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FORMULATION AND *IN VITRO* EVALUATION OF EMULGEL OF DESLORATADINE

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ABSTRACT

Formulation of Desloratadine Emulgel was done using various penetration enhancers and a gelling agent by dispersion in oil/water emulsion based method. Prepared emulgels was investigated for different parameters. All the prepared emulgels showed acceptable physical-chemical properties concerning colour, viscosity, melting point, pH value, spread ability and drug content, etc. *In-vitro* drug release studies were conducted using Franz-Diffusion cell. Desloratadine maximum wavelength is determined by UV-Visible spectrophotometer using 6.8 pH phosphate buffer and was detected to be 249 nm. Desloratadine emulgel was formulated using light liquid paraffin as oil phase and emulsifying agent tween 20 for emulsion and incorporated into gel using carbopol 934 polymer. FTIR studies showed that drug and all excipients are compatible. The data obtained from in-vitro drug release studies was treated by various conventional mathematical models to determine the release mechanism from the designed emulgel formulations. Selection of a suitable release model was based on the values of R2 (correlation coefficient), k (release constant) obtained from the curve fitting of release data. It was found that all the formulations follows the zero order kinetics. The optimized formulation F7 showed a shear thinning with thixotropic property with better spread ability, viscosity and *In-vitro* drug release compared to other formulations. In the study it was observed that the concentrations of tween 20 and linseed oil has shown effect on viscosity, spread ability and *In-vitro* drug permeability. Increased amount of linseed oil showed suppress activity of tween 20. The surface morphology of the optimized formulation was observed by Scanning Electron Microscopic study. Thus Desloratadine emulgel which could increase the drug permeability across the skin and fast release of the drug could be successfully achieved.

KEYWORDS

Emulgel, Desloratadine, Antihistamine and Topical drug delivery.

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INTRODUCTION

Topical drug administration is considered as simplest and easiest route of localized drug delivery anywhere in the body by different routes. These are wide spectrum of preparations in case of cosmetic as well as dermatological, to the healthy or diseased skin[1]. Gels and emulsions when used in combined form the dosage forms are referred as emulgels. In recent years, there has been great interest in the use of novel polymers with complex functions as

emulsifiers and thickeners because the gelling property of these compounds allows the formulation of stable emulsions and creams by increasing the viscosity of the aqueous phase and decreasing surface and interfacial tension. The gelling agent in the water phase converts a classical emulsion into an emulgel[2]. Both oil-in-water and water-in-oil emulsions are vehicles used to deliver various drugs to the skin. The emulsions possess a certain degree of elegance and can be easily washed off whenever desired. They have a high ability to penetrate the skin. Emulgels when used dermatologically show several desirable properties such as thixotropic nature, greaseless, easily spreadable, easily removable, emollient, non-staining, water-soluble, longer shelf life, bio-friendly, transparent and pleasing appearance[3].

Advantages of Emulgel as a drug delivery System[4,5]

Easy incorporation of Hydrophobic drugs into gels using d/o/w emulsions

Mostly hydrophobic drugs cannot be incorporated directly into gel base due to solubility which act as a barrier and problem arises during the release of the drug. In emulgel the addition of hydrophobic drugs into the oil phase is easy and the oily globules are then dispersed in aqueous phase resulting in formation of oil -in -water emulsion. This emulsion can be mixed into gel base easily. This proves better stability and release of drug than simply incorporating drugs into gel base.

Better stability

When compared to other transdermal preparations, the latter are found to be comparatively less stable than emulgels. For example powders are hygroscopic in nature, creams undergo phase inversion or breaking and ointment shows rancidity due to the presence of oily base.

Better loading capacity

Other novel approaches like niosomes and liposomes are of nano size and due to vesicular structures may result in leakage and result in lesser entrapment efficiency. But gels due to the presence of vast network have better loading capacity.

Feasibility in production and low cost preparation

Preparation of emulgels involves short and simpler steps which results in increase in the feasibility of the production. There is no need of specialized instruments for the production of emulgels. Moreover materials used are easily available and cheaper. This results in decrease in the production cost of emulgels.

No need of intensive sonication

Production of vesicular molecules require intensive sonication that sometimes results in drug degradation and leakage. This problem does not occur during the production of emulgels as there is no need of sonication.

Controlled release

Emulgels can be used for prolonging the effect of drugs having shorter t1/2.

Factors Affecting Topical Absorption of Drug

Physiological Factors[6]

1. Skin thickness.
2. Lipid content.
3. Density of hair follicles.
4. Density of sweat glands.
5. Blood flow.
6. Skin pH.
7. Inflammation of skin
8. Hydration of skin.

Physiochemical Factors[7]

1. Partition coefficient.
2. Molecular weight
3. Effect of vehicles

Degree of ionization (only unionized drugs gets absorbed well).

Important Constituents of Emulgel Preparation:

Aqueous Material[8]

This forms the aqueous phase of the emulsion. Commonly used agents are purified water and alcohols.

Oils

These agents are used to form the oily phase of the emulsion. For externally applied emulsions, mineral oils, either alone or combined with soft or hard paraffins, are widely used both as the vehicle for the

drug and for their occlusive and sensory characteristics[9].

