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Formulation and Evaluation of Proniosomal Transdermal Gel of Drug Luliconazole

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ABSTRACT

The aim of the study was formulation and evaluation of a proniosomal gel as a vesicular drug delivery system for improving stability and sustaining of drug release of Luliconazole, an antifungal drug. Initial studies focussed on the formulation parameters that impact the manufacturing process by using non-ionic surfactant and then evaluation parameters for optimization of formulation. Proniosomal gel was prepared by using Coacervation-phase separation method. The formulation of Luliconazole proniosomal gel was prepared using Tween 80, Tween 20 and Span 80 in four different batches. The drug excipients compatibility studies were carried out and FTIR revealed that the drug and excipients used were compatible with each other. This study came up with the affirmation that the proniosomal vesicles are valuable as transdermal drug delivery for Luliconazole to sustaining the drug release and intensify the stability of formulation. Proniosomal gel formulation KT02 containing Span80, cholesterol, methanol, chloroform showed highest drug release 94.04%.

Keywords: Vesicular delivery, Proniosome, Luliconazole, Evaluation, Characterization, FTIR

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INTRODUCTION

Proniosomal gels are generally present in transparent, translucent or white semisolid gel texture, which makes them physically stable during storage and transport. Due to the limited solvent system present, the proniosomes formed were the mixture of many phases of liquid crystal, viz. lamellar, hexagonal and cubic phase liquid crystals as given in dissolution of most surfactants in water, leads to the formation of lipotropic liquid crystals rather than micelle solution. Lamellar phase shows sheets of surfactants arranged in bilayer form, whereas in hexagonal phase cylindrical units are packed in hexagonal fashion. Cubic phase consists of curved bio-continuous lipid bilayer extending in three dimensions, separating two congruent networks of water channels. These liquid crystals present an attractive appearance because of their, transparency and high viscosity, although in the beginning of its formation, a short range of less viscous compositions (so called liquid/gel compositions) appear in some cases. Addition of water leads to interaction between water and polar groups of the surfactant results in swelling of bilayers.

When the concentration of solvent is increased above a limited value, the bilayer tends to form random spherical structures, i.e., multilamellar, multivesicular structures. When shaken with water i.e., the aqueous phase of water, complete hydration takes place leading to the formation of niosomes. The beauty of these proniosomes lies in their ability to rearrange as stable niosomal suspensions, on hydration with water.

MATERIALS AND METHOD:

Materials:

Luliconazole pure sample was procured as a gift sample from V-Kas Healthcare Roorkee, India. Other excipients are Non-ionic surfactants such as Span 80, Tween 80 and Tween 20, Cholesterol, Methanol, Chloroform, Glycerine.

Characterization of Proniosomal Gel:

Organoleptic properties:

The drug was examined for their organoleptic properties such as – colour, odour, taste etc.

Melting point:

The melting point of the drug was determined by using capillary method through the digital melting point apparatus by taking drug in capillary.

Solubility studies:

10 mg of Luliconazole was dissolved in 10 ml of different solvents i.e., water, ethanol, methanol and chloroform. Solubility was determined on the basis of their physical appearance.

Luliconazole found soluble in ethanol (90%), insoluble in methanol and formed precipitate in distilled water.

IR Spectroscopy:

IR spectroscopy was performed using Fourier-Transform Infrared Ray [FTIR] Spectrophotometer. The spectrum was recorded in the wavelength region of the pellets for the spectra were prepared by using dispersing Luliconazole in and compressed into disc. The pellet was then placed in the FTIR and the spectrum was recorded and compared with the standard FTIR of pure drug.

UV Spectroscopy:

The wavelength of maximum absorbance for the drug Luliconazole in distilled water and ethanol was determined with the help of UV-Visible Spectrophotometer. Prepared solutions of concentration 10 ug/ml were scanned in the range of 200-400.

Methods:

Method of preparation of Luliconazole loaded proniosomal gel using Coacervation-phase separation technique

Proniosomal gels were prepared by Coacervation-phase separation method with small modifications. In this preparation 12 different formulations were prepared by using numerous non-ionic surfactants such as – Span/Tween. The ingredients used to prepare proniosomal gel include – drug, surfactants, cholesterol were weighed accurately and transfer in a clean and wide mouth glass container of 5.0 ml volume and mix it well with the help of glass rod. After that add Chloroform 2ml to it and cover the container with aluminum foil to prevent the solvent loss and kept it on water bath, maintain the temperature at 60-65^{o}c and warm it until the surfactant gets liquefied in it. After warming, the glycerol solution was added into it and warmed again on water bath at 60^{o}c to form a clear solution. Then kept the solution for overnight in desiccator at room temperature until proniosomal gel formed and at another day clear proniosomal gel was obtained.

