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DEVELOPMENT, STATISTICAL OPTIMIZATION AND CHARACTERIZATION OF FLOATING ALGINATE BEADS OF NITROFURANTOIN

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Keywords:

Nitrofurantoin, Urinary tract infection, Emulsion gelation, Floating beads, Gastric residence time, Buoyancy

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ABSTRACT: The present study focuses on the formulation of floating beads of Nitrofurantoin to achieve sustained release, thereby enhancing patient compliance, especially for individuals who struggle to take the dose at regular intervals. Nitrofurantoin is a commonly used antibacterial agent for urinary tract infections, belonging to BCS Class II, characterized by poor aqueous solubility and a short half-life (0.5- 1hours). The floating beads were formulated by using sodium alginate, HPMC K100 and Carbopol 934 as polymers, and calcium chloride as cross-linking agent by the emulsion gelation technique. The compatibility of the drug and polymers were assessed using the FTIR technique. The particle size was analyzed usingoptical microscope. The developed beads were assessed for physical properties, swelling index, entrapment efficiency, buoyancy studies, *in-vitro* drug release and release kinetics. The formulation remains buoyant for 12 hours, and all thirteen formulations exhibited enhanced drug release. Among the formulations, optimized formulation showed entrapment efficiency of 95.51% and in vitro drug release of 98.86%. The optimized beads follow first order kinetics showing sustained release up to 12 hours. Stability testing over three months under accelerated conditions revealed no significant changes in the optimized formulation. Overall, the study concludes that the nitrofurantoin-loaded floating beads can be effectively developed to provide sustained release and reduce the frequency of dosing.

INTRODUCTION: Despite remarkable innovations in the drug delivery system, the oral route is the most preferred route of administration of therapeutic drugs due to its convenience, cost-effectiveness and patient compliance. The development of oral formulation still faces many challenges based on unfavourable physicochemical properties of certain drugs, such as low aqueous solubility, instability in the gastrointestinal tract, and limited membrane permeability [1].

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These limitations may reduce bioavailability of the drug, therapeutic effectiveness and increased dosing frequency. To overcome these barriers, several strategies have been employed to maintain the effectiveness of the drug for a prolonged period, thereby enhancing patient compliance can be achieved by reducing frequent drug administration [2].

Gastroretentive drug delivery system retains the dosage form in the stomach and enables the sustained release of the drug. This is beneficial for the drug, which has its target site of absorption in the upper part of the gastrointestinal tract. As the dosage form offers sustained release, it avoids the repeated administration of the drug, which is advantageous for drugs with short half-life [3]. Nitrofurantoin is an antibacterial medication with a

broad spectrum of activity, widely used in the treatment of urinary tract infections, which is a BCS class II drug having poor aqueous solubility. It is administered frequently due to its short biological half-life (0.5–1 hour). Nitrofurantoin is imidazolidinedione, it is activated by bacterial flavoproteins (nitrofuran reductase)to active reduced reactive intermediated, that are thought to modulate and damage ribosomal proteins or other macromolecules, especially DNA, causing inhibition of DNA, RNA, protein & cell wall synthesis. The overall effect is inhibition of bacterial growth or cell death [4].

Among various gastroretentive systems, floating drug delivery systems, especially alginate beads, have become essential tools in the development of sustained release formulations. These are typically spherical, low-density particles designed to remain buoyant in gastric fluid, thus prolonging gastric residence time. Their biocompatibility, potential for prolonged drug release, and ability to enhance bioavailability make them highly advantageous. Several techniques, including the ionotropic gelation method, emulsion-based methods, and polyelectrolyte complexation method, have been employed in their preparation [5].

The emulsion gelation method is a widely used technique for preparing floating beads, especially when a sustained release is desired. This technique involves emulsifying the aqueous drug-polymer solution into a continuous oil phase under stirring. Subsequently, cross-linking agents such as calcium chloride are introduced, which leads to gelation and formation of discrete, solid beads within the emulsion [6]. Hydrophilic polymers like sodium alginate play a crucial role in forming a gel matrix when exposed to calcium ions, which helps entrap the drug and control drug release. HPMC acts as a release-modifying agent, while Carbopol contributes to the structural integrity and floating behaviour of the beads [7].

