International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 30, Issue 12, December 2024 **ijppr.humanjournals.com** ISSN: 2349-7203

Formulation and Evaluation of Fexofenadine Hydrochloride Loaded Niosomal Gel

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Received: 2024-12-07 Revised: 2024-12-18 Accepted: 2024-12-24

ABSTRACT

Introduction: fexofenadine HCl is recommended as first line treatment for the treatment of urticaria. It significantly relieves hives and the itching provoked by hives. Aims: The present study aims to formulate, & evaluate fexofenadine HCl -loaded niosomal gel.Methodology: The ether injection approach was used to prepare niosomes. Particle size, EE, SEM, ZP, PDI, drug content, and in vitro diffusion experiments were all evaluated after five formulations were made. The optimized formulation F1 Consisted of fexofenadine HCl, span 60 and cholesterol in the ratio 1:1.5:1. A gel was prepared using the optimized formulation F1. Four gel formulations were made, and their drug content, pH, homogenicity, viscosity, spreadability, and in vitro diffusion tests were evaluated. 0.3% Optimized Niosomes and 1% Carbopol 934 made up the optimized niosomal gel 1% F1. The drug release kinectics were applied to the tailored gel. The stability tests were conducted at 60% relative humidity and 24°C ± 2°C. Results: The optimized niosomes demonstrated a zeta potential of -21.1 mV, a particle size of 147.6 nm, an entrapment efficiency of 65 % a drug content of 89 %, and a drug release of 96.24% after 8 hours. Optimized Niosomes and 0.1 % Carbopol 934 made up the optimized niosomal gel (1% F1). In a 24-hour period, the gel's pH was 6.1, its viscosity was 63144 cps, its spreadability was 0.534 g cm/sec, and its drug content was 89%. With an R2 value of 0.9949, the drug release kinetics experiments demonstrated that the optimized gel formulation (1% F1) adhered to the Higuchi model. The optimized niosomal gel was stable for 90 days, according to the stability studies.Conclusion: For ninety days, the stability tests validated the gel's physical characteristics and drug content. The formulation can be delivered by transdermal route, the formulation can therefore be considered stable and effective. fexofenadine HCl gel formulations may improve bioavailability of the drug.

Keywords: Niosomal gel, fexofenadine HCl, Niosomes, bioavailabilty, BCS class II

1. INTRODUCTION

The inflammatory skin disorder urticarial is primarily caused by activation of cutaneous mast cells. The released inflammatory mediators and histamine are responsible for the development of wheals and/or angioedema. Current guidelines recommend non-sedating second generation H_1 antihistamines such as fexofenadine hydrochloride as first-line therapy., Urticaria is a condition characterized by the appearance of wheals and/or angioedema. A wheal is a sharply circumscribed, superficial swelling accompanied by itching or burning. It may occur abruptly and returns to normal within 30 minutes to 24 hours. Angioedema develops more slowly than wheal and presents with localized edema in the lower dermis and subcutis or mucous membranes. Angioedema is characterized by tingling, burning, and tightness rather than itching. Recovery takes longer than for wheals, up to 72 hours[1].

In urticaria, dysregulation of mast cells and basophiles releases inflammatory mediators. These inflammatory mediators, such as histamine, TNF-α, and interleukins, stimulate signaling pathways that lead to the symptoms of urticaria. In most patients urticaria cannot be avoided. The guidelines strongly recommend treatment with oral second-generation H_1 antihistamines as first line . This group of agents is effective and well tolerated. Second-generation antihistamines do not cross or only minimally cross the blood-brain barrier and therefore only slightly or non-sedating as well as free of anticholinergic adverse side effects.[2]

Fexofenadine hydrochloride is a non-sedating antihistamine with selective peripheral H_1-receptor antagonist activity adopted for the symptomatic relief of allergic conditions including seasonal allergic rhinitis and chronic idiopathic urticaria.[3] The slight solubility of drug in water, its low passive permeability as well as the intestinal secretion promoted by P-glycoprotein efflux could account for the incomplete drug absorption (35%) following oral administration.[4]

Vesicular drug delivery systems increase drug distribution by encapsulating the drug into vesicle, which are tiny, spherical consist of lipid bilayer and/or other components. Vesicular drug delivery systems have many and significant advantages over conventional

method making them useful in pharmaceutical science[5]. many carriers such as like niosomes, transferosomes, ethosomes and transethosomes might improve drug delivery.

