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Formulation and Evaluation of pH-Responsive Natural Polymer Raft Gel of Dexlansoprazole for Gastric Ulcer Protection and Sustained Release

Dr. R. Narasimha Rao[1], Dr. N. Raghunandhan[2], Ch. Ramesh[3]

[1] Professor, Holy Mary Institute of Technology and Science, College of Pharmacy, Bogaram, Keesara, Medchal, Telangana, India – 501301.

[2] Principal & Professor, Holy Mary Institute of Technology and Science, College of Pharmacy, Bogaram, Keesara, Medchal, Telangana, India – 501301.

[3] Holy Mary Institute of Technology and Science, College of Pharmacy, Bogaram, Keesara, Medchal, Telangana, India – 501301.

Corresponding Author: Ch.Ramesh
Email id: chirlaramesh2002@gmail.com

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Abstract: The present work was designed to develop and evaluate a pH-responsive natural polymer raft-forming oral gel of dexlansoprazole using sodium alginate and pectin. Eight formulations, DRG1-DRG8, were prepared by adjusting the polymer concentrations while keeping the remaining formulation components constant. Preformulation testing confirmed the identity of the drug, its compatibility with selected excipients and the suitability of the analytical method. The formulations were evaluated for appearance, pH, viscosity, gelation time, floating behaviour, raft characteristics, drug content, in vitro release, release kinetics and stability. An increase in polymer concentration improved viscosity, raft strength and floating duration, but it also reduced pourability and slowed drug release. DRG5 produced the most balanced performance, with viscosity of 2260 ± 113 cP, gelation time of 25 ± 1 s, floating lag time of 30 ± 2 s, raft strength of 12.8 ± 0.6 g, drug content of 99.2 ± 0.9% and 88.4% release within 12 h. The optimized formulation remained stable for three months under accelerated storage. On this basis, DRG5 was selected as the optimized raft-forming system for sustained oral delivery of acid-protected dexlansoprazole.

Keywords: Dexlansoprazole, raft-forming gel, sodium alginate, pectin, gastroretentive drug delivery, sustained release, buoyancy.

INTRODUCTION

Gastric ulcer and related acid-peptic disorders develop when aggressive luminal factors exceed mucosal protective mechanisms. Acid suppression remains central to the management of acid-related disease, while formulation strategies that prolong gastric residence may be useful when sustained local gastric presence or controlled drug release is desired [1–4].

Dexlansoprazole is a proton-pump inhibitor used for acid suppression. The molecule is acid labile and is ordinarily protected from gastric degradation by delayed-release formulation technology. Any experimental gastroretentive system must therefore preserve acid protection while controlling subsequent drug release rather than exposing unprotected dexlansoprazole directly to gastric fluid [5–8].

Raft-forming systems are liquid or semisolid formulations that undergo gelation in the stomach and form a low-density layer capable of floating on gastric contents. Sodium alginate is commonly used because it forms calcium-mediated gels, while gas generated from carbonate or bicarbonate components can become trapped within the hydrated matrix and provide buoyancy [9–12].

Pectin is another natural polysaccharide capable of hydration and gel formation. Combining pectin with sodium alginate can modify viscosity, gelation, raft strength, water uptake, and drug diffusion. Increasing polymer concentration can improve raft integrity and floating duration, but excessive matrix strength may reduce pourability and slow drug release beyond the desired level [13–16].

Published work on alginate-based floating and raft-forming systems supports their use as gastroretentive platforms [17–20]. The present study therefore developed eight pH-responsive dexlansoprazole raft-gel formulations using sodium alginate and pectin and evaluated their physicochemical properties, buoyancy, raft strength, drug content, in vitro release, and accelerated stability.

MATERIALS AND METHODS

Chemicals

DXL was obtained from UniChem Labs Ltd., Mumbai. Sodium alginate was obtained from Global Exports Private Ltd., Mumbai. Pectin was obtained from Merck Life Science, India. Sodium bicarbonate was obtained from S.D. Fine-Chem Ltd, Mumbai. Calcium carbonate was obtained from S.D. Fine-Chem Ltd, Mumbai. Sodium citrate was obtained from Merck Life Science, India. Potassium sorbate was obtained from Merck Life Science, India.

Preformulation and analytical studies

Dexlansoprazole was examined for organoleptic characteristics, apparent solubility, UV response at 282 nm, and FTIR compatibility with the selected polymers.

