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Research Article

Formulation and In-Vitro Evaluation of Gabapentin Loaded Transferosomal Gel

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Abstract

Gabapentin is an anticonvulsant which is primarily used to treat peripheral neuropathy. It belongs to class III drugs having High solubility and low permeability. The present study is carried out on formulation and invitro evaluation of Gabapentin Transferosomal gel by using various surfactants, polymers. The Transferosomes were prepared by thin film hydration technique. Different proportions of surfactants have been utilized such as span 80 and tween 80. 8 distinctive formulations of Gabapentin transferosomes had been formulated and evaluated for parameters like FTIR, Organoleptic evaluation, Drug content, Entrapment efficiency, Invitro diffusion studies, SEM, Zeta potential and particle size analysis, pH, Spreadability, Viscosity, Stability testing and Kinetic studies. The optimized formulation Gf6 confirmed Entrapment efficiency of 86.54%, Drug content 96.11% Zeta potential of -31.64Mv, particle size of 164.2nm, In-vitro drug release ranging from (75.15-89.37%). The drug release data of selected formulation confirmed desirable fit into Zero order and Peppas release Kinetics. Overall, it can be concluded that the transferosomal gel can overcome problems associated with convectional routes of drug delivery.

Keywords: Gabapentin, Transferosomes, Edge activators, Thin film hydration method.

1.INTRODUCTION:

Transdermal delivery systems have gained much interest in recent years owing to their advantages compared to conventional oral and parenteral delivery systems. They are noninvasive and self-administered delivery systems that can improve patient compliance and provide a controlled release of therapeutic agents. The greatest challenge of transdermal delivery systems is the barrier function of the skin's outermost layer. Molecules with molecular weights greater than 500Da and ionized compounds generally do not pass through the skin. Therefore, only a limited number of drugs are capable of being administered by this route. Encapsulating the drugs in transferosomes is one of the potential approaches to overcome this problem. In addition, this development could represent a competitive advantage over other drug administration methods in terms of the delivered dose, cost-effectiveness, and therapeutic efficacy.[1,2] Transferosome is a term registered as a trademark by the German company IDEA AG, and used by it to refer to its proprietary drug delivery technology. The name means "carrying body", and is derived from the Latin word 'transferre', meaning 'to carry across', and the Greek word 'soma', for a 'body'. A Transferosome carrier is an artificial vesicle and resembles the natural cell vesicle. Thus, it is suitable for targeted and controlled drug delivery. Transfersomes overcome the skin penetration difficulty by squeezing themselves along the intracellular sealing lipid of the stratum corneum. Flexibility of transfersomes membrane is achieved by mixing suitable surface-active components in the proper ratios. TFs act as penetration enhancers that disrupt the intercellular lipids from stratum corneum, which ultimately enlarges the pores of the skin and facilitate the molecular interaction and penetration of drugs across the skin.[3]

The transferosomes suspension is added into polymers like Carbopols and Xanthun gum to obtain transferosomal gel. The rigidity of the gel is determined by the amount of fluid it entraps. These gels are wet and soft and look like a solid material.[4]

Neuropathic pain is pain caused by damage or disease affecting the somatosensory system.[5,6] Neuropathic pain may be associated with abnormal sensations called dysesthesia or pain from normally non-painful stimuli (allodynia). Common qualities include burning or coldness, "pins and needles" sensations, numbness and itching.[6] Gabapentin and pregabalin may reduce pain associated with diabetic neuropathy.[7,9] Gabapentin may reduce symptoms associated with neuropathic pain or fibromyalgia in some people[8]. A short trial period of gabapentin therapy is recommended, to determine the effectiveness for person. The present study aims to Formulate and Evaluate the Gabapentin loaded Transferosomal gel to treat neuropathic pain.

2.MATERIALS AND METHODS

2.1 Procurement of Drug and Excipients:

Gabapentin (Provided by Saraca Laboratories Pvt.Ltd, Hyd, Telengana), Soya lecithin, Span 80, Tween 80 (Himedia Labs Ltd), Carbopol 934, Xanthan gum, Chloroform, Methanol (S.D fine chem, Ltd), Distilled water.

2.2 Preformulation studies:

Organoleptic properties:

The color, odour and taste of the drug are evaluated using descriptive terminology.

Solubility:

Solubility test is carried by taking excess amount of Gabapentin in conical flask containing Distilled water, Phosphate buffer 6.8, Ethanol, Methanol of each solvent. Then solution is kept for shaking in an orbital shaker at room temperature. Samples are collected after 12hrs, 24hrs, 36hrs, 48hrs, 72hrs until constant values were obtained. The samples were filtered through whattman filter paper and diluted appropriately with same solvent and concentrations were determined by UV-VIS spectroscopy.

Melting point determination:

Determination of melting point of drug was done by capillary method using melting point apparatus.

Drug-Excipient compatibility studies.

Fourier-transform infrared spectroscopy was used to study the drug-excipient compatibility studies. FTIR of the pure drug (Gabapentin) and a mixture of drug with excipients were taken. The samples were analysed between wave numbers 4000 and 400 cm-1 The peaks of the pure drug were compared with the physical mixture of drug and excipients.[10]

Determination of Absorption Maxima:

UV scanning was done for 100µg/ml drug solution from 200-400 nm using pH 6.8 phosphate buffer as a blank in UV 2450 spectrophotometer. Then sample was kept for analysis and scanned in the same region. The wavelength maximum was found to be 265nm.

Calibration curve of Gabapentin:

Preparation of standard solutions:

Stock Solution I: Weight 100mg of Gabapentin API is taken and added to Phosphate buffer 6.8 in a 100ml volumetric flask and volume was made up to 100ml, resulting in a standard stock solution of 1000 mcg/ml.