The primary objective of this study was to formulate and characterize Nitrofurantoin-loaded floating beads using the emulsion gelation technique to achieve sustained drug release and reduced dosing frequency. This approach is expected to enhance therapeutic efficacy and especially for patients who struggle with frequent medication intake, and by maintaining a constant drug level for a specified period of time with minimum side effects.

METHODOLOGY:

Determination of Melting Point: Melting point of nitrofurantoin was determined by using capillary fusion method. A capillary was sealed at one end filled with small amount of nitrofurantoin and the capillary was kept inverted that is sealed end towards into the melting point apparatus. The temperature at which the sample gets melted gives the melting point of the sample [8].

Drug- excipient Compatibility: The spectra were taken by using FTIR spectrophotometer and were compared with standard spectra. In this study pelletisation of potassium bromide (KBr) was employed. FTIR spectra of pure drug, sodium alginate, HPMC K100, carbopol 934 and their physical mixture were taken. The spectrum was obtained through the software program which was further subjected to interpretation.

Solubility Studies: Solubility of nitrofurantoin was observed in different solvents such as distilled water, ethanol, 0.1N HCI (pH 1.2), dimethylformamide [9].

Method of Preparation of Floating Alginate Beads of Nitrofurantoin:

- Sodium alginate (2.5% w/v) was dissolved in distilled water under gentle stirring.
- HPMC K100 and Carbopol 934 were added in varying concentrations and stirred until completely hydrated.
- The accurately weighed quantity of Nitrofurantoin (100mg) was dispersed into the above polymer solution using a magnetic stirrer to ensure uniform distribution.
- A measured quantity of castor oil (3 mL) and Tween 20 was added to the polymer-drug solution to facilitate emulsification.
- The final solution was transferred into a syringe and added drop-wise through a 23-gauge needle into calcium chloride solution under gentle stirring.

- The formed beads were allowed to remain in the calcium chloride solution for a specific period and collected by filtration and then air dried.

TABLE 1: FORMULATION DESIGN OF FLOATING ALGINATE BEADS OF NITROFURANTOIN

Formulations	Nitrofurantoin (mg)	Sodium Alginate (%w/v)	HPMC K100 (mg)	Carbopol 934 (mg)	Castor Oil (ml)	Tween 20 (ml)	Calcium Chloride (%w/v)
F1	100	2.5	150	150	3	2	2
F2	100	2.5	150	100	3	2	2
F3	100	2.5	150	200	3	2	2
F4	100	2.5	200	150	3	2	2
F5	100	2.5	100	200	3	2	2
F6	100	2.5	150	150	3	2	2
F7	100	2.5	100	100	3	2	2
F8	100	2.5	200	200	3	2	2
F9	100	2.5	150	150	3	2	2
F10	100	2.5	100	150	3	2	2
F11	100	2.5	150	150	3	2	2
F12	100	2.5	200	100	3	2	2
F13	100	2.5	150	150	3	2	2

Evaluation of Floating Alginate Beads:

Micromeritics Properties: The prepared beads were characterized for their angle of repose, bulk density, tapped density and Carr's index.

Bulk Density: Bulk density is defined as the mass of powder divided by bulk volume. Accurately weighed sample of granule was placed into the bulk density apparatus. Volume occupied by the granules was noted without disturbing the cylinder. Bulk density was calculated using the equation, values expressed in g/cm^3.

Bulk density = Mass of beads/ Bulk volume of beads

Tapped Density: The tapping method can be used to calculate tapped densities. The volume of weighed quantity of beads was determined after 100 taps as well as 1000 taps using tapped density apparatus.

Tapped density = Mass of beads / Tapped volume of beads [10]

Angle of Repose: It is defined as maximum angle possible between the surface of the pile of powder and the horizontal plane. Lower the angle of repose, better the flow properties. It can be calculated by the following formula.

$\tan(\theta) = h / r$ Therefore, $\theta = \tan^{-1}(h / r)$

Where, θ is the angle of repose, h is the height in cm, r is the radius in cm.

The beads were allowed to flow through the funnel fixed to a stand at definite height (h). The angle of repose was then calculated by measuring the height and radius of the heap of beads formed.

Carr's Index: It indicates beads flow properties. It is expressed in percentage and is give:

% compressibility index = Tapped density – Bulk density / Tapped density × 100

Hausner's Ratio: Hausner's ratio is an indirect index of ease of beads flow. It is calculated by the following formula.

