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Formulation and evaluation of anti-acne Emulgel of isotretinoin

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Abstract
The object of presented work is to formulation of a topical emulgel of Isotretinoin for the treatment of mild to moderate acne, where systemic therapy is avoidable. Formulation of anti-acne emulgel of Isotretinoin using carbopol 934 as a gelling agent and tween 20, span 20 as some emulsifiers. For increase the permeation of the drug through skin and enhance its therapeutic activity by use propylene glycol as a penetration enhancer. The characterization of Isotretinoin drug sample was done using UV/visible spectrophotometric study at λmax 355nm, FTIR spectroscopy and melting point determination. All the observed data were comparable to the values report in literature. Preformulation study of Isotretinoin was performed, partition coefficient of the drug was found to be 5.6 (octanol/phosphate buffer). To rule out the physical incompatibility between the Isotretinoin and the excipients, blends of the drug and excipients were kept under varied temperature conditions for one month. The formulations were evaluated for their physical appearance, homogenecity, % drug content, pH, Spread ability, *in vitro* drug release and stability study. The pH of the formulation was found in the normal range 5.8-6.8, without produce any skin irritation, IE2 formulation showed highest spread ability 23.56 g.cm/sec, also have high percentage of drug content in IE2 formulation 92.02%. All formulations are transparent, homogeneous and have good consistency, alcoholic smell, free from stickiness and phase separation. IE1 emulgel formulation has highest viscosity 14500 cos. The *in vitro* release of prepared Isotretinoin emulgel have 80% of drug release and all the formulations are stable in 2-6 °C, 25 °C and 40 °C temperature. The topical anti acne emulgel of Isotretinoin was successfully formulated and evaluated for different parameters. The result indicate that the active component Isotretinoin is more effective when subjected in emulgel formulation and produces effective anti-acne activity in the management of nodulosystic acne vulgaris.

Keywords: Formulation, isotretinoin, anti-acne activity, Emulgel, sebaceous gland, Carbopol 934.

Introduction
Many people suffer from the most common disorder of skin is called acne vulgaris. The treatment of acne is aimed to reduce the rate of sebum production, reduce bacterial population in sebaceous follicle and reduce mild to moderate form of acne. Severe form of acne treated orally and mild to moderate acne is topically treated. Formulation of a topical emulgel to deliver the drug per cutaneous for the treatment of acne where systemic therapy is not show desired therapeutic effects. Some drugs have a poor absorption through intact skin incorporate of a penetration enhancer to increase the permeation of the drug through the skin & its therapeutic activity [1].

Acne is a skin condition that occurs when your hair follicles become plugged with oil and dead skin cells. It is most common among teenagers, thought it affects people of all ages. It often causes whiteheads, blackheads or pimples and usually appears on the face, forehead, chest upper back and shoulders. Acne is usually treatable, need several months to treat clear spots. Closed plugged pores (Whiteheads), Open plugged pores (Blackheads), Small red, tender bumps (papules), Pimples (pustules), which are papules with pus at their tips, Large, solid, painful lumps beneath the surface of the skin (nodules), Painful, pus-filled lumps beneath the surface of the skin (cystic lesions). Topical drug administration is simplest and easiest route of localised drug delivery anywhere in the body by route as ophthalmic, rectal, vaginal and skin. These are applied as wide spectrum of preparation in case of both cosmetic and dermatological, to the healthy or diseased skin. The formulations are available in different forms like from solid through semisolid to liquid [2, 3]. Drugs are administered topically for their action of the site of application. Drug absorption is enhanced through the skin if the drug substance is in solution, if it is a favorable lipid/water partition coefficient and if it is a non electrolyte.

Mostly pharmaceutical preparation applied to the skin are expected to serve some local action and are formulated to provide prolonged local action include antiseptic, antifungal agent, skin emollient and protectants. Topical delivery system proves beneficial by bypassing first passing metabolism. Avoidance of the risks and inconvenience of intravenous therapy and of condition of absorption like pH changes, presence of enzymes, gastric emptying time are other exe. of topical preparation.

Gels being newer class of dosage form are created by large amounts of aqueous or hydrophilic alcoholic liquid in a network of colloidal solid particles. For dermatological use emulgel show several favorable properties such as being thyrotrophic, greaseless, easily spreadable, easily removable, emollient, transparent & pleasing appearance of the factors that influence percutaneous absorption. Molecules can basically penetrate into skin by three routes through intact stratum corneum through sebaceous follicle. The surface of stratum corneum presents more than 99% of the total skin surface available for percutaneous drug absorption.

