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Original Article

# Fabrication and Evaluation of Floating Zidovudine Microbeads for Prolonged Kinetic Release and Bioavailability

**Kiran Dobhal[1], Shalu Verma[2,*], Alka Singh[3], Gauree Kukreti[3]**

[1]Department of Pharmaceutical Chemistry, College of Pharmacy, Shivalik Campus, Dehradun, Uttarakhand, INDIA.
[2]Department of Pharmaceutics, Uttaranchal Institute of Pharmaceutical Sciences, Uttaranchal University, Premnagar, Dehradun, Uttarakhand, INDIA.
[3]Department of Pharmaceutics, School of Pharmaceutical Sciences and Technology, Sardar Bhagwan Singh University, Dehradun, Uttarakhand, INDIA.

## ABSTRACT

**Aim:** AIDS (Acquired Immuno Deficiency Syndrome) is one of the most sexually transmitted diseases with chronic depletion of immunity in the body associated with social stigma, social isolation and depression. Zidovudine is an orally prescribed antiretroviral drug for AIDS. The current work's objective was to develop floating microbeads of zidovudine to achieve sustained release action. Floating microbeads are a non-effervescent, gastro-retentive drug delivery technology that has been designed to lengthen the gastric residence time of dosage forms. **Materials and Methods:** The ionotropic gelatin method has opted for the development of Zidovudine floating microbeads. Different ratio of used polymers affects the buoyancy, drug release, particle size, drug entrapment, density, and *in vitro* drug release of microbeads. Calcium chloride was used as a cross linker and Glyceryl monostearate was used as a disaggregating agent. **Results:** The resultant microbeads were furthermore evaluated by FT-IR, SEM, Micrometric, Density, drug entrapment efficiency, buoyancy and *in vitro* drug release and cumulative drug release studies. **Conclusion:** The microbeads were found to be spherical; the mean particle size was estimated to be 594 ± 7.46 µm with maximum drug entrapment efficiency of 82.30 ± 1.63% w/w. The *in vitro* percentage release of the drug after 12 hr of the formulation MB3 showed the highest drug release which was found to be 90.05 ± 0.64. SEM images showed smooth and spherical shapes.

**Keywords:** Microbeads, Sustained, Zidovudine, Floating, Gastro-retentive.

**Correspondence:**
**Ms. Shalu Verma**
Department of Pharmaceutics, Uttaranchal Institute of Pharmaceutical Sciences, Uttaranchal University, Premnagar, Dehradun-248007, Uttarakhand, INDIA.
Email: vermashalu339@gmail.com
ORCID: 0000-0003-3845-3710

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## INTRODUCTION

Zidovudine (ZDV) or Azidothymidine (AZT) is an antiretroviral drug, used in the treatment of Hepatitis B and AIDS (Acquired Immuno Deficiency Syndrome) with a combination of Lamivudine. It is the first anti-HIV drug.[1] It exerts its action against virus propagation by interrupting the nucleoside analogue incorporation which is essential for DNA formation.[2,3] The causative agent of AIDS is HIV (Human Immunodeficiency Virus); a kind of RNA virus. It directly affects the immunity of the living being.[4] Eradication of HIV requires a consistent and uniform supply of medication which is a tedious task to the till date. A single sustained-release formulation of zidovudine could be an alternate approach to delivering the medication for an extended duration.[5] Such kind of approach decreases the frequency of the dosing, and the side effects, improving potency and patient comfort.[6]

However, tablets, capsules, and syrup of ZDV are already commercially available; still microbeads are far away. Microbeads could be the novel approach to target the sustained-release formulation of ZDV.[7] There are mostly three methods to develop microbeads viz. ionotropic gelation method, emulsion gelation method and polyelectrolyte complexation method. Among these, the most applicable ionotropic gelation method is opted for the fabrication of ZDV microbeads because of its easy-to-operate, short-time consumption to obtain sustained-release formulations on an industrial scale.[8]

Floating microbeads are free-flowing particles that lie in the range of 10 µm to 1000 µm. To achieve constant drug release for sustained action, the drug must be present over the intestinal regimen for a certain period associated with first-order kinetics.[9] Floating microbeads could be a novel approach for the

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controlled release of ZDV.[10] Bioavailability raises the basic pH because ZDV becomes less soluble in this pH and lowers drug release by extending the transit time.[11-13] Polymers employed for the microbeads fabrication are HPMC, SCMC, and Glyceryl monostearate. These polymers have excellent gelation properties which bind the drug effectively and delay the drug release.

