

FORMULATION AND PHYSICOCHEMICAL CHARACTERIZATION OF DEXLANSOPRAZOLE NANOSPONGE-BASED DRUG DELIVERY SYSTEM

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Abstract

The present study aimed to formulate and characterize Dexlansoprazole-loaded nanosponges for sustained drug delivery using the emulsion solvent diffusion method. Dexlansoprazole nanosponges were prepared using Eudragit RLPO as the polymer, polyvinyl alcohol (PVA) as the stabilizer, and Pluronic F68 as the surfactant. Six formulations (F1–F6) were developed by varying the concentrations of Eudragit RLPO and PVA while maintaining a constant drug concentration. The prepared nanosponges were evaluated for percentage yield, entrapment efficiency, particle size, zeta potential, surface morphology, in vitro drug release, release kinetics, and stability. Among all formulations, F3 exhibited the highest percentage yield ($84.56 \pm 0.025\%$) and entrapment efficiency ($83.32 \pm 0.19\%$). The optimized formulation showed a mean particle size of 124.32 nm and a zeta potential of -36.65 mV, indicating nanoscale dimensions and good physical stability. Scanning electron microscopy revealed spherical particles with a porous surface structure. In vitro drug release studies demonstrated sustained release of Dexlansoprazole from nanosponges, achieving 96.65% cumulative drug release over 12 hours compared to rapid release from the plain drug. Release kinetic analysis indicated that the drug release followed first-order kinetics ($R^2 = 0.9859$) with diffusion-controlled release characteristics. Stability studies conducted for three months under refrigerated and room temperature conditions confirmed the physicochemical stability of the optimized formulation. The results suggest that Dexlansoprazole-loaded nanosponges represent a promising approach for enhancing drug stability and providing sustained drug release, thereby improving therapeutic efficacy and patient compliance.

Introduction

Oral drug delivery remains the most preferred route of administration due to its convenience, patient compliance, and cost-effectiveness. However, many therapeutic agents exhibit poor aqueous solubility, limited bioavailability, and instability in the gastrointestinal environment, which significantly affect their therapeutic performance [1]. Various novel drug delivery systems have been developed to overcome these limitations and improve the efficacy of poorly soluble drugs. Among these

approaches, nanosponge-based drug delivery systems have emerged as promising carriers due to their unique porous structure, high drug-loading capacity, controlled release characteristics, and enhanced stability [2].

Nanosponges are nanosized, highly cross-linked polymeric structures containing numerous cavities capable of entrapping drug molecules within their matrix. These carriers can improve the solubility, dissolution rate, stability, and bioavailability of poorly water-soluble drugs while

providing controlled and site-specific drug release [3]. Due to their biocompatibility, non-toxicity, and versatility, nanosponges have attracted considerable attention in pharmaceutical research for oral, topical, and targeted drug delivery applications [4].

Dexlansoprazole is a proton pump inhibitor (PPI) widely used in the management of gastroesophageal reflux disease (GERD), erosive esophagitis, and other acid-related disorders. It is the R-enantiomer of lansoprazole and exhibits superior pharmacokinetic properties compared to the racemic formulation [5].

Despite its therapeutic advantages, Dexlansoprazole possesses poor aqueous solubility and is susceptible to degradation under acidic conditions, resulting in variable absorption and reduced bioavailability. Therefore, the development of an advanced drug delivery system capable of protecting the drug and providing sustained release is of considerable pharmaceutical interest [6].

Nanosponges offer several advantages for the delivery of Dexlansoprazole, including enhanced drug entrapment, protection from environmental degradation, improved dissolution behavior, and prolonged drug release [7].

The porous architecture of nanosponges enables effective incorporation of the drug

into the polymeric matrix, thereby reducing rapid drug degradation and improving therapeutic effectiveness. Furthermore, controlled release from nanosponges can reduce dosing frequency and improve patient compliance [8].

Eudragit RLPO is a widely used polymer in nanosponge formulations because of its excellent film-forming ability, permeability characteristics, and capability to sustain drug release. Polyvinyl alcohol (PVA) serves as an effective stabilizing agent that prevents particle aggregation during nanosponge formation. The emulsion solvent diffusion method is one of the most commonly employed techniques for nanosponge preparation due to its simplicity, reproducibility, and ability to produce nanoparticles with narrow size distribution [9].