An emulsion based approach is being used so that a hydrophobic therapeutic moiety can be fruitfully incorporated and delivered through gels. When gels and emulsions are used in unites form, the dosage forms referred as emulgel. Emulgel is emulsions, either of the oil in water or water in oil type, which is gelled by mixing with a gelling agent. Both oil-in-water & water in oil emulsion are extensively used for their therapeutic properties and as vehicle to deliver various drugs to the skin. Emulsions possess a certain degree of elegance and are easily washed off whenever desired. They also have a high ability to penetrate the skin. In addition, the formulator can control the viscosity, appearance and degree of greasiness of cosmetics or dermatological emulsion. Oil-in-water emulsion are most useful as water washable drug bases and for general cosmetic purposes, while water-in-oil emulsion are most useful as water washable drug based and foe cosmetics purpose, while water-in-oil emulsion are employed more widely for the treatment of dry skin and emollient application [4, 5].

Materials and Equipment's

Materials: Isotretinoin was obtained from Samex Overseas Pvt. Ltd. Surat (Gujrat); All other chemicals used were of analytical grade and were used without any further chemical modification.

Equipment's: Weighing balance (Schimadzu) BL-220H, Melting point Apparatus (BTI-34), Heating Mantle, Magnetic stirrer (REMI), Digital pH meter (Chemiline-CL110), Brookfield Viscometer (LV DV-E), UV-Visible double beam spectrophotometer (2203).

UV spectrophotometric analysis of Isotretinoin:

Preparation of buffer solution: To prepare 5.8pH phosphate buffer solution, dissolve 0.4 gm of NaOH in 50ml water & make 0.2 M NaOH solution & dissolve 1.36 gm of KH2PO4 in 50 ml of distilled water, make 0.2 M KH2PO4 solution. Take 3.6 ml of NaOH solution and 50 ml of KH2PO4 solution and mix well. Make up the volume up to 200 ml with distilled water.

Preparation of stock solution and standard solution: Add 65 ml of above phosphate buffer solution and in 35 ml of ethanol at the ratio of 65:35 and make 100 ml stock solution and make stock solution concentration was 30 µg/ml to determine the λmax of Isotretinoin spectrum scan by UV-Visible spectrophotometer at 355nm.

Preparation of Calibration curve of Isotretinoin with chloroform: Weight 10 mg Isotretinoin and dissolve 10 ml of chloroform and make 1000 µg/ml solution. Then take 1 ml of above solution and volume make up 10 ml with chloroform (100µ/ml). Take 0.5, 1, 1.5, 2, 2.5, 3, 3.5 and 4 ml of above solution and make up the volume of 10 ml individually dilutions, the concentrations are 5, 10, 15, 20, 25, 30, 35 and 40 µg/ml. Plot the calibration curve of these different concentrations dilution by UV-Visible spectrophotometer at the range of 200-400 nm.

Preparation of calibration curve of Isotretinoin in ethanol: Phosphate buffer pH 5.8: Weight 10 mg Isotretinoin and dissolve 10 ml of phosphate buffer solution pH 5.8 and make 1000 µg/ml solution. Then take 1 ml of above solution and volume make up 10 ml with buffer solution (100 µ/ml). Take 0.5, 1, 1.5, 2, 2.5, 3, 3.5 and 4 ml of above solution and make up the volume of 10 ml individually dilutions, the concentrations are 5, 10, 15, 20, 25, 30, 35 and 40 µg/ml. Plot the calibration curve of these different concentration's dilution by UV-Visible spectrophotometer at the range of 200-400 nm.

Fourier transform infrared spectroscopy (FTIR): The FTIR spectroscopy study of Isotretinoin drug sample was conducted with the help of FTIR spectrometer and spectra were recorded in the range of 4000-400 cm^{-1}.