Hausner's ratio = Tapped density / Bulk density

Particle size: The particle size of beads were determined by using optical microscopy method, fitted with eye piece micrometer which was then calibrated with stage micrometer [11].

Determination of Swelling Index: For determining the swelling index, the accurately weighed quantities of Nitrofurantoin beads were suspended in 0.1 N HCl with pH 1.2. Liquid droplets adhered to the surface of beads was removed by using blotting paper and then weighed it with the help of a microbalance. The swollen beads were dried in oven at 60°C for 5h or until showed the constant weight. The variation in swelling of Beads before and after drying was used to calculate the % of swelling index. The following equation was used.

Swelling index = (Mass of swollen Beads - Mass of dry beads /Mass of dried beads) x 100 [12]

Entrapment Efficiency: The quantity of drug incorporated was determined by pulverizing the beads and performing repeated extractions with aliquots of 0.1 N HCl.

The extract was then transferred to a 100 ml volumetric flask, and the volume was adjusted using 0.1 N HCl. Afterward, the solution was filtered, and its absorbance was assessed with a UV spectrophotometer, using an appropriate blank for reference. The percentage of drug entrapped in the beads was calculated using the formula:

% Drug entrapment efficiency = Calculated drug concentration / Theoretical drug concentration × 100

Percentage Yield: Percentage yield of beads was calculated by dividing actual weight of product to total amount of all non volatile components used in the preparation of beads:

Practical yield (%) = [Practical Mass / Theoretical Mass (Drug+ Carrier)] × 100[13]

Buoyancy Studies: Buoyancy test was carried out by weighing 100 mg of the Beads and transferred to aUSP type II dissolution apparatus containing 900 ml of simulated gastric fluid (0.1N HCl) at 37°C. Then Beads were separate at different time intervals and dried until a constant weight obtained. The % buoyancy is calculated by using following equation.

Buoyancy % = Initial weight of floating beads x100/ Weight of floating beads [14]

***In-vitro* Drug Release Studies:** Dissolution studies of Nitrofurantoin floating beads were estimated by using USP dissolution apparatus II. Accurately weighed quantity of 100 mg floating beads was transferred into 900 ml of 0.1N HCl medium and stirring at100 rpm. Aliquots of samples were withdrawn at specified time intervals, filtered and diluted with similar medium finally assayed at 360nmusing double beam spectrophotometer. The samples withdrawn were replaced with same dissolution medium and all the samples were analyzed [15].

Formulation Optimization *via* Doe: A computer-aided optimization approach employing a statistical design of experiments was used to identify critical factors, their interactions, and the optimal process conditions necessary to achieve the targeted results. Design Expert Stat Ease Software was utilized to determine the optimal formulation. The optimization process utilized a central composite design. In this study, carbopol934 and HPMC K100 were selected as the two variables, while drug entrapment efficiency and in vitro drug release were considered as the two response variables. As a result, thirteen experimental trials were performed. Contour plots were created, and the optimal formulation was chosen based on the established optimization criteria [16, 18].

Drug Release Kinetics: Drug release data of optimized floating beads were fitted to various kinetic models to reveal the drug release mechanism from the beads. Those consist of Zero order, first order, Higuchi model and Korsmeyer-Peppas plot and R^2 values were determined.

- Zero Order Kinetics Model – Cumulative %drug release versus Time T.
- First Order Kinetics Model - Log cumulative percentage drug remaining versus Time T.
- Higuchi's model – cumulative percent drug release versus square root of Time T.
- Korsmeyer- Peppas model –Log cumulative percent Drug released versus log time [17].

Stability Studies: From the prepared beads optimized beads were selected for the stability studies and were placed in borosilicate screw capped glass containers and stored in different temperatures like Refrigeration temperature 4-8°C, Room temperature 25±2°C at 60%±5% RH and oven temperature 40±2°C at 75% ±5% RH in stability chamber. At the end of 30, 60, 90 days period, samples were withdrawn and the beads are analyzed for their entrapment efficiency and drug release [19, 20].

RESULT AND DISCUSSION:

Determination of Melting Point: Melting point of pure drug Nitrofurantoin was found to be 228 ± 1.8°C (n=3).

Drug – excipient Compatibility: Both the excipients and pure drugs infrared spectra are examined.

