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Formulation and Evaluation of Terbinafine Hydrochloride Topical Hydrogel

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***Abstract*-- The development of topical hydrogel formulation is needed because it offers an alternative for oral route to aachieving systemic effect of drug. The main advantage of topical hydrogel is that it has ability to deliver drugs to a specific site (local action). Avoid GI Irritation. First pass metabolism, and increase bioavailability of drug.. The aim of this work was to prepare a hydrogel formulation using polymers like Carbopol-940(0.2,0.9,1.6% w/w, Aloe vera gel(1,2,3% w/w). Terbinafine hydrochloride Hydrogel was prepared with Aloe vera Gel and Carbopol 940 as gelling agents. The formulations evaluated for the pH, spread ability, consistency, viscosity, homogeneity, drug content and stability. From FTIR and DSC study found that there is no interaction between drug and excipients. In vitro drug release study was carried out using Franz diffusion cell. The viscosity of all formulation follows a pseudo-plastic flow behaviour. The pH of formulation Lies in between 5 to 7.Among all the preparations formulation F6 was found to be show the maximum drug release of 98.99% at end of 8 hour and other evaluation parameters within specified limits. In vitro drug release kinetics followed non-fickian diffusion. Aloe vera Gel and Carbopol 940 independent variables had a significant effect on the dependent variables (p-values < 0.05). The prepared Topical hydrogel showed higher antifungal activity than Marketed cream . Therefore, Terbinafine Hydrochloride in the form of Hydrogel has the ability to penetrate the skin, overcoming the stratum corneum barrier.**

***Keywords*-- Topical Hydrogel, Fungal Skin Infection, Aloe Vera Gel, Carbopol 940**

I. Introduction

Fungal infection of the skin is now a days one of the common dermatological problems.[1]Infection is caused by microscopic organisms that invade the epithelial tissue. The fungi kingdom includes moulds, rusts and mushrooms which are commonly found on the skin, mouth, throat, stomach, colon, rectum.[2]When fungi infect the skin surface, they invade the stratum corneum to avoid being shed from the skin surface by desquamation, so the management of the superficial fungal infection begins with topical agent that can penetrate the stratum corneum cells. The physicians have a wide choice for treatment from solid dosage to semisolid dosage form and to liquid dosage formulation. Among the topical formulation, clear transparent gels have widely accepted in both cosmetics and pharmaceuticals.[3]

Topical drug administration is a localized drug delivery system anywhere in the body through ophthalmic, rectal, vaginal and skin as topical routes. Skin is one of the most readily accessible organs on human body for topical administration and is main route of topical drug delivery system[4]. The combination of active ingredients and base provides the opportunity for a wide range of topical preparations, appropriate for many types of drug delivery and therapy terms used to classify the bases of topical preparations in which therapeutically active ingredients are incorporated, may be based on their physical properties (suspension) or on their intended use (liniments) or on their composition ((hydrophilic creams).[5]Overall, the clinical evidence indicates that topical gel is a safe and effective treatment option for use in the management of skin related disease. Topical preparations are applied to the skin for surface, local or systemic effects. Advantages of topical drug delivery system such as avoiding first-pass hepatic metabolism, gastric degradation and frequent dosing.[6]

II. Materials And Method

Materials:

Terbnafine Hydrochloride was received as gift sample fromGlaxoSmithKline Ambad,Nashik ,Aloe Vera gel Purchesed from Uni Plus Healthcare India Private Limited,Carbopol 940 Was Purchesed fromResearch –Lab Fine Chem Industry Mumbai. All other materials used of analyatical grade.

Method

Formulation of Terbinafine Hydrochloride topical hydrogel

1. Hydrogels were fabricated using different concentrations of polymeric dispersions.
2. 0.2, 0.9, 1.6% concentrations of carbopol 940 colloidal dispersions were prepared using distilled water.
3. 3.1,2,3% concentrations of Aloe vera gel colloidal dispersions were prepared using distilled water.
4. After complete dispersion, both the polymer solutions were kept in dark for 24 h for complete swelling.

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5. Dispersions of polymers were made using magnetic stirrer (500rpm). After dispersing carbopol 940 in distilled water, colloidal dispersion of Aloe vera gel was added to it under magnetic stirring. Add pH adjustifier to modify the buffering capacity of the gel, if necessary.

Finally, the remaining distilled water was added to obtain a homogeneous dispersion of gel under magnetic stirring.[7]

3^2 factorial design was followed for the development of the formulations. In the design, 2 factors were evaluated each at 3 levels and experimental trials were performed at all 9 possible combinations as shown below in table I.