Determination of Partition coefficient of Isotretinoin: Partition coefficient is a measurement of drug's lipophilicity and its ability to cross cell membrane. For determination of the partition coefficient of Isotretinoin, add 10ml octanol in 5ml phosphate buffer solution 7.4pH and shake for 10min. Then stay for one hour. After 1 hour the organic phase has separate and discard the aqueous phase. Add 10 ml phosphate buffer solution in 5 ml octanol and stay at 1 hour. After that the aqueous phase has separate and discard the oil phase. Take 10 ml of organic phase in a separating funnel and add 10mg of drug Isotretinoin, shake for 10 min. Then add 1ml of saturated aqueous phase and shake for 15 min. The solution has stay for 12 hours without disturbing, After that separate both oil (organic) phase and aqueous phase. Scan the spectrum of both phases by UV visible spectrometry at 200-400nm.

Solubility: The maximum amount of a Isotretinoin drug sample that can be dissolved in different solvents as chloroform, ethanol, phosphate buffer solution, ethanolic buffer solution and water at room temperature to make saturated solution. The solutions was placed in mechanical shaker for 24 hours and filtered all samples and then determine the absorbance by UV-Visible spectroscopy at 200-400nm.

Drug excipients compatibility study: The study was performed to determine any physical change in the drug when kept in contact with other excipients. Drug was mixed with various excipients and kept in glass vials properly.

Capped and sealed with aluminum foil. One vial of each sample kept in room temperature and the second vial kept in an oven at 40 °C for one month. After every week the vials were withdrawn and any change in physical appearance and colour of the samples were observed. The observations were recorded

Melting point determination: Melting point of Isotretinoin was determined using open capillary tube method. Drug powder was filled in a capillary tube at the 3mm high, place the capillary tube in the melting point apparatus. Set the apparatus at the high enough level to make a rapid determination of M.P. Observe the melting process through the magnifying lens, observed the temperature when drug sample was melted.

Inference: The procured sample of Isotretinoin was characterized by FTIR spectroscopy, UV-Visible spectrophotometer and Melting point determination studies. The results of the analysis were found matching with the values reported in the literature for Isotretinoin.

Hence it was inferred that the procured drug sample of pure Isotretinoin and hence used for further studies.

Table 1: Formula of Emulgel

S. No.	Name of ingredients	IE1	IE2	IE3	IE4
1	Isotretinoin	0.05	0.05	0.05	0.05
2	Span 20	2	2	5	5
3	Tween 20	5	5	4	4
4	Carbopol 934	1	1.5	2	2.5
5	Propylene glycol	5	5	5	5
6	Methyl paraben	0.3	0.3	0.3	0.3
7	Propylene paraben	0.2	0.2	0.2	0.2
8	Light liquid paraffin	7.5	7.5	5	5
9	Ethanol	2.5	2.5	2.5	2.5
10	Water	76.45	75.95	75.95	75.45
11	Tri ethanol amine	Adjust pH 5.8 to 6.8			

Preparation of Emulgel: The oil phase of the emulsion was prepared by dissolving span 20 in light liquid paraffin and the aqueous phase was prepared by dissolving tween 20 in purified water with stirring. Methyl paraben & propyl paraben were dissolved in propylene glycol whereas Isotretinoin was dissolved in ethanol and both solution were mixed in the aqueous phase. Oil phase & aqueous phase were separately heated to 70-80 °C & then the oily phase was added to the aqueous phase with continuous stirring until it got cooled at room temperature. Gel was prepared using Carbopol 934 as a gelling agent and add a sufficient quantity of distilled water with constant stirring at a moderate speed using mechanical shaker & the pH was adjusted to 6-6.5 by the use of triethyl amine (TEA). Finally add emulsion in the gel formulation with constant stirring & the emulgel was prepared [6-8].

Evaluation of Emulgel

Physical examination of Isotretinoin emulgel formulation: The emulgel formulations were inspected visually for their color, odour, appearance, homogeneity, phase separation, consistency (texture analysis) and drying time.

pH determination of emulgel formulation: To determine the pH of emulgel, 1gm emulgel was accurately weighed & dispersed in 100 ml of distilled water & was measured using digital pH meter which was calibrated before use with standard buffer solution. Measurement was done in triplicate averages were calculated. The pH of all emulgel formulations in range 5.8-6.8 in which the normal range of the skin and would not produce any skin irritation.

