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DESIGN, FORMULATION AND CHARACTERIZATION OF NANOSPONGES LOADED WITH SERTRALINE HYDROCHLORIDE

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ABSTRACT

Nanosponges are a type of nanoparticle with a porous, sponge-like structure used for drug delivery and other applications. The aim of the present research work is to design, formulation and characterization of nanosponges loaded with sertraline hydrochloride. This work used varying quantities of the rate-retarding polymers polyvinyl alcohol (PVA) and ethyl cellulose (EC) in addition to surfactants, respectively, to construct and analyze nanosponges loaded with sertraline hydrochloride (NSG) using the solvent evaporation method. The final nanosponges were assessed for *in vitro* drug release, drug-polymer compatibility, particle size, incorporation efficiency, and percentage yield. Numerous nanoscopic channels and a porous structure were verified using Scanning Electron Microscopy (SEM). Sertraline hydrochloride was shown to be stable in the polymer mixture by Fourier Transform Infrared Spectroscopy (FTIR), which also revealed no drug-polymer interactions. Differential scanning calorimetry using DSC demonstrated the drug's involvement in the complexation with the nanosponges. Sertraline's mean particle size was also ascertained. The particle size was found to vary between 726 and 992 nm. Negative zeta potential values were attained to guarantee the nanosponges high stability. It was found that drug release from nanosponges might last up to 12 h. According to stability tests, the nanosponge demonstrated satisfactory stability for 90 days at 4 °C and 25 °C.

Keywords: Sertraline hydrochloride, nanosponges, zeta potential, solvent evaporation, obsessive-compulsive disorder

INTRODUCTION

The newly developed colloidal system has certain problems that can be solved. Drug release over a large area, reduced absorption, and medicine toxicity are all present. It can be modified to function with both kinds of medications. Due to their ease of reproduction, they have several advantages. Various treatments are available, including washing and stripping. Changing pH or ionic strength, mild healing, or comparatively harmless hot gases. They are put to use. In many locations, one type of reuptake inhibitor is sertraline. Currently in use as an anti-depressant, this BCS Class II drug has a high lipophilicity and low oral absorption. Approximately 44% of the body's weight is absorbed by it. The main goal of the study was to thoroughly and methodically evaluate the viability of nanosponges in practice. Sertraline's oral bioavailability has been improved through the development of four distinct sponge formulations. Sertraline hydrochloride's rate of dissolution can be accelerated, especially at the absorption site. As a Class II drug, sertraline was studied using nanosponges as the preferred method, which could facilitate future formulation processes. The nanosponges were synthesized at varying time intervals, with drug-to-carrier weight ratios determined through the emulsion solvent diffusion method **[1-3]**.

Sertraline is a medication used for depression, panic disorders, obsessive-compulsive disorder (OCD), social anxiety disorder (SAD), post-traumatic stress disorder (PTSD), and premenstrual dysphoric disorder (PMDD). Sertraline is an SSRI (serotonin reuptake inhibitor) that increases serotonin levels between neurons (nerves) by blocking serotonin from being absorbed. The aim of the present research work is to design, formulation and characterization of nanosponges loaded with sertraline hydrochloride **[4, 5]**.

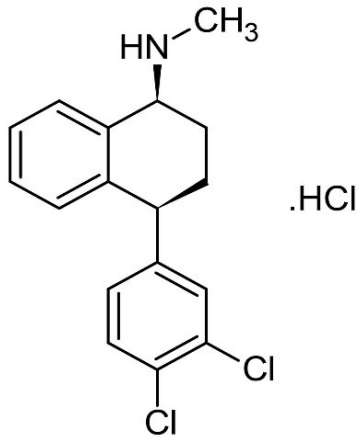

Figure 1: Chemical structure of sertraline hydrochloride

MATERIALS AND METHODS

Materials and chemicals

The API of sertraline hydrochloride was procured from Hetero Labs, Hyderabad, Telangana. Poloxamer, polyvinyl alcohol, β-cyclodextrin, and ethyl cellulose were purchased from Synpharma Research Lab, Hyderabad, Telangana. All reagents and chemicals used are analytical grade.

