EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Coden USA: EJBPBO
Volume: 13
Issue: 4
Year: 2026

FORMULATION AND EVALUATION OF NIFEDIPINE FLOATING *IN SITU* GEL FOR THE TREATMENT OF HYPERTENSION

Bhavyashree T.*, Hithesh Kumar M., Hruthik M., Jayaprabha K., K. A. Kavana, Karthik, Shabaraya A. R.

Department of Pharmaceutics, Srinivas College of Pharmacy, Mangalore, India.

***Corresponding Author: Bhavyashree T.**

Department of Pharmaceutics, Srinivas College of Pharmacy, Mangalore, India.

DOI: https://doi.org/10.5281/zenodo.19508033

How to cite this Article: Bhavyashree T.*, Hithesh Kumar M., Hruthik M., Jayaprabha K., K. A. Kavana, Karthik, Shabaraya A. R. (2026). Formulation and Evaluation of Nifedipine Floating in Situ Gel for the Treatment of Hypertension. European Journal of Biomedical and Pharmaceutical Sciences, 13(4), 398–403.

Article Received on 13/03/2026 **Article Revised on 02/04/2026** **Article Published on 10/04/2026**

ABSTRACT

Floating *in situ* gels represent an innovative pharmaceutical formulation designed to address challenges related to drug delivery through oral route. The aim of the present study was to formulate and evaluate floating *in situ* gel of Nifedipine. Floating *in situ* gel of Nifedipine was prepared by cation driven gelation method. In the present study four different formulations were prepared using different concentration of sodium alginate and gellan gum as polymers. The formulations were evaluated for physical parameters like pH, viscosity, water uptake by the gel, *in vitro* gelation, *in vitro* buoyancy, gel strength, drug content and *in vitro* drug release studies. FTIR spectra revealed that, there was no interaction between drugs and excipients. The drug content of all the formulations was ranged between 83.33% to 89.32% and cumulative drug release was ranged between 87.82% to 97.34%. Among the four formulations, F2 was identified as the potential candidate due to its immediate gelation and floating, optimum pH, viscosity and increased cumulative drug release.

KEYWORDS: Floating In situ gel, Nifedipine, sodium alginate and gellan gum.

INTRODUCTION

Hypertension is a disease characterized by persistently high blood pressure. Hypertension is one of the largest deaths causing disease for the human being. Since it is a chronic disease, it necessitates long term treatment. Hypertension is a cardiovascular disease accounts for a large proportional of all death and disability worldwide. It is directly responsible for 57% of all stroke death and 24% of coronary heart disease in India.[1]

Calcium channel blockers are used to lower the blood pressure and treat other conditions such as chest pain and an irregular heartbeat. They stop calcium from entering the cells of the heart and arteries. Calcium causes the heart and arteries to squeeze more strongly.

Nifedipine is one such calcium channel blocking agent used in the treatment of various cardiovascular diseases, long term treatment of hypertension and angina pectoris.[2]

The major problems associated with the conventional drug delivery system include high risk of toxicity, low patient compliance, and they are not suitable for delivery of drugs with narrow absorption window. Hence floating drug delivery systems (FDDS) are invented. They retain the drug in the stomach for sustained release and applicable for the drugs with poor solubility. The basis behind the FDDS is making the dosage form less dense than the gastric fluids to make it float on them. They remain buoyant in the stomach for prolonged period of time without affecting the gastric emptying rate. This results in enhanced gastric residence time and good control over plasma concentration fluctuations.[3]

Different dosage forms are developed in gastro retentive floating system such as microspheres, tablets, capsules, films etc.[4] But tablets and capsules must be swallowed as whole and they cannot be cut in half for dosage adjustments as they are designed for sustained release. Bulky tablets and capsules are difficult for the elderly, pediatric and dysphagic people to swallow. So, floating oral *in situ* gels can be alternative approach for this. Before administration, the *in situ* gel dosage form is a liquid, but once it gets in contact with gastric contents it transforms into gel that floats on top of it. Physiological

stimuli (e.g., temperature and pH), physical changes in biomaterials (e.g., solvent diffusion, swelling) and chemical reactions (e.g., enzymatic, ionic and photo-initiated polymerization) are the factors contribute to the gel transformations.[5]

Hence, present work focused on formulation of floating *in situ* gel of Nifedipine to sustain the drug release and to increase the gastric retention time.