Stock Solution II: From the above stock solution 1ml was taken and added to Phosphate buffer 6.8 in a 10ml volumetric flask and volume was made up to 10ml to obtain 100mcg/ml solution. From the working stock, dilutions were prepared using Phosphate buffer 6.8.

Preparation of Working standard solutions:

From the stock solution II, aliquots of 0.5ml, 1ml, 1.5ml, 2ml and 2.5ml were pipette into 10ml volumetric flasks. The volume was made up with pH 6.8 Phosphate buffer to get the final concentrations of 5, 10, 15, 20, and 25µg/ml respectively. The absorbance of each concentration was measured at 265 nm. A graph is plotted by taking absorbance (nm) on y-axis and concentration (µg/ml) on x-axis.

Formulation of Gabapentin Transferosomes:

Transferosomes were prepared by thin film hydration method using Gabapentin, Soya Lecithin, and different concentrations of surfactants (Span-80, Tween80). The amount of drug is kept constant (80mg) in all the formulations. Different formulations were prepared by using different ratios of phospholipid and surfactants in different ratios. The details about the surfactants used and amount of lecithin and surfactant used in each formulation are given in the table no.1. Lecithin, surfactants and the drug are dissolved in 30ml of organic solvent (Chloroform: Methanol 1:2). The organic solvent is then removed by evaporation while hand shaking above lipid transition temperature (43°C). Final traces of solvent are removed under vacuum. The deposited lipid film is hydrated with the phosphate buffer (pH 6.8) by rotation at 60rpm for 1hr at room temperature. The resulting vesicles are swollen for 2hrs at room temperature. The multilamellar lipid vesicles (MLV) are then sonicated using sonicator for 30 minutes.

Table 1: Formulation chart of Gabapentin transferosomes:

S.no	Ingredients	Gf1	Gf2	Gf3	Gf4	Gf5	Gf6	Gf7	Gf8
1	Gabapentin (mg)	80	80	80	80	80	80	80	80
2	Soya lecithin	90	85	80	75	90	85	80	75
3	Span 80	15	20	25	30	-	-	-	-
4	Tween 80	-	-	-	-	15	20	25	30
5	Chloroform(ml)	10	10	10	10	10	10	10	10
6	Methanol(ml)	20	20	20	20	20	20	20	20

Preparation of Transferosomal Gel:

Transferosomes aqueous dispersion was utilized for the formulation of topical gel. Polymers such as Xanthan gum, Carbopol 934 were utilized to prepare transferosomal gel. Xanthan gum, Carbopol 934 in quantities of 0.5g, 0.75g and 1.0g were dispersed into transferosomes dispersion and vigorously stirred (stirred by magnetic stirrer Remi 5MLH) in 100 ml distilled water and allowed to hydrate for 24hrs. The dispersion was neutralized with triethanolamine to adjust the pH [6.8] by using pH meter (Lab India Sab 5000).

Table 2: Formulation chart of Transferosmal gels:

Formulation Code	Ingredients				
	Xanthan gum	Carbopol 934	Propylene glycol	Distilled water(ml)	Triethanolamine
Gf6A	0.5g	-	10	100	q.s
Gf6B	0.75g	-	10	100	q.s
Gf6C	1.0g	-	10	100	q.s
Gf6D	-	0.5g	10	100	q.s
Gf6E	-	0.75g	10	100	q.s
Gf6F	-	1.0g	10	100	q.s

Characterization of Transferosomes:

Vesicle morphology:

Scanning electron microscopy (SEM) is used to determine the shape and size of formulated transferosomes.

Particle Size and Zeta Potential:

The particle size and zeta potential were assessed at 25°C using a dynamic light scattering instrument and particle size analysis. The produced sample is diluted with filtered water before being measured using a Malvern zeta sizer.

Polydispersity index:

PDI is a measure of heterogenecity of a sample based on size. polydispersity can occur because of agglomeration of sample. PDI can be obtained by dynamic light scattering microscopy (DLS). PDI of less than 0.1 is considered as homogenous and ≥0.4 heterogenous.[11]

Determination of Entrapment Efficiency (EE %)

5ml of sample transferosomes suspension is ultracentrifuge at 4000 rpm for 45min at 40°C to allow the separation the entrapped drug from the un-entrapped drug. After removal of the supernatant, the sediment is lysed using methanol and then analysed at 265nm using a UV spectrophotometer. The EE% of drug in the prepared transferosomes is calculated applying the following equation:

EE% = [Amount of Entrapped Drug/Total Amount of Drug] /100

Determination of *In-Vitro* diffusion Studies:

A diffusion study of Transferosomes formulations was carried out using Franz diffusion cell through dialysis membrane. Dialysis membrane was soaked in distilled water for 24 hours. Franz diffusion cell contain two compartments upper donor and lower receptor compartment. The receptor compartment was filled with 6.8 pH and donor compartment contain 5ml of transferosome suspension on dialysis membrane with exposure area of 2cm^2 to receptor medium and whole assembly was kept on magnetic stirrer at 600rpm for a period of 10 hours and samples were withdrawn at specified time interval of 1 hr and replaced with equal volume of buffer. Samples were appropriately diluted with buffer and analysed using UV spectrophotometer at 265nm.

Characterization of Transferosomal Gels

Detemination of pH of Gels

The pH of the gels was determined by using digital pH meter.

Spreadability:

A modified apparatus suggested was used for determining spreadability. the spreadability was measured on the basis of slip and drag characteristics of the gels. the modified apparatus was fabricated and consisted of two glass slides, the lower one was fixed to a wooden plate and the upper one was attached by a hook to a balance. The spreadability was determined by using the formula:

$$s=ml/t,$$

where s, is spread ability, m, is weight in the pan tied to upper slide, t, is the time, l, is the distance travelled. for the practical purpose the mass, length was kept constant and 't' was determined.[12,13]

Determination of Viscosity:

Viscosities of the gels were determined by using Brookfield viscometer .Spindle type,S-64 at 100rpm.

