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Design and In Vitro Evaluation of Transfersomal Gel System: A Novel Approach for Transdermal Drug Delivery

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ABSTRACT

The present research involves the formulation, optimization, and evaluation of a transfersomal gel (NTFG7) aimed at enhancing the dermal delivery of drugs. Transferosomes were formulated and incorporated into a gel base containing Carbopol 934 (0.25%), propylene glycol (0.5%), ethanol (0.5%), and methyl paraben (0.02%). The gel was optimized by adjusting the concentration of Carbopol 934 to obtain desirable consistency and drug release properties. The optimized formulation (NTFG7) was subjected to various physicochemical evaluations, including visual appearance, homogeneity, pH, viscosity, swelling index, and in vitro drug release studies.

The gel was found to be smooth, off-white, odorless, and homogeneous with a pH of 7.7 ± 0.05 and viscosity of 11,279 ± 0.63 cps. The swelling index was recorded as 65.11 ± 0.02%, indicating excellent hydration potential. In vitro drug release studies showed a sustained release profile, with 96.54% cumulative release over 12 hours. Kinetic modeling of the release data revealed that the drug followed Korsmeyer–Peppas kinetics (R^2 = 0.995), suggesting an anomalous non-Fickian diffusion mechanism. Stability studies conducted over three months at varying temperatures (4°C, 25°C, and 40°C) showed no significant changes in physical appearance, pH, or viscosity, confirming the formulation's stability.

These results suggest that the optimized transfersomal gel formulation (NTFG7) is a promising carrier for controlled and efficient transdermal drug delivery.

Keywords: *Transfersomal gel, Carbopol 934, transdermal delivery, in vitro drug release, optimization,* R*epaglinide, controlled release, Korsmeyer–Peppas model, stability study, NTFG7.*

1. INTRODUCTION

Transfersomal gel was prepared using sediment, i.e., Transferosomes, 0.25% of Carbopol 934, 0.5% of propylene glycol, and 0.02% of methyl paraben. Optimization of the prepared gel was done based on the concentration of Carbopol 934. In this, Carbopol 934 was allowed to disperse in a sufficient quantity of Distilled water for 1 h. In a separate beaker, methyl paraben was dissolved in another part of water. After 1 h of soaking of Carbopol 934, sediment, methyl paraben solution, and propylene glycol were mixed using a mechanical stirrer and were stirred for 10 min till a Transferosomal gel was formed, and the pH was adjusted using Triethanolamine

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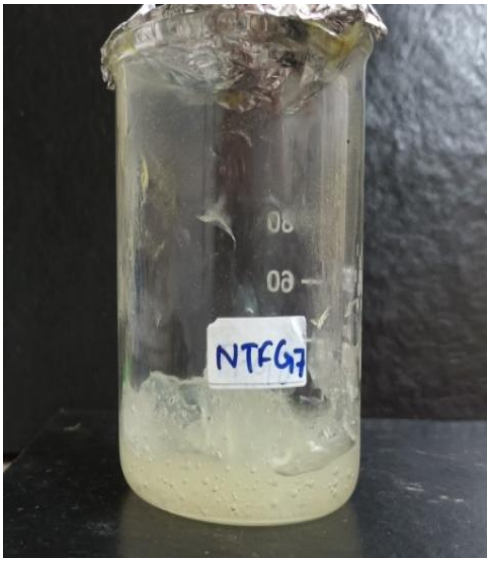


Figure 1: optimized gel formulation NTFG7

Table 1: Formulation of Gels of Transfersomal Gel

Chemical required	**NTFG7**
Transferosomes	100 mg
Carbopol 934	0.25%
Triethanolamine	q.s (2-3 drops)
Propyl paraben	0.1%
Ethanol	0.5 %
Distilled Water	q.s

CHARACTERISATION OF THE OPTIMIZED TRANSFEROSOMAL GEL

- **Visual characterisation**

The physical appearance or visual characterization of the gel was analysed by the visual and normal human senses. The organoleptic properties included color, odor, and texture.

2. RESULT

On careful visual inspection against a dark and white background, all the prepared dermal gel formulations were found to be free from any suspended particulate matter. All the formulations were found to be translucent gel. The texture was non-greasy and smooth to the touch.