It has been found in this investigation that there is no significant shifting of the peaks, indicating that there was no physical interaction due to bond formation between the drug and excipients.

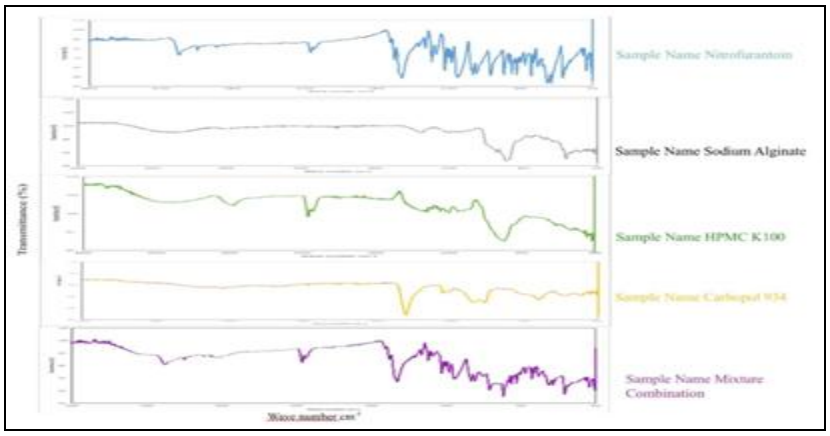

FIG. 1: FTIR SPECTRUM OF NITROFURANTOIN, SODIUM ALGINATE, HPMC K100, CARBOPOL 934, PHYSICAL MIXTURE (NITROFURANTOIN+SODIUM ALGINATE+HPMC K100+CARBOPOL 934)

Solubility Studies:

TABLE 2: SOLUBILITY PROFILE OF THE DRUG

Name of the media	Solubility of drug
Water	Slightly soluble
Ethanol	Slightly soluble
Dimethylformamide	Soluble
0.1 N HCl	Soluble

Standard Calibration Plot of Nitrofurantoin: The λ_{max} of Nitrofurantoin in 0.1 N HCl was found to be 360 nm. The curve was found to be linear and obeys Beer- Lambert's law in the range of 1- 10 µg/ml with regression co-efficient 0.9986. The absorbance values are tabulated in the **Table 3**.

TABLE 3: CALIBRATION CURVE DATA OF NITROFURANTOIN IN 0.1N HCL

Concentration (µg/ml)	Absorbance
0	0
2	0.161±0.002
4	0.286±0.004
6	0.463±0.001
8	0.617±0.003
10	0.762±0.002

All values expressed as mean of ± SD, n = 3

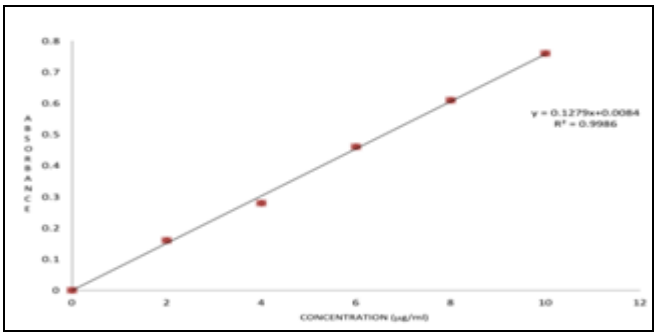

FIG. 2: STANDARD CALIBRATION CURVE OF NITROFURANTOIN IN 0.1N HCL AT 360 NM

Evaluation of Floating Beads:

Flow Properties of Floating Beads: The results of micromeretic properties of beads were showed in **Table 4**. Bulk density values for all batch beads was obtained in the range from 0.202- 0.231 g/cm^3 and the tapped density values obtained in the range from 0.223- 0.259g/cm^3. Angle of repose value for all the formulation was found in the range between 25.83- 29.32, showing good flow properties for all batch of alginate beads.

The % compressibility index value for all batch beads was found in the range of 10.31- 15.34, indicating excellent to good flow properties for all batches. Hausner's ratio for all batch beads was found between 1.11- 1.19, showing excellent flow properties of beads of all batches. Thus from the micromeritics study it was found that all batch formulations exhibiting the good flow and were non aggregated.

Particle size Analysis: The mean particle sizes of floating beads were measured by an optical microscope. The average particle size of floating beads was found to be 446 to 540µm. The results are showed in **Table 4**.