Table 1:
Composition of all Topical Hydrogel Formulations (all values are expressed in % w\v)

Formulation code	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Ingredients	**%**								
Terbinafine Hydrochloride	1	1	1	1	1	1	1	1	1
Aloe Vera gel	1	2	3	1	2	3	1	2	3
Carbopol 940	0.2	0.2	0.2	0.9	0.9	0.9	1.6	1.6	1.6
Propylene glycol (ml)	5	5	5	5	5	5	5	5	5
Sodium Benzoate	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Triethanolamine (ml)	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
Methanol	2	2	2	2	2	2	2	2	2
Water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

III. Evaluation Of Topical Terbinafine Hydrochloride Hydrogel

Physical Appearance[8]

The prepared Terbinafine Hydrochloride Hydrogel formulations were inspected visually for their colour, Homogeneity and consistency.

pH[8]

The pH of gel Formulations was measured, using a pH meter.

Drug content uniformity[8]

1 g of the prepared gel was mixed with 100ml of suitable solvent. Aliquots of different concentration were prepared by suitable dilutions after filtering the stock solution and absorbance was measured at 281 nm . Drug content was calculated using the equation, which was obtained by linear regression analysis of calibration curve.

Measurement of viscosity[8]

The viscosity of the formulated batches was determined using a Brookfield ViscometerDV-II+ Brookfield Engineering Laboratories, USA) with spindle 64. The formulation whose viscosity was to be determined was added to the beaker and was allowed to settle down for 30 min at the assay temperature (25±1ºC) before the measurement was taken. Spindle was lowered perpendicular in to the centre of gel taking care that spindle does not touch bottom of the jar and rotated at a speed of 50 rpm for 10 min. The viscosity reading was noted.

Spreadability[9]

It was determined by wooden block and glass slide apparatus. A ground glass slide was fixed on the block then the excess of formulated gel (2 g) was placed on it. Gel was sandwiched by using another glass slide which was provided with hook.

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Weight (100 g) was placed upon the upper slide for 5 minutes to remove entrapped air and to form a uniform thin gel layer between slides.. The two slides in positioned were fixed to a stand without slight disturbance and in such a way that only the upper slide to slip off freely by the force of weight tied to it. A 20 g weight was tied to upper slide carefully. The time taken for the upper slide to travel the distance of 6 cm. The determinations were carried out in triplicate and the average of three reading was recorded.

Spreadability was calculated by using the formula:

S=ML/T

where, S = Spreadability
M = Weight tide to upper slide
L = Length moved on the glass slide
T = Time taken to separate the slide completely from each other

Figure 1: Spreadability of formulation

In-vitro drug diffusion study[9]

Drug diffusion rate from different gel formulations were studied by Franz diffusion cell using cellophane membrane as a barrier. Diffusion membrane was immersed in receptor compartment having 40 ml of Phosphate buffer 7.4 as diffusion medium, maintained at 37±2oC for 24hr for equilibrium. Diffusion cell was assembled on magnetic stirrer along with diffusion membrane, which separates donor and receptor compartments. Gel (2g) was kept on membrane in donor compartment. The contents were stirred using magnetic stirrer at 50 rpm and aliquots each of 5 ml were withdrawn from the release medium at time intervals of 10min, 20min, 30min, 60min, 90min, 120min, 180min, 240min, 300min, 360min, 420min and 480 minutes. Withdrawn samples were replaced by equal volumes of same fresh medium. Absorbance of these samples was measured spectrophotometrically at 281nm by UV-Visible double beam spectrophotometer. Cumulative release (%) of Terbinafine Hydrochloride from different gel formulations was calculated. The data obtained from the in vitro release experiments were analyzed using linear regression method according to zero order (Ct = C0 – kt), and first order (in Ct = in C0 – kt).

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Figure 2: Laboratory- assembled apparatus for In vitro diffusion study

Antifungal study[10]

An agar diffusion method used for determination the antifungal activity of formulation. Standard petri dish 9 cm containing medium to depth of 0.5 cm were used. The sterility of the lots was controlled before used. Incubation were prepared by suspending 1-2 colonies of Aspergillus niger From 24 hr. Cultures in sabouraud's medium in to tube contain 10 ml of sterile saline. The tubes were diluted with saline. The inoculum spread over the surface of agar medium. The plate was dried at 35º C for 15 min prior to placing the formulation. The boars of 0.5 cm diameter were prepaid and 20 µl sample of formulation (1 % w/v) were added in the bores. After incubation at 35ºC for 24 hr then zone of inhibition around the boars are measure.

Accelerated stability studies[11,12]

Table 2:

Accelerated stability studies

Stability studies are performed by guidelines are shown in Table7.5.

Test Condition	
Duration Of study	**3 month**
Temperature condition	40°C± 2° and Room Temperature
Relative humidity condition	75% RH ± 5% RH and 65% RH ± 5% RH
Frequency of testing	3 months

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The formulation where evaluated mainly for their physical characteristics to, 3 months. Physical appearance in terms of colour, Ph, Viscosity, drug content and antifungal activity where evaluated.