Table 2 represents the physical properties of the transfersomal gel loaded with the drug.

S.N.	Formulation code	Parameters	Result
1	NTFG7	Color	Off white
		Texture	Smooth
		Appearance	Pleasant
		Odor	Odourless

		Gritty	Nongritty

- **Physical characterisation**
- **Homogeneity:**

Physical appearance and homogeneity of the prepared gels were evaluated by visual perception.

Result

The homogeneity of the transfersomal gel of the optimized formulation was shown that the formulation NTFG7 was a properly homogenized mixture. This uniformity was required for the proper penetration of the drug.

Table 3 represents the homogeneity of the transfersomal gel loaded with the drug.

S.N.	Formulation code	Parameters	Result
1	NTFG7	Homogeneity	Uniform mixture

pH

The pH of all prepared transferosomes gels was measured by using a pH meter pH of the formulated gel was determined using a Calomel glass electrode (pH meter) at room temperature. The pH meter was calibrated using standard buffer solutions of pH 4 and pH 7 before use. 1 g of gel was dissolved in about 10 ml of water and stirred until it formed a dispersion, and kept aside for 2 hours. The volume was made up to 100 ml, and the pH of the dispersion was measured with the help of a calibrated pH meter.

Result

The pH of the optimized formulations was found to be in the range of 6 to 7. Ideally, the dermal gel should possess a pH in the range of 6-7. The pH of the transfersomal gel was 7.7±0.05

Table 4represents the pH of the transfersomal gel loaded with the drug

S.N.	**Formulation code**	**Parameters**	**Result**
1	NTFG7	pH.	7.7±0.05

Swelling index

1 gm of gel was taken on porous aluminum foil and then placed separately in a 50 ml beaker containing 10 ml 0.1 N NaOH. Then samples were removed from beakers at different time intervals and put in a dry place for some time, and it reweighed.

Swelling Index (SW) % = [(Wt. – Wo) / Wo] × 100.

Where, (SW) % = Equilibrium percent swelling,

Wo = Original weight of formulation at zero time, after time t, Wt = Weight of swollen formulation

Table 5 represents the swelling index of the transfersomal gel loaded with the drug.

S.N.	**Formulation code**	**Parameters**	**Result**
1	NTFG7	Swelling index (%)	65.11±0.02

Viscosity

The viscosity of the prepared gels was measured using a
Brookfield Viscometer (Brookfield Engineering Laboratories, Inc., Middleboro, MA, USA) with S18 spindle, at a speed of 60 rpm. Rheological study of the gel was conducted in the shear rate range of 1–400 second^{-1}. Constant readings of the viscosity were taken after a specified time of 5 minutes and noted in centipoises.

Table 6 represents the Viscosity of the transfersomal gel loaded with the drug.

S.N.	Formulation code	Parameters	Result
1	NTFG7	Viscosity **(Viscosity (cps) at Room Temperature ± SD.)**	11279±0.63

In vitro drug release

The in vitro release study was performed via a dialysis membrane according to Hao's method. Briefly, an equivalent amount of transferosomal gel containing drug-loaded transferosomes was introduced into dialysis bags. The dialysis bags were suspended in an isotonic buffer solution (250 mL, pH 6.8, 37°C±2°C) at a speed of rotation of 1,500 rpm and placed within the dissolution flask of the USP dissolution apparatus. The samples (5 mL) were withdrawn and analyzed spectrophotometrically at λ_{max}=293 nm every 45 minutes for 12 hours. The withdrawn samples were replaced with the same volume of fresh isotonic buffer solution (pH 6.8). The concentration percentage of lidocaine at time (t) was estimated as follows:

Kinetic model

The data of in vitro insulin release from various transferosomal gels were evaluated kinetically using various mathematical models like zero-order, first-order, Higuchi, and Korsmeyer–Peppas model equations.

Zero-order Kinetics: $F = K_0 t$,

where F represents the fraction of drug released in time t, and K_0 is the zero-order release constant.

First-order Kinetics: $\ln(1 - F) = - K_1 t$,

where F represents the fraction of drug released in time t, and K_1 is the first-order release constant.

Higuchi Model: $F = K_H t^{1/2}$,

where F represents the fraction of drug released in time t, and K_H is the Higuchi dissolution constant.