Compatibility analysis of drug excipients

Using spectroscopy, the compatibility of the medicine and excipient was determined. The FTIR spectra from Bruker were used to identify any potential interactions between the excipients and the pure medication in the solid form. In a mortar, 100 times as much KBr was used to grind the solid powder sample. It's a finely milled powder. Was squeezed between polished steel anvils at an 8t/in^2 pressures. Wave numbers ranged from 4000 to 400 cm^{-1}.

Table 1: Formulations

Components	F1	F2	F3	F4	F5	F6	F7	F8	F9
Sertraline hydrochloride (gran)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Cellulose ethyl ether (gran)	0.5	0.75	1	-	-	-	-	-	-
β-Cyclodextrin (gran)	-	-	-	0.5	0.75	1	-	-	-
Poloxamer (gm)	-	-	-	-	-	-	0.5	0.75	1
PVA	200	200	200	200	200	200	200	200	200
Methanol (ml)	20	20	20	20	20	20	20	20	20
Water (ml)	40	40	40	40	40	40	40	40	40

Method of formation of nanosponges using the solvent evaporation method [6-8]

The solvent evaporation process was used to create nanosponges utilizing various ratios of β-cyclodextrin, ethyl cellulose, poloxamer (a rate-retarding polymer), and copolymers such as polyvinyl alcohol. A dispersed phase consisting of the drug and the necessary amount of PVA dissolved in 10 ml of solvent (methanol) was progressively combined with a certain amount of PVA in a 40 ml aqueous continuous phase created with a magnetic stirrer. To remove all of the organic solvents from the formulation, the reaction mixture was put on a hot plate and stirred with a magnetic stirrer for 2 h at 1000 rpm. The produced nanosponges were collected and given time to dry after being filtered via filter paper.

Assessment criteria for nanosponges [9-12]

Efficiency of entrapment: By dissolving the material in 10 ml of methanol, a 25mg nanosponge suspension of sertraline hydrochloride mass equivalent was examined. Ten ml of the drug's transparent layer are taken once it has dissolved. A UV-spectrophotometer was used to measure the amount of medicine in the aqueous phase using a UV-spectrophotometric method at 244 nm. The drug concentration is established using a calibration curve. The amount of drug inside the particles was calculated by subtracting the amount of drug in the aqueous phase of the suspension from the total amount of drug in the nanoparticle suspension. The entrapment efficiency of the medication was calculated using the following formula (%).

Particle size: The size of each created batch of nanosponge was examined under a microscope. A tiny drop of the Nano sponge dispersion was placed on the glass slide at various points to measure the Nano sponge size from each batch, and the average size was calculated.

SEM examination: SEM analysis was employed to investigate NPG's morphology. The sample was lyophilized, deposited on aluminium stubs, and then a layer of gold particles was applied to the surface using a sputter coater. Utilizing a scanning electron microscope (SEM) (XL30, Philips, The Netherlands), the shape of the NPs at 750 mA and 15 kV was ascertained.

Zeta potential: The zeta potential represents the overall charge and formulation stability of the particle. Differential light scattering (DLS) was used to quantify zeta potential using the Zeta Sizer Nano-ZS90, which is produced by Malvern Instrument Ltd. in the UK. Milli-Q water is used to redistribute nanoparticle samples. At 25 °C, each measurement was carried out three times.

Study of dissolution: Parameters of dissolution

- ✓ 900 cc of 7.4 pH buffer for 18 h is the medium.
- ✓ Device: Basket (USP-I)
- ✓ Rotational speed: 50
- ✓ Climate: 37°C ± 0.5
- ✓ Points in time: 1, 2, 3, 5, 6, 8, 10, 12, 14, 16, and 18 h.

Method: For oral dose forms, the *in vitro* dissolving study must be conducted in a dissolve medium that mimics real physiological parameters or *in vivo* conditions. *In vitro* drug release tests for the generated formulation were carried out for 12 h using an Electro Lab model dissolution tester USP Type-1 (rotary basket) set at 50 rpm and 37 ±0.5 °C for a weight equivalent of 10 mg of mushrooms. The drug nano was put in a capsule, kept in a basket device, and submerged in 900 ml of the medium. At specified times, 5 ml samples were taken out of the dissolving media and replaced with the fresh medium to maintain a constant volume. A UV-visible spectrophotometer was used to measure the sample solution's absorbance at 244 nm to check for the presence of the model medication.