Formulation design

Eight formulations, DRG1–DRG8, were prepared by varying sodium alginate and pectin while maintaining dexlansoprazole, sodium bicarbonate, calcium carbonate, sodium citrate, and potassium sorbate at the specified quantities.

Table 1: Formulation composition of dexlansoprazole raft gels

Formulation	DXL (mg)	Sodium alginate (g)	Pectin (g)	Sodium bicarbonate (g)	Calcium carbonate (g)	Sodium citrate (g)	Potassium sorbate (g)	Purified water q.s. to (g)
DRG1	300	1.00	0.25	0.50	0.50	0.20	0.05	100
DRG2	300	1.00	0.50	0.50	0.50	0.20	0.05	100
DRG3	300	1.00	0.75	0.50	0.50	0.20	0.05	100
DRG4	300	1.50	0.25	0.50	0.50	0.20	0.05	100
DRG5	300	1.50	0.50	0.50	0.50	0.20	0.05	100
DRG6	300	1.50	0.75	0.50	0.50	0.20	0.05	100
DRG7	300	2.00	0.25	0.50	0.50	0.20	0.05	100
DRG8	300	2.00	0.50	0.50	0.50	0.20	0.05	100

Preparation method

Sodium citrate and potassium sorbate were dissolved in purified water, followed by gradual addition and hydration of sodium alginate. Pectin was separately dispersed in warm water, cooled, and incorporated into

the alginate dispersion. Calcium carbonate and sodium bicarbonate were added under gentle stirring, and acid-protected dexlansoprazole microgranules were dispersed uniformly. The final weight was adjusted with purified water, deaerated, and transferred to airtight amber containers.

FTIR compatibility study

FTIR spectra of pure dexlansoprazole, sodium alginate, pectin, and the optimized formulation were compared over 4000–400 cm^{-1} to assess retention of characteristic functional-group bands and possible formulation interactions.

Evaluation

The formulations were evaluated for appearance, homogeneity, pH, viscosity, gelation time, floating lag time, total floating duration, raft strength, and drug content.

In vitro drug release

Drug release was studied using the biphasic conditions reported in the thesis, with an initial acidic phase followed by phosphate-buffer conditions to evaluate acid protection and subsequent release over 12 h.

Stability study

The optimized formulation was stored at 40 ± 2°C/75 ± 5% RH for three months. The principal quality attributes were assessed.

RESULTS AND DISCUSSION

Preformulation and compatibility

Dexlansoprazole showed low apparent solubility in purified water and greater solubility in selected analytical media.

Table 2: Apparent solubility of dexlansoprazole in selected media

Solvent or medium	Apparent solubility (mg/mL)
Purified water	0.019 ± 0.001
Phosphate buffer pH 6.8	0.43 ± 0.02
Methanol	18.70 ± 0.86
Acetonitrile	21.50 ± 1.02
Water–acetonitrile (60:40)	9.80 ± 0.46
0.1 N HCl	Unstable; not quantified

FTIR study

FTIR comparison showed retention of the principal drug and polymer bands in the optimized formulation with only limited shifts and broadening, supporting absence of a major chemical incompatibility.