This study comprised the fabrication and evaluation of ZDV floating microbeads through the ionotropic gelation method.[14,15] Polymers used in the formulation are sustained release polymer support to achieve the controlled drug release in different ratios.[16] Evaluate and optimize the in *vitro* drug release and kinetics behaviour of ZDV floating microbeads.[17]

## MATERIALS AND METHODS

### Materials

ZDV is purchased from Cipla Pvt. Ltd., (Indore). HPMC K15M and SCMC are purchased from JPEE, drugs, and industrial area (Agra). Calcium Chloride is purchased from Ay Polychem (Delhi). Glyceryl Monostearate (GMS) used as disaggregating agent; purchased from Abees Pharma (Delhi).

### Preformulation studies

Organoleptic properties of the drug samples like colour, taste, odour, and physical form were determined using suitable methods. The capillary method was used to measure the melting point in triplicate, and the mean value was presented. The aqueous solubility of the drug was measured in triplicate using the shake flask solubility saturation method. The solutions were then filtered and diluted if needed and analyzed in an Ultraviolet-visible (UV-visible) spectrophotometer. It has been reported that zidovudine is sparingly soluble in water but readily soluble in ethanol and 0.1N HCl. Drug excipients compatibility study with polymer was confirmed by FT-IR.[1]

### Method of Preparation of Microbeads

Microbeads are prepared by the ionotropic gelation method. ZDV, HPMC, SCMC, and glyceryl monostearate were incorporated and dissolved in distilled water at room temperature. The resultant mixture was transferred gradually into 6%w/v Calcium chloride solution by using a hypodermic needle with constant stirring, until the appearance of microbeads. This colloidal solution was subjected to filtration and washing; followed by air drying for 24 hr in a desiccator. Different ratios of polymers along with fixed content of calcium chloride and glyceryl monostearate were proposed for optimization purposes (Table 1).

### Evaluation of floating microbeads of ZDV

#### *Surface Morphology and Shape*

SEM was used to examine the microbeads' morphology.[18]

### Micromeritic characteristics

Micromeritic characteristics of microbeads, such as bulk density, particle size, porosity and real density, have been studied.[19]

### Bulk Density and true density

The true density and bulk density were calculated using the tapping method.[20,21]

### Process Yield of ZDV

The percentage yield for the different floating microbead formulations of ZDV was determined by the following formula.

$$\% \text{ yield} = \text{Total weight of floating microbeads} \times 100 / \text{Total weight of polymer and drug}$$

### Drug Entrapment Efficiency and Drug Loading

50 mg of the microbead converted into powder form and suspended in 10 mL of 0.1N HCl; continuous stirring for 2 hr until a homogenous mixture is obtained. The resultant mixture is examined by UV at 200 nm and 300 nm wavelength.[22]

### Buoyancy/Floating characteristics

100 mg of microbeads were mixed into 300 mL of 0.1N HCl at 37°C, pH 1.2. The floating and settling microbeads portions of the mixture were reported individually after subjecting continuous stirring.[23]

### *In vitro* Drug Release Study

The USP paddle type II Dissolution equipment (Electrolab, India Pvt. Ltd., Mumbai) was used to examine the *in vitro* dissolution of floating microbeads of ZDV at a speed of 50 rpm. The microbeads were dispersed in the 900 mL of acidic buffer (0.1N HCL). The

**Table 1: Formulation table of ZDV floating microbeads.**

| Formulation | MB1 | MB2 | MB3 | MB4 | MB5 |
|---|---|---|---|---|---|
| ZDV (mg) | 500 | 500 | 500 | 500 | 500 |
| HPMC (mg) | 150 | 150 | 300 | 150 | 450 |
| SCMC (mg) | 150 | 300 | 150 | 450 | 150 |
| Calcium Chloride (mL) | 35 | 35 | 35 | 35 | 35 |
| GMS (g) | 1 | 1.5 | 1 | 1.5 | 1 |
| Distilled Water (mL) | 100 | 100 | 100 | 100 | 100 |

temperature of the dissolution medium was kept constant at 37.5°C throughout the study. At regular intervals, a sufficient volume of samples was collected and promptly filtered using a membrane filter. After each sampling, a volume of dissolving medium equal to the volume of the samples removed was added to the vessel. The UV spectrophotometer was used to determine the concentration of the drug in the samples at 267-300 nm. The amount of dissolved ZDV was calculated from standard curves.[24,25]

## RESULTS

### Pre-formulation studies

ZDV microbeads were evaluated for various pre-formulation parameters like organoleptic properties, melting point, solubility, and drug excipient compatibility studies. The drug was found to be tasteless, odorless and an off-white crystalline powder. The drug's melting point was between 5 ± 106°C. The drug is sparingly soluble in water and firmed colloidal solution, while in ethanol and warm water, it is completely soluble. Water solubility was measured at 750 g/L.