TABLE 4: MICROMERETIC PROPERTIES AND PARTICLE SIZE OF FORMULATIONS F1 - F13

Formulation	Particle Size (μm)	Angle of repose	Bulk density(g/cm^3)	Tapped density (g/cm^3)	Carr's index	Hausner's ratio
F1	510±0.03	27.42±1.03	0.2214±0.0051	0.2562±0.003	13.71±0.42	1.147±0.041
F2	470±0.743	27.71±0.273	0.2232±0.005	0.2472±0.0041	13.9±1.77	1.156±0.04
F3	495±0.554	28.48±0.253	0.2313±0.0055	0.2592±0.005	12.07±1.15	1.196±0.04
F4	540±0.743	26.36±0.472	0.2027±0.0055	0.2523±0.004	10.31±0.48	1.114±0.01
F5	460±0.23	29.32±0.33	0.2319±0.0051	0.259±0.0054	12.08±0.51	1.193±0.044
F6	505±0.54	27.65±0.544	0.2267±0.005	0.259±0.004	13.63±0.54	1.151±0.043
F7	450±0.31	26.77±0.38	0.2147±0.012	0.2421±0.004	15.24±0.45	1.179±0.04
F8	510±0.43	25.83±0.355	0.2237±0.0052	0.2568±0.0045	13.64±1.71	1.152±0.093
F9	525±0.34	27.72±0.52	0.2238±0.0054	0.258±0.0051	13.29±1.77	1.139±0.021
F10	446±0.26	28.81±0.233	0.2128±0.0052	0.2447±0.003	14.91±1.45	1.113±0.047
F11	478±0.43	27.22±0.435	0.2211±0.001	0.2586±0.004	13.84±0.11	1.153±0.0021
F12	530±0.11	26.46±0.131	0.2113 ±0.001	0.223±0.0041	12.04±1.65	1.149±0.056
F13	528±0.48	27.51±0.21	0.2231±0.0012	0.251±0.0045	14.68±0.14	1.153±0.002

All values expressed as mean of ± SD, n = 3

Drug Entrapment Efficiency (%): The drug entrapment efficiency of floating beads was found in the range 88.5- 96.6%. The drug entrapment efficiency of all batches of beads was found to be increased progressively with increasing concentration of polymers. Formulation F8 showed highest drug entrapment efficiency. The results are shown in **Table 5.**

Percentage Yield (%): The percentage yield for all the formulations of F1-F13 was determined. The yield of floating alginate beads was found to be in the range of 75.1- 87.9%. As the concentration of polymer increases the percentage yield of beads also increases. The results are showed in **Table 5.**

Swelling index (%): The release of the entrapped drug from the floating beads depends on the swelling behaviour, because swelling is directly proportional to the drug release. The dynamic swelling study was carried out in 0.1N HCl of pH 1.2 and the results are depicted in **Table 5**. The polymer concentration has significant effect on swelling ratio of beads.

***In-vitro* Buoyancy:** The buoyancy percentage for all formulations was above 70%, which was studied for 12 hr. *in-vitro* buoyancy of all formulation was found between 76.4%-95.9%.

The highest buoyancy percentage was obtained with formulation F8.Result indicated that increase in the amount of polymers there was an increase in the buoyancy percentage of formulation **Table 5.**

TABLE 5: PERCENTAGE YIELD, ENTRAPMENT EFFICIENCY, BUOYANCY AND SWELLING INDEX OF FORMULATION F1 -F13

Formulation	Percentage yield %	Drug entrapment efficiency %	Buoyancy %	Swelling index %
F1	82.2±1.25	93.2±1.03	89.5±0.4	267.8±0.0021
F2	76.4±1.22	89.6±0.273	80.4±0.022	183.6±0.04
F3	81.1±1.2	90.3±0.253	85.4±0.05	181.2±0.015
F4	84.5±1.89	93.4±0.472	91.2±0.077	216.8±0.13
F5	80.7±1.27	89.7±0.33	78.1±0.013	163.4±0.063
F6	82.3±1.21	93.2±0.544	88.6±0.1	230.5±0.08
F7	79.8±1.5	88.5±0.38	76.4±0.001	162.2±0.05
F8	87.9±1.2	96.6±0.355	95.9±0.043	249.2±0.7
F9	82.8±2.76	93.4±0.52	90.2±0.32	216.7±0.077
F10	75.1±2.42	89.1±0.233	79.2±0.054	164.3±0.06
F11	82.3±3.12	91.9±0.435	86.7±0.01	188.5±0.6
F12	86.1±1.2	94.2±0.131	93.7 ±0.06	218.8±0.077
F13	82.6±0.28	93.2±0.21	93.2±0.012	264.7±0.065