Table 1: Composition of various proniosomal gel formulation (mg)

Formulation	Drug	Span 60	Tween 80	Tween 20	Cholesterol	Chloroform
KT1	20	250	-	-	50	5
KT2	20	200	-	-	100	5
KT3	20	150	-	-	150	5
KT4	20	100	-	-	200	5
KT5	20	-	250	-	50	5
KT7	20	-	150	-	150	5
KT8	20	-	100	-	200	5
KT9	20	-	-	250	50	5
KT10	20	-	-	200	100	5

KT11	20	-	-	150	150	5
KT12	20	-	-	100	200	5

Evaluation of proniosomal gel

Spreadability:

The Spreadability of the gel formulation was determined at 24 hrs. after preparation, by measuring the spreading diameter of 1gm gel between two horizontal plates [20 x 20 cm^2] after 1 min. The standardized weight toed on the upper plate. The Spreadability was calculated by using the following formula

$$[S = M \times L/T]$$

Entrapment efficiency:

To find out the entrapment efficiency, the entrapped drug in proniosomal gel was separated by dialysis, centrifugation and gel filtration.

Table 2: Different methods for the separation of entrapped and unentrapped drug

Separation method	Advantages	Disadvantages
Exhaustive dialysis	Suitable for large vesicles > 10 micrometres, suitable for highly viscous systems, inexpensive	Extremely slow (5-24 hrs.), Large volume of dialysis required
Centrifugation	Process is fast, Cheap instrument	Fails to sediment the sub-micron dispersion, which may lead to the destruction of fragile systems
Gel filtration	The process is fast	Gels are expensive, not suitable for highly viscous formulations

Drug Content:

This is determined by dissolving 0.1 g of gel in 50 ml of phosphate buffer solution, pH 6.8. Then make dilutions of this solution by transferring 1 ml of this solution into a volumetric flask of 10 ml capacity, and the final volume was made up by phosphate buffer, and then the absorbance of the prepared solution was measured using UV UV-visible spectrophotometer.

In-Vitro Drug Release Studies:

The in-vitro release of the drug Luliconazole from the prepared proniosomal gel was determined using the membrane diffusion technique. A certain weight of the prepared proniosomal gel equivalent to 2 mg of the drug Luliconazole was transferred to a glass cylinder having a length of 10 cm and a 2.5cm diameter, fixed at its lower end with a pre-soaked cellulose membrane on which the gel was poured. The glass cylinder was attached to the shaft of the dissolution apparatus and then suspended in the dissolution flask of a USP dissolution apparatus containing 100 ml of Methanol kept at a temperature of 37 0.5°c. The glass cylinder was allowed to rotate at a constant speed of 25 rpm. Aliquots of 5 ml sample were withdrawn periodically, and after

each withdrawal, the same volume of medium was replaced. The collected samples were analyzed using a UV spectrophotometer at 225 nm.

Permeation Analysis:

The permeation profile of the gel was drawn by plotting the cumulative amount of Luliconazole permeated per unit dialysis membrane area vs. time. The steady state of Luliconazole was calculated from the slope of the plot using linear regression analysis. The permeability coefficient of the drug through the membrane was calculated by the equation given below –

$$[Kp = \frac{Jss}{C}]$$

Drug Release Kinetics:

Data obtained from in Vitro release studies were fitted to various kinetic equations to determine the mechanism of drug release from the gel. The dissolved amount of the drug is a function of time. To determine the drug release mechanism, the following mathematical expressions were employed.