### Drug-excipients compatibility study

To evaluate the compatibility between the drug and polymers, FTIR-spectra was used. The FTIR spectrum of ZDV, HPMC, SCMC. The FT-IR test results exhibited the absence of any drug or polymer interaction. Figures 1, 2, and 3 were the depiction of the FT-IR study of ZDV, HPMC and SCMC respectively.

### Evaluation

Average diameter, drug entrapment efficiency, percentage yield, drug loading, and buoyancy/floating properties have been summarized in Table 2.

### Cohesiveness

Disaggregating agents influence the flowing property of microbeads. GMS was employed to resist the cohesiveness among the microbeads. Flow property is an essential parameter to ensure dose uniformity in the microbeads. The powder blend of all formulations was evaluated to ensure good flow properties and the selection of disaggregating agents. Carr's compressibility index, Hausner's ratio and Angle of repose were calculated for flow characterization. The results showed good to excellent flow properties which are desirable for the compression of the tablets as given in Table 3.

### *In vitro* Drug Release Study

The data of *in vitro* drug release studies are shown in 0.1 N HCl (Figure 5). An extended-release pattern exhibited initial burst release was evident from release data. Drug release in the first hour for formulations MB1, MB2, MB3, MB4, and MB5 was 23.73%, 22.05%, 25.05%, 24.86% and 28.98% respectively whereas after 12 hr it was 86.17%, 82.05%, 90.11%,88.05% and 87.85% respectively. It is depicted that wetting of the polymers first produced swelled the microbeads that caused initial burst release. Table 4 illustrates that increasing the content of SCMC inclines excellent drug release while HPMC content increments satisfactory drug release from microbeads. As the microbeads encountered the medium, the core part of the microbeads swelled up initially, and its destruction raised when swelling continued with time. Cumulative % drug release data showed that all formulations showed sustained release. The formulation (MB3) containing the HPMC: SCMC in the ratio of 2:1 released 90.11 % drug after the 12$^{th}$ hr and was therefore chosen as the best formulation.

### Kinetic Analysis of Release Data

Drug release data from floating microbeads were further justified by using a defined kinetic approach viz. Korsmeyer-Peppas