Niosomal carriers are suitable for the delivery of numerous pharmacological and diagnostic agents, including antioxidants, anticancer, anti-inflammatory, antiasthma, antimicrobial, anti-Alzheimer's, and antibacterial molecules, oligonucleotides, and others[6]. Depending on the type of drug, surfactant, disease, and anatomical site involved, various routes of administration exist for niosomal drugs, ie, intravenous, intramuscular, oral, ocular, subcutaneous, pulmonary, and transdermal[7]. Niosomes have been demonstrated to be promising controlled delivery systems for percutaneous administration of both hydrophilic and lipophilic drugs. The potential of niosomes can be enhanced by using novel preparation, loading, and modification methods.[8]

The purpose of the study was to introduce the drug into vesicular system and examine stability, drug-excipient interaction Entrapment, efficiency, and drug release.

2. Material and Methods / Experimental Details / Methodology

2.1 Materials

Fexofenadine HCl was obtained from Dr. Reddy's Laboratories Ltd., Hyderabad. Span 60, Span 40, Cholesterol, Carbopol, Methyl paraben were purchased from SD fine-CHEM limited, Mumbai. Methanol, Potassium dihydrogen orthophosphate, Sodium hydroxide, Distilled water, Diethyl ether, Triethanolamine were procured from Thermo Fisher Scientific Pvt Ltd, Mumbai.

2.2 Methods

2.2.1 Calibration curve of fexofenadine by UV-Spectroscopy:

A Preparation of standard stock Solution: Standard stock solution was prepared by dissolving drug equivalent to 10 mg of drug in 0.1M NaOH into 100 ml volumetric flask and then volume was adjusted to 100 ml with 0.1M NaOH. The resultant solution was scanned in a range of 200-400 nm on UV-Visible spectrophotometer and absorption maximum (λmax) was determined.[9]

The stock solution was suitably diluted with 0.1M NaOH to get concentration range from 5 to 30µg/ml. The solutions were scanned in UV regions between 400 to 200 nm then absorption was measured at maximum λmax. Calibration curve was plotted by using absorbance and concentrations.[9]

2.2.2 FT-IR spectroscopy for Drug-excipient Compatibility Studies

FTIR spectroscopy can be used to investigate and predict any physicochemical interactions between different components in a formulation and therefore it can be applied to the selection of suitable chemically compatible excipients. The aim of the present study is to test whether there are any interactions between the drug and excipient. Approximately 0.1 to 1.0 % sample is well mixed with KBr powder and then finely pulverised and put into a pellet-forming die. A force of approximately 8 tons is applied under a vacuum of several mm Hg for several minutes form transparent pellets. The FTIR spectra of samples were recorded over a range of 4,000-400 cm^{-1}.

2.2.3 Formulation of Fexofenadine loaded Niosomes:

Drug-loaded niosomes were prepared by ether injection method, The weighed amount of cholesterol, span 40, span 60, and the drug were dissolved in diethyl ether. The resulting solution was slowly injected into the aqueous solution of surfactant mix using a microsyringe at a specific rate as per the design. The solution was stirred (500 rpm) continuously using a magnetic stirrer at 60-65° which resulted in the evaporation of the organic solvent, and the formation of niosomal dispersion.The dispersion was sonicated for 1 to 2 min.[10]

Table 1: Formulation table of Fexofenadine loaded Niosomes

Formulation	Drug (mg)	Span 60 (mg)	Span 40 (mg)	Cholesterol (mg)	Drug/Surfactant/cholesterol ratio
F1	100	150	-	100	1:1.5:1
F2	100		150	100	1:1.5:1
F3	100	150	-	100	1:1.5:1
F4	100	-	150	100	1:1.5:1
F5	100	150	150	100	1:1.5:1

2.2.4 Characterization and Evaluation of fexofenadine HCl Loaded Niosomes:

2.2.4.1 Particle size, PDI and Zeta Potential:

Nano particle Analyzer (HORIBA SCIENTIFIC) was used to determine the average particle size, poly dispersity index (PDI) and Zeta potential [11,12,13..]