Koresmeyer - Peppas Model: $F = K_p t^n$,

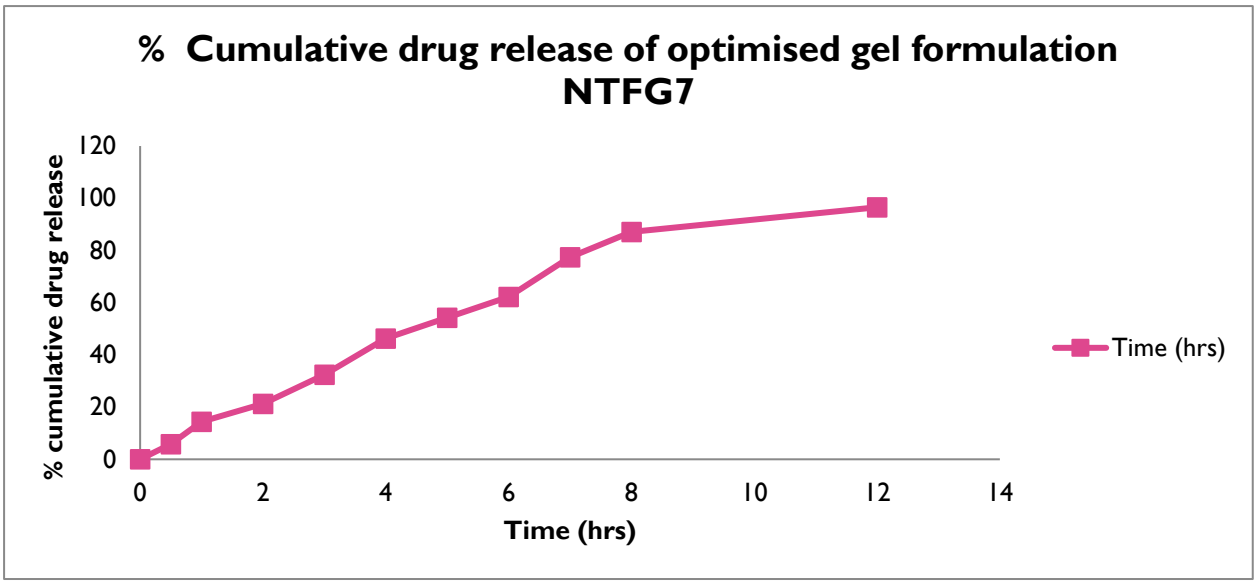
where F represents the fraction of drug released in time t, and K_p is the Koresmeyer–Peppas release rate constant, and n is the diffusion exponent.

Result

Table 7 represents the % cumulative drug release of the transfersomal gel loaded with the drug

S.N.	Time (hrs.)	% Cumulative drug release **NTFG7**
1	**0**	0
2	0.5	5.78±0.11
3	1	14.36±0.23
4	2	21.22±0.41
5	3	32.47±0.44
6	4	46.34±0.26
7	5	54.28±0.32
8	6	62.24±0.47
9	7	77.47±0.33
10	8	87.15±0.45