Spreadability study of emulgel formulation: Spreadability denotes the extent of area to which the emulgel readily spreads on application to the skin or affected part. Bioavailability of emulgel also depends on its spreading value. Spread ability of the formulation was measured as 0.5 gm of emulgel was placed within a circle of 1cm diameter on a glass plate of 4 cm, over which second glass plate was placed. A weight of 20 gm was placed on the upper slide for 5 min. the time required increase in the diameter due to emulgel spreading was measured by using following formula: S = M.L/T

Where, S is spredability
M is weight tied of upper slide L is length of glass slide
T is time taken

Determination of drug content of formulated emulgel: To a quantity of emulgel formulation containing 0.5 mg Isotretinoin and added 10 ml of dichloro methane, shaken gently with glass rod until the emulgel has dispersed and solution was transferred into volumetric flask dilute the solution to 100 ml with 5 ml of 0.1 M HCl with ethanol (96%). The obtained solution was filtered using Whatman filter paper. Measured the absorbance of the solution at maximum at about 360 nm using ethanolic hydrochloric solution in the reference cell and drug content calculate using absorbance. The experiment was repeated for 5 times and average value calculated by drug content calculation.

Evaluation of Stickiness of emulgel: Stickiness of emulgel was evaluated that after application of the small quantity of the Isotretinoin emulgel checking whether there was the presence or absence of stickiness.

Evaluation of odour of emulgel formulation: The evaluation of odour of emulgel formulation was done by checking odour of formulation to 5-6 volunteers and then considered the odour were acceptable, non-acceptable and alcoholic.

Viscosity study of emulgel formulation: The viscosity of the formulation was determined as such without dilution by Rheometer (Brookfield viscometer). The values obtained for

the sample and for water were noted. The preparation was placed in the beaker and allowed to settle down at the room temperature, spindle was then lowered down and rotated at 2, 5, 10 and 12 rpm. The viscosity in centipoises was observed & reported.

Brookfield factor finder was used as follows:
Dial reading x factor = Viscosity in centipoises (mpa s)

Skin irritation test of emulgel: Skin irritation test for emulgel formulation was conducted over skin of human volunteers the study was conducted by taking volunteers consent. Healthy 5 human volunteers were selected for the skin irritation test. The prepared emulgel formulation was applied on the skin of hand and observed for any type of undesirable effects (skin changes) i.e. change in colour, change in skin morphology and inflammation of the skin.

***In vitro* drug release (skin permeation) study by Franz diffusion cell:** *In vitro* drug release through skin permeation study carried out using the Franz diffusion cell, the formulation was applied on dialysis membrane& placed between receptor and donor compartment of the Franz diffusion cell the donor compartment was open at the top and was exposed to atmosphere. For *in vitro* diffusion the mixture of phosphate buffer pH5.8: Ethanol (65:35) v/v was used as a dissolution media.
The dialyzing membrane was soaked in phosphate buffer 24 hrs. before use. Temperature maintained at 37°C by water circulating jacket. The assembly was kept on a magnetic stirrer for 6 hours and solution continuously stirring by a magnetic bead. A similar blank set was assembled with fresh dissolution media. After that 2 ml of phosphate buffer solution withdrawn through syringe and replaced with fresh phosphate buffer solution. The time interval was maintained as 15min, 30 min, 1hr and 2hrs, up to 6 hr. The samples were analyzed by spectrophotometer at 355 nm & drug release percentage was calculated.

Stability studies of the emulgel formulation: Determine stability study of emulgel formulation by keeping the sample at 40 °C, 25 °C and 2-4 °C and sample were withdrawn on at a regular interval of one month for evaluation of physical changes in sample and checked the sample every week of an interval period note the changes of emulgel [9-13].

Results and Discussion

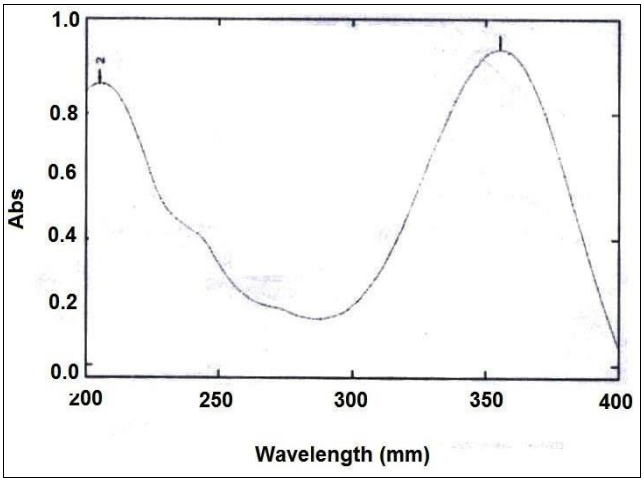

Fig 1: Ultraviolet spectrum of Isotretinoin

Results: The Isotretinoin drug sample exhibited λmax at 355 nm which was comparable to the reported value.