Emulsifiers

These agents are used to promote emulsification at the time of manufacture as well as to control stability during a shelf life that can vary from days for extemporaneously prepared emulsions to months or years for commercial preparations. eg Polyethylene glycol 40 stearate, Sorbitan mono-oleate (Span 80), Polyoxyethylene sorbitan mono-oleate (Tween 80), Stearic acid, Sodium stearate[10].

Gelling Agent

Gelling agents used to increase the consistency of any dosage form. They can also be used as thickening agent[11]. Some of the examples are HPMC, HPMC K-100, carbopol 940, carbopol 934, sodium carboxy methyl cellulose, xanthan gum etc.

Penetration Enhancers[12]

Penetration enhancers are the agents used to enhance bioavailability and increase the range of drugs applied topically. Some of the examples are essential oils, oleic acid, lecithin, urea, DMSO, linolic acid etc.

MATERIAL AND METHODS

Materials

Desloratadine was procured as a gift sample from the Chandra Laboratories Pvt. Ltd, Hyd Carbopol 943, Light Liquid Paraffin, Castor oil, Linseed oil, Clove oil, Tween 20, Propylene Glycol were obtained from Research Lab Fine Chem Ltd., Mumbai. All the chemicals used were of analytical grade and used as supplied by the manufacturer.

Pre formulation Studies

Pre-formulation can be defined as an investigation of physical and chemical properties of a drug substance alone. The main objective of pre-formulation studies is to generate information useful to the formulator in developing stable dosage forms[13].

Appearance[14,15]

Physical appearance of the drug was examined by organoleptic properties and results were obtained.

Solubility

The solubility of the drug sample was carried out in different solvents (aqueous and organic) according to I.P. The results are then compared with those mentioned in the official books and Indian Pharmacopoeia.

Melting point

The melting point of Desloratadine was determined by capillary method using digital melting point apparatus.

ANALYTICAL METHODS

STANDARD CURVE

Preparation of standard solution:

Stock solution-I

Accurately weighed amount of 100 mg of Desloratadine was transferred into a volumetric flask made up to 100mL with pH 6.8 Phosphate buffer. The resulted solution have the concentration of 1mg/ml and labelled as ‘stock’.

Preparation of working standard solutions

From this stock solution 10ml was taken and diluted to 100ml with pH 6.8 Phosphate buffer which has given the solution having the concentration of 100mcg/ml.

Calibration curve for the estimation of Desloratadine

Calibration curve of Desloratadine was estimated in 6.8 pH buffer.

COMPATIBILITY STUDIES

The FTIR spectroscopy is a useful tool for identifying both organic and inorganic chemicals. It can be utilized to quantify some components of an unknown mixture and can be used to analyze liquids, solids and gases. The FTIR spectrum didn't show presence of any additional peaks for new functional groups indicating that no chemical interaction have occurred between drug and the used polymers.

EMULGEL PREPARATION

Gel preparation

The composition of Desloratadine emulgel was shown in the formulation code table. The carbopol

gel was prepared by dispersing carbopol 934 in purified water with constant stirring at moderate speed and soaked overnight. The gel was obtained by neutralizing the dispersion with tri ethanol amine and pH is adjusted to 6.5.

Emulsion preparation

The oil phase of emulsion was prepared by dissolving span 20 in light liquid paraffin and heated upto 70-80°C.Castor oil/Clove oil /Linseed oil was mixed in oil phase. Aqueous phase was prepared by dissolving tween 20 and drug in ethanol and heated upto 70-80^{0}C. Methylparaben, propylparaben were mixed in propylene glycol this added this mixture was dissolved in aqueous phase. Then oil phase was added slowly to aqueous phase with continuous stirring and allowed to cool to room temperature.

Emulgel preparation

The obtained emulsion was mixed with the gel base with gentle stirring to get Desloratadine emulgel.

RESULTS AND DISCUSSION

Appearance

Color

White fine crystalline powder.

Melting point

The melting point of Desloratadine was determined and found to be 157°C

CHARACTERIZATION OF EMULGEL

Physical appearance[14,15]

The prepared emulgel formulations were evaluated for different physicochemical parameters like color, homogeneity and consistency.

Measurement of pH[16]

The pH of developed emulgel formulations was determined using digital pH meter by dipping the glass electrode into the emulgel. The measurement of pH of each formulation was done in triplicate manner and average values were calculated.

Spreadability studies[17]

Spreadability was determined by using a modified wooden block and glass slide apparatus. It was determined using the formula,

$S = M^* L/T$

Where, S is Spreadability in g/s, M is the mass in grams and T is the time in seconds.

Rheological studies[18]

The viscosity of gel during handling, transport and storage is an important criterion. The viscosity of different emulgel formulations was determined at 25^{0}C using Brook field viscometer. The emulgels were rotated using spindle 6 at 10 rpm and viscosities were measured.

Drug content determination[19]

Drug concentration in emulgel was measured by UV-Visible spectrophotometer. Desloratadine content in emulgel was measured by dissolving accurately 5ml of emulgel in 6.8pH phosphate buffer by sonication and diluted to 10 folds prior to absorbance. Absorbance was measured at 249nm using UV-Visible spectrophotometer 1700 (Shimadzu, Japan). The test was conducted in triplicate and the average % drug content was determined.