Therefore, the present study was undertaken to formulate and physicochemically characterize Dexlansoprazole-loaded nanosponges using the emulsion solvent diffusion method. The prepared formulations were evaluated for percentage yield, entrapment efficiency, particle size, zeta potential, surface morphology, in vitro drug release behavior, release kinetics, and

stability. The study aims to develop a stable nanosponge-based drug delivery system capable of enhancing the therapeutic performance of Dexlansoprazole through sustained and controlled drug release.

Material and Methods

Material

Dexlansoprazole was used as the model drug for the preparation of nanosponges. Eudragit RLPO served as the polymer matrix, while polyvinyl alcohol (PVA) was employed as a stabilizing agent. Pluronic F68 was used as a surfactant to improve formulation stability. Dichloromethane was utilized as the organic solvent for preparing the dispersed phase, and distilled water was used as the aqueous phase. All chemicals and reagents used in the study were of analytical grade and procured from reputable commercial suppliers.

Methods

Formulation and Development of Nanosponges

Dexlansoprazole nanosponges (F1–F6) were prepared by the emulsion solvent diffusion method using varying concentrations of Eudragit RLPO and polyvinyl alcohol (PVA), while keeping the drug and Pluronic F68 constant. For each formulation (F1–F6), 60 mg of Dexlansoprazole was accurately

weighed and dissolved along with the required quantity of Eudragit RLPO (100–350 mg as per formulation) in 15 mL of dichloromethane to form the organic (dispersed) phase. The solution was stirred until a clear solution was obtained. Separately, the aqueous phase was prepared by dissolving the specified amount of polyvinyl alcohol (200–800 mg) and Pluronic F68 (100 mg) in 100 mL of distilled water under continuous stirring to obtain a uniform solution ^[10]. The organic phase was then slowly added dropwise into the aqueous phase under continuous stirring using a magnetic stirrer maintained at 1000 rpm. The stirring was continued for 2 hours to allow proper diffusion of the solvent and formation of nanosponges. After complete solvent evaporation and formation of nanosponges, the resulting dispersion was subjected to vacuum filtration to collect the nanosponges. The collected product was then dried in a hot air oven at 40°C for 24 hours to obtain dry, free-flowing Dexlansoprazole nanosponges.

All formulations (F1–F6) were prepared using the same procedure, with variation only in the concentrations of Eudragit RLPO and PVA as specified in Table 1.

Table 1: Composition of Dexlansoprazole loaded nanosponges

Ingredients	F1	F2	F3	F4	F5	F6
Dexlansoprazole (mg)	60	60	60	60	60	60
Polyvinyl alcohol (mg)	200	300	400	500	600	800
Eudragit RLPO (mg)	100	150	200	250	300	350
Pluronic F68 (mg)	100	100	100	100	100	100
Dichloromethane	15	15	15	15	15	15
Distilled water (ml)	100	100	100	100	100	100

Characterization of Nanosponges

Percentage yield

The Dexlansoprazole nanosponges obtained after drying was weighed. Percentage yield value was calculated as follows:

$$\% \text{ yield} = \frac{\text{Weight of nanosponges} \times 100}{\text{Total solids weight}}$$

Entrapment efficiency

UV spectrophotometric method was used to estimate entrapment efficiency of Dexlansoprazole nanosponges [11]. A calibration curve was plotted for Dexlansoprazole in 0.1 N HCl in the range of 5-25 µg/mL (Beer's Lambert's range) at 286nm.

A good linear relationship was observed between the concentration of Dexlansoprazole and its absorbance

($r^2=0.999$, $m=0.092$, $n=3$). 10 mg of Dexlansoprazole nanosponges of each batch were selected, powdered in a mortar and placed in 10 mL of 0.1 N HCl. Dexlansoprazole was extracted by centrifuging at 1000 rpm for 30 min, filtered and analyzed concentration in supernatant from calibration curve data after necessary dilution. Percentage entrapment was calculated as follows:

$$\% EE = \frac{\text{Total drug} - \text{Free (unentrapped) drug}}{\text{Total drug}} \times 100$$

Particle size, polydispersity index

Average particles size, polydispersity index (PDI) of prepared nanosponges was determined using Zetasizer (DTS were 4.10, Horriba instrument, India). The nanosponges formulation was diluted with deionized

water (1:9 v/v) and analysed for average size and PDI ^[12].