Zero-Order Model

In this case, the drug release is at a constant rate.

$$[M_t = M_0 + K_0 t]$$

Here, M_t = the amount of drug release at time t

K_0= zero-order constant

M_0= initial amount of drug in the solution in a result of a breakout in effect

First-Order Model

In this case, the drug release in each and every time is directly proportional to the residual drug inside the dosage form.

$$[\ln M_t = \ln M_0 + K_1 t]$$

Here, K_1= first-order release rate constant

Higuchi Model

This is the most extensively used model to explain drug release from pharmaceutical sources.

$$[M_t = M_0 + K_H t^{1/2}]$$

Here, M_t = amount of drug release at time t

K_H = Higuchi release rate

Korsemayer-Peppas Model

$$[M_t/M_1 = M_0/M_1 + K_{KP}\, t^n]$$

Here, K_{KP} = constant including structural and geometric characteristics

n = release exponent

RESULTS AND DISCUSSION:

Characterization of the drug:

Table 3: Properties of Luliconazole

Sr. No.	Properties	Official Specification	Experimental Value
1	Appearance	An off-white to pale yellow, crystalline powder	White, Crystalline powder
2	Melting point	152°c	150°c
3	Solubility	Freely soluble in dimethyl formamide and acetone, soluble in acetonitrile and methanol, sparingly soluble in ethanol, and practically insoluble in water.	Freely soluble in dimethyl formamide and acetone, insoluble in methanol, sparingly soluble in ethanol, practically insoluble in water.

FTIR Spectroscopy:

From the FT-IR spectroscopic study, all characteristic peaks of drug Luliconazole were present in the spectrum of the drug and the polymer solution, indicating affinity between the drug and polymer. All spectra were recorded over the wave number range of 4000-700cm^{-1}. Major peaks observed were shown in the table given below –