All values expressed as mean of ± SD, n = 3

***In-vitro* Drug Release Studies:** The *in-vitro* drug release studies of 13 formulations were performed and cumulative percentage drug release was represented in **Fig. 3**. It is evident that the

formulation F8 showed highest release of drug (99.2% at 12 hours) from the floating alginate beads. All the formulation showed sustaining the drug release for extended period of time. Data for *in-vitro* drug release of floating beads was shown **Fig. 3.**

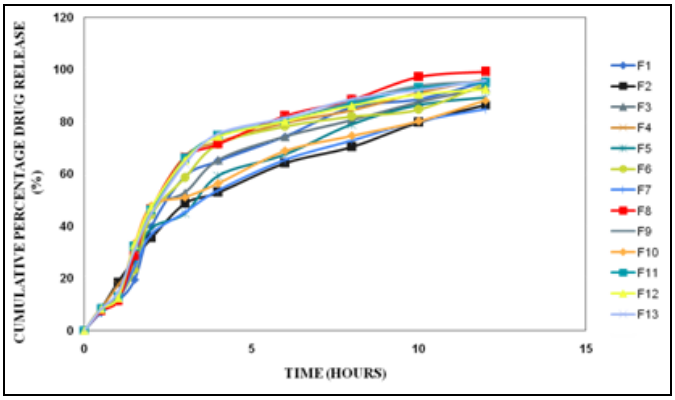

FIG. 3: *IN-VITRO* DRUG RELEASE STUDIES OF FORMULATIONS F1-F13

Optimization by Design Expert Stat Ease Software: The formulation is optimized by Design expert Software version 13.0.7.0. Central composite design was used to find the optimized formulation. Two input factors HPMC K100 and Carbopol 934 was selected and concentration of these factors for preparing the formulations were suggested by the software. 13 formulations were prepared and the values of responses, ie., drug entrapment efficiency and in vitro drug release were given to the software for optimization. After optimization of the analyzed data, 3 solutions were obtained. From the 3 solutions, one was selected by considering the drug entrapment efficiency and in vitro drug release. The batch with HPMC K100-200mg and Carbopol 934- 182.599 with desirability 1 was found to be optimum.

TABLE 6: NUMERICAL TEST RESULTS OF MODEL ADEQUACY CHECKING FOR INFLUENCE OF INDEPENDENT VARIABLES ON RESPONSE VARIABLES

Response	Model	Sequential p value	R^2	Adjusted R^2	Predicted R^2	Adequate precision	CV %
Drug entrapment efficiency	Linear	<0.0013	0.7362	0.6835	0.5708	10.9162	1.46
Drug release	Quadratic	<0.0001	0.9133	0.8844	0.8075	18.5261	1.59

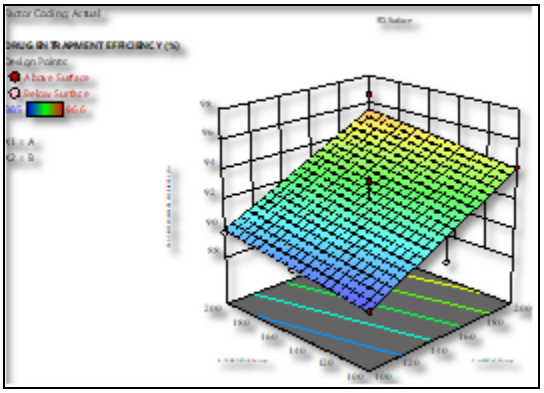

FIG. 4: 3-D RESPONSE SURFACE PLOT SHOWING THE EFFECT OF AMOUNT OF HPMC K100 AND CARBOPOL 934 FOR ENTRAPMENT EFFICIENCY (%)