Shape and surface morphology

The shape and surface morphology of the nanospongess were investigated using scanning electron microscopy (IISER, Bhopal). The nanospongess were fixed on supports with carbon-glue, and coated with gold using a gold sputter module in a high-vacuum evaporator. Samples were then observed with the Scanning Electron Microscope at 10 kV ^[13].

In vitro drug release of nanosponges

Dissolution Parameters

Medium	900ml, 0.1 N HCl
Apparatus	Paddle (USP-II)
RPM	55
Temperature	37°C±0.5
Time Points	0.5, 1, 1.5, 2, 3, 4, 6, 8, 10, 12 hrs.

Procedure: For the oral dosage forms the *in vitro* dissolution study must be conducted in the dissolution medium which simulate the in-vivo conditions (actual physiological conditions). The *in vitro* drug release studies for the prepared formulation were conducted for a period of 12 hrs using an Labindia DS 8000 model dissolution tester USP Type-II apparatus (rotating paddle) set at 100 rpm and a temperature of 37±0.5°C formulation was placed in the

Dissolution is pharmaceutically defined as the rate of mass transfer from a solid surface into the dissolution medium or solvent under standardized conditions of liquid/solid interface, temperature and solvent composition. It is a dynamic property that changes with time and explains the process by which a homogenous mixture of a solid or a liquid can be obtained in a solvent. The test determines the time required for formulation to release percentage of drug under specified conditions ^[14].

900ml of the medium. At specified intervals 5ml samples were withdrawn from the dissolution medium and replaced with fresh medium to keep the volume constant. The absorbance of the sample solution was analyzed at 286nm for the presence of model drug, using a UV-visible spectrophotometer.

Stability studies of optimized nanosponges formulation (F3)

The prepared nanosponges subjected to stability studies at $40\pm 2^{\circ}\text{C}/75\pm 5\%$ RH and $30\pm 2^{\circ}\text{C}/60\pm 5\%$ RH as per ICH guidelines for a period of 3 months. Samples were withdrawn at 1 month time intervals and evaluated for physical appearance and drug content.

Results and Discussion

The present study was undertaken to formulate and evaluate Dexlansoprazole-loaded nanosponges using the emulsion solvent diffusion method with varying concentrations of Eudragit RLPO and polyvinyl alcohol (PVA). The influence of polymer and stabilizer concentrations on nanoparticle formation, entrapment efficiency, particle size, drug release, and stability was systematically investigated.

Dexlansoprazole-loaded nanosponges were successfully prepared using Eudragit RLPO as the polymer matrix and PVA as the stabilizing agent. Six formulations (F1–F6) were developed by varying the concentrations of Eudragit RLPO and PVA while maintaining constant amounts of drug and Pluronic F68 (Table 1). The formulation variables significantly influenced the physicochemical characteristics of the prepared nanosponges.

The percentage yield and entrapment efficiency of all formulations are presented

in Table 2. The percentage yield ranged from $74.25 \pm 0.045\%$ to $84.56 \pm 0.025\%$, while entrapment efficiency varied from $72.25 \pm 0.25\%$ to $83.32 \pm 0.19\%$. Among all formulations, F3 exhibited the highest percentage yield ($84.56 \pm 0.025\%$) and maximum entrapment efficiency ($83.32 \pm 0.19\%$). The enhanced entrapment efficiency observed in F3 may be attributed to the optimum concentration of Eudragit RLPO, which provided sufficient polymeric matrix for effective encapsulation of Dexlansoprazole. However, further increases in polymer concentration beyond the optimum level resulted in a slight reduction in entrapment efficiency, possibly due to increased viscosity and non-uniform particle formation.

Particle size is an important parameter influencing drug release, stability, and bioavailability of nanosponge formulations. The optimized formulation F3 exhibited a mean particle size of 124.32 nm as determined by dynamic light scattering (Figure 1). The obtained particle size falls within the nanometer range, indicating successful preparation of nanosized carriers suitable for enhancing drug dissolution and absorption. The relatively small particle size may contribute to increased surface area and improved drug release characteristics.