MATERIALS AND METHODS

Materials

Materials used in the present study were of analytical grade and were procured from different chemical suppliers. Nifedipine, Gellan gum and Peppermint oil were procured from Yarrow Chem, Sodium alginate from Nice Chem, Calcium carbonate and Sodium saccharine were from Loba Chemie Pvt Ltd and Methyl paraben was from HiMedia Laboratories.

Methods

Determination of absorption maxima

The λ_{max} of Nifedipine was determined by using UV spectrophotometer. The solution containing 20µg/ml concentration of Nifedipine was prepared using 0.1N Hydrochloric acid (HCl, pH 1.2) and was scanned between the range of 200-400nm against blank reagent using UV-visible spectrophotometer.

PREPARATION OF FLOATING *IN SITU* GEL BY CATION DRIVEN GELATION APPROACH

Table No. 01: Composition of *in situ* gel.

Ingredients	Formulation Code			
	F1	F2	F3	F4
Nifedipine(mg)	90	90	90	90
Sodium alginate (mg)	150	200	-	-
Gellan gum (mg)	-	-	150	200
Trisodium citrate(mg)	75	75	75	75
Calcium carbonate(mg)	200	200	200	200
Methyl paraben(mg)	4.5	4.5	4.5	4.5
Sodium saccharine(mg)	6	6	6	6
Peppermint oil(ml)	0.05	0.05	0.05	0.05
Distilled water (q.s to ml)	30	30	30	30

Floating oral *in situ* gel was prepared by cation driven gelation method. Different concentrations of polymers were dissolved in distilled water containing trisodium citrate by using a magnetic stirrer (at 800rpm). The above polymeric solution was heated to 70℃. After cooling to below 40℃, drug and calcium carbonate were added. The resulting formulation was continuously stirred to get uniform dispersion. Also, some preservatives and sweeteners were added.[6]

EVALUATION OF *IN SITU* GELS

Prepared *in situ* gel formulations were subjected to various evaluation parameters as follows.

pH

The pH of the prepared formulations was measured using a calibrated Digital pH meter. The pH measurements were taken thrice for each formulation and the average reading was considered.[7]

Viscosity

The viscosities of different formulations were determined by using Brookfield viscometer. The formulation under study was placed in the sample holder and then the spindle (Spindle number 27) was inserted perpendicular into the sample. The spindle rotated at constant optimum speed (50 rpm). The temperature was maintained during the process. The average of three readings was considered for each measurement.[6]

In vitro gelation study

The *in vitro* gelling capacity of prepared formulations was measured by placing 20ml of gelation solution (0.1N HCl, pH 1.2) in a beaker and maintained at 37±0.5℃ temperature. 2ml of formulation solution was added to it. As the solution comes in contact with the gelation solution, it was immediately converted into stiff gel like structure. The gelling capacity of solution was evaluated on the basis of stiffness of formed gel and time period for which the formed gel remains as such. The *in vitro* gelling capacity was graded in three categories

(+) Gels after few minutes, dispersed rapidly.

(++) Gels immediately and the formed gel remains buoyant for 12 hours.

(+++) Gels immediately and the formed gel remains buoyant for more than 12 hours.[8]

In vitro buoyancy study

The *in vitro* floating study was done by introducing 10ml of the formulation into a beaker containing 900ml of 0.1N Hydrochloric acid (HCl pH 1.2) at 37±0.5℃ without much disturbance. The time taken by the formulation to emerge on the medium surface (floating lag time) and also the time the formulation constantly floated on surface of the dissolution medium (duration of floating) were recorded.[9]

Water uptake by the gel

In this study, the formulation was added to 40ml solution of 0.1N Hydrochloric acid (HCl pH 1.2). The formed gel was separated from 0.1N HCl using Whatmann filter

paper and the excess HCl solution was blotted out with a tissue paper. The initial weight of the gel taken was weighed and to this gel 10ml of distilled water was added. After 30 min of the water was decanted. The same procedure was carried for 2hours. The Final weight of the gel was recorded and the difference in the weight was calculated.[10]