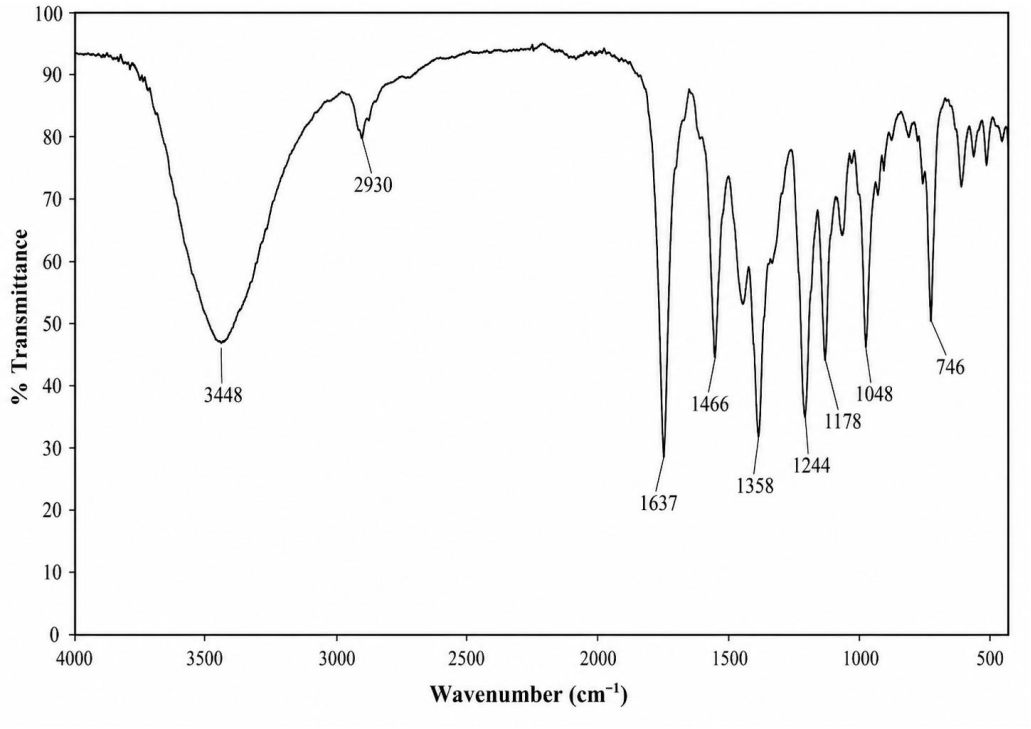

Fig 1: FTIR spectrum of pure dexlansoprazole.

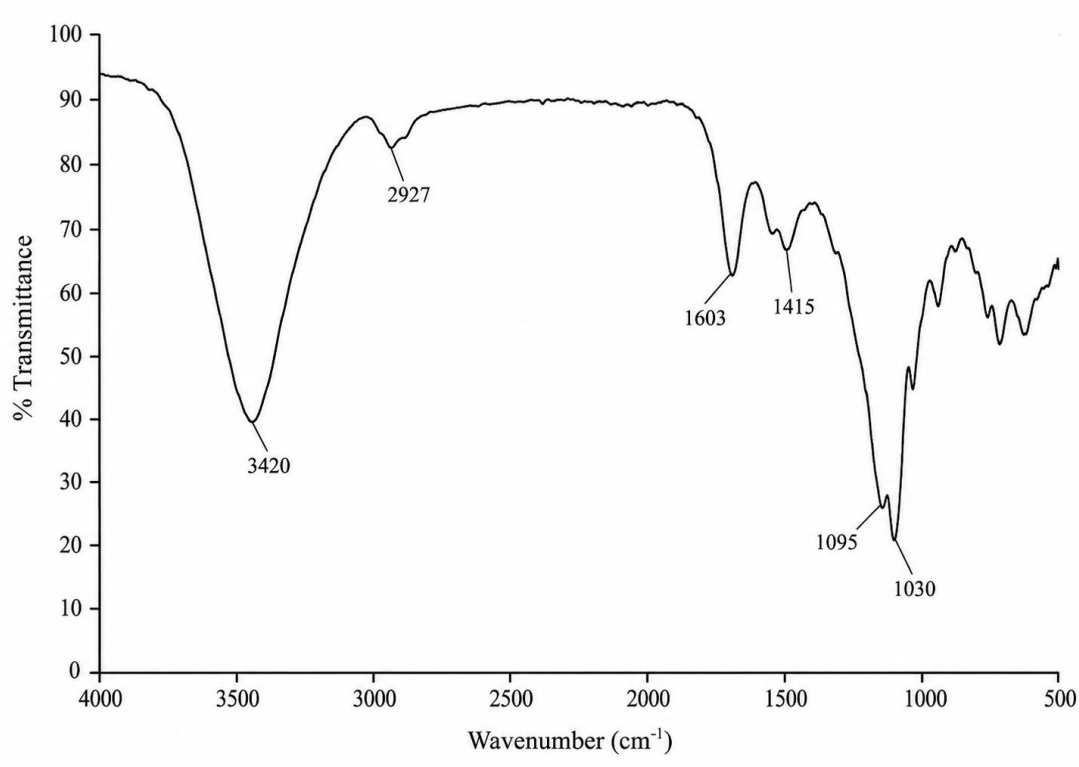

Fig 2: FTIR spectrum of sodium alginate.