***In-Vitro* Drug release studies**[20]

In-vitro drug release study was carried out using keishary chein cell having capacity of 18ml volume. Egg membrane was isolated and used for the study. 5ml of emulgel was spread evenly on to the egg membrane. The egg membrane was clamped between donor and receptor compartment. The receptor compartment was filled with 16ml of 6.8pH phosphate buffer maintained at 37ºC and stirred by using magnetic stirrer. The sample (2ml) was collected at suitable time intervals and analyzed for drug content by UV-Visible Spectrophotometer 1700 (Shimadzu, Japan) at 249nm after appropriate dilutions.

***In-Vitro* Drug Release Kinetic Studies**

In-vitro drug release mechanism was determined by using PCP DISSO V2 software. Depending upon R and k values obtained from different models, the best-fit model was selected.

Scanning Electron Microscopy (SEM) study

Surface morphology

The surface morphology of the Emulgel was determined by using scanning electron microscope (Shimadzu SSX-550 SEM EDX) using gold sputter

technique. The system was vacuum dried, coated with gold palladium, and observed microscopically.

STABILITY STUDIES[21]

Results from stability studies indicate that the formulated Desloratadine emulgel are stable for a period of 3 months under 2 different conditions at 25±2˚C; 65±5% RH and 40±2 ˚C and 75±5%RH. There were no remarkable changes were observed during the period of storage.

SUMMARY

The purpose of topical dosage form is to conveniently deliver drug across a localized area of the skin. To develop an ideal dosage form, one must take into account flux of the drug across the skin, nature of drugs, patient acceptability of the formulation etc. Although having plenty of advantages over other routes of administration, topical drug delivery system is having certain limitations including hydrophilic drugs cannot easily penetrate across skin, to overcome this problem the drug is made into sufficient lipohillic or drugs are sued along with certain penetration enhancers which help to achieve desired results.

Desloratadine is a tricyclic 2nd generation antihistamine that has selective and peripheral H1 receptor antagonist activity. On this contest, emulgel was formulated using carbopol 934, liquid paraffin as oil phase, oils (clove, castor and linseed) as penetration enhancers and emulsifying agent like tween 20.

On basis of quality of emulgel produces total eight formulations F1 to F9 were selected. They were evaluated for physical appearance, pH, rheological study, spreadability, drug content and in-vitro drug release study. Prior to formulation drug polymer interaction studies were carried by FTIR and found to be compatible and to find out the maximum wavelength of desloratadine UV-Visible spectroscopy was used using 6.8 pH phosphate buffer. The formulated emulgel had a distinct advantage over existing conventional dosage form in that the drug permeation was found to be rapid across the skin and hence the increased therapeutic response by bypassing 1st pass metabolism and with no gastro intestinal problems and better patient compliance.

Table No.1: Standard Calibration Curve of Desloratadine in pH 6.8 Phosphate buffer

S.No	Conc.(µg/ml)	Absorbance
1	0	0
2	5	0.21±0.02
3	10	0.416±0.01
4	15	0.601±0.01
5	20	0.753±0.04
6	25	0.904±0.03
7	30	1.076±0.04

Table No.2: Formulation Code

S.No	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Desloratadine(mg)	5	5	5	5	5	5	5	5	5
2	Carbopol 934(mg)	5	5	5	5	5	5	5	5	5
3	Light liquid paraffin(ml)	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5
4	Span 20(ml)	1	1	1	1	1	1	1	1	1
5	Castor Oil (ml)	2.5	3.75	5	-	-	-	-	-	-
6	Clove Oil (ml)	-	-	-	2.5	3.75	5	-	-	-
7	Linseed Oil (ml)	-	-	-	-	-	-	2.5	3.75	5
8	Tween 20 (ml)	1	1	1	1	1	1	1	1	1
9	Propylene glycol (ml)	1	1	1	1	1	1	1	1	1
10	Ethanol (ml)	5	5	5	5	5	5	5	5	5
11	Methylparaben	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
12	Propylparaben	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005	0.005
13	Purified water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

Table No.3: Physical appearance and pH Determination

S.No	Formulation Code	Color	Homogeneity	Consistency	Phase separation	pH
1	F1	Creamy white	Homogenous	Smooth	Not occurred	6.4±0.43
2	F2	Creamy white	Homogenous	Smooth	Not occurred	6.1±0.63
3	F3	Creamy white	Homogenous	Smooth	Not occurred	6.7±0.25
4	F4	Creamy white	Homogenous	Smooth	Not occurred	6.0±0.72
5	F5	Creamy white	Homogenous	Smooth	Not occurred	6.3±0.11
6	F6	Creamy white	Homogenous	Smooth	Not occurred	6.4±0.24
7	F7	Creamy white	Homogenous	Smooth	Not occurred	6.6±0.88
8	F8	Creamy white	Homogenous	Smooth	Not occurred	6.5±0.02
9	F9	Creamy white	Homogenous	Smooth	Not occurred	6.4±0.20