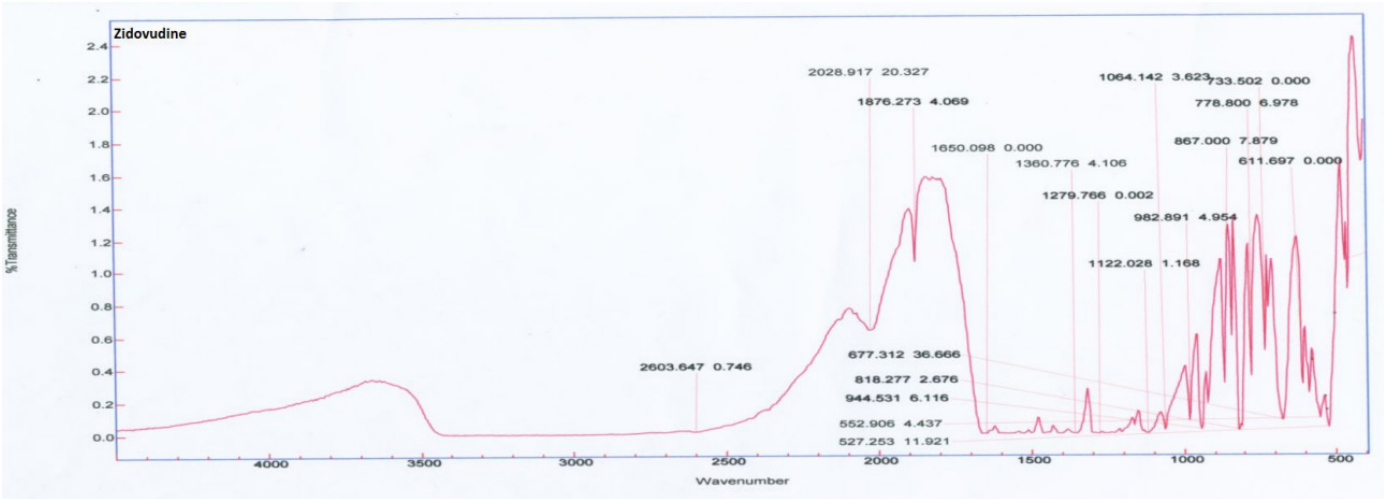


**Figure 1:** FTIR-spectra of ZDV.

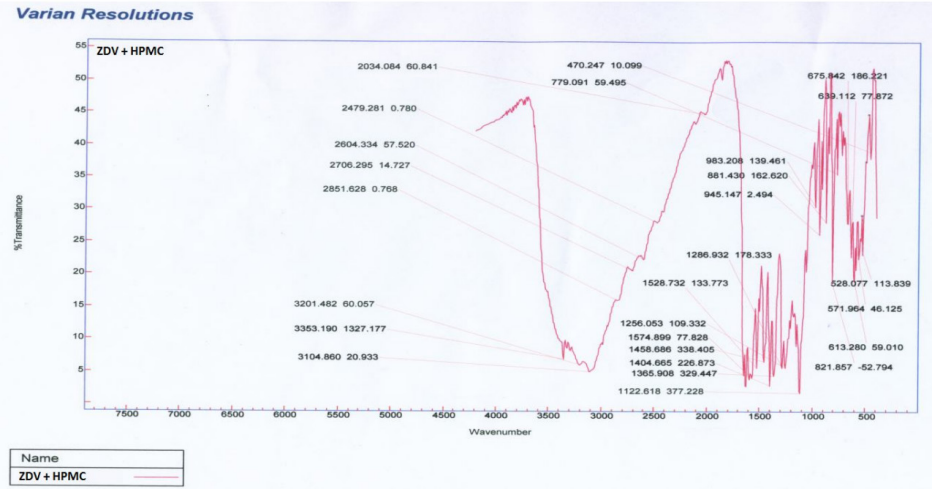


**Figure 2:** FTIR-spectra of HPMC.

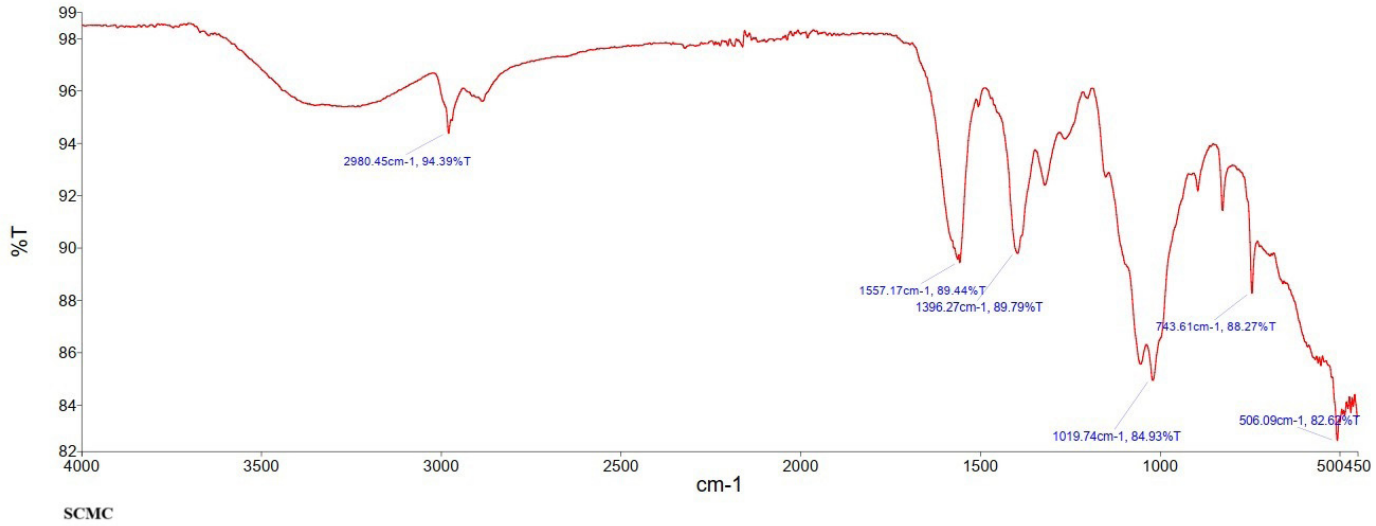


**Figure 3:** FTIR-spectra of SCMC.

**Table 2: Different properties of the floating microbeads of ZDV.**

| Formulation | Diameter (μm) | DEE (%w/w) | Cohesiveness (%) | Drug content (%w/w) | Buoyancy* (%) |
|---|---|---|---|---|---|
| MB1 | 436.33±8.64 | 70.07±3.45 | 86.11±3.12 | 13.74±2.02 | 73.66±3.88 |
| MB2 | 575.21±6.22 | 82.30±1.63 | 90.42±1.25 | 16.13±1.18 | 87.43±1.61 |
| MB3 | 421.25±6.83 | 66.22±3.12 | 74.13±3.65 | 24.64±2.12 | 46.34±2.95 |
| MB4 | 594.79±7.46 | 76.03±3.45 | 80.80±3.85 | 19.01±2.48 | 84.25±3.20 |
| MB5 | 486.14±4.61 | 44.16±4.32 | 66.36±4.78 | 25.21±2.45 | 34.75±4.62 |

*Buoyancy was determined after 12 hr.