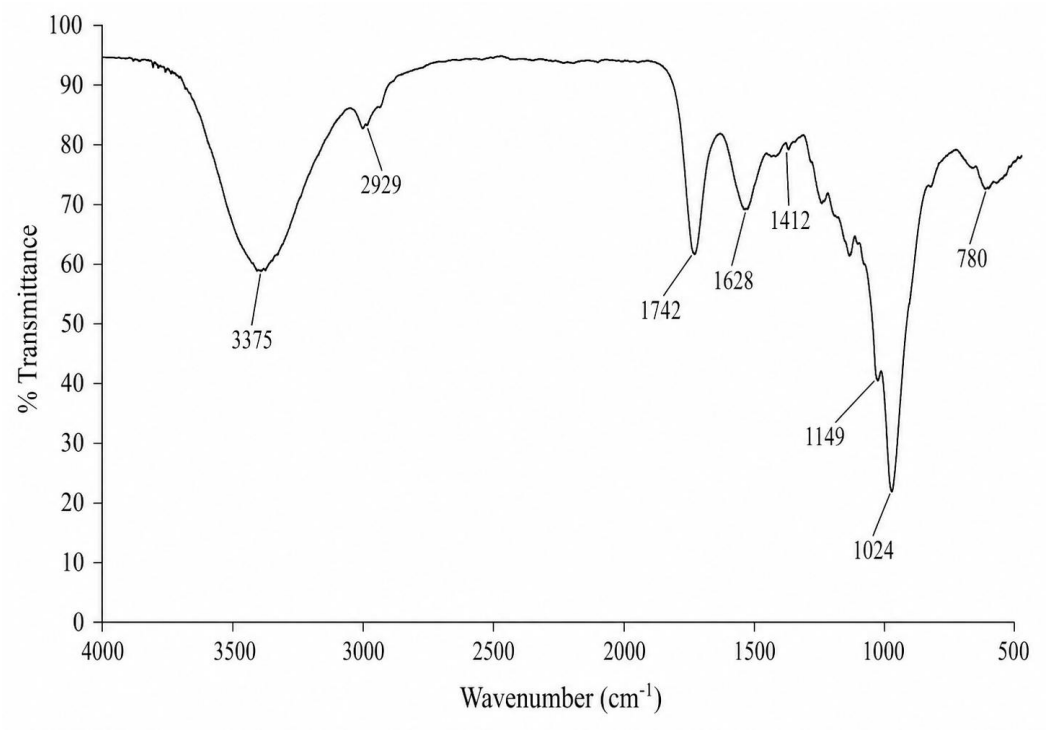

Fig 3: FTIR spectrum of pectin.