2.2.4.2 Drug entrapment Efficiently:

A volume of niosome formulation was centrifuged at 12000 rpm for 30 min). The free (un-encapsulated) drug was measured in the filtrate by a UV spectrophotometer at 222 nm[11,12]. The EE % was calculated from the following equation:

%Drug entrapment = (Total drug - Drug in supernatant / Total drug) x 100

2.2.4.3 Drug Content:

To determine of drug present in the niosomes, Niosomal suspension equivalent to 10mg taken in a volumetric flask of 100ml & volume was made up by phosphate buffer pH 7.4, after that 1ml of this mixture was diluted to 10ml by phosphate buffer 7.4 & the % drug content was calculated or observed at using UV spectrophotometer.

[12,13,14.]

2.2.4.4 In Vitro diffusion Studies:

It can be determined by the Franz-diffusion cell. A membrane was used to separate 10 ml of formulation from the receptor compartment which is filled with phosphate buffer pH 7.4. the medium was stirred at room temp at 100 rpmusing magnetic stirrer. At regular intervals, the sample is withdrawn periodically to calculate the drug content. Samples were withdrawn and fresh buffer solution was added regular time intervals. The obtained samples, after dilution, were subjected to spectrophotometrically at 224 nm[11,15..]

2.2.5 Formulation of niosomal gel of fexofenadine HCl :

The Carbopol 934 was used as a gelling agent for the niosomal gel. The polymer was dispersed using Distilled water. The mixture then continued to be stirred until it thickened. Following full dispersion, triethanolamine and methyl paraben were added. The polymer gel was combined with the required quantity of the optimised niosomal dispersion while being constantly stirred. A sufficient amount of distilled water was added to get the required quantity of gel. [16]

Table 2: Formulation table for fexofenadine HCl in Niosomal Gel

Ingredients	0.5 % F1	1% F1	1.5% F	2% F1
F1 optimized niosomes suspension	100 ml	100 ml	100 ml	100 ml
Carbopol 934	0.5 %	1%	1.5%	2 %
Methyl Paraben	0.15%	0.15%	0.15%	0.15%
Triethanolamine	q.s	q.s	q.s	q.s
Distilled Water	Up to 100ml	Up to 100ml	Up to 100ml	Up to 100ml

2.2.6 Characterization and Evaluation of fexofenadine HCl Loaded Niosomal Gel

2.2.6.1 Physical Appearance:

The visual characteristics of every prepared gel formulation, including transparency, color, texture, stickiness, greasiness, smoothness, stiffness was determined[17,18.]

2.2.6.2 Homogeneity:

By visual inspection, the homogeneity of the Fexofenadine Niosomal gel was verified. The gels were filled into glass tubes and exposed to light to check for the presence of any lumps or particles.[17,18.]

2.2.6.3 Viscosity study of Gels:

Niosomal gel is stored at different temperatures, and is evaluated for rheological parameters, i.e., shear stress, shear rate, and viscosity. The study is conducted by Brookfield viscometer.[17,18]

2.2.6.4 pH measurement:

The pH of the niosomal gel was determined using a digital pH metre. Before measurement, pH metre should be calibrated

and readings should be taken by dipping the glass electrode into niosomal gel taken in a beaker.[18]

2.2.6.5 Spreadability:

Good amount of sample was placed in between two glass slides and was squeezed to a consistent thickness by keeping one kg weight over it for 5 min[17].