**Table 3:** Flow characteristics of Different microbeads.

| Formulation | Carr's index | Hausner's ratio | Angle of repose | Flow property |
|---|---|---|---|---|
| MB1 | 13.24±0.51 | 1.12±0.006 | 23.74±0.11 | Good |
| MB2 | 12.51±0.86 | 1.14±0.008 | 21.10±0.60 | Good |
| MB3 | 12.36±0.49 | 1.12±0.007 | 25.76±0.32 | Good |
| MB4 | 12.49±0.45 | 1.14±0.012 | 20.44±0.34 | Good |
| MB5 | 13.88±0.34 | 1.15±0.009 | 20.48±0.31 | Good |

**Table 4:** *In vitro* release profile of Zidovudine in 0.1N HCl.

| Time (hr) | Cumulative % Drug Release | | | | |
|---|---|---|---|---|---|
| | 1:1 | 1:2 | 2:1 | 3:1 | 1:3 |
| 0.5 | 17.36±1.08 | 16.05±0.94 | 18.11±0.78 | 18.48±0.46 | 21.48±0.74 |
| 1 | 23.73±0.83 | 22.05±0.64 | 25.05±0.52 | 24.86±0.49 | 28.98±0.62 |
| 2 | 31.98±0.76 | 28.98±0.53 | 33.11±0.79 | 33.11±0.59 | 37.80±1.06 |
| 3 | 37.80±0.96 | 34.98±0.45 | 39.30±1.18 | 38.93±0.66 | 44.93±0.54 |
| 4 | 44.93±0.59 | 41.92±0.37 | 47.93±0.94 | 46.43±0.51 | 53.93±0.89 |
| 5 | 53.93±0.67 | 49.98±0.84 | 57.11±0.86 | 55.80±0.46 | 61.98±0.57 |
| 6 | 61.98±1.15 | 56.92±0.64 | 65.17±0.64 | 63.86±0.97 | 69.86±0.69 |
| 7 | 69.86±1.07 | 63.86±0.59 | 73.05±0.81 | 71.74±0.64 | 77.73±0.37 |
| 8 | 75.11±0.67 | 69.86±0.57 | 79.98±0.93 | 77.73±0.59 | 84.11±0.94 |
| 9 | 79.98±0.59 | 75.11±0.82 | 84.48±0.52 | 82.98±0.61 | 89.17±1.13 |
| 10 | 82.98±0.55 | 78.30±0.33 | 86.55±1.12 | 85.05±0.81 | 91.23±1.02 |
| 11 | 85.23±0.54 | 80.93±0.78 | 88.61±0.66 | 87.30±0.56 | 92.18±0.76 |
| 12 | 86.17±0.61 | 82.05±0.64 | 90.11±0.49 | 88.05±0.86 | 88.05±0.86 |

model, Hixon Crowell's cube root rule and Higuchi matrix model. The data were examined using the regression coefficient technique. Table 5 displayed Regression coefficient ($R^2$) values, which were computed using the least-squares approach with a 95% confidence level. Analysis of the regression coefficient values of all formulations revealed that MB1, MB2, MB3, MB4, and MB5 satisfied the Korsmeyer-Peppas model with the greatest Regression ($R^2$) values close to 0.990. Satisfaction of the Korsmeyer-Peppas equation exposed these microbeads followed the non-Fickian behaviour for the sustained drug. Investigation of all formulations revealed that all formulations fit into the Higuchi matrix model. For the Higuchi model, MB3 and MB5 had the greatest $R^2$ values of 0.989 and 0.998, respectively. Hixon Crowell's cube root rule was fit into MB2, MB3 and MB5 revealing $R^2$ values of 0.947, 0.958, and 0.982, respectively. All the mentioned data emphasized that drug release was the consequence of swelling with erosion.

## DISCUSSION

### Percent drug entrapment

The percent drug entrapment was found to be 82.30 ± 1.63%. Percent drug entrapment decreased with an increase in particle size and decreased with a reduction in particle size and a rise in polymer content.

### Buoyancy

*In vitro* buoyancy tests were performed to determine if the manufactured microbeads floated. For batch optimization, significant *in vitro* percentage buoyancy was seen. This property may be utilized to explain the microbeads' ideal porosity and low bulk density. As the average particle size of the microbeads increased, their bulk density fell. Microbeads became more porous in the same order that cavity volume grew. In this instance, microbeads buoyancy also increased.