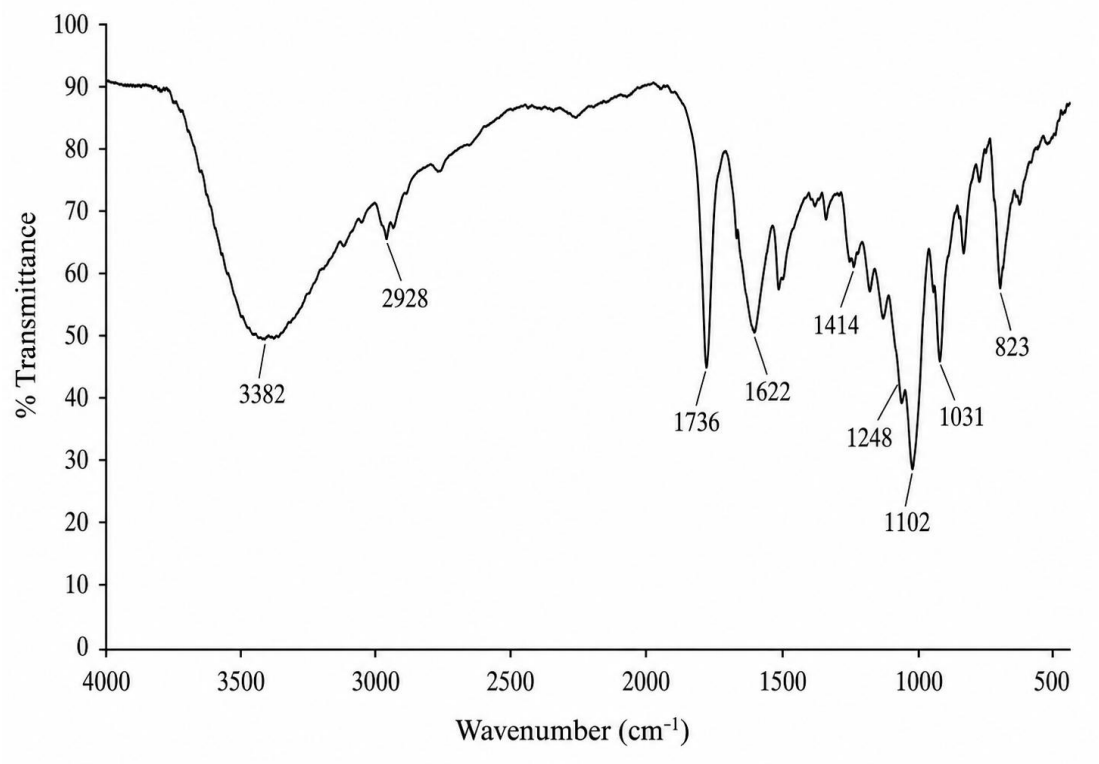

Fig 4; FTIR spectrum of the optimized formulation.

Table 3: Comparative FTIR peak assignments

Functional group	Pure DXL (cm^{-1})	Sodium Alginate (cm^{-1})	Pectin (cm^{-1})	Optimised formulation (cm^{-1})
O–H stretching	3448	3420	3375	3382
Aliphatic C–H stretching	2930	2927	2929	2928

Ester C=O stretching	–	–	1742	1736
Aromatic C=C stretching	1637	–	–	–
Carboxylate C=O stretching	–	1603	1628	1622
CH bending	1466	–	1412	1414
Sulfoxide S=O stretching	1358	–	–	–
C–O stretching	1244	–	–	1248
Glycosidic C–O–C stretching	–	1095	1149	1102
C–O stretching	1178, 1048	1030	1024	1031
Aromatic C–H out-of-plane bending	746	–	780	823

The FTIR spectrum of pure DXL exhibited characteristic bands at 3448, 2930, 1637, 1466, 1358, 1244, 1178, 1048 and 746 cm-1, assigned to hydroxyl stretching, aliphatic C-H stretching, aromatic ring vibrations, bending vibrations, sulfoxide absorption and fingerprint-region bands. Sodium alginate showed important peaks at 3420, 2927, 1604, 1415, 1095 and 1030 cm-1, while pectin showed characteristic bands at 3375, 2925, 1742, 1628, 1442, 1149, 1042 and 760 cm-1. In the optimized formulation, the DXL peaks remained visible with no major shift or disappearance. This finding indicated that the main functional groups of DXL were retained in the formulation and that the selected excipients did not show significant incompatibility.

Raft-gel characteristics

All formulations were homogeneous. Increasing the total polymer concentration increased viscosity, raft strength, and floating duration, while excessively high polymer levels reduced pourability. DRG5 showed an appropriate intermediate matrix strength and rapid gelation without the excessive viscosity observed in the highest-polymer batches.

Table 4: Appearance and homogeneity of dexlansoprazole raft gels

Formulation	Appearance and homogeneity
DRG1	Smooth, homogeneous and freely pourable
DRG2	Smooth and homogeneous
DRG3	Homogeneous and moderately viscous
DRG4	Smooth, uniform and pourable
DRG5	Homogeneous with suitable consistency
DRG6	Homogeneous and comparatively thick
DRG7	Thick but redispersible
DRG8	Very thick and slowly pourable

Table 5: Physicochemical and floating properties

F code	pH	Viscosity (cP)	Gelation time (s)	Floating lag time (s)	Total floating duration (h)
DRG1	7.18 ± 0.05	1050 ± 52	44 ± 2	58 ± 3	7.3 ± 0.4
DRG2	7.16 ± 0.04	1320 ± 66	38 ± 2	49 ± 2	8.5 ± 0.4
DRG3	7.14 ± 0.05	1610 ± 81	33 ± 2	43 ± 2	9.6 ± 0.5
DRG4	7.21 ± 0.05	1820 ± 91	31 ± 2	38 ± 2	10.4 ± 0.5
DRG5	7.19 ± 0.04	2260 ± 113	25 ± 1	30 ± 2	>12
DRG6	7.17 ± 0.05	2710 ± 136	22 ± 1	27 ± 1	>12
DRG7	7.24 ± 0.06	3250 ± 163	24 ± 1	33 ± 2	>12
DRG8	7.22 ± 0.05	3910 ± 196	20 ± 1	29 ± 1	>12