Drug content:

1gm of the prepared gel was mixed with 100ml of water. Samples of different concentrations were prepared by suitable dilutions after filtering the stock solution. The absorbance was measured at 265nm.[12,14]

***In-vitro* drug diffusion studies:**

In-vitro drug release study was performed by using Modified Franz diffusion cell on egg membrane in phosphate buffer solution (pH 6.8). Egg membrane was mounted horizontally on the receptor compartment of Franz diffusion cell. The effective permeation area of donor compartment exposed to receptor compartment was 2cm2 and capacity of receptor compartment was 30ml of phosphate buffer (pH 6.8) maintained at 37± 0.5°C and stirred by a magnetic bar at 100rpm. Transferosomal gel formulation equivalent to 5mg drug was placed on the skin and the top of the diffusion cell was covered. At appropriate time intervals 5ml aliquots of the receptor medium were withdrawn and immediately replaced by an equal volume of fresh phosphate buffer (pH 6.8) to maintain sink conditions. The samples were analysed spectrophotometrically at λ max.[13,14]

Stability studies

The stability can be determined by assessing the structure and the size of formulation with respect to time. The optimized formulations can be stored in tightly sealed amber vials at different temperature conditions. The optimized formulation was stored in sealed glass ampoules at refrigeration temperature (4±2°C), room temperature (25±2°C) for a period of at least 3 months. The percentage entrapment of the drug and

% drug content was determined. The percent drug lost was calculated taking the initial entrapment of drug as 100%.

Drug Release Kinetics

The drug release kinetics are estimated to determine the type of release mechanism followed.

4 RESULTS AND DISCUSSIONS

PREFORMULATION RESULTS

A.Organoleptic properties (Colour, Odour, and Appearance)

Table 3: Organoleptic Properties of Gabapentin

S.no	Parameter	Result
1	Colour	White to off-white colour
2	Odour	Odourless
3	Appearance	Crystalline powder

B. Melting point determination:

Table 4: Melting point determination of Gabapentin

Reported melting point	Observed melting point
165-167°C	166°C

Observation: The reference melting point of Gabapentin is in the range of 165-167°C. The observed melting point was found to be 166ºC. This indicates the purity of drug sample.

C.SOLUBILITY RESULTS

Table 5: Solubility of Gabapentin

SOLVENTS	SOLUBILITY PROPERTIES OF GABAPENTIN
Distilled Water	46.32µg/ml
Methanol	14.95µg/ml
Phosphate buffer 6.8	49.17µg/ml
Ethanol	9.82µg/ml

The data presented as mean value ± S.D (n = 3).

Observation: Gabapentin was found to be highly soluble in distilled water and phosphate buffer 6.8. and slightly soluble in methanol and ethanol.

D. UV-Spectroscopy-Analysis of drug

Determination of lambda max of Gabapentin in phosphate buffer 6.8 by UV:

Solution of Gabapentin concentration of 10 ug/ml was scanned in the range of wavelength 200-300 nm. It was observed that the API showed considerable absorbance at wavelength of 265nm. The absorption spectrum was found to be sharp and maximum at wavelength of 265nm, therefore, it was selected as the wavelength for detection in phosphate buffer 6.8

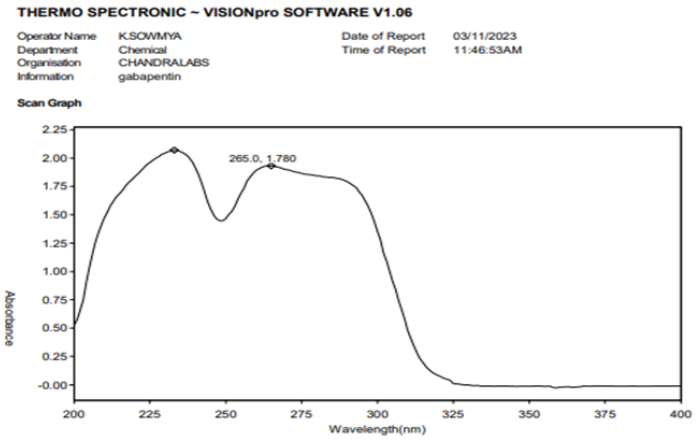

Figure 1: λ Max of Gabapentin

E. Calibration Curve:

R^2 Value was found to be 0.998.

Table 6: Calibration Curve Data of Gabapentin in Phosphate buffer 6.8:

S.no	Concentration(µg/ml)	Absorbance
1	0	0
2	5	0.159±0.1
3	10	0.350±0.3
4	15	0.541±0.2
5	20	0.718±0.4
6	25	0.875±0.5

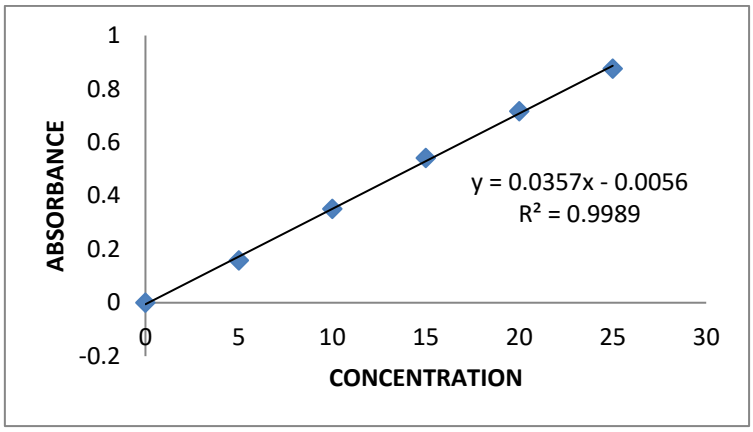

Figure 2: Standard Graph of Gabapentin in Phosphate Buffer pH 6.8

E. DRUG AND EXCIPIENT COMPATIBILITY STUDIES:

Compatibility studies were performed on drug-using an FTIR spectrophotometer. The samples were analysed by making a KBr disc & scanned between wavenumbers 4000 and 400 cm-1. The characteristic absorption peaks were obtained at different wavenumbers.