Spreadability = (Weight applied to the upper slide / Length moved on the glass) / Time

2.2.6.6 Drug content:

1 gm of the gel was combined with 100 ml of methanol. The stock solution was filtered and aliquots of different concentrations were made with suitable dilutions and the absorbance at 224 nm.[17,18.]

2.2.6.7 In vitro diffusion studies:

The permeation study is conducted in phosphate buffer saline (PBS) of pH 7.4, which is maintained at 37 ± 0.2°C in a Franz diffusion cell (FDC). The diffusion medium is maintained at a stirring speed of 100 ± 4 rpm. Membrane is fixed in the base of the donor compartment of FDC, which acts as the diffusion barrier between the donor and receptor compartments. Formulation (10 ml) is kept in the donor compartment over the membrane, and the diffusion study is carried out for 8 h. The sample (1 ml) is withdrawn at predetermined time intervals and the withdrawn volume is replaced with a fresh buffer. Withdrawn samples were filtered through a 0.20-µm membrane filter and analysed by a UV spectrophotometer. [17,18.]

2.2.6.8 Drug Release kinetics studies:

Various release models like zero order, first order, Higuchi-equation, and Peppas-Korsemeyer were fitted to Niosomal gel formulation to ensure the drug release mechanism.

2.2.7 Stability studies:

This study of the Niosomal gels was performed as per ICH guidelines. Freshly prepared formulations were categorised into groups and stored at specific storage conditions. The sample was withdrawn periodically and evaluated.[18]

3. Results and Discussion

3.1.1 Calibration Curve Results:

The calibration curve of the fexofenadine HCl was developed by dissolving in 0.1 NaOH for stock solution and made dilutions. The standard graph demonstrated strong linearity, with $R^2 = 0.9913$, signifying its adherence to the "Beer-Lambert" law.

3.1.2 Drug and Excipient Compatibility Studies:

The functional groups in FT-IR spectrum of pure drug and excipient were almost similar and show no significant interactions and thus proves its compatibility.

3.1.3 Characterization and Evaluation Results of fexofenadine HCl Niosomes

The Prepared Niosomes were characterized for various physicochemical properties.

Table 3 gives the results.

Table 3: Characterization and Evaluation Results of all fexofenadine HCl Niosomal formulations

Formulation	Particle size (nm)	PDI	Zeta Potential (mV)	Entrapment efficiency (%)	Drug Content (%)
F1	147.6 ± 3.03	0.227	-21.1	65 ± 0.31	89.6 ± 1.20
F2	245.8 ± 5.36	0.312	-18.8	61 ± 0.52	81.3 ± 3.68
F3	180.2 ± 8.73	0.296	-19.1	58 ± 0.89	84.7 ± 2.41
F4	261.5 ± 6.45	0.325	-19.4	63 ± 1.12	82.6 ± 2.64
F5	324.5 ± 8.94	0.394	-18.6	59 ± 0.98	86.4 ± 1.81

3.1.3.1 In vitro diffusion studies:

Table 4: In vitro diffusion studies results of F1-F5 Niosomal formulations

Time (Hour)	F1 (% released)	F2 (% Released)	F3 (% Released)	F4 (% Released)	F5 (% Released)
0	0	0	0	0	0
1	36.08 ± 1.06	28.94 ± 0.47	33.43 ± 1.57	30.15 ± 3.68	34.41 ± 1.53
2	49.57 ± 0.87	34.24 ± 1.84	43.96 ± 3.14	41.64 ± 1.97	42.67 ± 2.18
3	58.46 ± 2.38	46.68 ± 3.21	52.03 ± 1.48	51.19 ± 0.84	54.83 ± 2.86
4	67.04 ± 1.24	57.37 ± 1.87	60.24 ± 3.27	59.87 ± 1.39	60.47 ± 0.48
5	74.63 ± 1.87	65.41 ± 3.49	70.16 ± 0.74	67.24 ± 2.59	69.58 ± 1.89
6	81.12 ± 0.46	73.05 ± 1.78	77.31 ± 2.47	75.23 ± 1.63	78.83 ± 2.31
7	90.32 ± 0.94	80.14 ± 2.45	84.73 ± 0.87	83.67 ± 2.51	86.24 ± 0.58
8	96.24 ± 0.14	88.46 ± 1.31	92.13 ± 1.11	91.47 ± 0.69	93.61 ± 1.61