Modeling of dissolution profile: The drug release kinetics from the matrix tablets were explained in this work by fitting the in vitro release data to a variety of equations and kinetic models. Both first-order and zero-order kinetic models were employed. models of Korsmeyer-Peppas and Higuchi relaxing, kinetic studies.

Mathematical models: The release rate of the drug from matrix systems for the improved formulation was interpreted using a variety of release kinetic equations, including zero-order, first-order, Higuchi's

equation, and Korsmeyer-Peppas equation. The correlation coefficient (r^2) of the best fit was determined.

Zero-order model: Drug dissolving from dosage forms that release the drug gradually and do not break down. where Qt is the drug's dissolution period in time 1. The zero-order release constant, or KO, is given in units of concentration/time, and Q0 is the initial concentration of the drug in the solution (usually Q00). Data from in vitro drug release studies were shown as the cumulative amount of drug released vs time to investigate the release kinetics.

Application: Used to describe how well drugs dissolve in a range of modified-release pharmaceutical dosage forms, such as osmotic systems, coated tablets with poorly soluble drugs, and specific transdermal systems.

Initial order model: A first-order equation describes the release from systems in which the rate of dissolution is determined by the solute concentration. The releasing behaviour is usually governed by the first-order equation as follows:

Log C = Log Co-kt/2.303

Where, the drug's disintegration at time t is denoted by C. K is the first-order rate constant, and Co is the amount of medication dissolved at t=0. Plotting the logarithmic cumulative medication remaining against time results in a straight line.

In pharmaceutical dosage forms that follow this dissolution profile, such as those that contain water-soluble pharmaceuticals in porous matrix, the amount of medication released per unit of time decreases. This is due to the fact that the amount of medicine that is released is proportionate to the amount that is still inside of them.

Higuchi model: The first mathematical model example designed to explain drug release from a system was provided by Higuchi in 1961. Before being applied to a range of porous and geometric systems, it was initially created for planar systems. This strategy's underlying assumptions are that,

- Diffusion occurs in a single dimension, disregarding edge effects; and
- The drug's starting concentration is greater than its solubility.
- There is very little swelling or breakdown, and the drug particles are much smaller than the system's thickness.
- The diffusivity of drugs does not alter.

The following is a representation of the Higuchi model:

Kht1/2 = Mt/M∞

Where, Kh stands for the Higuchi release kinetic constant, Mt/M∞ is the fraction of drug released at each time point (t), Mt is the amount of drug released in time t, and M∞ is the amount of drug released

after time ∞. The findings were displayed as the square root of time vs the percentage of drug released.

Application: Drug dissolution in a range of modified release pharmaceutical dosage forms, such as transdermal systems and tablets containing water-soluble medications, can be described using this relationship.

Ritger-Peppas model: A straightforward relationship characterizing drug release was established by Korsmeyer, using the polymer system equation. 60% of the drug release data were first run through the Korsmeyer-Peppas model in order to identify the mechanism of drug release.

$$Mt/M\infty = Ktn$$

The drug release rate at time t is denoted by Mt/MV, the release index by n, and the release rate constant by k. The output of circular matrices is described by the n values. Plotting data from *in vitro* drug release trials as the logarithm of percent drug release vs. the logarithm of time allows researchers to examine release kinetics.

Stability studies of optimized formulation [13-16]

The stability of the best formulations was assessed at three distinct temperatures: 25°C, 45°C, and 60°C. Three months were spent evaluating drug release trials. There was no discernible change in drug release experiments. Findings and interpretation investigations of drug-excipient compatibility (FTIR). The FTIR peak-matching approach was used to evaluate the drug's compatibility with the designated lipid and additional excipients. In the drug-lipid mixture, no peaks appeared or vanished, suggesting that there was no chemical interaction between the drug, lipid, and other components.