### Bulk density, True density, and Porosity

The range of bulk density values was 0.5294 ± 0.021 to 0.5917 ± 0.019 g/cm$^3$ while their true density ranged from 1.0016 ± 0.0041 to 1.0102 ± 0.0039 g/cm$^3$. All of the microbeads composition's porosity was found to be between 47.14 ± 0.67 to 41.42 ± 0.084 is given in Table 6 and shown graphically in Figure 4.

### *In vitro* Drug Release Study

The amount of dissolved ZDV was calculated from standard curves (Figure 5).

**Table 5:** Flow characteristics of Different microbeads.

| Formulations | zero order | first order | Higuchi | Hixon Crowell | Korsmeyer-Peppas | |
|---|---|---|---|---|---|---|
| | $R^2$ | $R^2$ | $R^2$ | $R^2$ | $R^2$ | *n* |
| MB1 | 0.899 | 0.790 | 0.975 | 0.935 | 0.940 | 0.540 |
| MB2 | 0.906 | 0.812 | 0.982 | 0.947 | 0.951 | 0.625 |
| MB3 | 0.909 | 0.825 | 0.989 | 0.958 | 0.966 | 0.590 |
| MB4 | 0.914 | 0.765 | 0.994 | 0.969 | 0.974 | 0.647 |
| MB5 | 0.920 | 0.808 | 0.998 | 0.982 | 0.990 | 0.588 |

**Table 6:** Effect of Bulk density and Porosity on Buoyancy of microbeads.

| Batch | Polymer ratio (HPMCK 15M/EC) | Bulk density (gm/cm³) | True density (gm/cm³) | Porosity (%) | Buoyancy (%) after 12 hr |
|---|---|---|---|---|---|
| M1 | 1:1 | 0.5294±0.021 | 1.0016±0.0041 | 47.14±0.67 | 73.66±3.88 |
| M2 | 1:2 | 0.4433±0.015 | 1.0012±0.0024 | 55.72±0.51 | 87.43±1.61 |
| M3 | 2:1 | 0.6682±0.024 | 1.0169±0.0035 | 34.29±0.45 | 46.34±2.95 |
| M4 | 1:3 | 0.4865±0.022 | 1.0018±0.0031 | 51.43±0.59 | 84.25±3.20 |
| M5 | 3:1 | 0.5917±0.019 | 1.0102±0.0039 | 41.42±0.84 | 34.75±4.62 |