Gel strength

The specific weight of 10g of formed gel was used for the study. A 12g weight was kept in the middle of the gel surface and allowed to pass through the gel. The time it took for the weight to sink 5cm through the prepared gel was used to evaluate its strength. Three readings were averaged together.[6]

Drug content analysis

Accurately, 10ml of the formulation (containing 30mg of Nifedipine) from different batches were measured and transferred to 100ml beaker. To this 50-70ml of 0.1N HCl was added and stirred continuously on a magnetic stirrer for 1h. The resultant solution was then filtered using Whatmann filter paper and made up to volume 100ml with 0.1N HCl. From this solution, 1ml was taken and diluted to 100ml with 0.1N HCl. Then absorbance was measured using UV-visible spectrophotometer.[6,7]

***In vitro* drug release study**

The release of Nifedipine from the formulations was determined using dissolution test apparatus USP Type II with a paddle stirrer at 50rpm. The dissolution medium used 900ml of 0.1N Hydrochloric acid (pH 1.2) solution and temperature was maintained at 37±0.5℃. Ten milliliter of the formulation was added into the dissolution medium without disturbing the medium. Five milliliter of sample solution was withdrawn at 0, 0.5, 1, 2, 3, 4, 5, 6 and 7h and replaced with fresh medium. The collected samples were filtered using whatmann filter paper and suitably diluted with the dissolution medium. The filtered samples were analyzed by UV-visible spectrophotometer.[6,11]

RESULTS AND DISCUSSIONS

Determination of λ_{max}

The λ_{max} of Nifedipine was determined in 0.1N Hydrochloric acid which was scanned between 200-400nm in the UV spectrophotometer. The absorption maximum (λ_{max}) of 236.7nm was selected for the present study. The following graph represents the (λ_{max}) of Nifedipine.

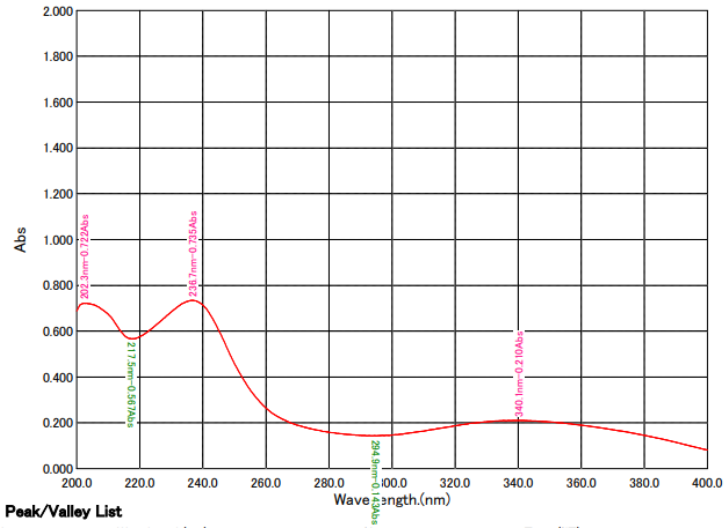

Figure No. 1: UV spectrum of Nifedipine.

EVALUATION OF FLOATING *IN SITU* GEL CONTAINING NIFEDIPINE

In the current study, a total of 4 formulations of floating *in situ* gels of Nifedipine were developed and evaluated for pH, Viscosity, *in vitro* gelation study, *in vitro* buoyancy study, water uptake by the gel, gel strength, drug content and *in vitro* drug release study.

The results obtained for the experiments conducted on the floating *in situ* gels are as follows

pH

The pH of the formulation should be such that it should not cause any irritation to the gastric mucosa after the administration of the dosage form. pH of the *in situ* gel was determined by using digital pH meter. From the results (Table No.02) it was found that pH value of all formulations ideal for the gastric mucosa.

Viscosity

The viscosity of formulations is a crucial factor to consider when designing oral drug delivery system. The viscosity should be optimized to ensure ease of administration for the patient. The viscosities of all the formulations were measured and the results are presented in the below Table No.2. The formulations showed an increase in viscosity with increasing the concentration of gel forming polymer.