Release kinetics of selected formulation[12]

To examine the drug release kinetics and mechanism, the cumulative release data were fitted to models representing Zero order (cumulative % drug release v/s. time), First order (log cumulative % drug retained v/s. time), Higuchi model (cumulative % drug retained v/s.

Korsmeyer/Peppa's model – log % cumulative drug release Vs log time. Square root of time.

IV. Result And Discussion

Preformulation Study:

Organoleptic properties of drug:

A White Crystaline Powder

Melting Point:

Table 3:
Melting Point of Terbinafine Hydrochloride

Melting Point	
Reported Value	**Practical value**
195^0c	195-196^0c

All the physical properties of the drugs were within the limit of reported standards which assures the purity of the drug samples.

Solubility:

Solubility of Terbinafine Hydrochloride has been shown in the following table 4. Result of Phase Solubility study have been Reported in the Table 4.

Table 4:
Solubilityof Terbinafine Hydrochloride

Solvent	**Solubility**
Water	Very Slightly Soluble
Methanol	Freely Soluble
Ethanol	Freely Soluble
7.4 PBS	Freely Soluble
Dichloromethane	Freely Soluble

Table 5:
Phase Solubility study of Terbinafine Hydrochloride

Solvent	**Solubility mg\ml**
Water	2.25±0.02
Methanol	22.5±0.01
7.4 PBS	18.3±0.02

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Ultraviolet – Visible Spectroscopy study:

Determination of (λ max) of Terbinafine Hydrochloride in Methanol

λ max of Terbinafine Hydrochloride in Methanol are shown in Figure 8.

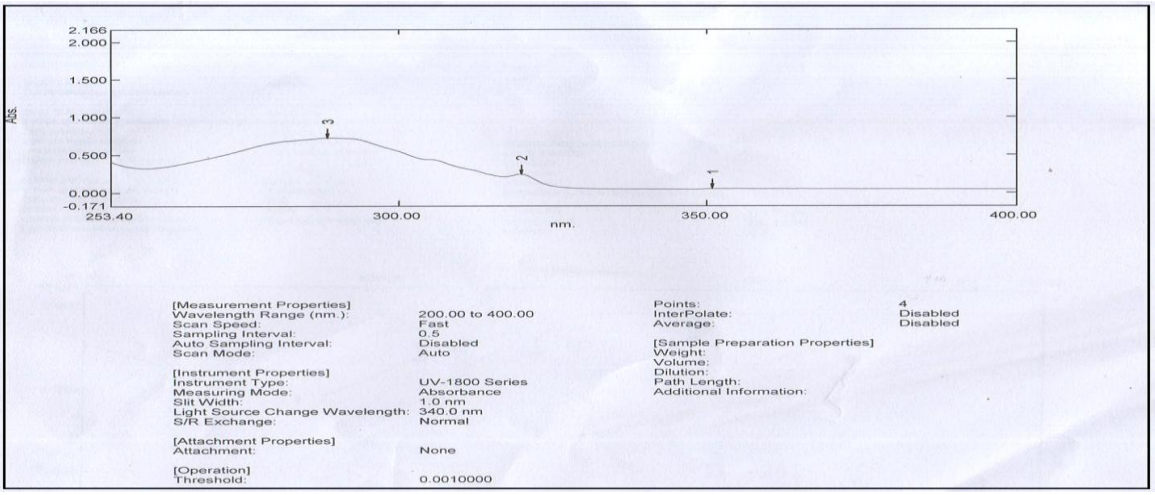

Figure 3: Ultraviolet – Visible Spectroscopy of Terbinafine Hydrochloride in Methanol

Calibration Curve of Terbinafine Hydrochloride in Methanol

Table 6:
Absorbance of Terbiafine Hydrochloride in Methanol.

Sr.No.	Concentration.(ppm)	Absorbance
1.	2	0.092
2.	4	0.185
3.	6	0.275
4.	8	0.342
5.	10	0.402