Table No.4: Spreadability studies

S.No	Formulation code	Spreadability (cm/sec)*
1	F1	3.0±0.01
2	F2	3.5±0.40
3	F3	3.2±0.55
4	F4	3.4±0.48
5	F5	3.5±0.62
6	F6	4.1±0.12
7	F7	4.0±0.75
8	F8	2.3±0.23
9	F9	2.1±0.62

Table No.5: Rheological studies

S.No	Formulation code	Viscosity (cps)
1	F1	3600
2	F2	3300
3	F3	3900
4	F4	3650
5	F5	4300
6	F6	3100
7	F7	4800
8	F8	3100
9	F9	3200

Table No.6: Drug content determination

S.No	Formulation code	Mean%
1	F1	98.41±0.06
2	F2	99.15±0.05
3	F3	98.02±0.08
4	F4	99.47±0.06
5	F5	98.83±0.09
6	F6	97.54±0.12
7	F7	98.74±0.16
8	F8	99.90±0.20
9	F9	99.40±0.25

Table No.7: *In-Vitro* Drug release data

S.No	Time (hrs)	% Cumulative drug release								
		F1	F2	F3	F4	F5	F6	F7	F8	F9
1	0	0	0	0	0	0	0	0	0	0
2	1	12.02	8.61	7.25	13.42	7.93	6.15	16.51	7.51	8.95
3	2	25.16	19.13	12.28	32.75	17.62	11.20	38.64	16.54	15.4
4	3	41.31	34.40	28.41	45.27	32.85	25.34	55.13	30.24	28.6
5	4	58.46	49.83	37.12	62.84	46.42	34.65	70.61	40.69	39.2
6	5	68.32	59.82	49.53	76.85	52.64	46.74	83.45	52.25	50.21
7	6	76.77	69.53	60.31	83.32	62.06	58.09	93.10	63.42	60.12

Table No.8: Release Kinetics of Optimized Formulation

S.No		ZERO	FIRST	HIGUCHI	PEPPAS
		% CDR Vs T	Log % Remain Vs T	%CDR Vs √T	Log C Vs Log T
1	Slope	15.8982143	-0.18602898	44.2116478	1.60288959
2	Intercept	3.36821429	2.1291774	-8.19548191	0.99324521
3	Correlation	0.99347739	-0.97015776	0.96620435	0.69816422
4	R 2	0.98699732	0.94120608	0.93355084	0.48743328

Table No.9: Stability Studies of Optimized Formulation

S.No	Time	Colour	Assay		Cumulative % drug release at 6 hrs		pH	
			25±2°C and 65±5%RH	40±2°C and 75±5%RH	25±2°C and 65±5%RH	40±2°C and 75±5%RH	25±2°C and 65±5%RH	40±2°C and 75±5%RH
1	First day	White	99.2	99.3	95.1	96.4	6.7	6.8
2	30 days	White	99.1	98.85	95.0	96.31	6.7	6.7
3	60 days	White	98.3	98.65	94.85	96.16	6.6	6.7
4	90 days	White	98.7	97.49	94.05	95.02	6.6	6.6