11	12	96.54±0.54



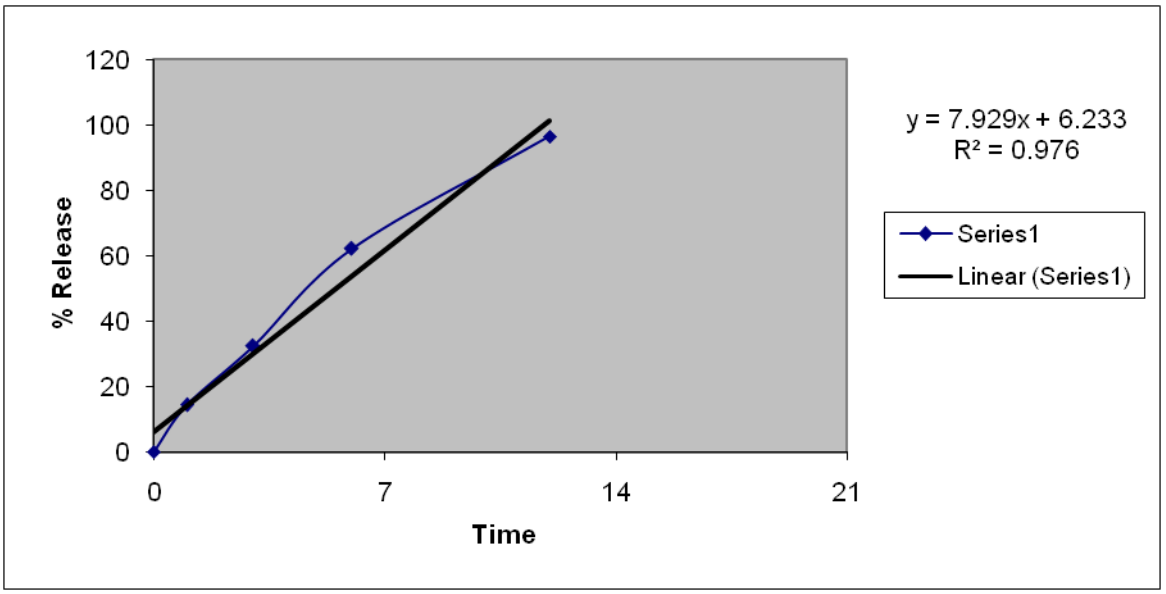
Graph 1 % cumulative drug release of NTFG7

- **Kinetic release model for the optimized formulation** NTFG7

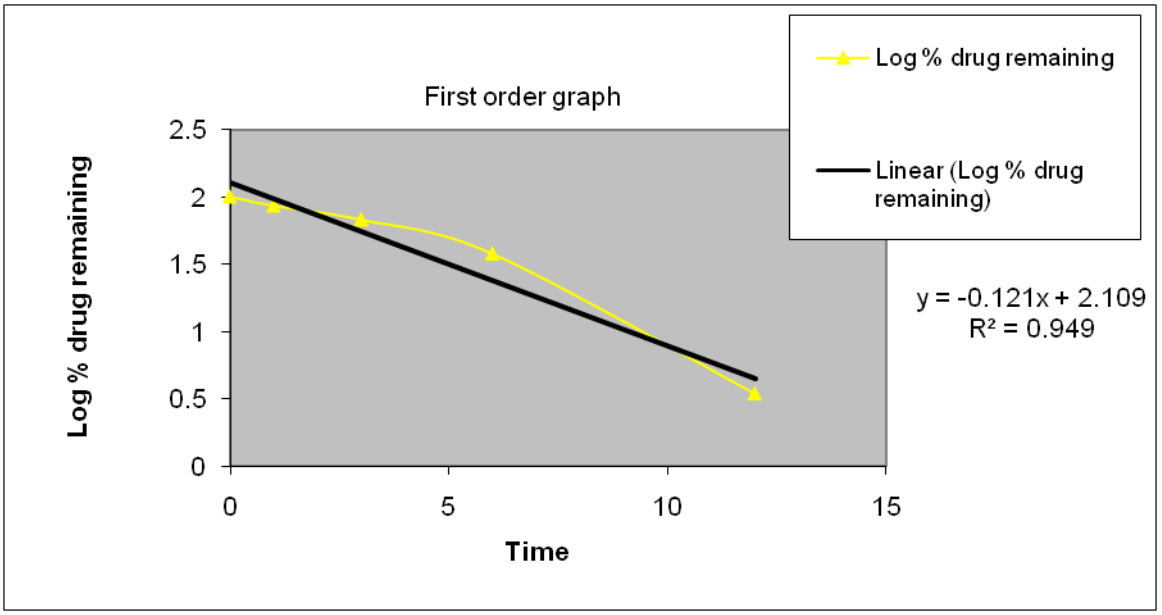
Table 8 represents the % cumulative drug release of the transfersomal gel loaded with NTFG7.