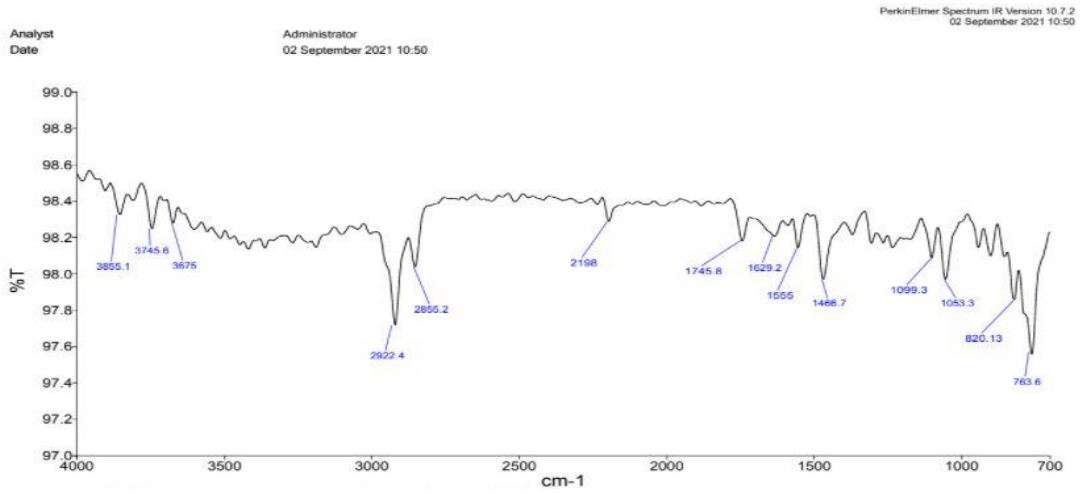

Figure 1: IR Spectra of Drug Luliconazole

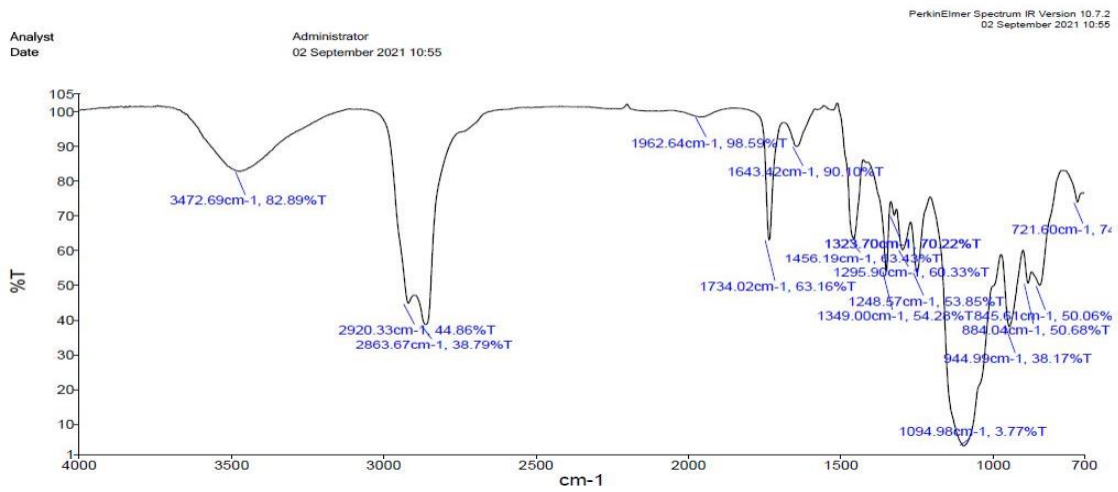

Figure 2: IR Spectra of Drug Luliconazole + Non-ionic surfactants

Table 4: Interpretation of IR Spectra of Drug Luliconazole

S. No.	Functional Group	Standard wave no. (cm^{-1})	Reference wave no. (cm^{-1})
1.	C≡N Stretch	2100-2400	2198
2.	C=N Stretch	1600-1700	1555
3.	C=C Aromatic	1450-1680	1466.7
4.	C-Cl Stretch	600-800	820.1, 763.6
5.	C-H Aliphatic	2700-3300	2855.2, 2922.4
6.	N-H Stretch	3000-3700	3675, 3745.6

UV Spectrophotometric method:

Table 5: Summary of validation parameters for UV method

Parameters	Results
Linearity and Range	4-16 ug/ml
Correlation Coefficient	0.9996
Accuracy	99.86-101.37%

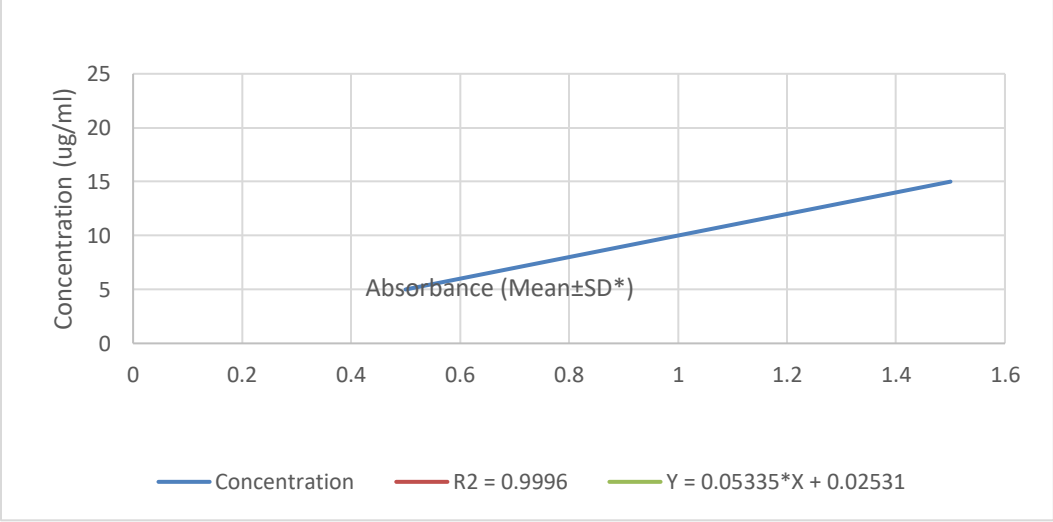

Figure 3: UV-Visible method-based standard Plot of Luliconazole

Evaluation of Proniosomal Gel:

Drug Content: The drug content of the Luliconazole proniosomal gel was found to be 89.87 ± 1.4% to 96.07 ± 0.1% and tabulated in the table given below.

Table 6: Drug content study

Formulation Code	Drug Content (%v/w)
KT01	95.44 ± 0.014
KT02	97.05 ± 0.027
KT03	93.85 ±0.050
KT04	94.89 ± 0.035
KT05	97.25 ± 0.034
KT06	96.52 ± 0.052
KT07	93.45 ± 0.034
KT08	89.18 ± 2.1
KT09	92.55± 2.6
KT10	89.87 ± 1.4
KT11	90.42 ± 2.6
KT12	89.52 ± 2.5