*Average of three values

± Standard deviation

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 30, Issue 12, December 2024 ijppr.humanjournals.com ISSN: 2349-7203

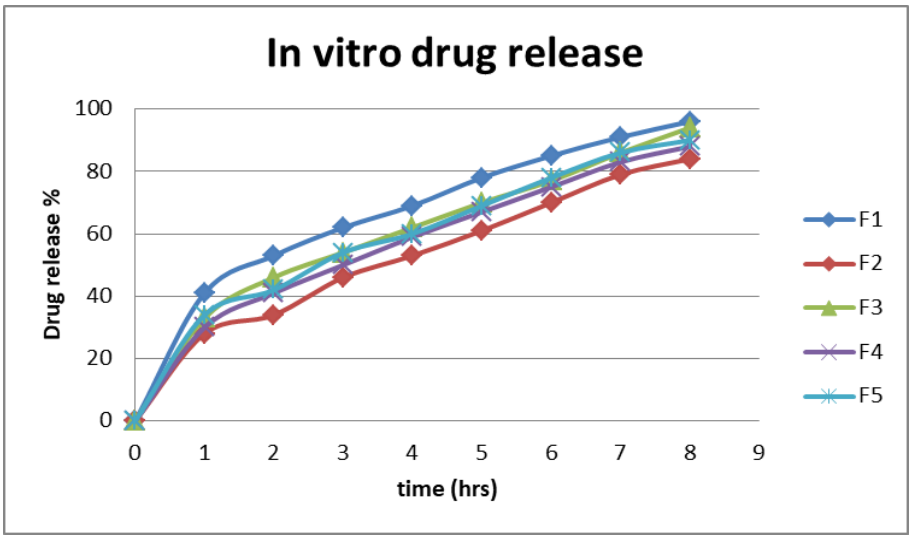

Fig.1 – In vitro diffusion studies of all niosomal formulations

The F1 formulation showed appropriate particle size for transdermal delivery of 147.6 ± 3.03, EE % of 65 ± 0.31 and high ZP of -21.1 along with high in vitro drug release of 96.24 ± 0.14. Thus the F1 formulation was taken as optimised formulation.

3.1.3.2 Particle size and Zeta potential:

The optimized Niosomal formulation F3 was subjected to SEM analysis for describing the niosomes dimensions and form. Microscopic assessment showed, spherical Uni-lamellar vesicles size.