Table 2: Calibration curve of isotretinoin with chloroform

S. No.	Concentration (µg/ml)	Absorbance
1	0	0.0
2	5	0.134
3	10	0.265
4	15	0.310
5	20	0.389
6	25	0.476
7	30	0.521
8	35	0.619
9	40	0.752

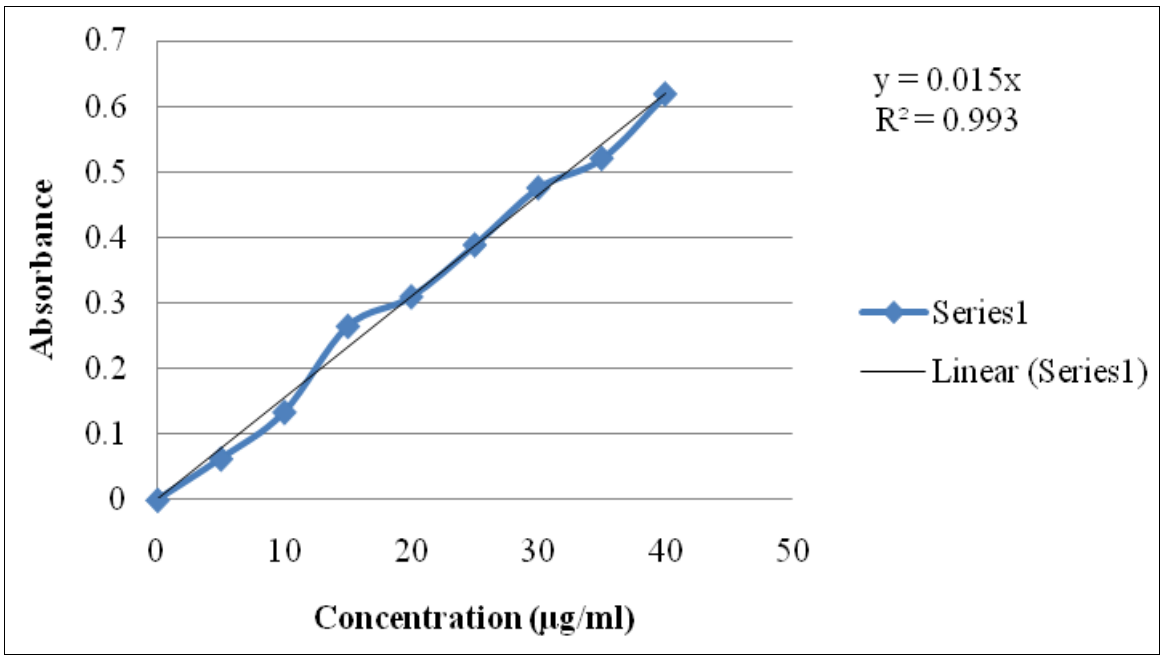

Fig 2: Standard calibration curve of Isotretinoin with chloroform

Results: Calibration curve of Isotretinoin in chloroform was plotted at 360 nm. The linearity of the graph showed that the Beer's law was obeyed in the concentration range of 5-40 µg/ml with regression value of 0.993.

Table 3: Calibration curve of Isotretinoin in ethanol: phosphate buffer pH 5.8

S. No.	Concentration µg/ml	Absorbance
1	0	0
2	5	0.139
3	10	0.236
4	15	0.332
5	20	0.469
6	25	0.586
7	30	0.657
8	35	0.712
9	40	0.799