Table No. 02: pH and viscosity readings of formulations.

Formulation	pH(Mean±SD) *	Viscosity(Mean±SD)*
F1	7.51±0.05	151.34±0.018
F2	7.77±0.02	195.14±0.003
F3	7.64±0.01	850.73±0.014
F4	7.91±0.02	3007.48±0.058

*All values are represented as mean of 3 readings ± SD (n=3)

***In vitro* gelation study**

Gelation occurs when the insoluble calcium carbonate solubilizes when it comes in contact with acidic medium releasing carbon dioxide and calcium ions. The calcium ions interact with the anionic polymer in the formulation causing instantaneous gelation. Gelation characteristics were evaluated using a standard scale ranging from + to +++. All the 4 formulations demonstrated successful and immediate gelation as shown in table 3. Also, they have remained in the gel state for more than 12h providing the sustained release of the drug.

Fig No. 2: *In vitro* gelation study.

Gel strength

Gel strength is an important parameter that reflects the ability of a gelled mass to withstand peristaltic movement *in vivo*. It indicates the strength and integrity of the gel. In our study, the gel strength of the formulations was measured and results are represented in table 3. The gel strength values ranged from 32.46 to 80.98sec. The formulation F4 exhibited good gel strength with value 80.98s.

Table No. 03: Gelling capacity and gel strength of prepared formulations.

Formulation	Gelling capacity	Gel strength (sec)*
F1	+++	32.46±0.15
F2	+++	69.85±0.95
F3	+++	46.22±0.56
F4	+++	80.98±0.64

*All values are represented as mean of 3 readings ± SD (n=3)

***In vitro* buoyancy study**

The *in vitro* buoyancy study involved evaluating the formed gel's floating lag time and floating duration. The results of this study are represented in table no.4.

The formulation F2 exhibited an immediate gel formation within 9sec, faster than the other formulations. Gel formed by F2 formulation remained buoyant more than 24hours, indicating an extended floating duration.

Table No. 04: Floating lag time and floating duration of formulations.

Formulation	Floating lag time (sec)	Floating duration (h)
F1	10	>24
F2	9	>24
F3	11	>24
F4	13	>24

Water uptake by the gel

The release of the drug from the polymer matrix depends on the amount of water associated with the system. The release of the drug may involve the penetration of the water into the matrix and simultaneously release the drug via dissolution or diffusion. The percentage of water uptake by all the formed gels was found to be in the range of 31.50% to 42.98%. The formulation F2

demonstrated better water uptake than the other formulations (42.98%). As the polymer concentration increased, there was increase in the water uptake by the gel.

Drug content studies

The drug content in all the formulations was found to be in the range of 83.33±0.32 to 89.32±0.609%. The highest drug content was observed in the formulation F2 i.e., 89.32% followed by 86.36% in F1 as given in Table No.5.

Table No. 5: Drug content of prepared.

Formulation code	Drug content (%±SD)*
F1	86.36±0.554
F2	89.32±0.609
F3	83.90±0.284
F4	83.33±0.320

formulations

*All values are represented as mean of 3 readings ± SD (n=3)

In vitro drug release studies

A drug release study was conducted for 7h using 0.1N HCl with a pH 1.2. The study pattern is graphically represented in Fig.No:3. The percentage cumulative drug release after 7h of study was found to be 96.18%, 97.34% 88.28% and 87.82% for formulations F1, F2, F3 and F4 respectively.