Table 6: Raft strength and drug content

Formulation	Raft strength (g)	Drug content (%)
DRG1	5.1 ± 0.3	97.1 ± 1.0
DRG2	6.8 ± 0.3	97.8 ± 1.1
DRG3	8.4 ± 0.4	98.2 ± 1.0
DRG4	9.6 ± 0.5	98.5 ± 1.1
DRG5	12.8 ± 0.6	99.2 ± 0.9
DRG6	15.6 ± 0.8	98.9 ± 1.0
DRG7	17.4 ± 0.9	98.6 ± 1.1
DRG8	20.1 ± 1.0	98.4 ± 1.0

In vitro release and formulation selection

Only limited dexlansoprazole was released during the initial acidic phase, followed by progressive release after the medium change. DRG5 released 3.8% during the acidic phase and 88.4% by 12 h. It showed viscosity of 2260 ± 113 cP, gelation time of 25 ± 1 s, floating lag time of 30 ± 2 s, floating duration greater than 12 h, raft strength of 12.8 ± 0.6 g, and drug content of 99.2 ± 0.9%, and was selected as the optimized formulation.

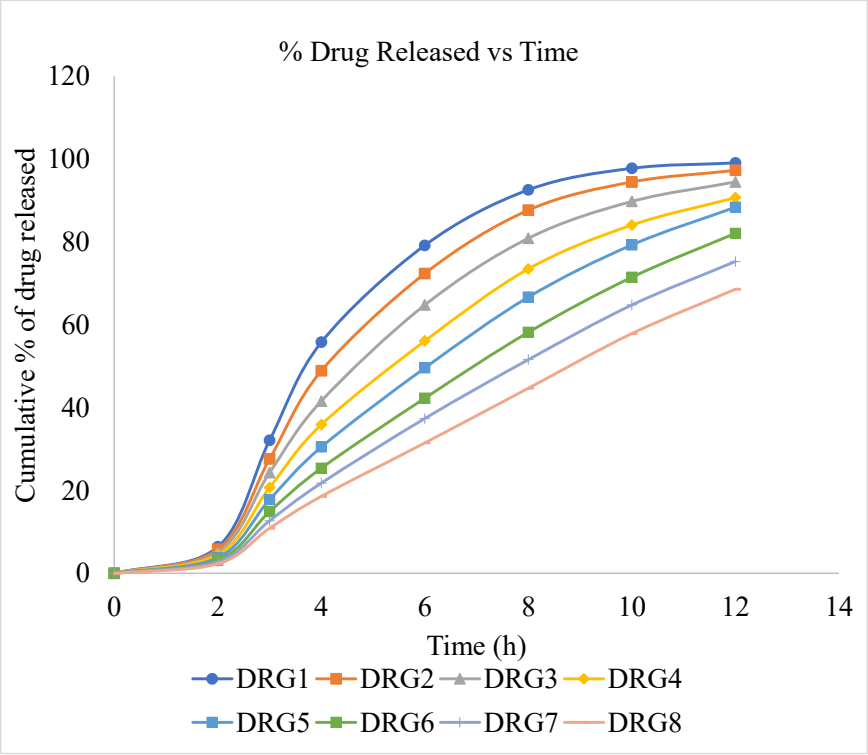

Fig 5: In vitro drug-release profiles of dexlansoprazole raft-gel formulations.

Stability study

DRG5 remained homogeneous during three months of accelerated storage without visible phase separation or premature gas formation. Only minor changes in the measured quality attributes were reported.

CONCLUSION

A pH-responsive natural-polymer raft gel of dexlansoprazole was successfully developed using sodium alginate and pectin. Increasing polymer concentration improved raft integrity and floating duration but also increased viscosity and slowed drug release. DRG5 provided the best balance of handling, rapid gelation, prolonged buoyancy, raft strength, drug content, and controlled release, with 88.4% release at 12 h after limited release in the acidic phase. The optimized formulation remained acceptable during three months of accelerated storage.

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