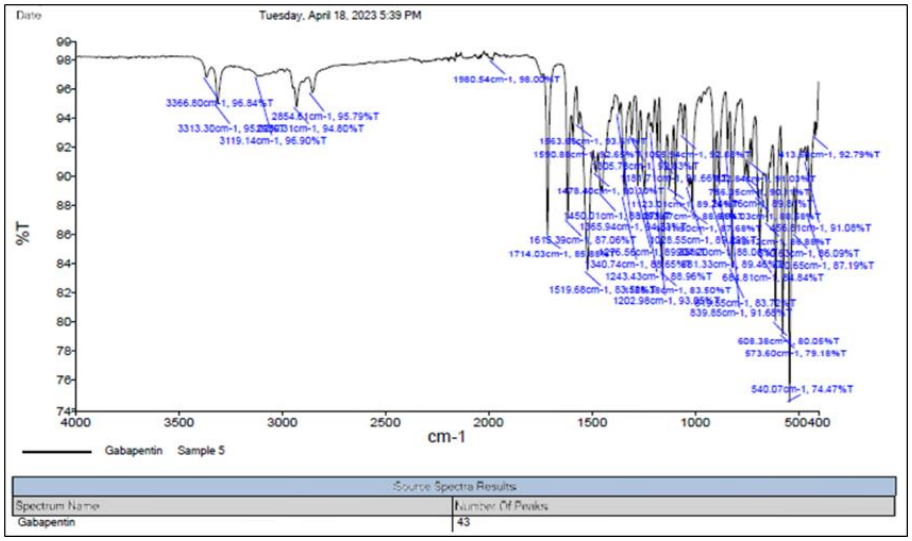

Figure 3: Functional groups of Gabapentin pure drug

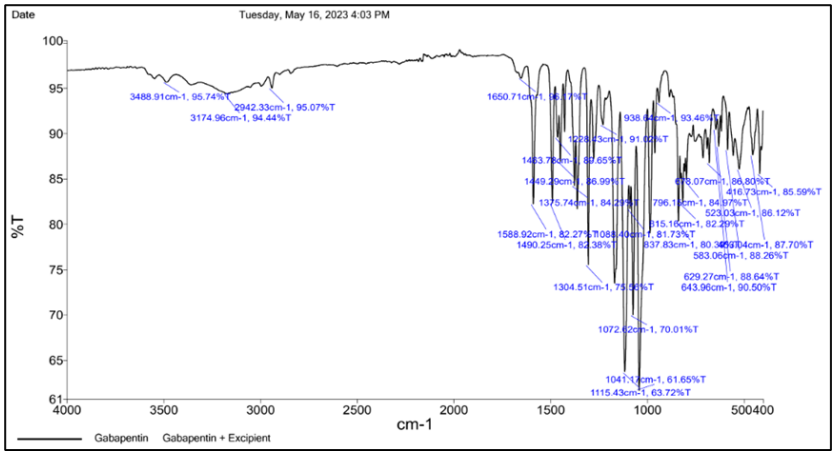

Figure 4: Functional groups of Gabapentin with Excipients

Table 7: FTIR INTERPRETATION TABLE

CHARACTERISTIC PEAK	LITERATURE VALUES	OBSERVED VALUES PURE DRUG	OBSERVED VALUES OPTIMISED FORMULATION
C=0	1275-1200	1202.06	1228.13
C-N	1342-1266	1340.74	1304.51
OH	3200-3600	3366.80	3488.91

CHARACTERIZATION OF TRANSFEROSOMES

A) PARTICLE SIZE OF TRANSFEROSOMES

Particle Size of Prepared Gabapentin transferosome Gf6 showed the least particle size of 164.2±16.30 nm.

Table 8: Particle Size

FORMULATION	*PARTICLE SIZE (nm)*
Gf1	221.4±0.654
Gf2	215.7±0.457
Gf3	205.7±0.590
Gf4	199.2±0.765
Gf5	180.6±0.654
Gf6	164.2±16.30
Gf7	177.9±0.896
Gf8	172.6±0.721

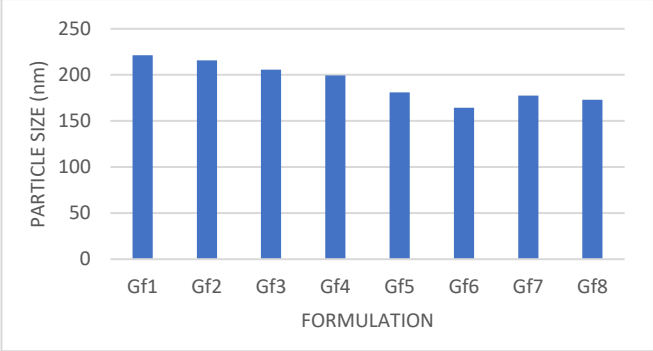

Figure 5: Particle size Gf1-Gf8

B) ZETA POTENTIAL AND POLYDISPERSITY INDEX

Gf6 formulation showed highest zeta potential and it had good stability compared to other formulations. PDI of Gf6 formulation was least when compared to other formulations.