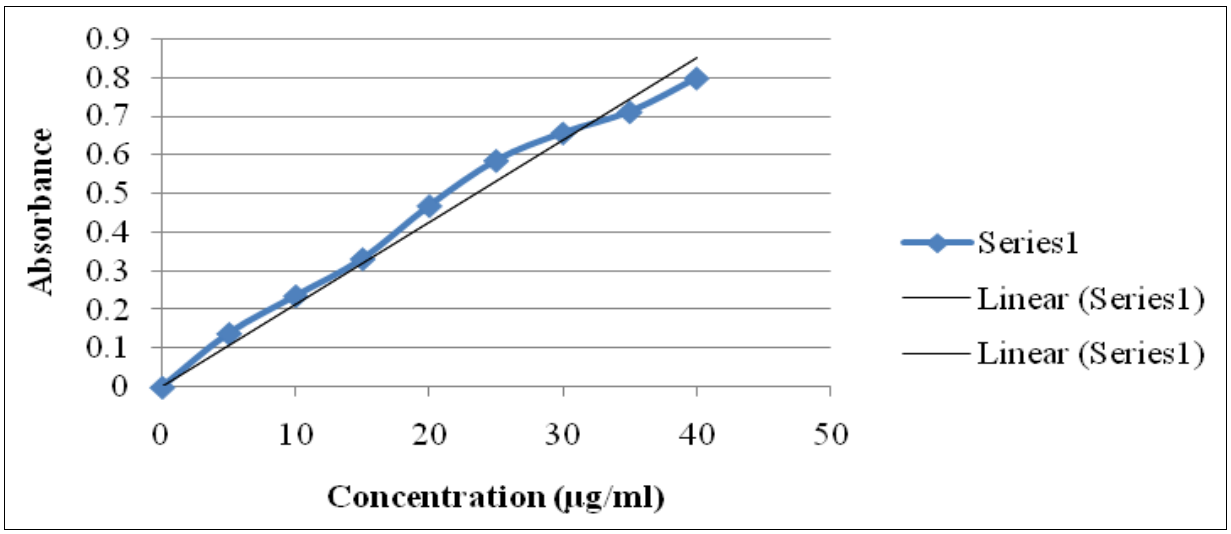

Fig 3: Standard calibration curve of Isotretinoin with Ethanolic phosphate buffer

Result: Calibration curve of Isotretinoin in ethanolic phosphate buffer (35:65), pH 7.4 was plotted at 360 nm. The linearity of the graph showed that the Beer's Lambert's law was obeyed in the concentration range of 5-40 µg/ml with regression value of 0.982.

Table 4: Characteristics IR Absorption frequencies of Isotretinoin drug sample

S. No.	Functional group	Type of Vibration	Absorption	Intensity
1	C-O	stretch	1050-1150	strong
2	C-H	stretch	2850-3000	strong
3	-C-H	bending	1350-1480	variable
4	=C-H	bending	675-1000	strong
5	C=C	stretch	1620-1680	variable
6	C-F	stretch	1000-1400	strong
7	C-Cl	stretch	600-800	strong
8	C-N	stretch	1080-1360	Medium-weak
9	C=C	stretch	1400-1600	Medium-weak, multiple bands
10	C=O	stretch	1670-1820	Strong

Results: The IR spectrum of drug sample had shown corresponding peaks to the chemical structure of Isotretinoin

Table 5: Drug excipients physical compatibility study

S. No.	Drug excipients blend ratio	Initial description on	Room temperature (25 °C)				Temperature at 40 °C			
			1 Week	2 Week	3 Week	4 Week	1 Week	2 Week	3 Week	4 Week
1	Isotretinoin: Carbopol	Orange in color	NC	NC	NC	NC	NC	NC	NC	NC
2	Isotretinoin: Liquid paraffin	Orange in color	NC	NC	NC	NC	NC	NC	NC	NC
3	Isotretinoin: Propylene glycol	Orange in color	NC	NC	NC	NC	NC	NC	NC	NC
4	Isotretinoin: Tween 20	Orange in color	NC	NC	NC	NC	NC	NC	NC	NC
5	Isotretinoin: Span 20	Orange in color	NC	NC	NC	NC	NC	NC	NC	NC
6	Isotretinoin: Propyl paraben	Orange in color	NC	NC	NC	NC	NC	NC	NC	NC
7	Isotretinoin: Methyl paraben	Orange in color	NC	NC	NC	NC	NC	NC	NC	NC
8	Isotretinoin: Ethanol	Orange in color	NC	NC	NC	NC	NC	NC	NC	NC

