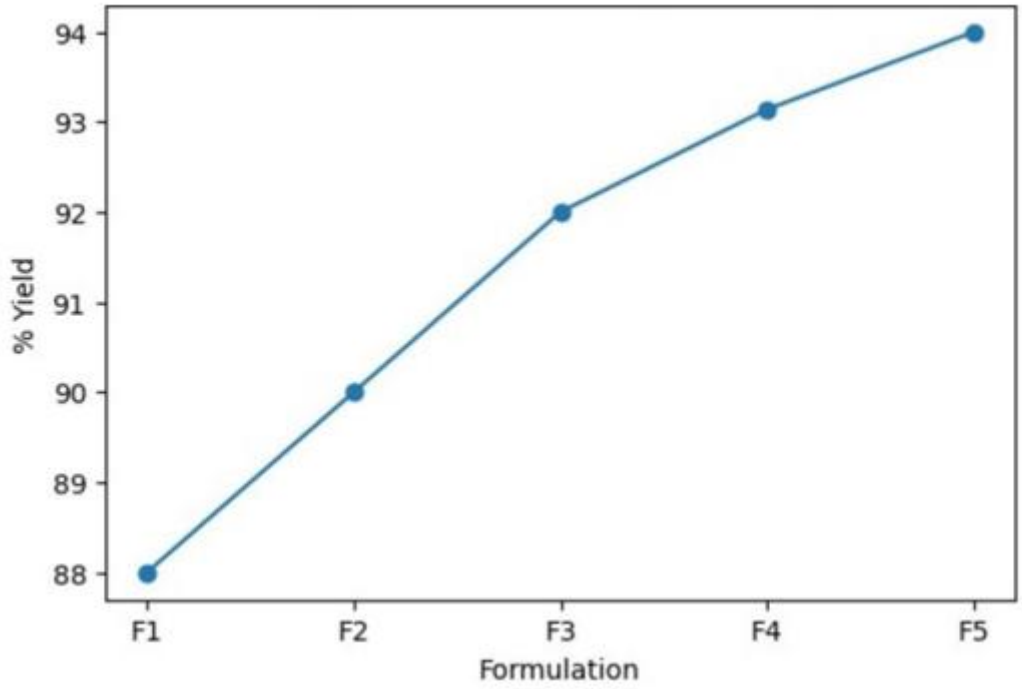


Figure8: [graph for practical yield of amoxicillin microspheres]

DISCUSSION

Prepared amoxicillin microspheres showed satisfactory physical appearance with white colour, odourless nature, spherical shape and smooth texture. The pH values were within the acceptable range indicating the stability of the formulation. Dissolution and in-vitro drug release studies confirmed sustained drug release behaviour. Polymer concentration increase resulted in increase in drug content and entrapment efficiency indicating effective incorporation of drug in the polymer matrix. The percentage yield was improved from F1 to F5 indicating better recovery of the microspheres**.**

CONCLUSION

The present study successfully formulated and evaluated amoxicillin microspheres by solvent evaporation method by HPMC polymer and PVA as emulsifying agent. The prepared microspheres were having good physical appearance with white colour, odourless nature, spherical shape and smooth texture. The pH values were within the acceptable range, indicating the stability and compatibility of the formulation. Dissolution and in-vitro drug release studies confirmed the controlled and sustained release profile of drug. The drug content and the entrapment efficiency increased with the increase in the polymer concentration, indicating the efficient encapsulation of azithromycin within the polymer matrix. The percentage yield also showed increasing trend from F1 to F5 with good recovery of microspheres. Among all the formulations, F5 showed the best results for the maximum drug release, drug content and entrapment efficiency.

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