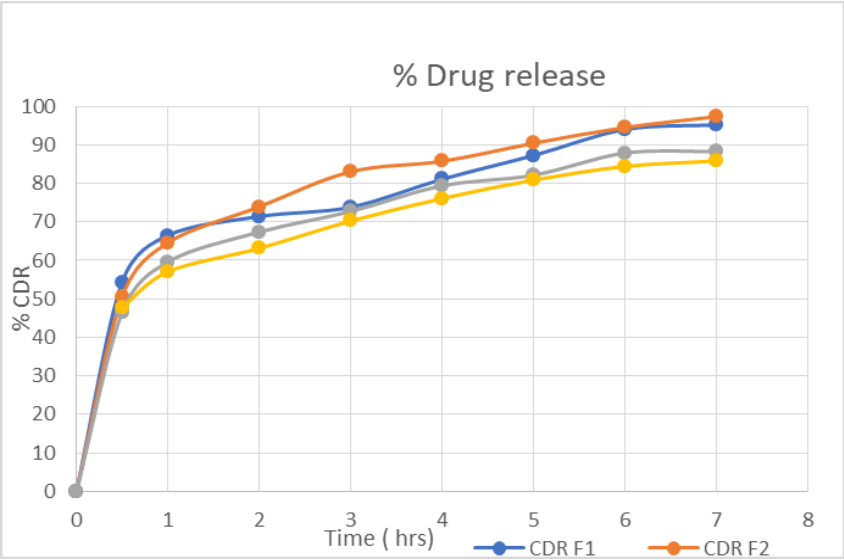

Fig No. 3: *In vitro* drug dissolution profile of formulations (F1-F4).

CONCLUSION

The present study successfully formulated floating *in situ* gels of nifedipine using sodium alginate and gellan gum by a cation-induced gelation method. All formulations showed suitable pH, acceptable viscosity, immediate gel formation, good buoyancy and adequate water uptake. The floating lag time ranged from 9 to 13 seconds and the gels remained buoyant for more than 24 hours. Drug content and *in vitro* drug release were within acceptable limits, showing sustained drug release over 7 hours.

Among all formulations, F2 exhibited the most desirable characteristics and was considered as the best formulation for nifedipine floating *in situ* gel with potential for prolonged gastric retention and improved drug release.

ACKNOWLEDGEMENT

Authors are thankful to Srinivas college of Pharmacy, Mangalore for providing necessary facilities to carry out the research work.

REFERENCES

1. Yadav PK, Mishra S. Transdermal patch of an antihypertensive drug: Its development and evaluation. World J. Pharm. Res., 2017; 6(4): 1355-74.
2. Shaikh KN, Payghan SA, Desouza JI. Formulation of gastroretentive drug delivery system (Floating Tablets) of Nifedipine. Int. J. Pharm. Sci. Res., 2011; 2(11): 2929-33.
3. Niharika MG, Krishnamoorthy K, Akkala M. Overview on floating drug delivery system. Int. J. App. Pharm., 2018; 10(6): 65-71.
4. Shendge RS, Jamdhade AA, Pande VV, Kadam RN. Design, development and characterization of floating *in situ* gelling system for Lisinopril dihydrate. World J. Pharm. Res., 2021; 10(3): 1479-94.
5. Harika SKM, Sudhakar M, Rao VVB. Formulation and characterization of nimodipine *in situ* gels for oral delivery. Int. J. Health Sci., 2022; 6(S1): 5445-63.

6. Shabaraya AR, Ashwini TT, Vineetha K. Formulation and evaluation of gastroretentive *in situ* gelling system of Ketoprofen. Eur. Pharm. J., 2023; 70(2): 1-10.
7. Thoams LM. Formulation and evaluation of floating oral *in situ* gel of Metronidazole. Int. J. Pharm. Pharm. Sci., 2014; 6(10): 265-69.
8. Jayswal BD, Yadav VT, Patel KN, Patel BA, Patel PA. Formulation and evaluation of floating *in situ* gel based gastroretentive drug delivery of Cimetidine. Int. J. Pharm. Res. Sch., 2012; 1(2): 327-37.
9. Pashikanti S, Jyothsna B. Formulation and evaluation of floating *in situ* gel of Ciprofloxacin. Int. J. App. Pharm., 2019; 11(1): 198-204.
10. Maheswaran A, Padmavathy J, Nandhini V, Saravanan D, Angel P. Formulation and evaluation of floating oral *in situ* gel of Diltiazem hydrochloride. Int. J. App. Pharm., 2017; 9(1): 50-53.
11. Xu H, Shi M, Liu Y, Jiang J, Ma T. A Novel *in situ* gel formulation of Ranitidine for oral sustained delivery. Biomol. Ther., 2014; 22(2): 161-165.