S.N.	Time (hrs)	NTFG7	% drug remaining	Log % drug remaining	Square root of time	log T	Log % Rel	CDR% % drug remaining
1	**0**	0	100	2	0	0	0	4.641589
2	0.5	5.78±0.11	94.22	1.974143	0.707107	-0.30103	0.761928	4.55038
3	1	14.36±0.23	85.64	1.932677	1	0	1.157154	4.407837
4	2	21.22±0.41	78.78	1.896416	1.414214	0.30103	1.326745	4.286854
5	3	32.47±0.44	67.53	1.829497	1.732051	0.477121	1.511482	4.07223
6	4	46.34±0.26	53.66	1.729651	2	0.60206	1.665956	3.771814
7	5	54.28±0.32	45.72	1.660106	2.236068	0.69897	1.73464	3.575763
8	6	62.24±0.47	37.76	1.577032	2.44949	0.778151	1.79407	3.354883
9	7	77.47±0.33	22.53	1.352761	2.645751	0.845098	1.889134	2.824362

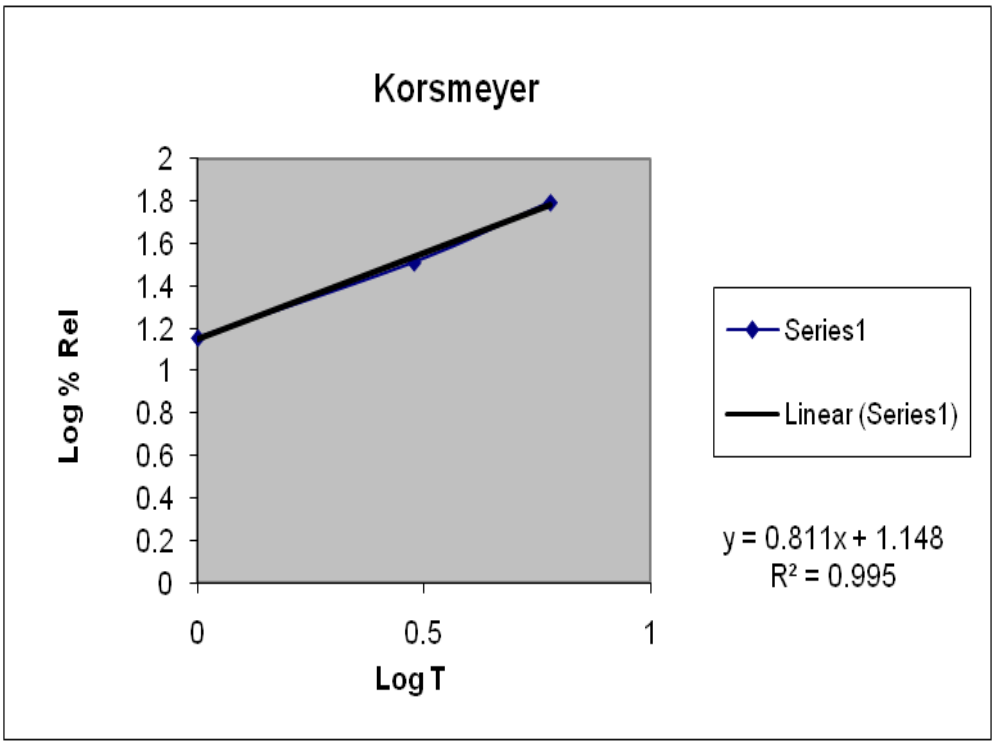
10	8	87.15±0.45	12.85	1.108903	2.828427	0.90309	1.940267	2.342256
11	12	96.54±0.54	3.46	0.539076	3.464102	1.079181	1.984707	1.512488