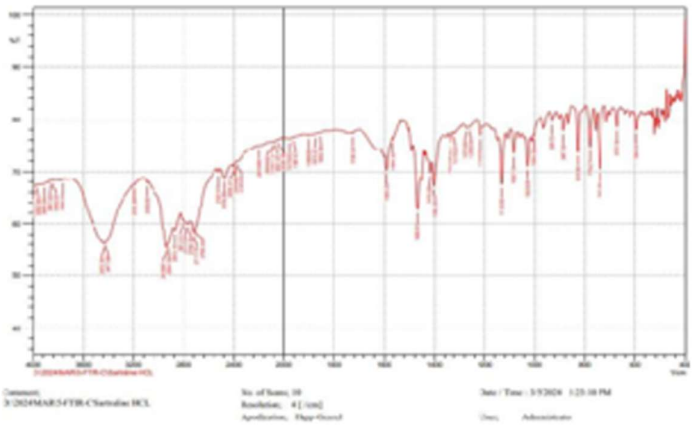

Figure 2: Sertraline hydrochloride FTIR analyses

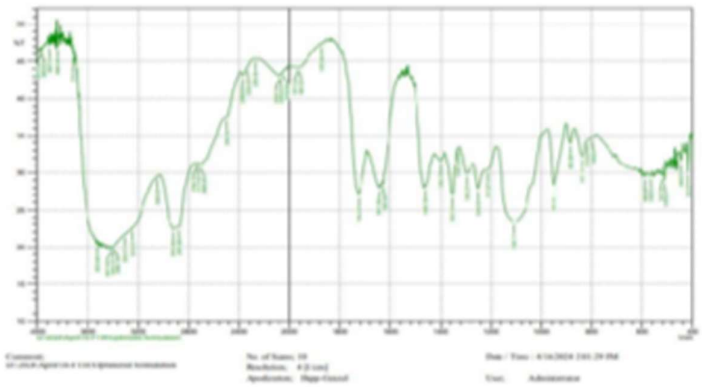

Figure 3: FTIR studies

RESULTS AND DISCUSSION

XRD study of formulations that have been optimized **(Figure 4)**.

Scanning electron microscopy: A ZEISS Electron Microscope, EVO MA 15, was used to examine the surface properties of the generated crystal. Before examination, powder samples were sputter-coated with a thin layer of gold at 10 Torr vacuum and mounted onto an aluminium stub using double-sided adhesive tape. An electron beam with a 20 kV acceleration potential was used to scan the specimens, and the secondary electron mode was used to capture the photographs **(Figure 5)**.

Electrokinetic potential: The charge on a vehicle's surface is measured by its zeta potential. It was computed based on the electrophoretic mobility of charged particles in the Nano carrier system and employing phase analysis light scattering using a Malvern zetasizer at a field strength of 20V/cm in clean water. Charged particles are drawn to electrodes with the opposite charge when an electric field is applied.

Zeta potential: The inclusion of membrane additives influences the zeta potential value, depending on the type of membrane additives. Zeta potential of the optimized Sertraline hydrochloride Nanosponge After measurement, the formulation was discovered to be -32 20 mV. The generated formulation's obtained zeta potential shows that the particles in it stay suspended and are hence stable **(Figure 6)**.

Size of particles intensity of distribution: In general, particles have a diameter of <794 nm. The surfaces of the nanosponges were smooth **(Figure 7)**.

Characterization of nanosponges of sertraline hydrochloride (Table 2) (Figure 8)

Efficiency of entrapment

All eight formulations drug entrapment effectiveness was evaluated. When compared to other formulations, the F5 formulation showed the highest drug entrapment efficiency, 90.22%. Electrophoretic light scattering with a zetasizer Nano ZS was used to measure the

zeta potential, or change on the surface of colloidal particles in Sertraline hydrochloride Nano sponges. At 25°C, the particle charge of nanosponge containing sertraline hydrochloride was measured. The samples were roughly diluted with deionized water in order to measure the particle size **(Table 3) (Figure 9)**.