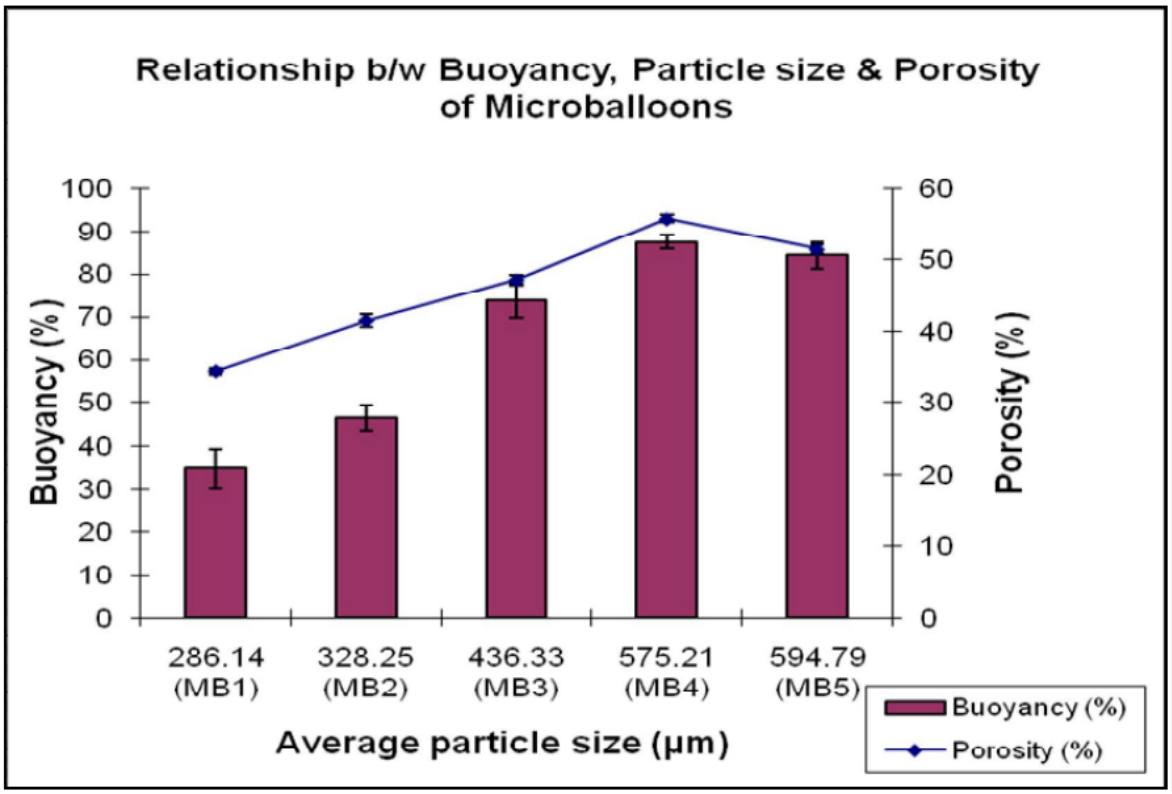


**Figure 4:** Relationship between Buoyancy, Particle Size & porosity of microbeads.

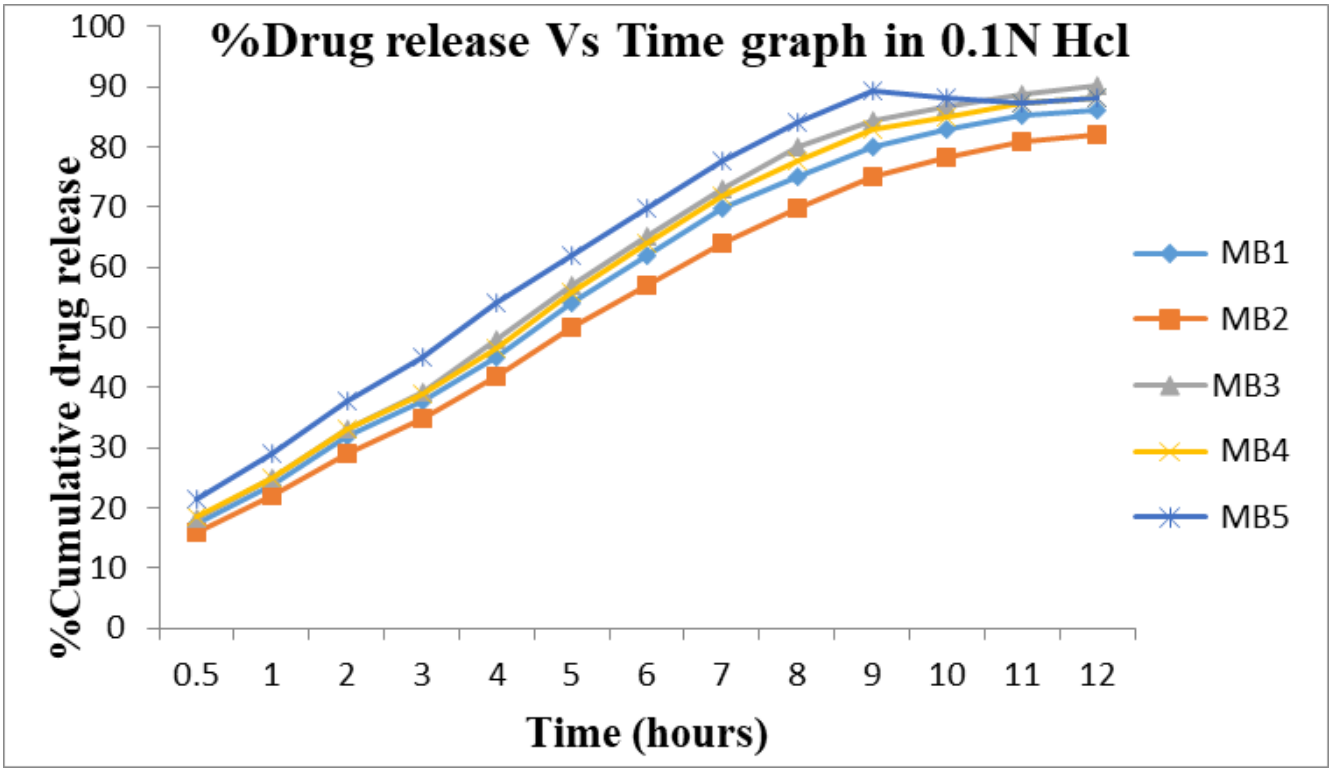


**Figure 5:** *In vitro* release profile of ZDV Microbeads in 0.1 N HCl.

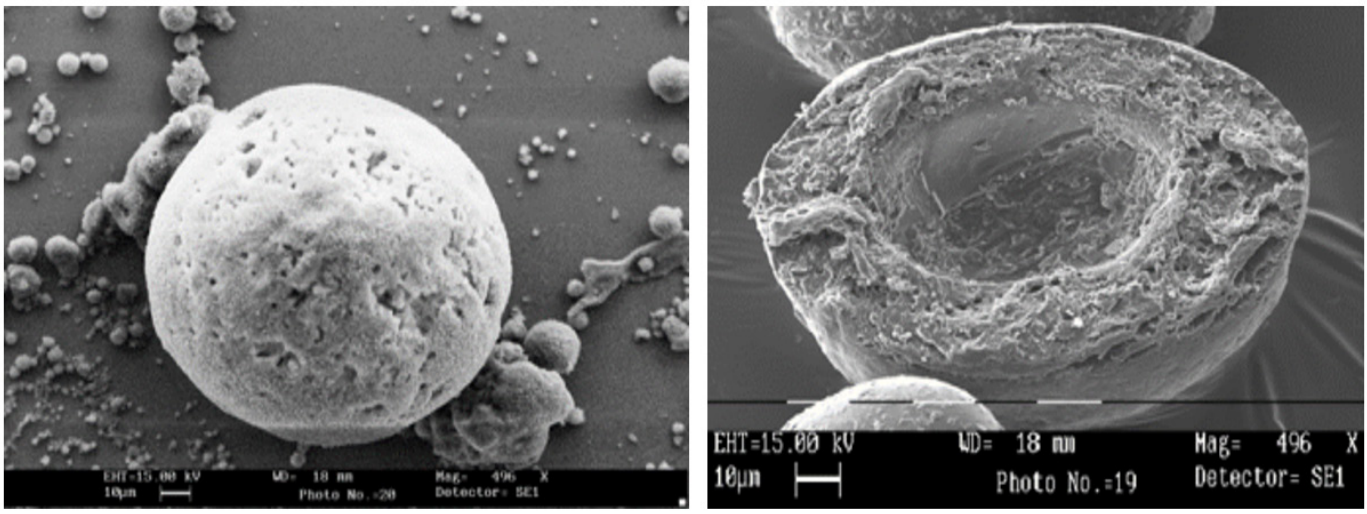


**Figure 6:** Depiction of shape and surface morphology by SEM.

## Determine the shape and surface morphology

The SEM analysis of the prepared drug-loaded microbeads showed flawless spheres possessing smooth texture and distinct pores. Microbeads resembled a hollow hole surrounded by stiff shells made of active drug ZDV and polymer. Such surface morphology boosts drug release. The drug and polymer solutions became ionized simultaneously and coagulated into the calcium chloride solution, resulting converted into a solid shell enveloping the droplet (Figure 6).

## CONCLUSION

The goal of the study was to prepare and characterize zidovudine floating microbeads for sustained release. In the current work, a preformulation study for zidovudine floating microbeads generated by ionotropic gelation employing polymers HPMC and SCMC in various ratios was carried out. The typical peak of various groups was observed during an FT-IR investigation that was conducted for the identification and compatibility study of drugs with polymers and was related to pharmacopeia standards.

According to the findings and analysis, the formulation of MB-3 demonstrated superior physicochemical and micrometric qualities. ZDV microbeads have outstanding floating capabilities, as demonstrated by *in vitro* buoyancy. The drug-loaded microbeads demonstrated up to 95% encapsulation efficiency. Due to the thicker outer shells, it was found that an increase in polymer content lowered the drug release from the microbeads. Lower-density