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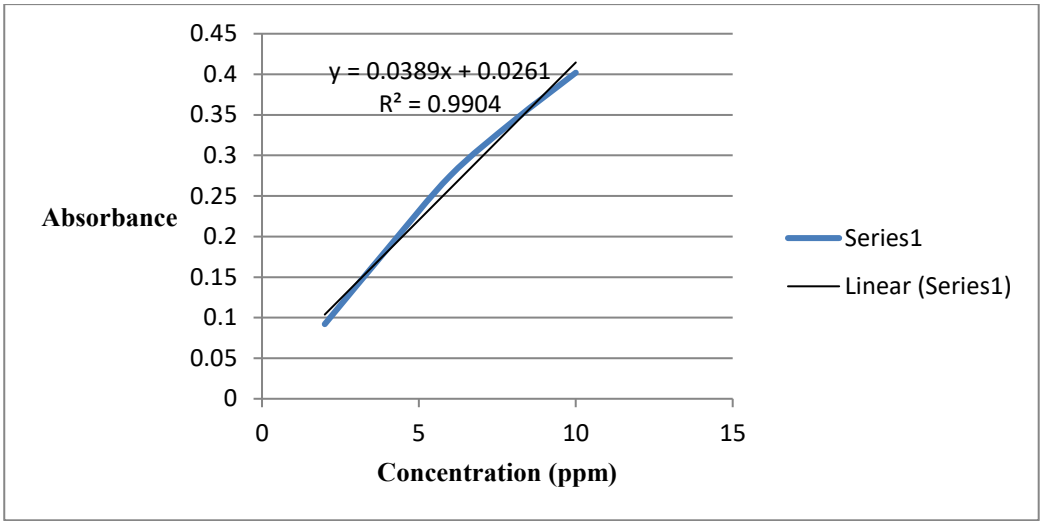

Figure 4: Calibration curve of Terbinafine Hydrochloride in Methanol

Determination of (λ max) of Terbinafine Hydrochloride in Phosphate Buffer 7.4

λ max of Terbinafine Hydrochloride in Phosphate Buffer 7.4are shown in Figure 4

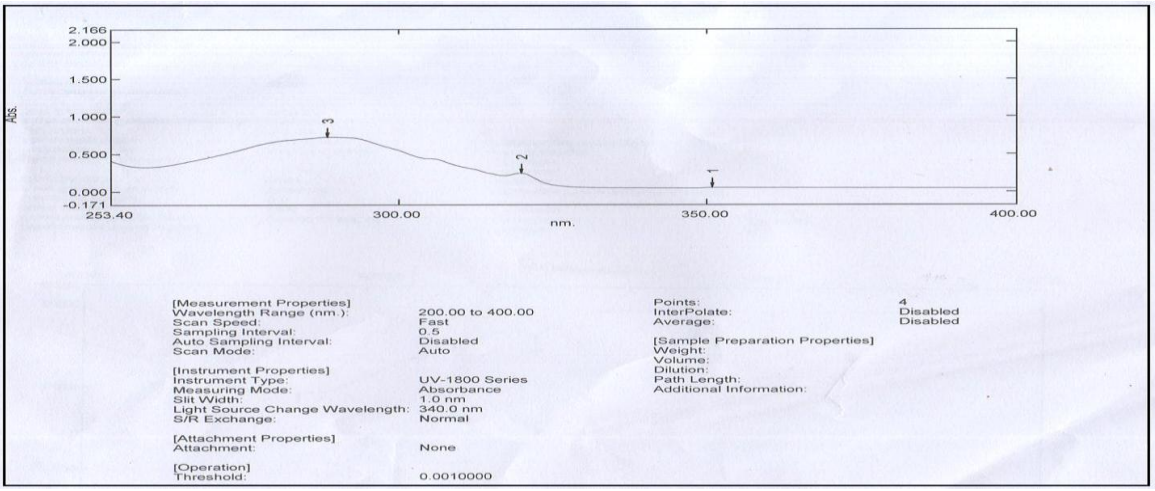

Figure 5:Ultraviolet – Visible Spectroscopy of Terbinafine Hydrochloride in Phosphate Buffer 7.4.

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Calibration Curve of Terbinafine Hydrochloride in Phosphate Buffer 7.4.

Table 7:
Absorbance of Terbinafine Hydrochloride in Phosphate Buffer 7.4.

Sr. No.	Concentration.(ppm)	Absorbance
1.	2	0.194
2.	4	0.414
3.	6	0.612
4.	8	0.808
5.	10	0.992

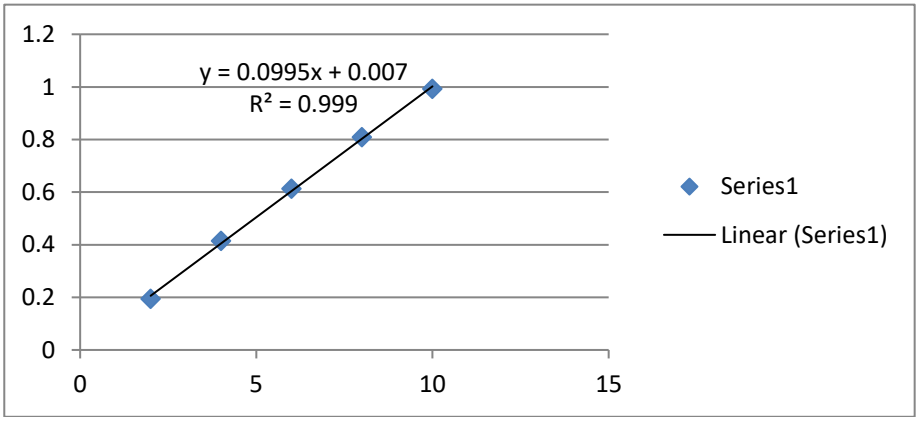

Figure 6: Calibration curve of Terbinafine Hydrochloride in Phosphate Buffer 7.4.