Zeta potential analysis was performed to evaluate the surface charge and physical stability of the optimized formulation. The zeta potential of formulation F3 was found to be -36.65 mV (Figure 2). Generally, zeta potential values greater than ± 30 mV indicate good colloidal stability due to sufficient electrostatic repulsion between particles. Therefore, the obtained value suggests excellent stability of the prepared nanosponges and a lower tendency toward particle aggregation.

The surface morphology of the optimized nanosponge formulation was evaluated using scanning electron microscopy. The SEM image (Figure 3) revealed discrete, nearly spherical particles with a porous surface structure characteristic of nanosponge systems. The porous nature of the particles provides a larger surface area for drug incorporation and controlled release, thereby enhancing the therapeutic performance of the formulation.

The in vitro drug release profile of Dexlansoprazole-loaded nanosponges was compared with that of the plain drug (Table 3). The plain drug exhibited rapid release, reaching 83.32% within 2 hours, whereas the nanosponge formulation showed a sustained release pattern with 96.65% drug release over 12 hours. At the initial stages,

only 11.12% drug release was observed from nanosponges after 0.5 hours compared to 26.65% from the plain drug. This controlled release behavior can be attributed to the encapsulation of Dexlansoprazole within the polymeric nanosponge matrix, which retards drug diffusion and prolongs drug release.

The release kinetics of the optimized formulation F3 were further analyzed using various mathematical models. The kinetic data utilized for the analysis are presented in Table 4, while the regression coefficients are summarized in Table 5. Among the tested models, the first-order model exhibited the highest regression coefficient ($R^2 = 0.9859$), followed by the Higuchi model ($R^2 = 0.9525$), Korsmeyer–Peppas model ($R^2 = 0.9346$), and zero-order model ($R^2 = 0.8435$). These results indicate that drug release from the nanosponges predominantly followed first-order kinetics and was concentration dependent. The high correlation with the Higuchi model further suggests that diffusion played a major role in the release mechanism.

The stability of the optimized formulation F3 was evaluated under refrigerated ($4 \pm 0.2^\circ\text{C}$) and room temperature ($25\text{--}28 \pm 2^\circ\text{C}$) conditions for a period of three months. The results are presented in Table 6. The

formulation remained physically stable throughout the study period without any noticeable changes in appearance. Only slight increases in particle size and minor reductions in entrapment efficiency were observed during storage. At refrigerated conditions, the particle size increased from 124.32 ± 0.45 nm to 125.95 ± 0.36 nm over

three months, while entrapment efficiency decreased from $80.33 \pm 0.15\%$ to $78.85 \pm 0.65\%$. Comparatively, greater changes were observed at room temperature. These findings indicate that the nanosponge formulation possesses satisfactory stability, particularly under refrigerated storage conditions.

Table 2: Percentage yield and Entrapment Efficiency for different formulation

Formulation code	Percentage Yield*	Entrapment Efficiency (%)
F1	74.25 ± 0.045	72.25 ± 0.25
F2	79.98 ± 0.036	77.98 ± 0.18
F3	84.56 ± 0.025	83.32 ± 0.19
F4	76.65 ± 0.036	75.45 ± 0.26
F5	79.85 ± 0.015	78.98 ± 0.36
F6	78.85 ± 0.038	76.65 ± 0.45

*Average of three determinations (n=3)