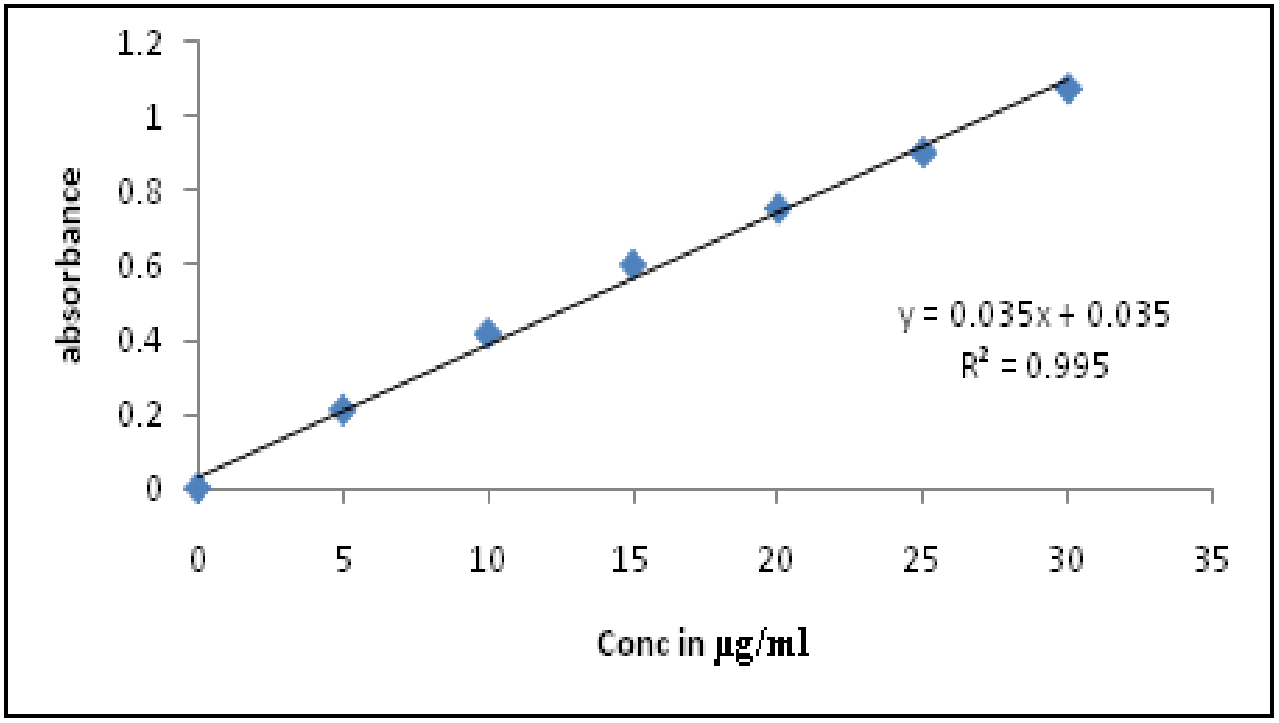

Figure No.1: Calibration Curve of Desloratadine in pH 6.8 Phosphate Buffer

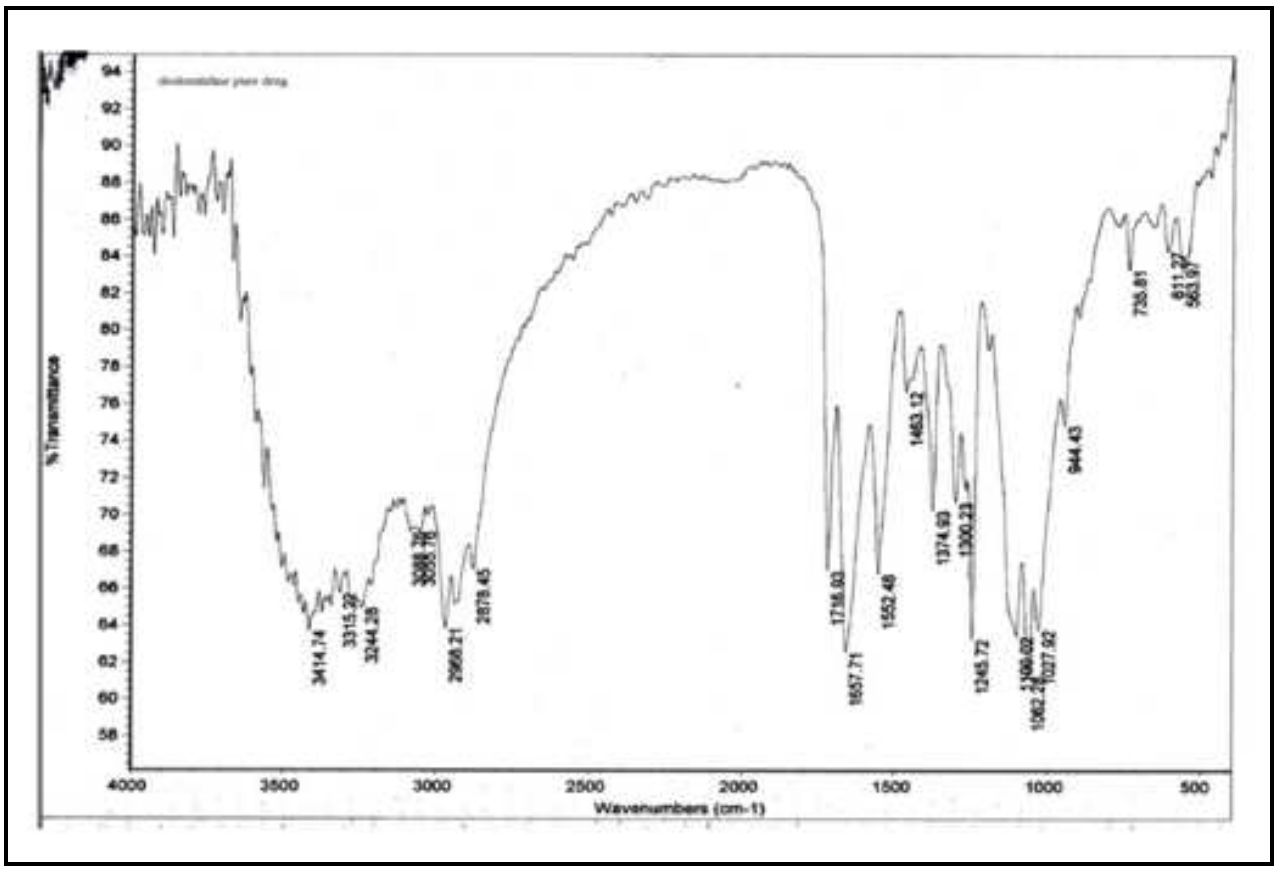

Figure No.2: FTIR Spectra of Desloratadine Pure drug

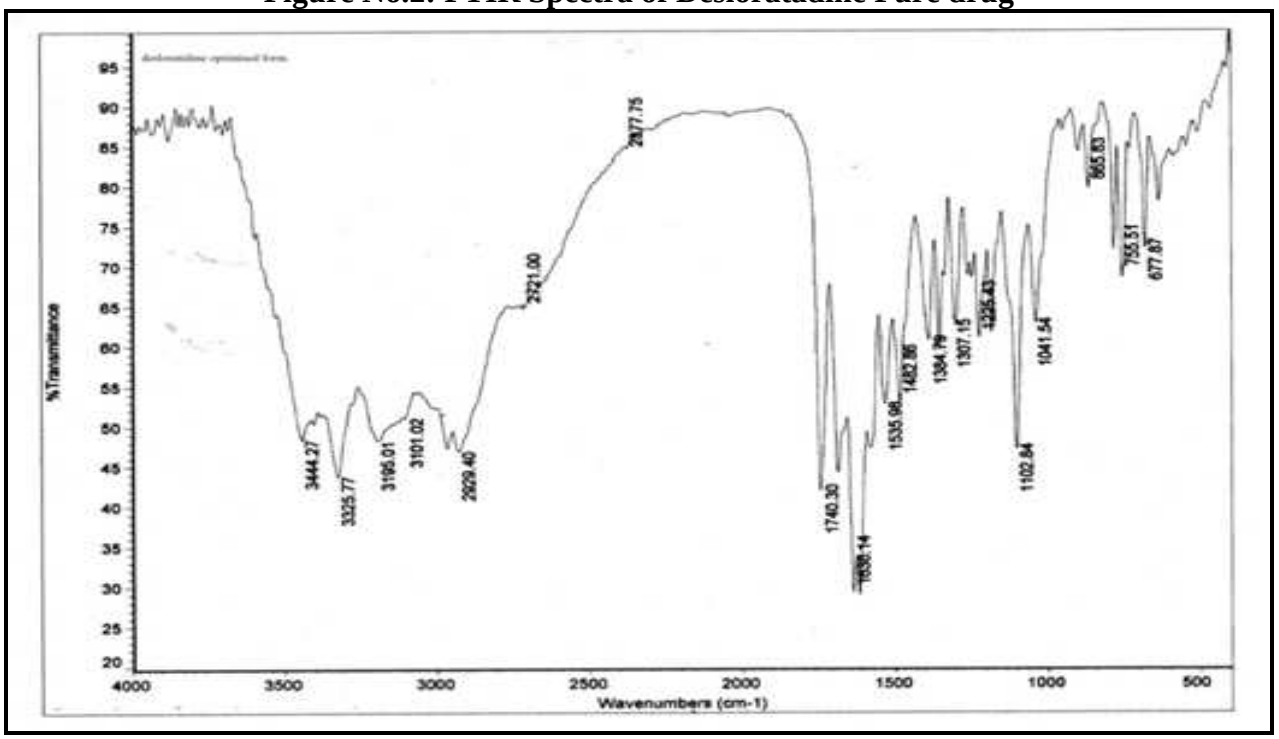

Figure No.3: FTIR Spectra of Desloratadine and excipients

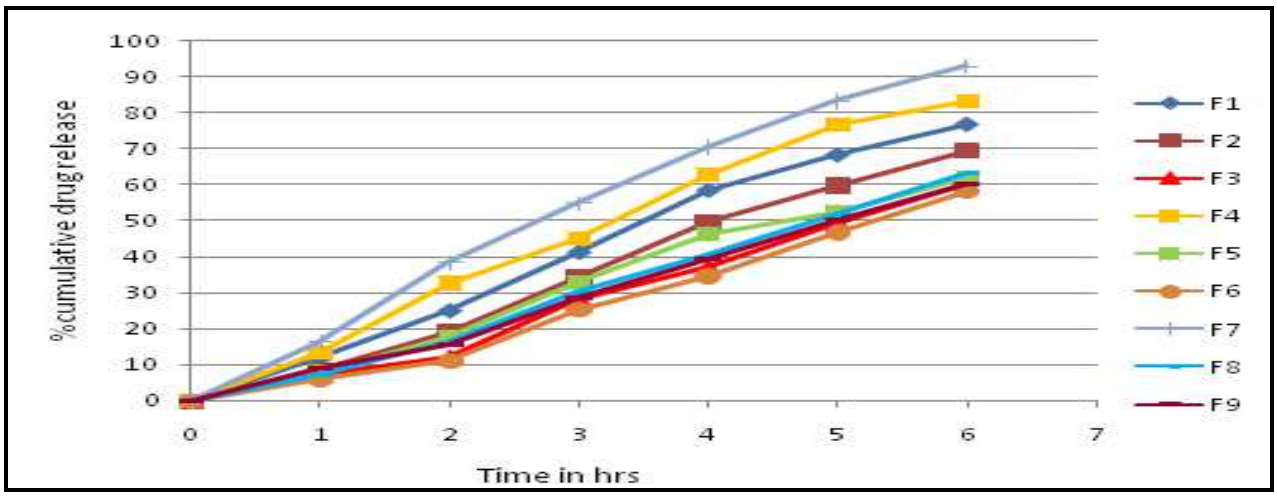

Figure No.4: Drug Release Profile of F1-F9

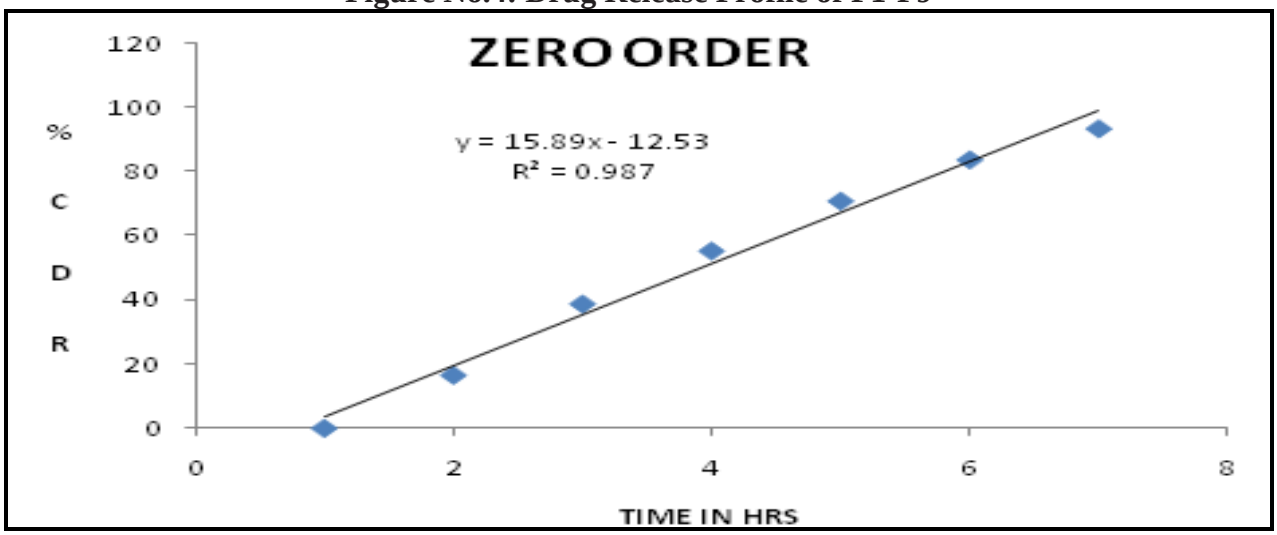