Fourier Transform Infrared Spectroscopy

The major peaks observed and corresponding functional groups are given in Table 8.6. The spectrum shows characteristic peaks for Terbinafine Hydrochloride.

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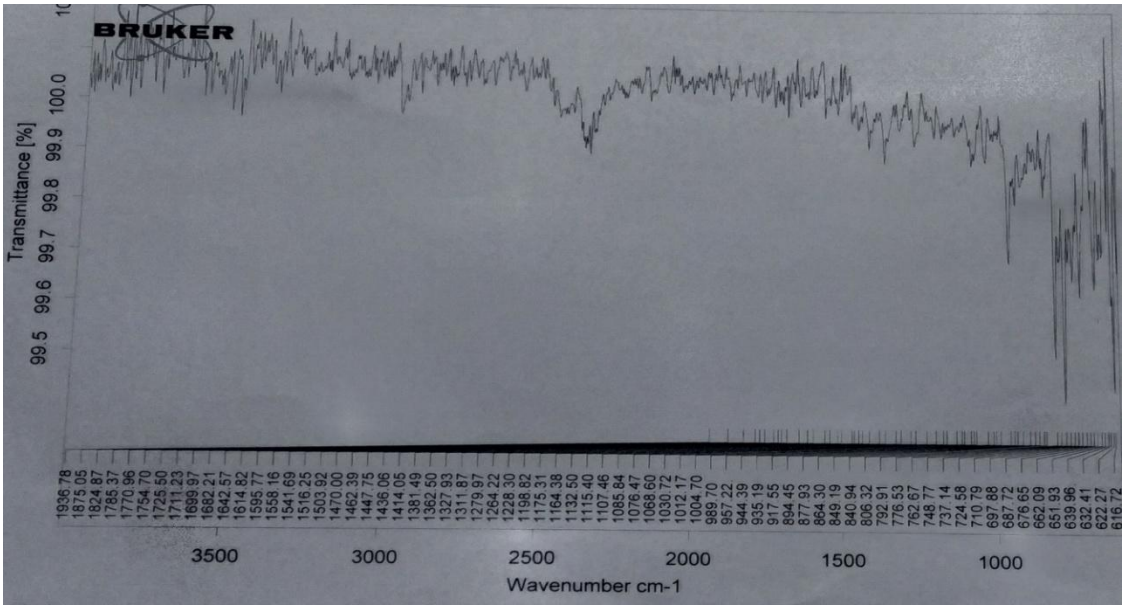

Figure7: FTIR Spectrum Terbinafine Hydrochloride

Table 8:
Major Peak observe in FTIR spectrum of Terbinafine Hydrochloride.

Sr.No	Functional Group	Standard frequency (cm^{-1})	Observe IR frequency (cm^{-1})
1.	COOH stretching	1400-1200	1381
2.	C=C stretching	1680-1600	1642
3.	C-N stretching	1350-1000	1327
4.	S=O stretching	1200-1000	1068
5.	C-H bending	1375	1362
6.	C=O stretching	1800-1600	1725
7.	C-Cl stretching	800-600	792

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The absorption bands shown by Terbinafine Hydrochloride are characteristics of the groups present in its molecular structure. The presence of absorption bands corresponding to the functional groups present in the structure of Terbinafine Hydrochloride confirms the identification and purity of the Terbinafine Hydrochloride sample used in the study.

Differential Scanning Calorimetry

The DSC Thermogram peaks value matches with value found in literature.