NC= No Change

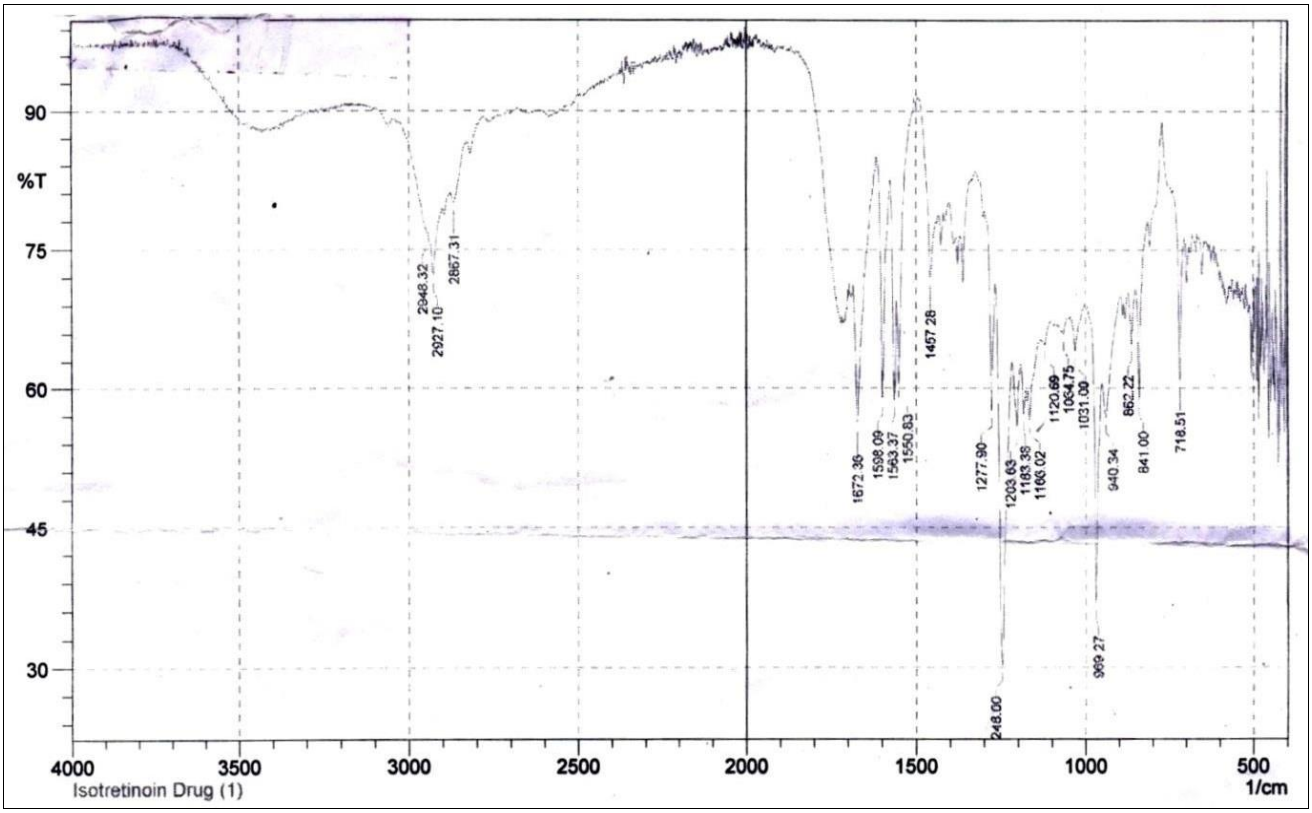

Fig 4: Infrared spectrum of Isotretinoin

Results: In one-month compatibility study no changes were observed in the color and other physical characteristics of the drug and excipients. This showed that the drug and excipients used in the study were compatible and can be used for the further formulation development studies.

Physical Examination of Isotretinoin emulgel: The physicochemical properties of the emulgel formulation are shown in Table 6. From the results it is evident that all the emulgel formulations showed good homogeneity, smooth as texture and transparent in physical appearance.

Table 6: Physical evaluation of Emulgel formulations

S. No.	Formulation code	Drying Time in min	Physical appearance	Homogenecity	Consistency	Skin irritation	Phase separation
1	IE 1	5	Transparent	Homogeneous	Good	None	None
2	IE 2	7	Transparent	Homogeneous	Good	None	None
3	IE 3	8	Transparent	Homogeneous	Excellent	None	None
4	IE 4	10	Transparent	Homogeneous	Excellent	None	None

pH determination: The pH of Isotretinoin emulgel formulation was in the range of 5.8-6.8, which lies in the normal pH range of the skin. It doesn't produce any skin irritation. There was no change in pH values as a function of time for all emulgel formulations in Table 7.