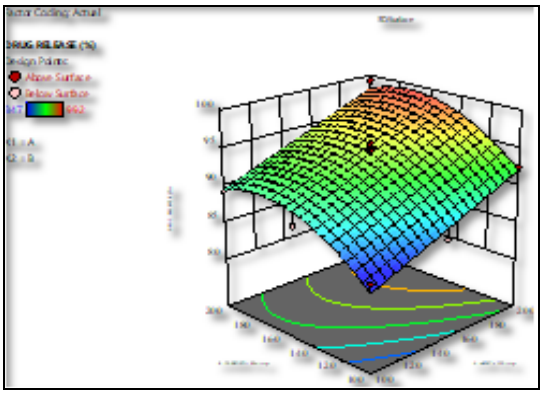

FIG. 5: 3-D RESPONSE SURFACE PLOT SHOWING THE EFFECT OF AMOUNT OF HPMC K100 ANDCARBOPOL 934 FOR *IN-VITRO* DRUG RELEASE (%)

TABLE 7: DESIRABILITY TABLE

Number	HPMC K100	Carbopol 934	Drug entrapment efficiency	drug release	Desirability	
1	200.000	182.599	95.307	99.099	1.00	**Selected**
2	200.000	183.017	95.313	99.086	0.94	
3	200.000	183.403	95.319	99.074	0.93	

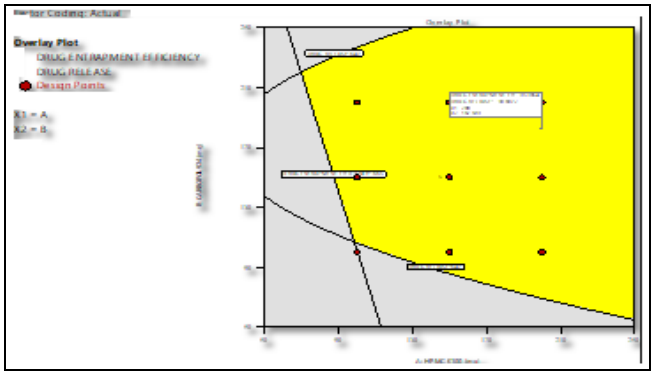

FIG. 6: OVERLAY PLOT OF OPTIMIZED FORMULATION

TABLE 8: RESPONSE VALUES OF PREDICTED, EXPERIMENTAL AND PERCENTAGE ERROR OBTAINED AT OPTIMAL LEVELS OF THE FACTORS

Response	Predicted	Experimental	%Error
Drug entrapment efficiency	95.3	95.51	0.22
Drug release	99.09	98.86	0.23

FIG. 7: OPTIMIZED FORMULATION OF FLOATING ALGINATE BEADS

Drug Release Kinetics: The data obtained from the *in-vitro* drug release of optimized formulation was fitted into the various kinetic models to check whether the release is following first order or zero order kinetics. The optimized formulation exhibited first order kinetics (R^2= 0.9651) followed by non-fickian transport.

TABLE 9: RELEASE KINETIC STUDIES OF OPTIMIZED FORMULATION

Zero order	First order	Higuchi	Korsmeyer-Peppas
R^2	R^2	R^2	R^2
0.9365	0.9651	0.9097	0.9861