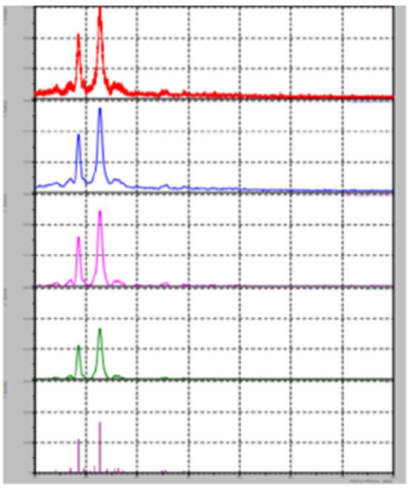

Figure 4: XRD analysis of the optimized formulation

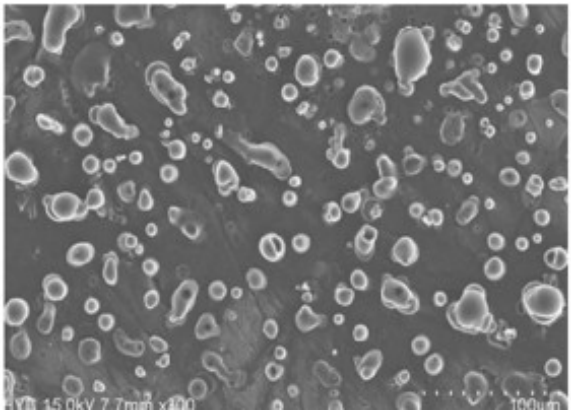

Figure 5: SEM analysis of nanosponges

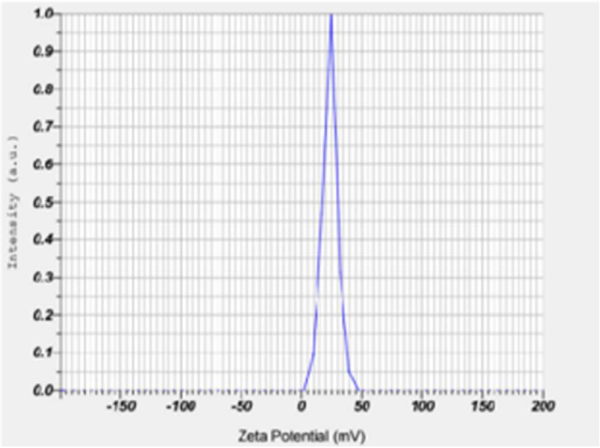

Figure 6: Zeta potential of the formulation that has been optimized

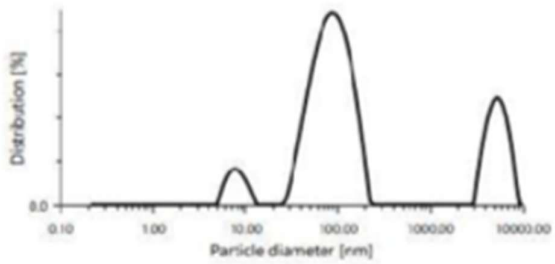

Figure 7: Particle size of improved formulations

Table 2: Evaluation studies on particle size nanosponge

Formulation	Dimensions (nm)
F1	856
F2	992
F3	726
F4	976
F5	794
F6	990
F7	785
F8	792
F9	816

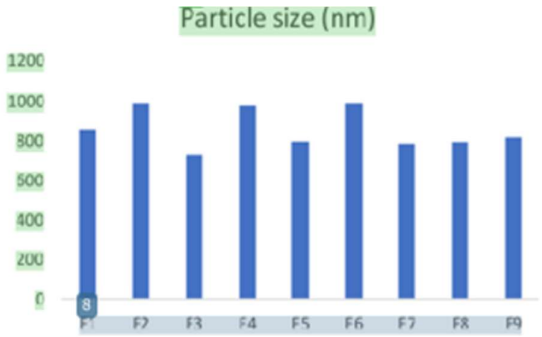

Figure 8: Evaluation studies of particles size nanosponges

Table 3: Evaluation studies of entrapment efficiency in nanosponge

Formulation	Entrapment efficiency (%)
F1	90.28
F2	87.25
F3	87.93
F4	88.90
F5	91.27
F6	90.28
F7	89.35
F8	84.21
F9	87.35

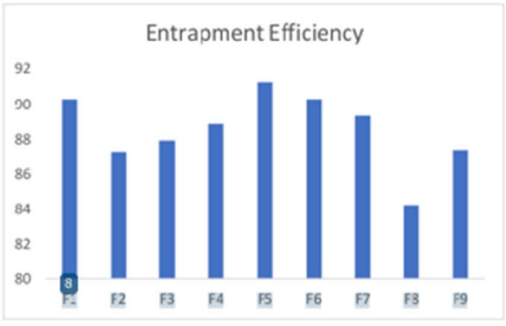

Figure 9: Evaluation of entrapment efficiency in nanosponge

Table 4: Evaluation studies of zeta potential nano sponge

Formulation	Zeta Potential (mV)
F1	-33.72
F2	-30.10
F3	-34.52
F4	-28.50
F5	-32.20
F6	-35.15
F7	-34.90
F8	-38.71
F9	-34.58