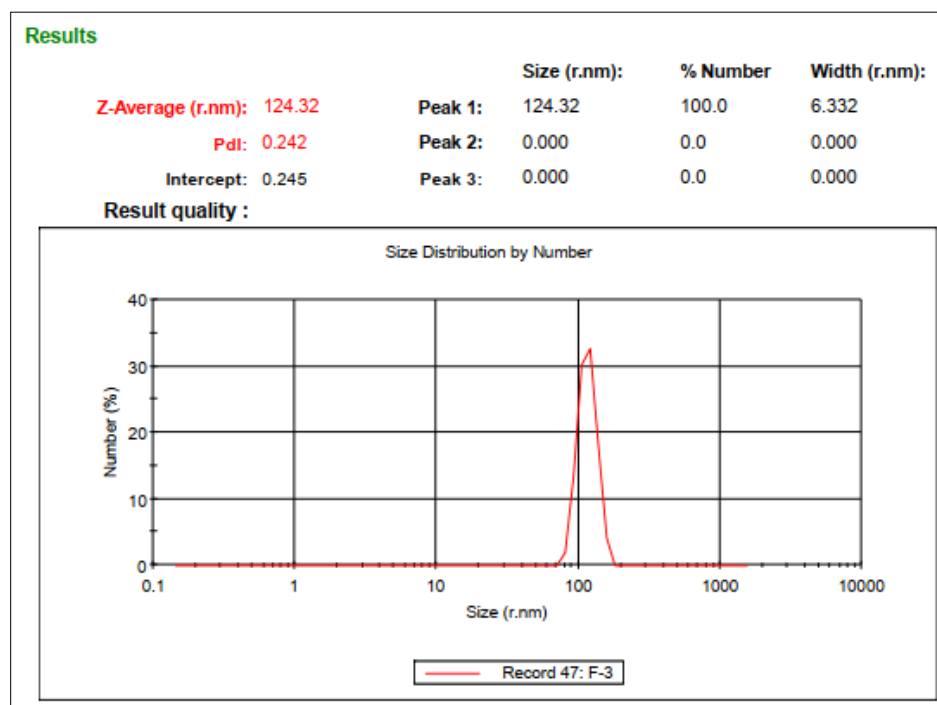
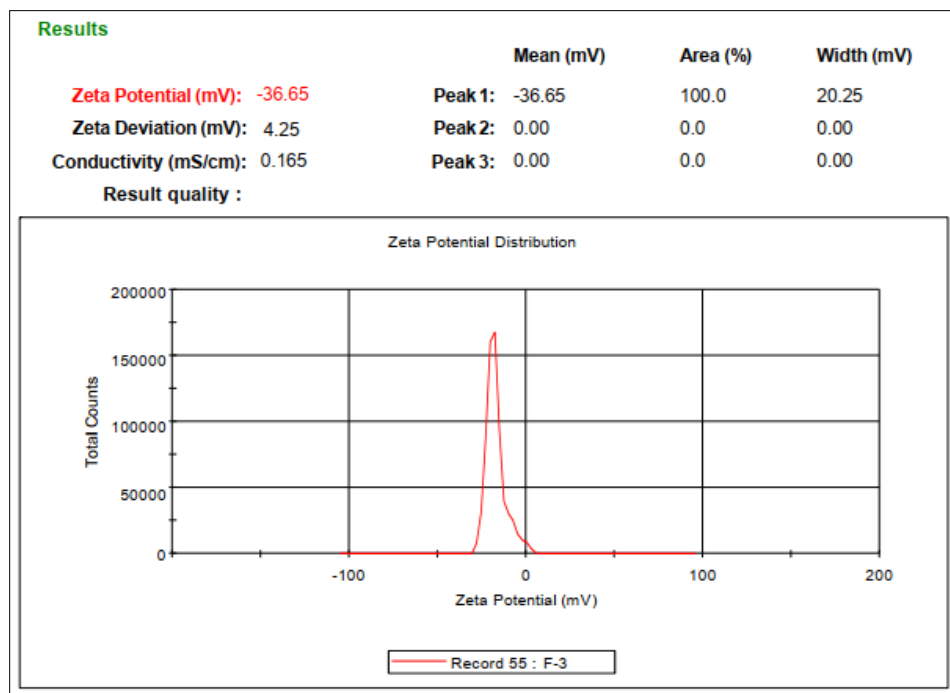
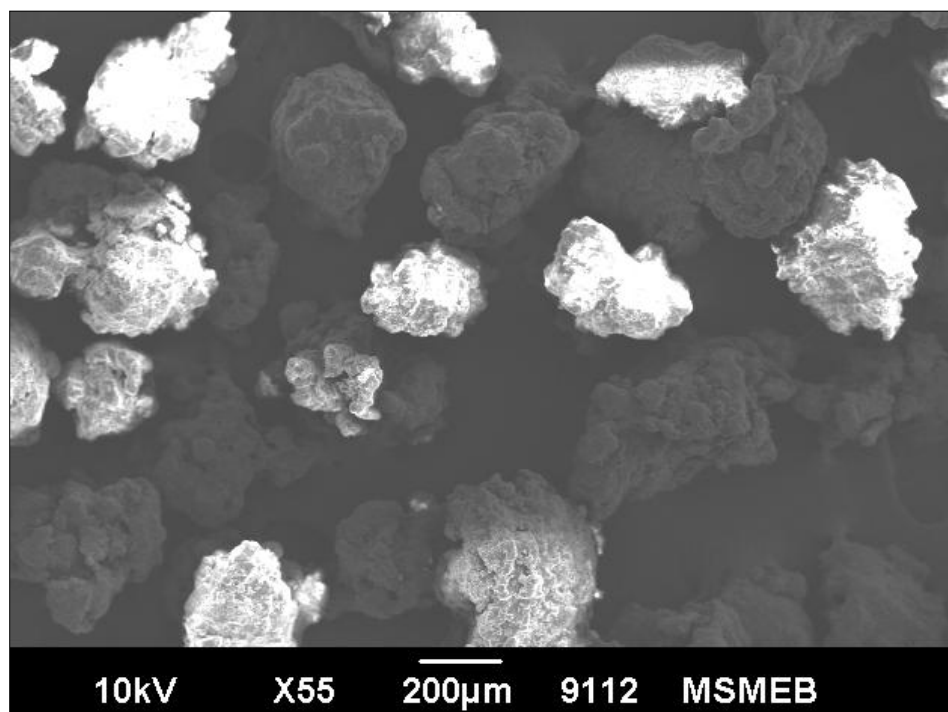