Table 9: Zeta Potential and PDI

FORMULATION	*ZETA POTENTIAL (mV)*	*PDI*
Gf1	-22.67±5.78	0.586
Gf2	-18.12±0.32	0.564
Gf3	-17.08±1.49	0.432
Gf4	-20.85±5.35	0.286
Gf5	-25.98±2.66	0.227
Gf6	-31.64±2.27	0.192
Gf7	-23.2±3.21	0.421
Gf8	-19.67±0.32	0.398

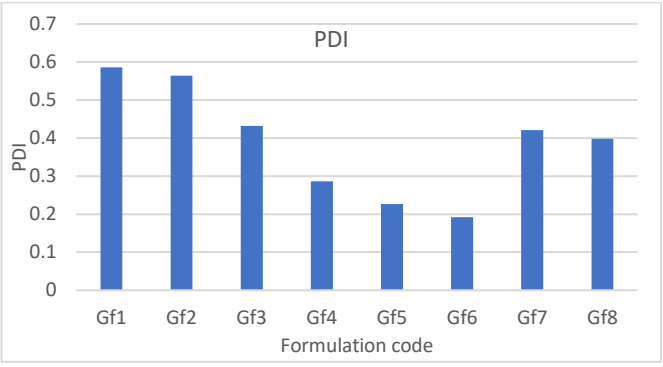

Figure 6: PDI for Gf1-Gf8 formulations

C) ENTRAPMENT EFFICIENCY

The % Entrapment efficiency of deformable vesicles formulations was found to be in the range of 82.02 to 86.54 were shown in Table. Entrapment efficiency of the Gf6 formulation was highest (maximum 86.54).

Table 10: Entrapment Efficiency

Formulation	*% Entrapment Efficiency*
Gf1	83.4±0.12
Gf2	82.2±0.17
Gf3	84.18±0.19
Gf4	83.51±0.24
Gf5	85.48±0.22
Gf6	86.54±0.18
Gf7	85.12±0.09
Gf8	84.19±0.16

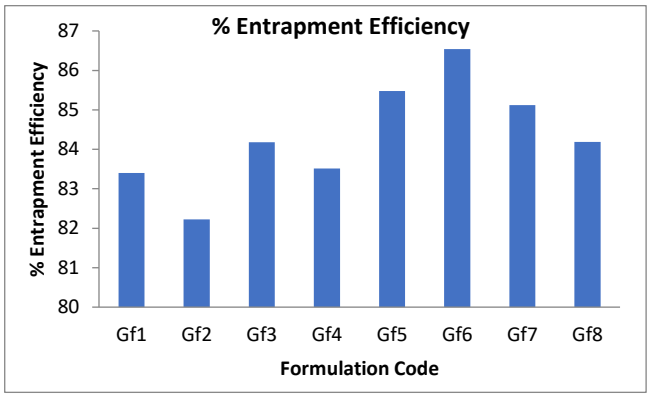

Figure 7: % Entrapment efficiency for Gf1 –Gf8

D) % DRUG CONTENT

Percent drug content of transferosomes formulations were determined according to procedure described. The results obtained shows 91.26 -96.11% drug content in the formulations. The results obtained are shown in table.

Table 11: Drug Content

Formulation	% Drug Content
Gf1	91.26±0.14
Gf2	92.42±0.18
Gf3	93.20±0.27
Gf4	92.26±0.22
Gf5	94.52±0.16
Gf6	96.11±0.21
Gf7	94.34±0.17
Gf8	93.41±0.28

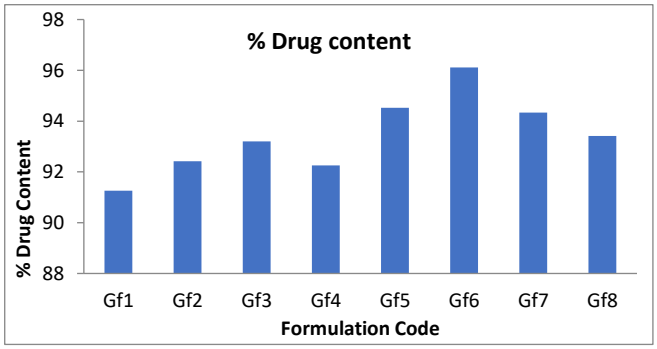

Figure 8: %Drug content for Gf1 –Gf8

INVITRO DIFFUSION STUDIES

The in-vitro diffusion study of transferosomes in phosphate buffer pH 6.8 were carried out using Franz diffusion cell according to procedure. The results are shown in **Table no:12**

Table 12: In-vitro diffusion

Time(hrs)	Gf1	Gf2	Gf3	Gf4	Gf5	Gf6	Gf7	Gf8
0	0	0	0	0	0	**0**	0	0
1	14.4	12.34	10.24	18.16	18.7	**19.24**	17.37	12.44
2	24.16	20.14	21.36	24.28	29.34	**28.26**	28.34	19.28
3	35.27	29.48	27.52	35.57	37.27	**37.37**	36.52	24.54
4	40.32	37.16	34.12	41.22	46.52	**48.25**	47.17	33.36
5	51.29	43.37	46.26	50.52	50.21	**58.51**	52.41	42.41
6	62.14	55.46	52.39	67.26	61.36	**65.26**	64.28	57.26
8	70.24	68.3	65.41	75.24	77.24	**74.15**	76.24	68.81
10	71.15	70.27	72.37	77.24	81.26	**89.37**	80.34	74.28

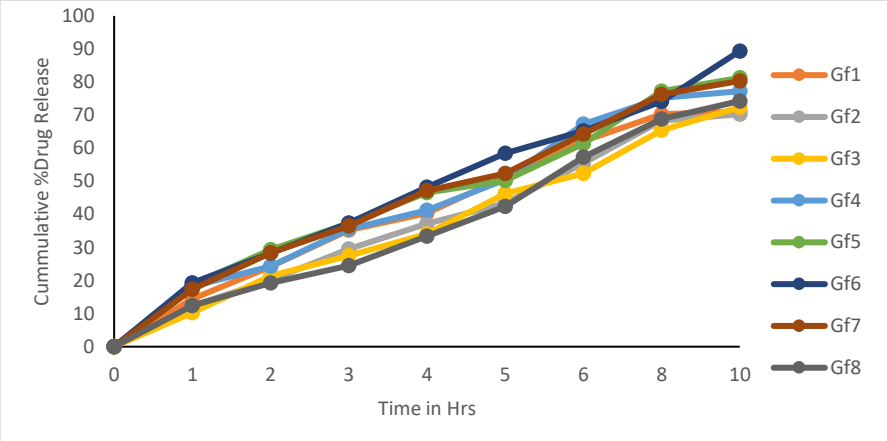

Figure 9: Comparative *IN-VITRO* drug release of formulations Gf1-Gf8.