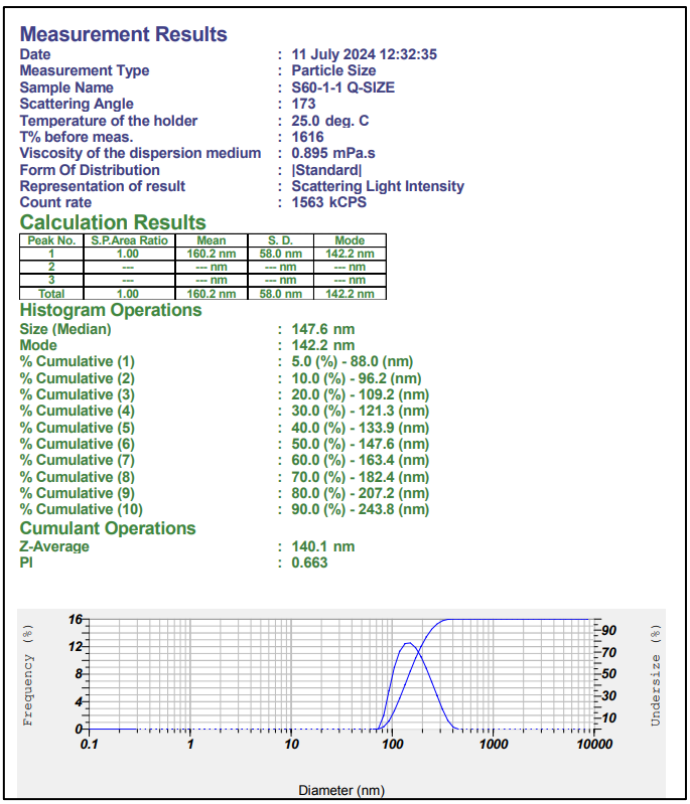

Fig. 2 – Particle size F1 Formulation

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 30, Issue 12, December 2024 ijppr.humanjournals.com ISSN: 2349-7203

Measurement Results

Date	: 11 July 2024 17:02:23
Measurement Type	: Zeta Potential
Sample Name	: S40 2-1 Q-ZETA
Temperature of the holder	: 25.0 deg. C
Viscosity of the dispersion medium	: 0.894 mPa.s
Conductivity	: 0.425 mS/cm
Electrode Voltage	: 3.3 V

Calculation Results

Peak No.	Zeta Potential	Electrophoretic Mobility
1	-2.2 mV	-0.000017 cm2/Vs
2	-41.8 mV	-0.000324 cm2/Vs
3	--- mV	--- cm2/Vs

Zeta Potential (Mean)	: -22.7 mV
Electrophoretic Mobility mean	: -0.000176 cm^2/Vs

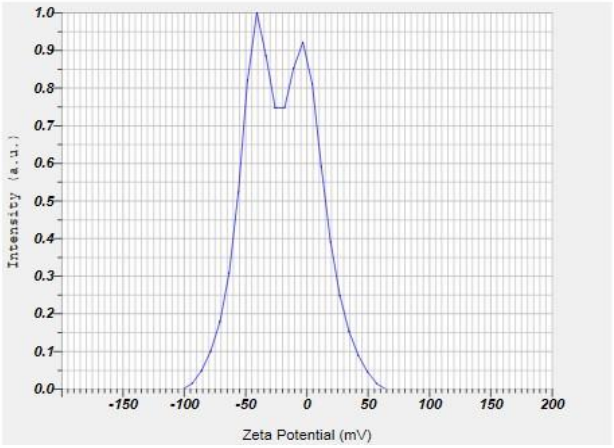

Fig. 3 – Zeta potential value of F3 Formulation

3.1.4 Characterization and Evaluation Results of The Niosomal Gels

Table 5: Evaluation Parameters of Gels

Formulation	pH	Viscosity	Spreadability (g.cm/sec)	homogeneity	Drug content
F1 optimised 0.5%	5.1	61871	0.421 ± 0.28	Satisfactory	86%
F1 optimised 1%	6.2	63144	0.534 ± 0.17	Satisfactory	89%
F1 optimised 1.5%	7.4	66842	0.487 ± 0.42	Satisfactory	83%
F1 optimised 2%	6.8	68043	0.426 ± 0.39	Satisfactory	79%

3.1.4.1 In vitro release Study:

Table 6: In vitro release studies of niosomal gels

Time (hr)	0.5 % F1	1% F1	1.5 % F1	2 % F1
1	27.64 ± 0.47	31.58 ± 0.96	34.85 ± 1.37	31.95 ± 2.68
2	35.44 ± 1.34	42.97 ± 1.07	46.06 ± 1.84	44.44 ± 1.77
3	44.61 ± 2.29	52.36 ± 2.78	53.31 ± 1.87	51.89 ± 1.87
4	53.37 ± 1.77	60.74 ± 1.64	61.24 ± 0.27	60.67 ± 1.93
5	66.41 ± 3.49	68.68 ± 1.07	69.97 ± 2.24	68.64 ± 0.59
6	73.05 ± 2.69	76.22 ± 0.66	74.12 ± 1.47	75.38 ± 1.73
7	80.44 ± 2.05	86.32 ± 0.84	83.03 ± 1.27	82.67 ± 1.81