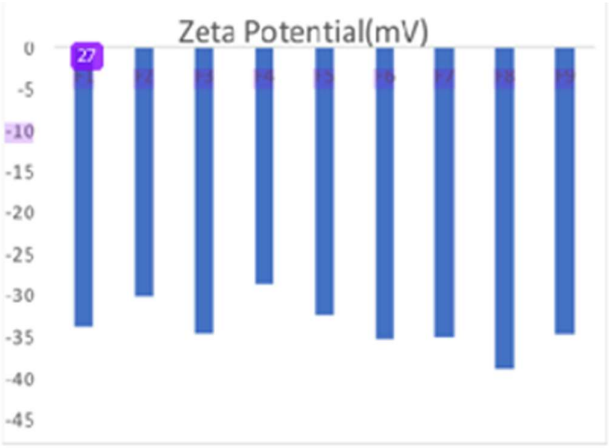

Figure 10: Evaluation of zeta potential nanosponges

In vitro drug release testing

Table 5: Formulations *in vitro* drug release assay

Time in h	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	8.96	9.68	8.53	8.17	8.20	8.46	8.20	7.96	8.10
2	13.59	14.20	15.12	16.30	17.83	18.39	15.90	16.38	15.92
3	28.90	27.93	28.90	30.32	39.92	29.68	25.93	24.93	24.25
4	37.13	36.92	39.21	38.17	40.93	42.31	40.28	42.15	41.54
6	49.86	47.63	45.38	44.35	56.89	59.86	53.19	50.32	49.73
8	59.60	60.15	61.21	58.93	59.89	57.59	55.92	60.25	58.92
10	68.20	65.90	70.25	66.34	72.94	70.32	71.25	70.21	70.21
12	75.98	72.36	74.98	75.89	76.98	74.10	73.64	73.15	75.95
14	79.86	80.34	81.69	78.16	80.68	81.43	80.36	80.20	80.20
16	83.64	84.25	83.55	85.37	86.89	84.72	85.21	82.17	83.25
18	93.25	94.68	91.35	92.41	95.60	94.60	93.64	94.52	94.52

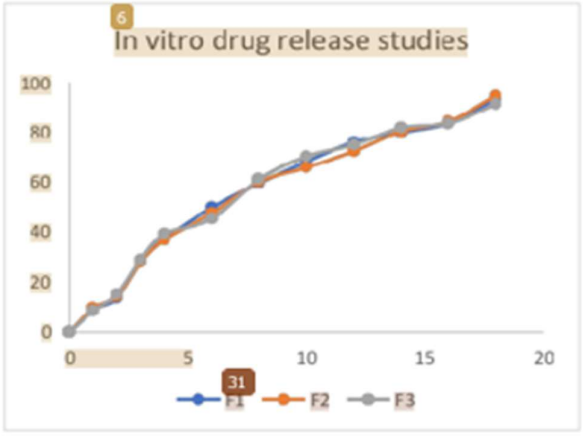

Figure 11: *In vitro* drug release tests of formulations F1–F3

Figure 12: *In vitro* drug release studies of formulations F3–F6

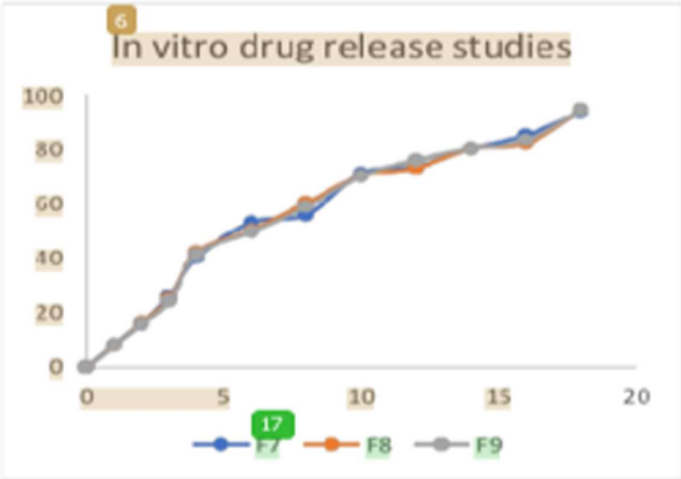

Figure 13: *In vitro* drug release studies for formulations (F6-F9)