Comparison of results obtained from diffusion studies for all eight formulations have been done. It was found that formulation Gf6 shows higher drug release rate than other formulations.

pH of Gels*:*

The pH of topical transferosomal gels was measured by using digital pH meter (LabindiaSab 5000 pH meter) at the room temperature. The pH of all topical transferosomal gels were found to be in the range of 5.1±0.15 to 5.7±0.41. The values are shown in Table no.13.

Viscosity of Gels:

Viscosities of the gels were determined by using Brookfield viscometer. Spindle type,S-64 at 100rpm. The viscosities of the prepared gels were found to be in the range of 3210-4170 Pa s. The values are shown in Table no.13.

CHARACTERISATION OF OPTIMIZED FORMULATION

A) SURFACE MORPHOLOGY OF OPTIMIZED Gf6 FORMULATION

The transferosomes were subjected to microscopic examination (S.E.M) for characterizing size and shape of the transferosomes. It is revealed that transferosomes showed spherical vesicles size.

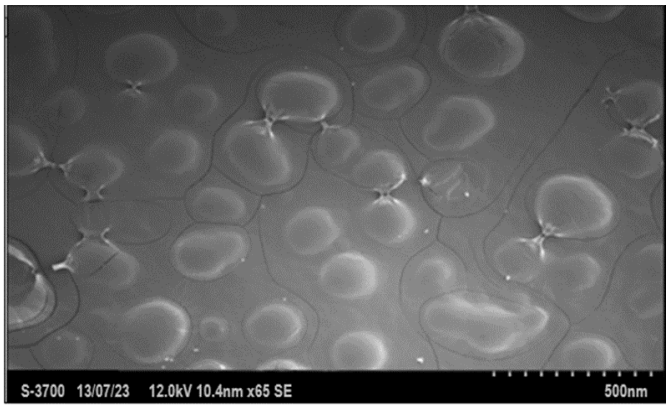

Figure 10: SEM Photograph of Gabapentin Transferosomes (Formulation-Gf6)

B) ZETA POTENTIAL FOR Gf6 FORMULATION

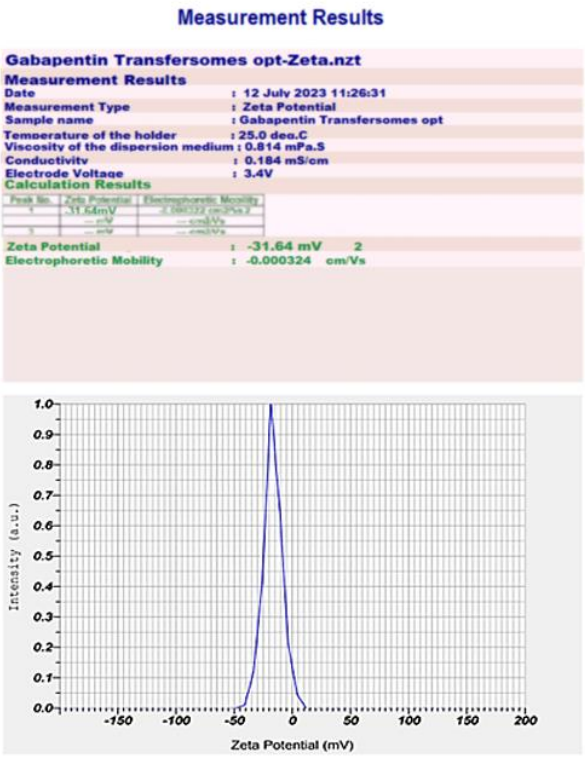

Figure 11: Zeta potential graph of Gf6 formulation

C)PARTICLE SIZE ANALYSIS FOR Gf6 FORMULATION

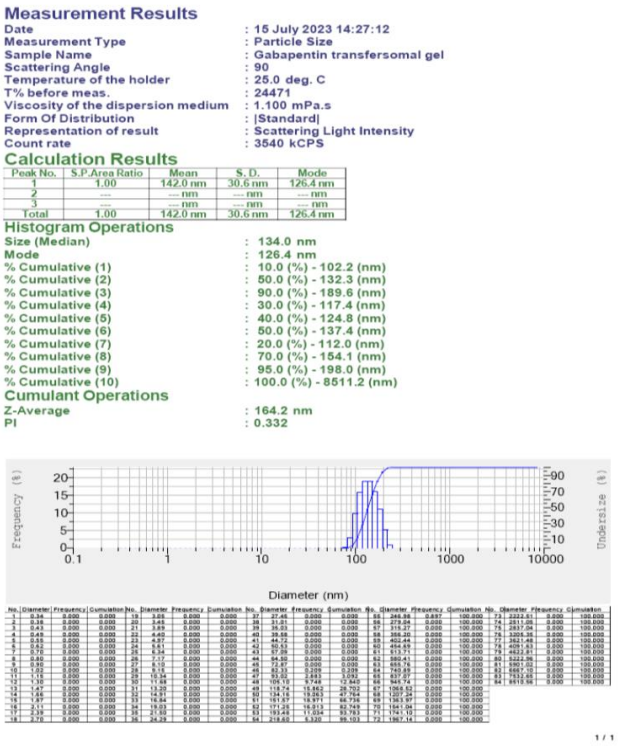

Figure 12: Particle Size Analysis for Gf6 formulation

CHARACTERIZATION OF GEL

TABLE 13: GEL EVALUATION PARAMETERS (GF6 FORMULATION)