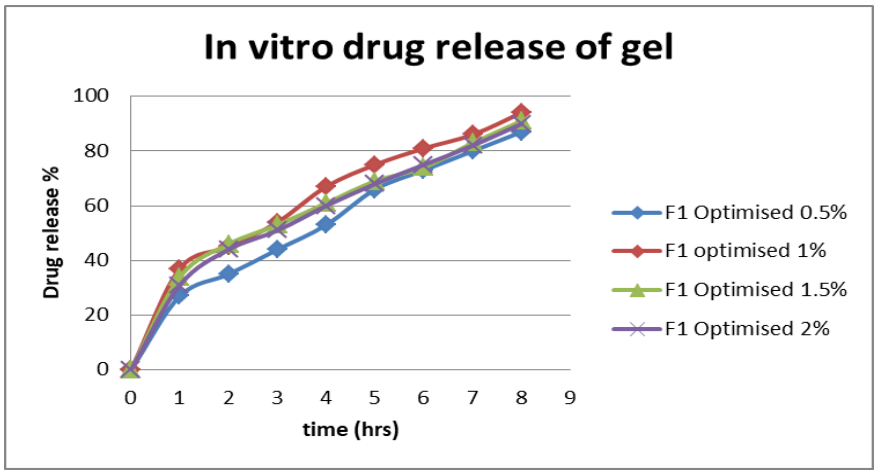

Fig. 4 – In vitro release of different conc. niosomal gels

1% F1 shows maximum release (94.24 over 8 hrs) good viscosity, highest drug concentration and spreadability. So it is considered the best formulation.

3.1.4.2 Drug Release Kinetic Studies:

Table 7: Regression (R^2) values of various pharmacokinetic profiles of the optimized gel formulation (1% F1)

Zero order	First order	Korsmeyer-Peppas	Higuchi
0.7643	0.9573	0.9896	0.9949

The F1 optimised 1 % preparation niosomal gel was subjected to the drug release kinetics and release mechanism. The best correlation value indicates that the preparation best release mechanism is Higuchi (0.9949).

3.1.5 Stability Studies

Table 8: Stability studies of the optimized gel (1% F1)

Formulation	1% F1			
Storage Condition	24 °C ± 2 °C / 60% RH ± 5 % RH			
Time Intervals (Days)	0	30	60	90
pH	5.1	5.3	5.5	5.8
Viscosity (cP)	63144	62851	61990	60654
Spreadability	0.534 ± 0.17	0.521± 0.07	0.520 ± 0.12	0.519 ± 0.19
Drug Content Uniformity (%)	94.24	94.12	93.86	93.34

The sample did not show much difference and retained all properties in storage condition as per ICH guideline, suggesting that formulation is stable.

4. Conclusion

Preparing, characterizing, and assessing a niosomal gel loaded with fexofenadine hcl was the aim of the current investigation. pre-formulation investigations indicated that fexofenadine hcl was soluble in methanol & 0.1 naoh. additionally, ftir analysis revealed no interactions between the drug and excipients. from the five niosome formulations, the f1 formulation, which contained the drug, span 60, and cholesterol in a ratio of 1:1.5:1, was the most effective.f1 is taken as an optimised formulation as it shows desirable particle size of 147.6 nm, zeta potential of 21.1 with EE of 65% and drug content of 89.6. the optimized F1 formulation were prepared into four different formulation where 1% F1 shows pH of 6.2 viscosity of 63144 cps, spreadability 0.534 ± 0.17 g.cm/sec. with 89% drug content and 94.24 % drug release. the best correlation value indicates that the preparation follows to higuchi model,

not show much difference is observed in throughout 90 days stability studies for intended use of transdermal delivery the formulation can be considered safe & effective. Thus fexofenadine HCl niosomal gel may improve bioavailability.

Acknowledgements

We are grateful to Dr. Reddy's Laboratories for generously providing the drug sample used in this study.

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How to cite this article:
Mohammed Arshaduddin et al. Ijppr.Human, 2024; Vol. 30 (12): 218-226.

Conflict of Interest Statement: All authors have nothing else to disclose.