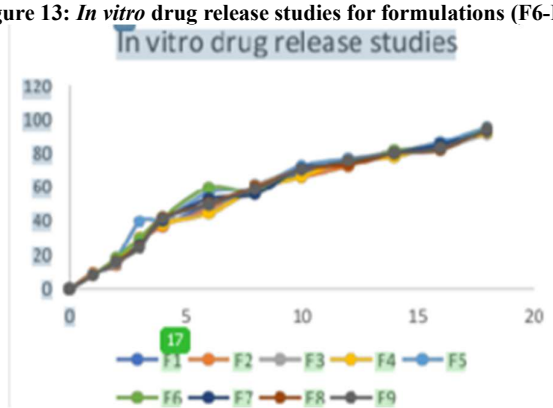

Figure 14: Drug release tests of (F1- F9) formulations *in vitro*

Using diffusion equipment, drug release tests were conducted for 8 h on all formulations of sertraline hydrochloride nanosponge. The fifth formulation exhibited the highest drug release rate, 95.60% within 18 h, according to the drug release trials shown in the **Figures 11-14**.

Kinetics of drug release

To ascertain the release behaviour of sertraline hydrochloride from the created

Nano sponges, the release kinetics of each prepared Nano sponge were evaluated. In addition to the Higuchi kinetic model, the zero-order, first-order, and Korsmeyer-Peppas kinetic models were used to assess the release data. It was discovered that the release data from Nanosponges fit. The Higuchi kinetic model had the highest (r) value, however, the release date for free sertraline hydrochloride nanosponges fit the zero-order kinetic model.

***In vitro* drug release kinetics**

Zero-order kinetics: (Figure 15)