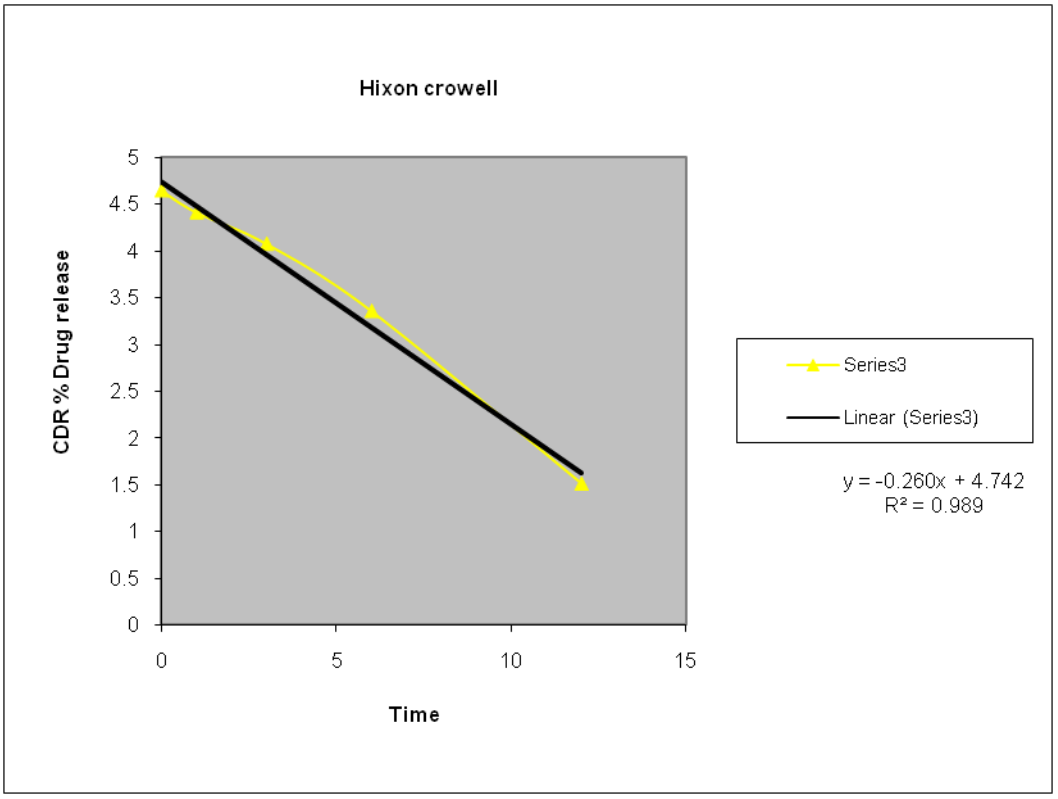
Graph 2: zero-order kinetic release model for NTFG7



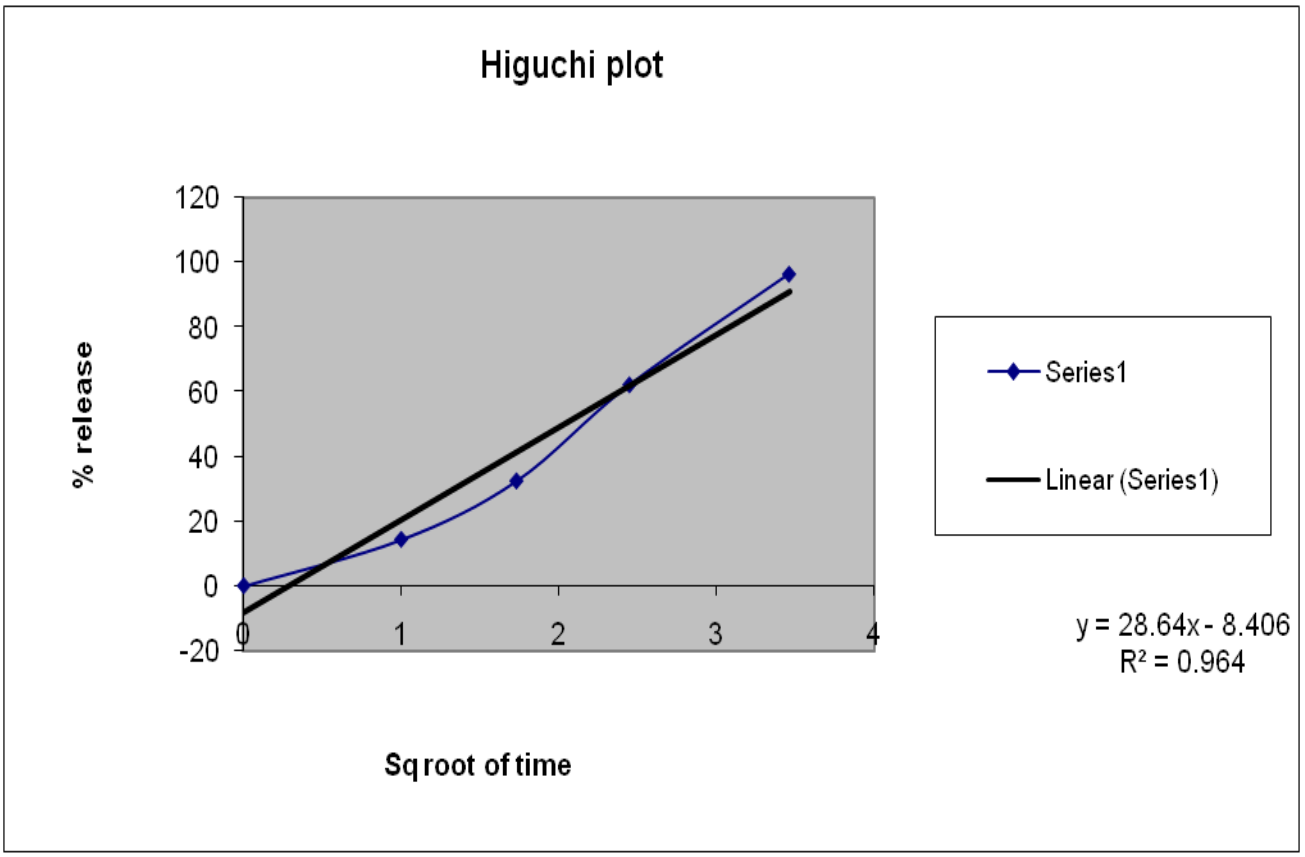
Graph 3: First-order kinetic release model for NTFG7