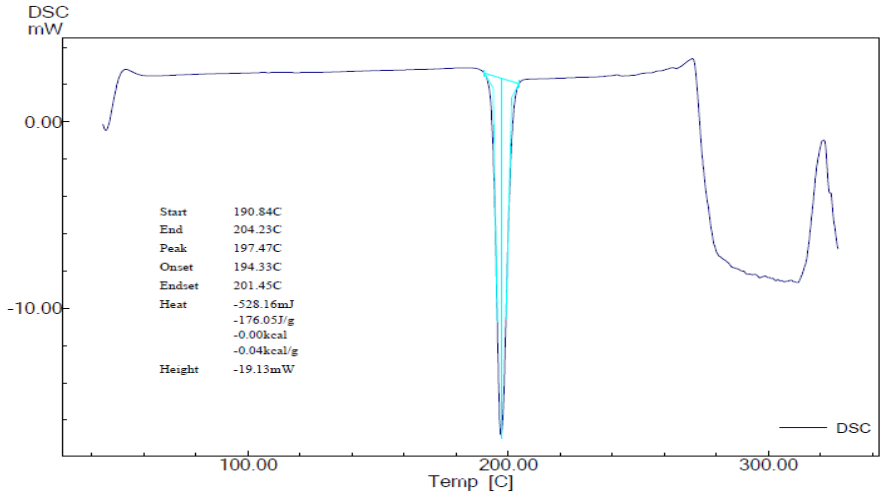

Figure 8: Thermogramof Terbinafine Hydrochloride

Compatibility Study

Fourier transforms Infra Red Spectroscopy

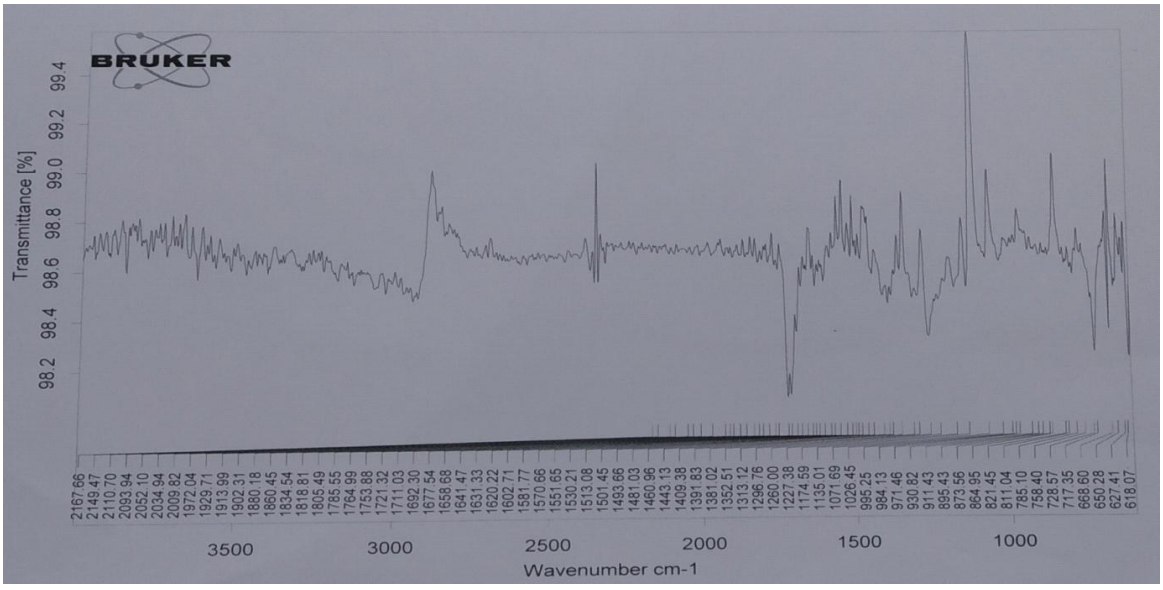

Figure 9: FTIR of Physical mixture

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Table 9:
Interpretation of FTIR Spectrum of physical mixture

Functional group	Peaks	
	Pure drug	Physical mixture
COOH stretching	Yes	Yes
C=C stretching	Yes	Yes
C-N stretching	Yes	Yes
S=O stretching	Yes	Yes
C-H bending	Yes	Yes
C=O stretching	Yes	Yes
C-Cl stretching	Yes	Yes

Differencial Scanning Calorimetry

The DSC Studies disperse in polymer showed the same thermal behavior as pure compound. This endothermic peak was also observed for formulation (Physical Mixture) at 209 ^{0}c which does not correspond to the melting point of the pure drug.

From DSC study it has been found that there is no significant change in drug's melting peak. From the DSC results it has been concluded that drugs and other excipients are compatible which each other and selected for further formulation studies.

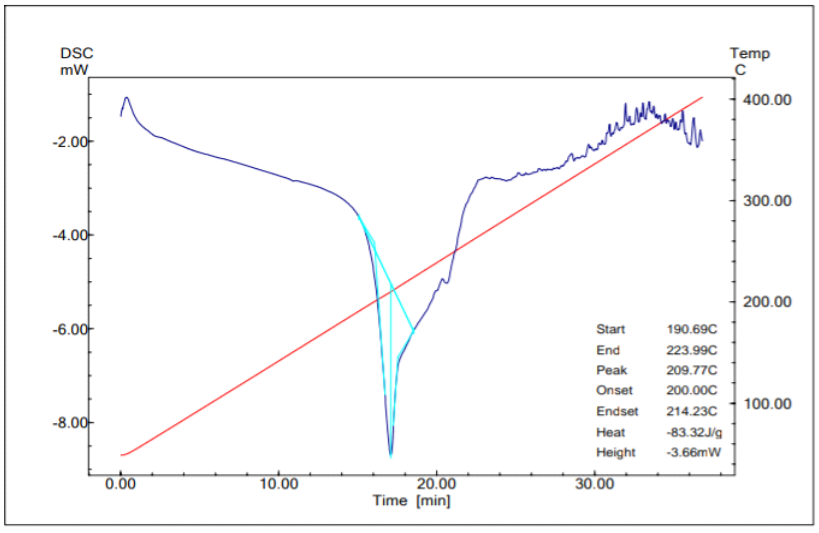

Figure 10:Thermogram Of Physical Mixture

Evaluation of Topical Hydrogel

Physical Appearance

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Table 10:
Physical Appearance of Formulation