microbeads have great buoyant properties and can stay in the stomach environment for up to 10 hr. As a result, the present formulations aid in increasing bioavailability. Due to their outstanding physicochemical characteristics, good stability, and regulated drug release pattern, the produced gastro-retentive floating drug delivery systems of zidovudine were able to increase the drug's bioavailability.

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## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

## ABBREVIATIONS

**ZDV:** Zidovudine**; HPMC:** Hydroxypropyl methylcellulose; **SCMC:** Sodium carboxymethyl cellulose; **SEM:** Scanning electron microscopy; **FTIR:** Fourier transform infrared; **DEE:** Drug entrapment efficiency; **GMS:** Glyceryl monostearate; **HCl:** Hydrochloric acid.

## SUMMARY

This study aimed to develop floating microbeads of ZDV by ionotropic gelation method. HPMC and SCMC polymers were the prime sustained polymers adhered by using calcium chloride and GMS. Studies on *in vitro* drug release have depicted that the drug release increases with the increasing HPMC content. Swelling Indices were the chief factor involved in the drug eruption which increased as the increasing the time parallel. It was satisfactory for all formulations in aspects of cumulative drug release. ZDV floating microbeads are developed to achieve the desired therapeutic level in the blood. Zidovudine is an oral anti-HIV drug. The floating microbeads approach was economical, easy to operate and effective by employing various rations of HPMC and SCMC. MB1 to MB5 formulations could establish the sustained drug release for more than 12 hr and, thus able to maintain the active drug content at optimum level.

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