Formulation code	PH	Viscosity	Spreadability (cm/sec) *	Extrudability	% Drug content	Skin Irritation Test
Gf6A	5.2 ±0.21	3210	3.2±0.14	+	91.26±0.14	No
Gf6B	5.1±0.15	3460	2.8±0.15	+	92.42±0.18	No
Gf6C	5.5±0.24	4020	3.4±0.20	++	93.20±0.27	No
Gf6D	5.4±0.36	3640	3.2±0.17	+	92.26±0.22	No
Gf6E	5.4±0.28	3760	3.3±0.42	+	94.52±0.16	No
Gf6F	5.7±0.41	4170	3.6±0.18	++	96.11±0.21	No

TABLE 14: IN-VITRO DIFFUSION STUDIES OF Gf6 TRANSFERSOMAL GEL:

Time(hrs.)	Gf6A optimized 0.5g Xanthan gum gel	Gf6B optimized 0.75g Xanthan gum gel	Gf6C optimized 1.0g Xanthan gum gel	Gf6D optimized 0.5g Carbopol gel	Gf6E optimized 0.75g Carbopol gel	Gf6F optimized 1.0g Carbopol gel
0	0	0	0	0	0	**0**
1	24.14	21.52	25.41	29.18	27.41	**14.16**
2	42.27	42.26	34.24	45.46	41.26	**25.81**
4	56.73	59.61	47.41	67.21	57.27	**44.27**
6	63.51	68.12	65.37	74.28	68.83	**61.15**
8	72.42	79.58	82.26	87.66	80.42	**79.24**
10	91.24	92.67	94.62	92.18	90.37	**97.17**

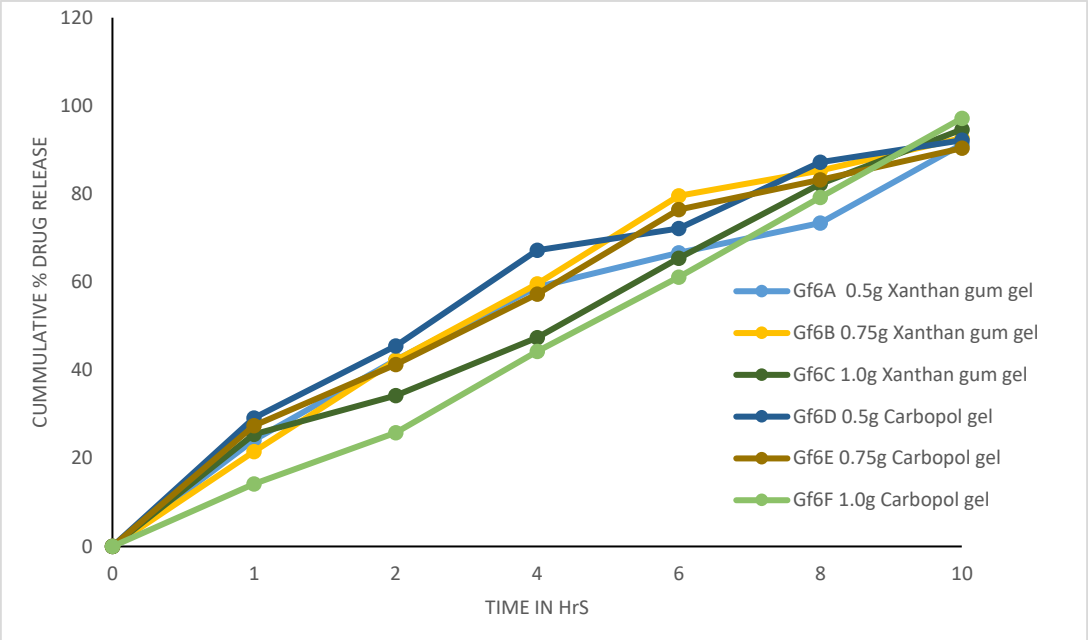

Figure 13: *In vitro* diffusion studies for Transferosomal gel with different concentrations of polymers

The Gf6F optimized formulation with 1.0g Carbopol 934 gel showed highest drug release (97.48% for 10hrs), good Homogeneity, Highest drug content, proper viscosity. Hence it was considered as optimized formulation.

Drug Release Kinetics

The release constant was calculated from the slope of the appropriate plots, and the regression coefficient (r^2) was determined. The results are shown in Table no 15.

Table 15: Drug Release Kinetics

Time(hr.)	cumulative % drug release	Sqr. time	log % cdr	log time	% Drug remaining	log % Drug remaining
0	0	0			100	2.00
1	14.16	1.00	1.15	0	85.84	1.93
2	25.81	1.41	1.41	0.30	74.19	1.87
4	44.27	2.00	1.65	0.60	55.73	1.75
6	61.15	2.45	1.79	0.78	38.85	1.59
8	79.24	2.83	1.90	0.90	20.76	1.32
10	97.17	3.16	1.99	1.00	2.83	0.45