Sr. No	Parameter	Inference
1.	Colour	Translucent gel
2.	Homogeneity	Homogeneous
3.	consistency	Consistent

pH

Table 11. gives pH value for the formulations

Table 11:
pH values of all formulations

Sr.No	Formulation code	Observed pH (± SD)
1.	F1	6.60±0.02
2.	F2	6.55±0.01
3.	F3	6.75±0.01
4.	F4	6.43±0.01
5.	F5	6.53±0.02
6.	F6	6.70±0.02
7.	F7	6.40±0.01
8.	F8	6.31±0.02
9.	F9	6.55±0.01

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Drug content uniformity

Table 12:
Drug content of all formulations

Sr. No.	Formulation code	Drug content (%)± SD
1.	F1	96±0.2
2.	F2	91±0.5
3.	F3	94±0.7
4.	F4	93±0.6
5.	F5	95±0.7
6.	F6	98±0.5
7.	F7	94±0.8
8.	F8	96±0.8
9.	F9	94±0.4

The percentage drug content of all prepared hydrogel formulations was found to be in the range of 91 to 98%. Therefore uniformity of content was maintained in all formulations. The F6 Formulation drug content was found to be 98%.

Measurement of viscosity

Table 13:
Viscosity of all formulations

RPM	Viscosity of formulations (cP)								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
10	14200	13450	13750	14500	14500	14960	12500	13800	12600
20	13050	12390	13400	14250	14200	14500	12250	12600	11800
30	13000	13000	12350	12750	13700	13800	11200	12000	10500
40	12350	11500	12010	12520	12750	12500	11000	11900	9750
50	13450	13050	11250	12500	12520	12000	10900	10900	9550

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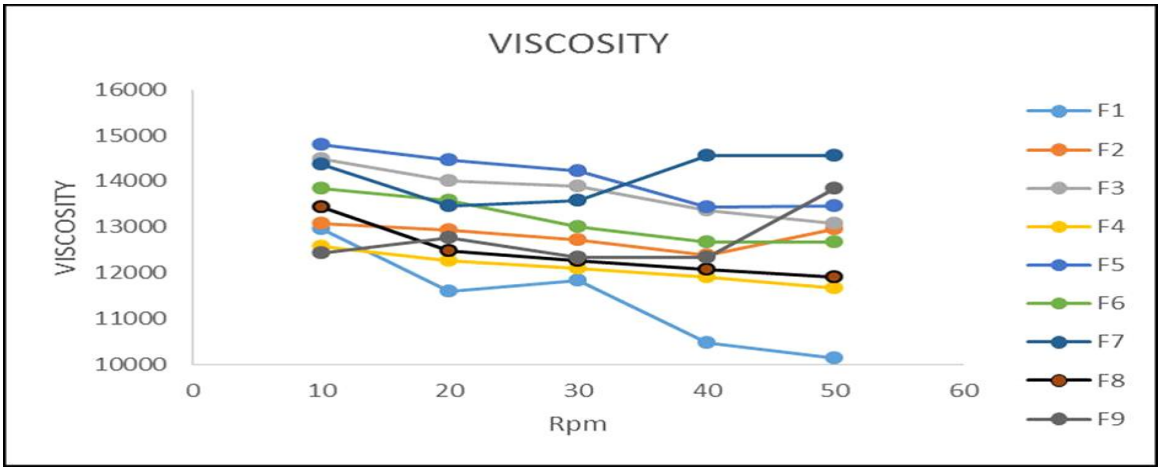

Figure 11: viscosity of all formulations

The formulation with different ratio of polymer show difference in viscosities. This is attributed to the complex molecular structure of polymer like carbopol aloe Vera gel are comparatively simple molecules.

Viscosity v\s rpm plots for all formulations (figure 11) shows decrease in viscosity as shear rate was increased. This indicates that gel has the pseudo plastic flow. Concentration and type of polymer used was the major factor affecting on viscosity of formulations.