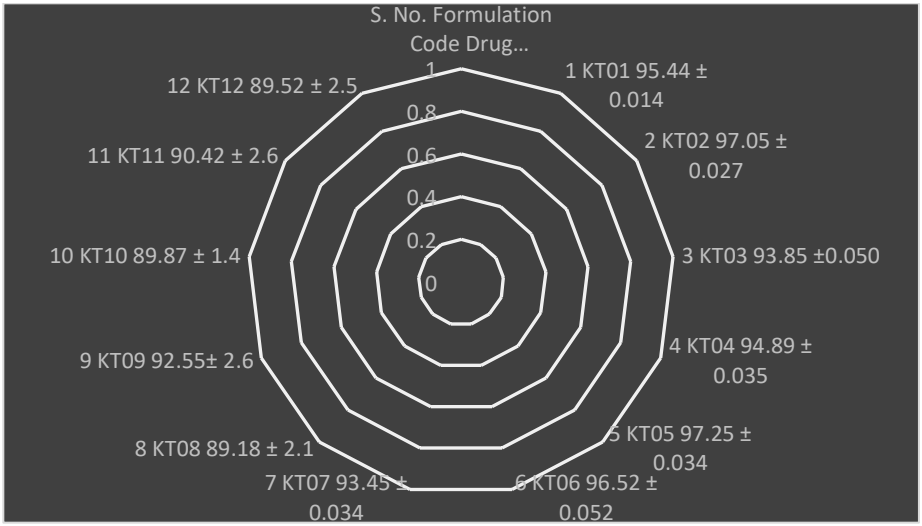

Figure 4: Drug Content Study

Spreadability Study of Luliconazole Gel:

All the formulated gel was evaluated for spreading diameter at 1 min, as a measure of rigidity. On increasing the concentration of the polymer, the Spreadability of gel formulations decreases.

Table 7: Spreadability Test for Gel Formulation of Drug

S. No.	Formulation Code	Spreadability ($gm.cm^2$)
1.	KT 01	11.15
2.	KT 02	11.04
3.	KT 03	11.19
4.	KT 04	10.45
5.	KT 05	11.80
6.	KT 06	11.18

In-Vitro Drug Release Kinetics:

A Diffusion experiment was performed in a 6.8 pH phosphate buffer solution for whole gel formulation for approximately 06 hours. Due to the drug release experiments, drug release from formulation KT02 was observed at the end of the 06th hour. The kinetics of drug release profiles were found by plotting different graphical models.

Table 8: In-Vitro drug release

Time in hours	KT01	KT02	KT03	KT04	KT05	KT06
1	6.12±0.34	7.57±0.44	5.15±0.17	6.67±0.25	5.05±0.09	6.15±0.31
2	11.52±0.46	14.72±0.52	11.12±0.39	13.22±0.52	12.06±0.34	11.89±0.78
3	19.45±1.02	22.07±0.59	20.06±0.54	21.07±0.67	19.72±0.76	20.92± 0.67
4	30.15±1.15	32.02±0.67	29.89±1.45	31.05±0.45	29.15±1.34	30.89±1.45
5	41.24±1.2	43.75±1.62	39.87±1.56	42.65±1.76	39.56±1.34	41.89±1.21
6	51.92±1.25	54.03±1.57	47.26±1.67	52.13±1.57	49.42±1.45	52.05±1.68

Table 9: Drug Release Kinetic Profile of Luliconazole Formulation KT02

Time in hours	√T	Log T	% Cumulative Drug Release	Log % Cum Drug Release	% Cum Drug Retained	Log % Cum Drug Retained
1	1.294	0.094	15.15	1.160	86.58	1.920
2	1.930	0.288	25.32	1.440	76.38	1.857
3	2.129	0.390	32.12	1.551	68.87	1.974
4	2.718	0.434	39.82	1.630	60.18	1.782
5	3.162	0.494	45.54	1.677	54.47	1.738
6	3.464	0.526	52.12	1.785	48.87	1.650