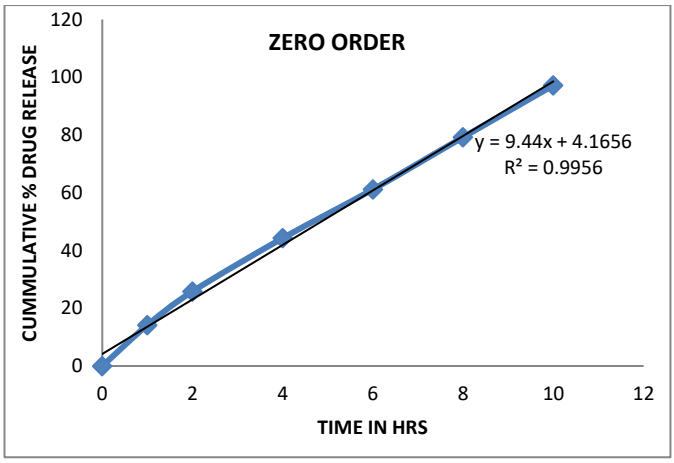

Figure14 (a): Zero order plot of Gf6F optimized formulation

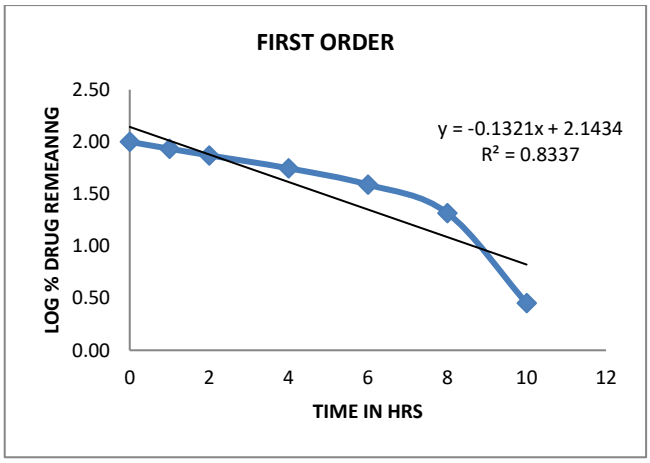

Figure 15 (b): First order plot of Gf6F optimized formulation

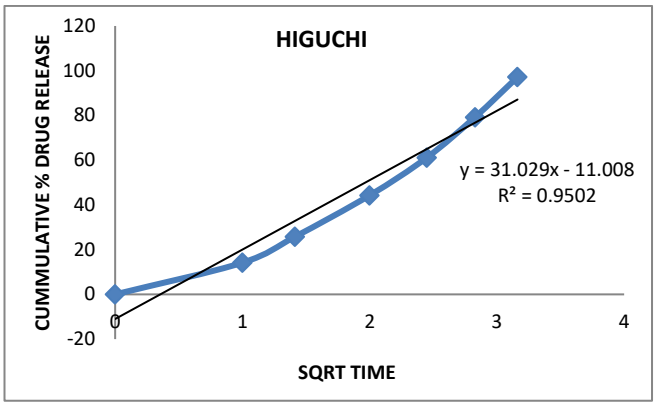

Figure 16 (c): Higuchi graph plot of Gf6F optimized formulation

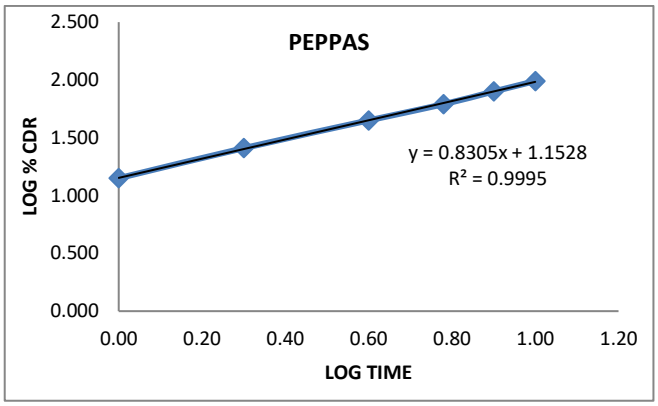

Figure 17 (d): Peppas plot of Gf6F optimized formulation

INFERENCE:

The formulation Gf6F optimized 1.0g Carbopol 934 Transferosomal gel was analyzed for the drug release mechanism. The best fit model for selected formulation was found to be Plot with Zero order and Peppas release Kinetics. The correlation coefficient value (R^2=0.9995) indicates the best release mechanism.

Stability Studies

Stability studies were conducted for the optimized Gf6F Carbopol transferosomal gel. The %Entrapment efficiency and % Drug content was assessed at different temperatures for 3 months. The results are shown below in the table no. 16.

Table 16: Stability studies of Gf6F optimized 1.0g Carbopol 934 transferosome gel for %Entrapment efficiency and % Drug content

No.of days	% Entrapment Efficiency		% Drug Content	
	4±2°C	25±2°C	4±2°C	25±2°C
15	86.54	72.54	96.11	86.11
30	85.24	70.24	95.38	85.12
45	83.38	69.34	94.23	84.20
90	82.12	67.08	94.45	82.13

INFERENCE:

The results inferred that transferosomal gels have showed least drug loss at refrigerated temperature ang higher drug loss at elevated temperatures. It can be concluded that trnsferosomal gels must be kept at low temperature to reduce the drug loss improve its shelf-life.

5. CONCLUSION

The goal of the present study was to formulate and evaluate Gabapentin Transferosomal Gel. Pre-formulation studies indicate that Gabapentin is highly soluble in phosphate buffer 6.8 and distilled water. FTIR indicate no interaction among drug and excipients. Absorption maxima of Gabapentin in phosphate buffer 6.8 was observed to be 265nm. Total 8 formulations have been prepared. Different formulations have been prepared by various concentrations of various concentrations of Soy lecithin, span 80, Tween 80, Chloroform, methanol with the aid of using thin film hydration technique. The prepared formulations have been evaluated for various parameters like FTIR, Organoleptic evaluation, Drug content, Entrapment efficiency, Invitro diffusion studies ,etc. Gf6 was the optimized formulation with %EE of 86.54%, Drug content 96.11%, Zeta potential of -31.64Mv, Particle size of 164.2nm, *In-vitro* drug release of 89.37%. Thus, formulated Gabapentin transferosomes and gel has a potential to be efficient and stable for the transdermal delivery. The formulation developed is simple, easy to prepare and effective with remarkable applicability in the course of providing ease in peripheral neuropathy.

SCOPE:

- *In-vivo* animal model studies can be carried out on the prepared gels.
- PK-PD parameters are to be determined further.
- Long-term stability testing is needed to be done.

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