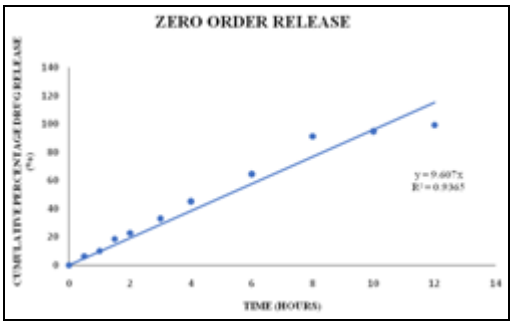

FIG. 8: ZERO ORDER RELEASE KINETICS OF THE OPTIMIZED FORMULATION

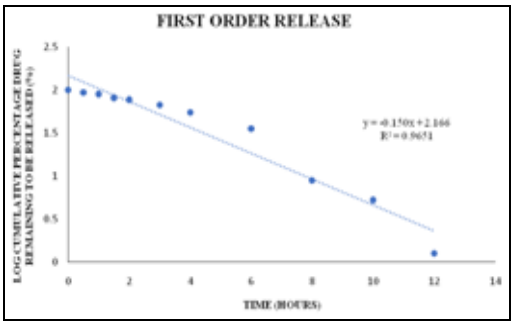

FIG 9: FIRST ORDER RELEASE KINETICS OF THE OPTIMIZED FORMULATION

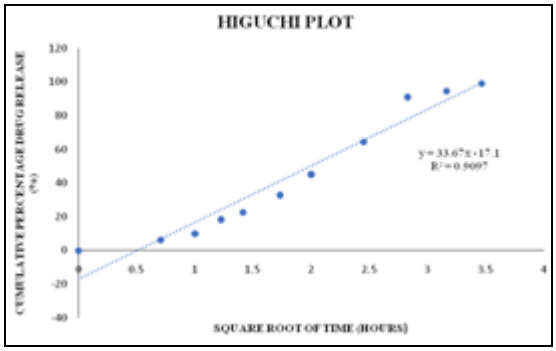

FIG 10: HIGUCHI PLOT OF THE OPTIMIZED FORMULATION

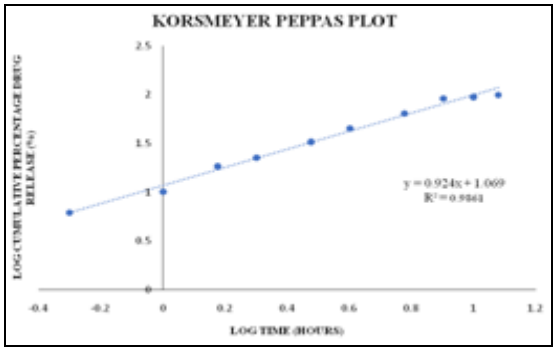

FIG. 11: KORSMEYER-PEPPAS PLOT OF THE OPTIMIZED FORMULATION

Stability Studies: Accelerated stability studies were carried out for optimized formulation as per ICH guidelines. From the stability studies data which was carried out for a period of 3 months showed that the optimized formulation passes stability studies with no significant changes in drug entrapment efficiency and *in-vitro* drug release. The results of stability data were shown in **Table 10.**

TABLE 10: STABILITY STUDIES OF OPTIMIZED FORMULATION

Storage condition	Sampling interval	Drug entrapment efficiency (%)	*In-vitro* drug release (%)
40°C ±2°C, 70%±5% RH	0 days	95.51± 0.13	98.86 ± 0.08
	30 days	94.95± 0.143	98.24± 0.122
	60 days	94.2± 0.43	97.89 ± 0.002
	90 days	93.83± 0.18	97.39 ± 0.176
25°C, ±2°C, 60%±5% RH	0 days	95.51± 0.15	98.86 ± 0.37
	30 days	95.19± 0.19	98.47 ± 0.03
	60 days	94.67± 0.66	98.2 ± 0.165
	90 days	94.43± 0.94	97.71 ± 0.38
5°C±3°C	0 days	95.51± 0.005	98.86± 0.16
	30 days	95.11± 0.043	98.36± 0.5
	60 days	94.78± 0.82	97.7± 0.19
	90 days	94.41± 0.31	97.5± 0.58

All values expressed as mean of ± SD, n = 3

CONCLUSION: In the present study floating alginate beads of Nitrofurantoin were formulated to achieve sustained release of the drug. From the preformulation studies like melting point, solubility and UV analysis were complied with standards. The FTIR spectra revealed that, there were no interactions between the drug and excipients.

The floating alginate beads were prepared by emulsion gelation method using polymers like HPMC K100 and Carbopol 934 in different concentrations. The obtained beads were found to be free flowing. The percentage yield was found to be 75.1 to 87.9%, drug entrapment efficiency was found to be 88.5 to 96.6% and the swelling index of beads was satisfactory. The dissolution was performed up to 12 hours and the drug release of optimized formulation was found to be 98.86%. Comparing different concentrations of HPMC K100 and Carbopol 934 provided better sustained release characteristics with excellent in-vitro drug release. The results of *in-vitro* release kinetics of optimized formulation indicated sustained release and exhibited first order kinetics followed by non-fickian transport mechanism. Therefore, the floating alginate beads of Nitrofurantoin are promising approach to drug delivery systems by reducing the frequency of drug administration. The prepared formulation shows an alternative to the conventional dosage form for the treatment of urinary tract infection.

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CONFLICT OF INTEREST: Nil

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