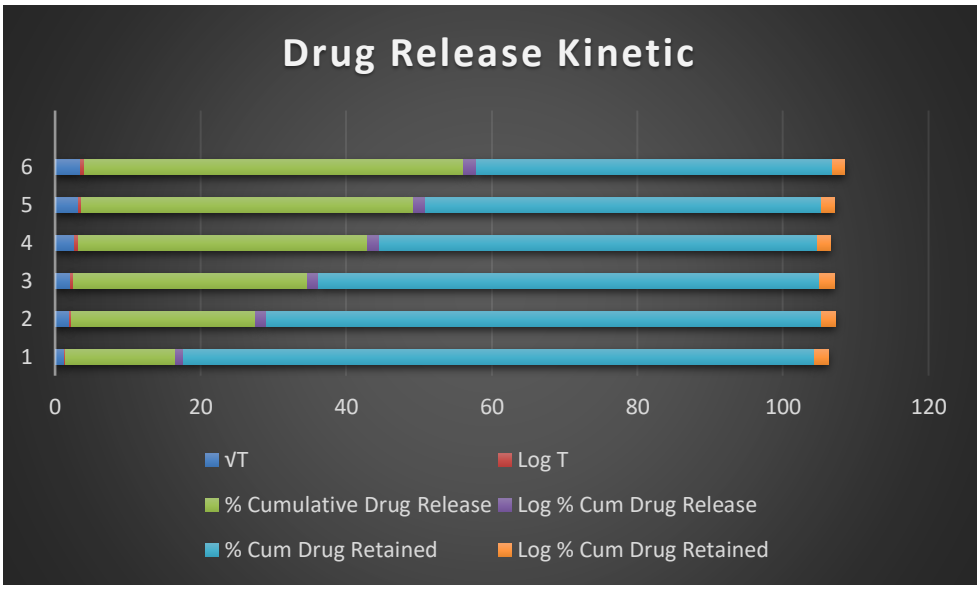

Figure 5: Drug Release Kinetics

Stability Study:

In order to discover the amount of drug content, a stability study test of Luliconazole drug proniosomal gel was carried out for 60 days. At the end of the last day, a stability test was

conducted on the developed formulation KT02. Although the drug quality of the formulation KT02 did not improve remarkably.

Table 10: Stability studies of Optimized KT02 formulation

Sampling Intervals in Days	Drug content 25°c/60% RH	Drug content 30°c /65%RH	Drug content 40°c /75%RH
1	95.67	95.67	95.67
15	97.19	97.27	97.31
45	98.16	98.12	98.49
60	98.32	98.39	98.41

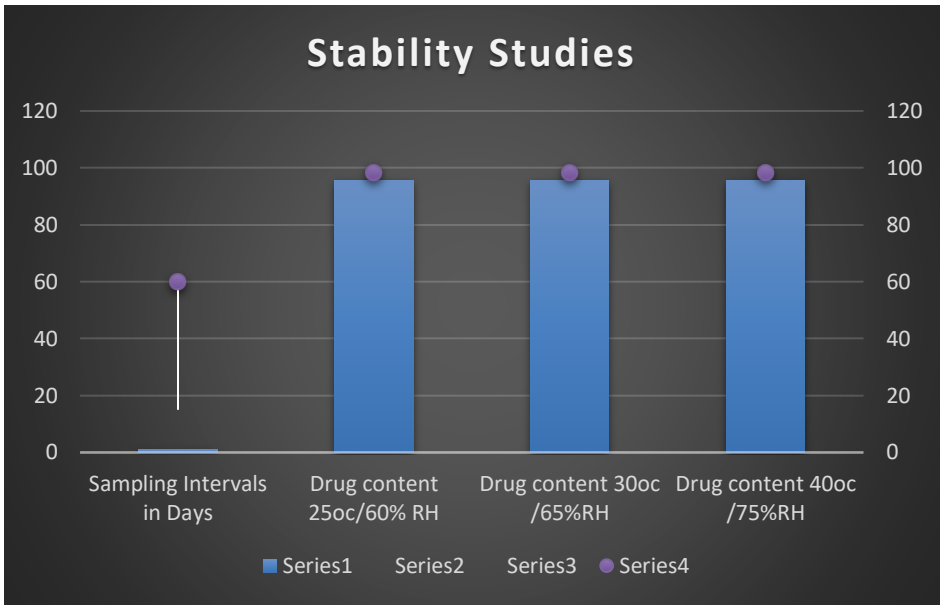

Figure 6: Stability Studies

CONCLUSION:

The present study was carried out to evaluate the antifungal activity of drug Luliconazole with different polymers. Formulation KT02 was selected as the optimized formulation and shows the highest drug permeation and good controlled release properties. Overall result of the present study indicated that drug Luliconazole proniosomal gel containing Cholesterol and Span 80 as surfactant produces prolonged release of the drug. The proniosomal gel could be another effective carrier for conveying the drugs through the transdermal route.

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