Figure 1: Measurement of mean particle size

**Figure 2: Graph of zeta potential****Figure 3: Scanning electronic microscopy of optimized formulation (F3)****Table 3: *In vitro* drug release study of Dexlansoprazole loaded nanosponges**

	Cumulative % Drug Release
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S. No.	Time (hrs.)	Plain Drug	Nanosponges
1.	0.5	26.65	11.12
2.	1	43.32	22.36
3.	1.5	69.98	35.45
4.	2	83.32	46.65
5.	3	-	55.58
6.	4	-	68.98
7.	6	-	76.65
8.	8	-	85.55
9.	12	-	96.65

Table 4: *In-vitro* drug release data for optimized formulation F3

Time (h)	Square Root of Time(h) ^{1/2}	Log Time	Cumulative*% Drug Release	Log Cumulative % Drug Release	Cumulative % Drug Remaining	Log Cumulative % Drug Remaining
0.5	0.707	-0.301	11.12	1.046	88.88	1.949
1	1	0	22.36	1.349	77.64	1.890
1.5	1.225	0.176	35.45	1.550	64.55	1.810
2	1.414	0.301	46.65	1.669	53.35	1.727
3	1.732	0.477	55.58	1.745	44.42	1.648
4	2	0.602	68.98	1.839	31.02	1.492
6	2.449	0.778	76.65	1.885	23.35	1.368
8	2.828	0.903	85.55	1.932	14.45	1.160
12	3.464	1.079	96.65	1.985	3.35	0.525

Table 5: Regression analysis data of Dexlansoprazole loaded nanosponges

Batch	Zero Order	First Order	Higuchi	Korsmeyer Peppas
	R ²	R ²	R ²	R ²
F3	0.8435	0.9859	0.9525	0.9346

Table 6: Characterization of stability study of Optimized formulation (F3)

Characteristic	1 Month		2 Month		3 Month	
Temperature	4.0 ± 0.2°C	25–28 ± 2°C	4.0 ± 0.2°C	25–28 ± 2°C	4.0 ± 0.2°C	25–28 ± 2°C
Average Particle Size (nm)	124.32 ± 0.45	126.55 ± 0.15	125.65 ± 0.25	128.85 ± 0.22	125.95 ± 0.36	130.32 ± 0.15
% Entrapment Efficiency	80.33 ± 0.15	75.65 ± 0.85	79.98 ± 0.92	74.45 ± 0.88	78.85 ± 0.65	72.25 ± 0.74
Physical Appearance	Normal	Normal	Normal	Normal	Normal	Normal

Conclusion

Dexlansoprazole-loaded nanosponges were successfully formulated using the emulsion solvent diffusion method. Among the prepared formulations, F3 exhibited the highest percentage yield, entrapment efficiency, optimal particle size (124.32 nm), and good zeta potential (−36.65 mV), indicating excellent stability. The optimized formulation showed sustained drug release over 12 hours and followed first-order release kinetics. Stability studies confirmed that the formulation remained stable during storage. Therefore, Dexlansoprazole-loaded nanosponges can be considered a promising drug delivery system for enhancing drug stability, controlling drug release, and improving therapeutic effectiveness.

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