Table 7: pH determination of emulgel

Formulation code	pH
IE 1	5.8
IE 2	5.9
IE 3	6.2
IE 4	6.4

Table 8: Spreadability of emulgel formulation

Formulation	Spreadability gm cm/sec
IE1	20
IE2	23.56
IE3	22.78
IE4	24

Spreadability of emulgel: The Spreadability of emulgel was evaluated to test the ease of application of emulgel on skin, the Spreadability of the emulgel formulations was between 20-24 gm cm/sec in Table 8.

Determination of drug content of Isotretinoin emulgel formulation: The result of drug content was listed in Table 9, determination of percentage drug contents of prepared emulgel was done by UV spectrophotometer. The observed absorbance data was measured and calculated percentage drug content. The drug content of emulgel formulation was found to be uniform among various formulations prepared and was found to be in range 83.56-92.01%.

Table 9: Drug content of Isotretinoin emulgel

S. No	Formulation	Drug content %
1	IE1	87.32%
2	IE2	92.02%
3	IE3	83.56%
4	IE4	85.44%

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Stickiness evaluation of emulgel formulation: Stickiness evaluation of Isotretinoin emulgel formulation was listed in Table No. 10, From this, it was clear that emulgel of

Isotretinoin was free from Stickiness after application and it was freely spread on the skin.

Table 10: Stickiness evaluation of emulgel

S. No	Formulations	Presence or absence of Stickiness
1	IE1	Absence of Stickiness
2	IE2	Absence of Stickiness
3	IE3	Absence of Stickiness
4	IE4	Absence of Stickiness

Odour of emulgel formulation: The odour of Isotretinoin emulgel formulation was evaluated by checked it through 5-6 volunteers and then it was considered as acceptable, non-acceptable or alcoholic odour. Show in Table 11.

Table 11: Odour evaluation of emulgel

S. No	Formulations	Odour		
		Alcoholic	Acceptable	Non-acceptable
1	IE1	++	+	-
2	IE2	++	+	-
3	IE3	++	+	-
4	IE4	++	+	-

Table 12: Viscosities of emulgel formulation

Formulations	Viscosity (CP.S)
IE1	14500
IE2	10300
IE3	8600
IE4	1498

Viscosity of Isotretinoin emulgel formulation: The viscosity of all emulgel formulations was evaluated by Brookfield Viscometer. The viscosity of IE4 is less as compared to other formulations shown in Table 12.

Table 13: Cumulative percentage release of Isotretinoin emulgel formulation

S. No	Time (min)	Cumulative percentage drug release			
		IE1	IE2	IE3	IE4
1	0	0.0	0.0	0.0	0.0
2	15	1.45	1.1	0.96	1.8
3	30	9.94	15.37	12.9	14.67
4	60	24.5	23.49	20.86	24.83
5	120	41.6	35.43	31.82	36.29
6	180	51.77	43.71	36.13	42.52
7	240	64.1	58.65	51.88	48.49
8	300	70.59	65.27	63.76	64.41
9	360	78.49	79.19	70.70	80.12

***In vitro* drug release study:** The *in vitro* drug release study shows percentage release pattern of the anti-acne emulgel of Isotretinoin (0.05% w/w). The highest drug release percentage is 80.12 of IE 4 formulation.

Stability study of the emulgel formulation of Isotretinoin: The result of the Stability study shows in Table 14 the data indicates that emulgel formulation is stable for one-month study period.

Table 14: The Stability study of Isotretinoin emulgel formulation

S No.	Storage condition	Assay %				
		0 day	1 week	2 week	3 week	4 week
1	40°C	99.90	99.31	98.58	97.49	96.45
2	25°C	99.98	99.94	99.52	98.60	98.39
3	2-5°C	99.96	99.74	98.81	98.76	98.57

Conclusions

The emulgel formulation of Isotretinoin showed promising characteristics such as good homogeneity, spreadability, and drug release, making it a potential candidate for acne treatment. Further studies are needed to evaluate its efficacy and safety in clinical settings.

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