Figure No.5: Zero order kinetic graph for optimized formulation

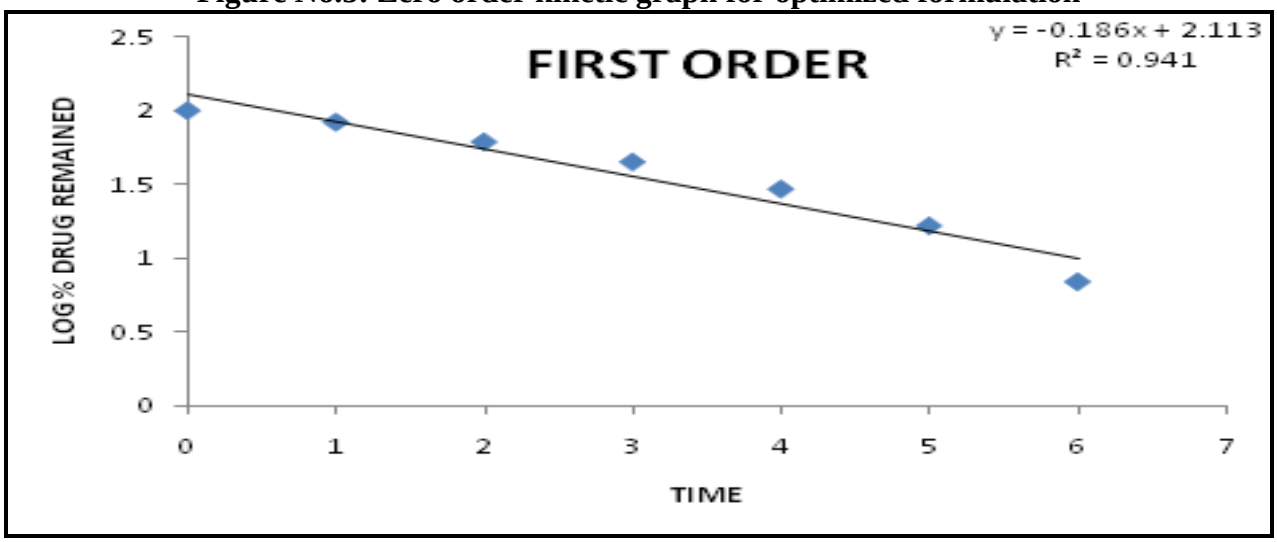

Figure No.6: First order kinetic graph for optimized formulation

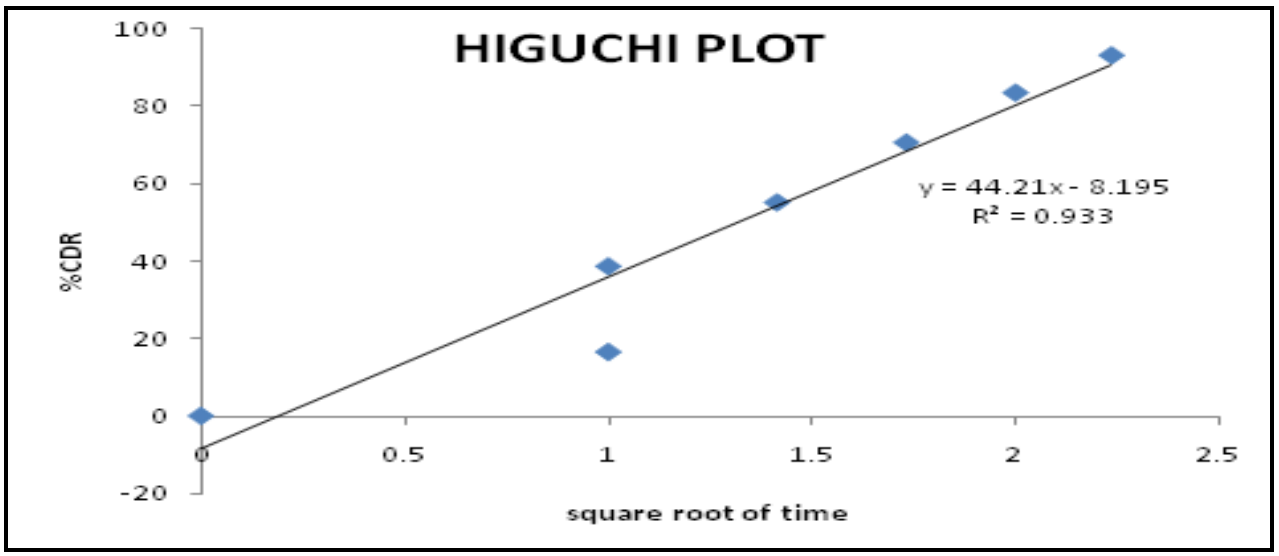

Figure No.7: Higuchi kinetic graph for optimized formulation

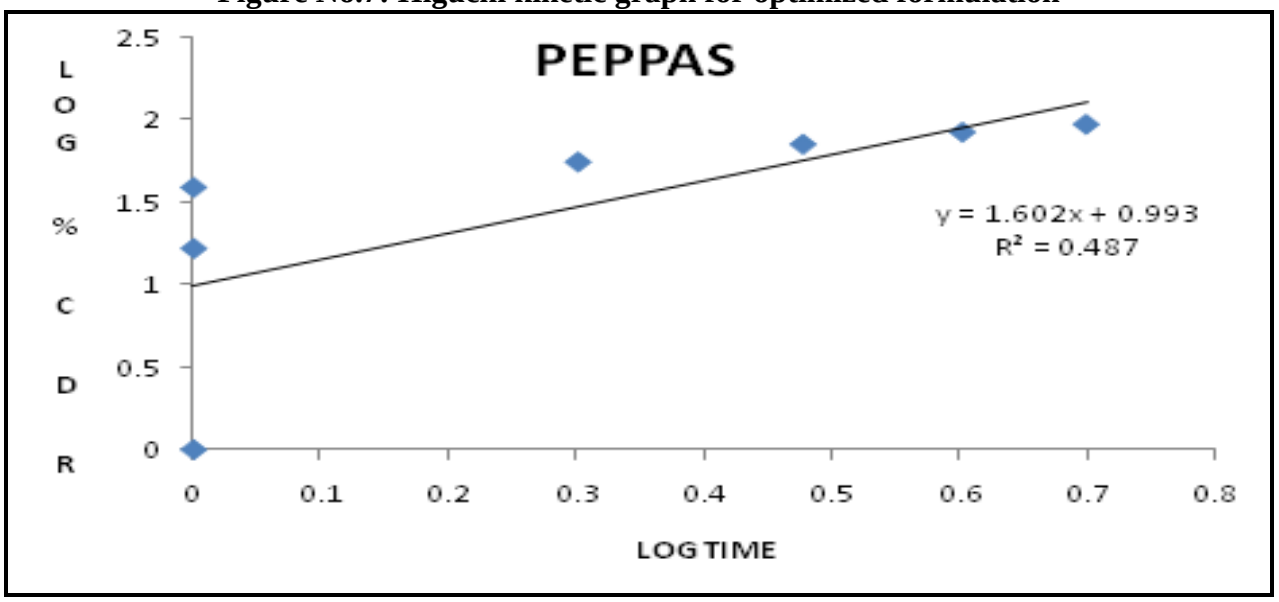

Figure No.8: Peppas kinetic graph for optimized formulation

CONCLUSION

Desloratadine maximum wavelength is determined by UV-Visible spectrophotometer using 6.8 pH phosphate buffer and was detected to be 249 nm. Desloratadine emulgel was formulated using light liquid paraffin as oil phase and emulsifying agent tween 20 for emulsion and incorporated into gel using carbopol 934 polymer. The optimized formulation F7 showed a shear thinning with thixotropic property with better spreadability, viscosity and in-vitro release compared to other formulations. In the study it was observed that the concentrations of tween 20 and linseed oil has shown effect on viscosity, spreadability and in-vitro drug release. Increased amount of linseed oil showed suppress activity of tween 20. The surface morphology of the optimized formulation was observed by Scanning Electron Microscopic study. Thus Desloratadine emulgel which could increase the drug permeability across the skin and fast release of the drug could be successfully achieved.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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