Graph 4: Korsmeyer kinetic release model for NTFG7



Graph 5: Hixon Crowell kinetic release model for NTFG7



Graph 6: Higuchi kinetic release model for NTFG7

Table 9 represents the kinetic release model regression values of the Transfersomal gel NTFG7

S.N.	Formulation code	Zero Order Release (R^2)	First-order kinetic release (R^2)	Higuchi kinetic release (R^2)	Korsmeyer kinetic release (R^2)	Hixon Crowell Kinetic release (R^2)
1	**NTFG7**	0.976	0.949	0.964	0.995	0.989

The release profiles from the formulation NTFG7 were illustrated in the above tables and graphs of the cumulative release. It was found that the cumulative % drug release from was greater.

Different kinetic models were applied to the results of the in vitro release studies and were used to calculate the regression coefficients (R2), as shown in the above table. The drug released from all investigated NTFG7 formulations followed a Korsmeyer kinetic release with a correlation coefficient greater than zero and first-order kinetics. The Korsmeyer–Peppas release exponent data showed a non-Fickian anomalous release with a regression R^2 of 0.999 for the NTFG7 optimized formulation.

Stability

The prepared gel formulation NTFG7 was stored in opaque bottles with a cap covered with a plastic sheet. The stored bottles were kept at three different temperatures (4°C±1°C, 25°C±1°C, and 40°C±1°C), 75% relative humidity (RH) ±5% for a period of up to 3 months. Drug content in the stored gel formulations was determined periodically. Any change in the appearance of the stored gel formulations was recorded.

Table 10: The stability study of the prepared transfersomal gel during storage at 4°C, 25°C, and 37°C over 3 months

Parameter	Formula number	4°C	25°C	37°C
Texture	**NTFG7**	smooth	smooth	**smooth**
Appearance		No change	No change	**No change**
pH		7.7	7.6	**7.69**
Viscosity		**13568±0.012**	**13547±0.052**	**13577±0.021**

3. CONCLUSION

The present study successfully formulated and optimized a transfersomal gel (NTFG7) intended for enhanced transdermal drug delivery. The formulation containing 0.25% Carbopol 934, 0.5% propylene glycol, and other excipients demonstrated desirable physicochemical properties, including smooth texture, homogeneity, and a suitable pH of 7.7 ± 0.05 for dermal application. The gel exhibited good viscosity and swelling index, which are essential for stability and skin adherence.

In vitro drug release studies showed sustained and controlled drug release over 12 hours, with a cumulative release of 96.54%. Kinetic modeling indicated that the drug release followed Korsmeyer–Peppas kinetics ($R^2 = 0.995$), suggesting a non-Fickian, anomalous diffusion mechanism. Stability studies conducted under different storage conditions for three months confirmed that the formulation retained its physical integrity and chemical stability.

Overall, the optimized transfersomal gel (NTFG7) presents a promising and effective transdermal delivery system that can enhance drug permeability, sustain release, and improve therapeutic efficacy. This platform may be further explored for delivering various other therapeutic agents via the dermal route

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