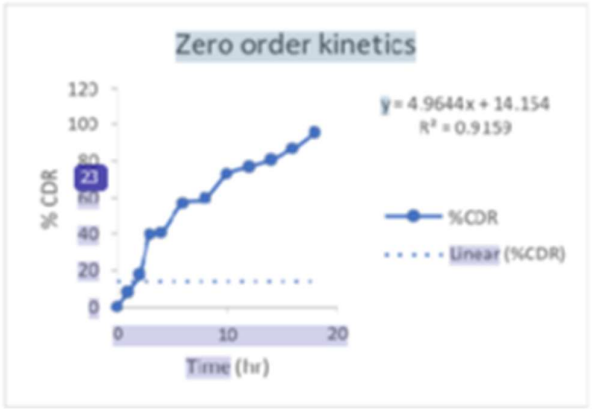

Figure 15: An enhanced formulation's zero-order kinetics

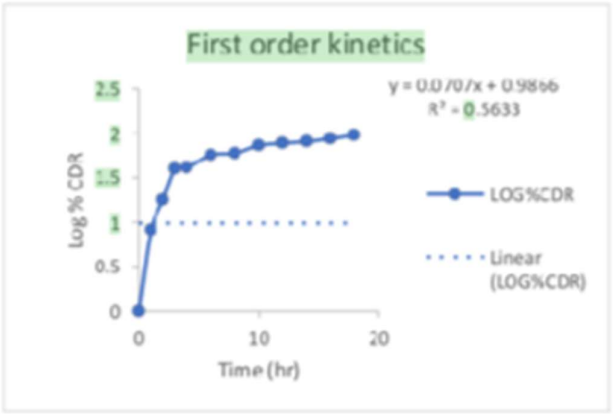

Figure 16: An improved formulation's first-order kinetics

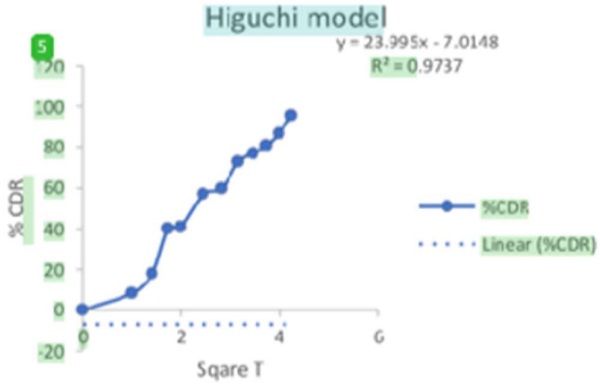

Figure 17: Higuchi miniature for optimal conception

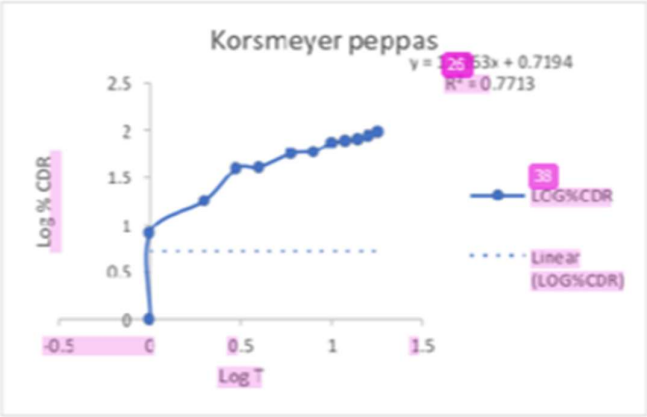

Figure 18: Korsmeyer-Peppas of streamlined, and stability studies

Stability studies: The nanosponge formulation F-5's chemical and physical characteristics did not alter after ninety days. The parameters that were measured at various points in time were shown **(Table 6)**.

Table 6: Stability analysis for all formulations

Formulation	Specification	Primary	1st Month	2nd Month	3rd Month	Limit as specified
F5	25°C/60% RH % Releases	95.60	94.89	93.58	92.65	Not less than 85%
F5	30°C/75% RH 95.60 % Releases	95.60	94.80	93.64	92.48	Not less than 85%
F5	40°C/75% RH % Releases	95.60	94.75	93.54	92.35	Not less than 85%

CONCLUSION

Drugs that are hydrophilic or lipophilic may be absorbed by the nanosponges and then released in a predictable and regulated manner at the intended location. By adjusting the ratios of polymer to cross-linker, you can change the particle size and release rate. NSGs increase drug solubility while shielding the active ingredients from physicochemical degradation and regulated discharge. The primary purpose of this research was to create nanosponges that could improve the solubility, encapsulation, dissolution rate, and oral medicinal efficacy of lipophilic or weakly water-soluble medications. To screen the formulation's components, a preliminary nanonization procedure was devised. Several solvents, including dimethylformamide, dimethyl sulfoxide, ethanol, methanol, and double distilled water, as well as polymers like as β-cyclodextrin and ethyl cellulose, were used to build stable NSGs for the preceding medicines. Polyvinyl alcohol was a type of polymer stabilizer. Cross-linkers comprised of dichloromethane and nanosponges were generated by altering excipient ratios with sertraline hydrochloride.

The present work examined particle characteristics following the

formation of nanosponges loaded with sertraline hydrochloride. The solvent evaporation procedure was successful in producing Nanosponges. The amounts of crosslinker and cyclodextrin (used as a sustained-release polymer) were adjusted to optimize the formulation. The improved formulation, which contained sertraline hydrochloride-loaded NSGs, exhibited suitable characteristics, like particle size, zeta potential, %EE, and % DR, for its intended use. FTIR and SEM investigations showed that sertraline hydrochloride-loaded NSGs were compatible with polymers without causing significant chemical interactions, and the encapsulated drug was found to be in an amorphous form with a spongy-smooth surface. The diffusion results of sertraline hydrochloride-loaded NSGs demonstrated that the rate followed a continuous release phase after an initial burst impact of the drug release. Following 12 h of release trials, the pure sertraline hydrochloride suspension and sertraline hydrochloride loaded NSGs showed drug release rates of around 95.60%, respectively. The sertraline hydrochloride-filled NSGS displayed asymmetrical non-fiction release according to the Higuchi-matrix model of release kinetics. Finally, the NSGs loaded with sertraline hydrochloride showed improved sustained sertraline hydrochloride release and may have depressive disorder effects.

Declarations

Author contributions

All authors contributed to experimental work, data collection, drafting or revising the article, gave final approval of the version to be published, and agreed to be accountable for all aspects of the work.

Competing interest statement

All authors declare that there is no conflict of interests regarding publication of this paper.

Financial support and sponsorship

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Ethical approval

Not required.

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