Spreadability

Table 14:

Spreadability of all formulations

Sr. No.	Formulation code	Spreadability (g.cm/sec) ± S.D.
1.	F1	16 ±0.035
2.	F2	15.38 ±0.028
3.	F3	15.23± 0.011
4.	F4	15.68 ±0.018
5.	F5	14.81± 0.054
6.	F6	16.81± 0.012
7.	F7	14.81± 0.012
8.	F8	15.53± 0.012
9.	F9	15.38 ±0.028

Spread ability of gel is very important in the topical gel formulations. Spread ability shows the inverse relationship with the viscosity of the gel. Formulation with higher viscosity is very thick in nature, difficult to spread.

Hence gel having optimum viscosity provides proper spread ability to the formulations. Formulation F6, having optimum viscosity and spread ability of this formulation is 16.81gm.cm/sec.

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In-vitro drug diffusion study

Table 15:

Avarage (n=3) Cumulative amount of Terbinafine Hydrochloride diffused (%) from all the formulations through egg membrane using Modified Franz diffusion cell

Time hrs	(n=3) Cumulative amount of Terbinafine Hydrochloride diffused (%)								
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
0	0	0	0	0	0	0	0	0	0
1	9.50±0.20	14.50±0.30	12.96±1.06	12.08±0.51	13.28±0.73	17.30±0.70	16.13±0.75	7.14±o.20	9.40±0.70
2	13.30±0.40	17.60±0.50	12.96±0.39	20.21±0.16	22.25±0.74	30.40±1.07	23.12±0.74	16.44±0.31	16.74±0.97
3	20.10±0.65	20.70±0.70	25.66±0.64	29.65±0.12	27.63±0.38	44±1.06	41.99±0.50	30.45±0.69	23.49±0.88
4	30.20±0.80	25.50±0.90	45.66±0.95	38.57±0.52	32.57±0.38	51±0.70	50.49±0.88	42.83±1	32.65±0.38
5	40.50±1.20	38.98±1.20	58.67±0.10	47.45±0.94	41.45±0.31	62±1.06	65.18±0.76	54.10±0.73	40.42±0.85
6	50.5±1.40	48.60±1.50	65.09±1.2	55.15±0.16	50.15±0.27	72.30±0.28	74.12±0.74	63.05±0.72	54.60±1.2
7	60.90±2.20	58.85±1.70	75.66±0.19	65.3±0.32	60.3±0.28	85.50±1.04	87.89±1.05	71.89±0.50	64.49±0.33
8	70.20±2.80	64.69±1.90	96±0.45	74.25±0.30	68.85±0.38	98.99±0.66	98± 0.50	82.89±0.50	75.25±0.32

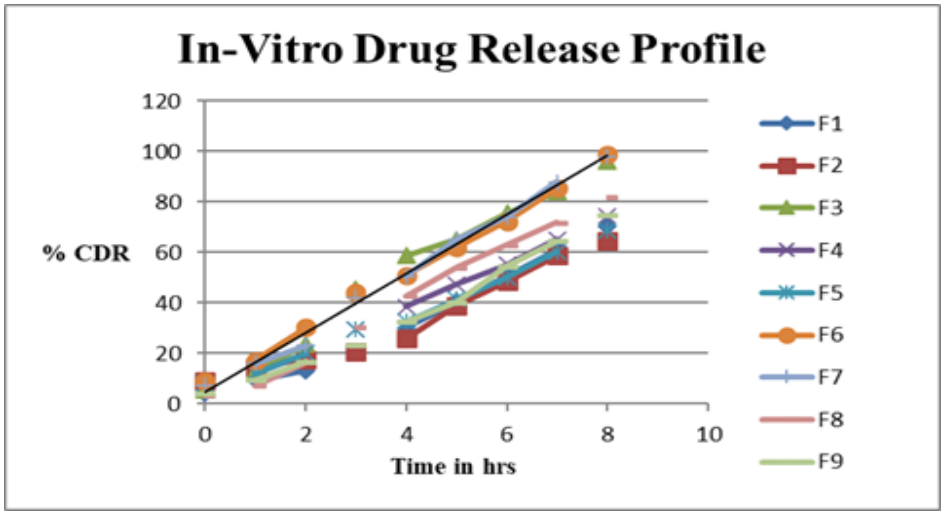

Figure 12: Avarage (n=3) Cumulative amount of Terbinafine Hydrochloride Pemeated (%) from formulations.

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The vitro drug release profile of Terbinafine Hydrochloride through egg membrame was represented in fig.8.10. and table 8.15. The data was also compared for release pattern and % drug release after 8 hours from various formulations. The F6 formulation showed consistent and maximum drug release Compared to the other formulation. The Drug release of F6 formulation after 8 hrs where found to be higher.

Antifungal study

In the antifungal studies the fugi used was Aspergillus Niger. The studies were carried for F6 formulations and zone of inhibitions of gel was measured. Theresult was shown in table 16.The result was found satisfactory. This result was compared with the marketed product. The F6 Formulation showed highest zone of inhibition.

Table 16:
Antifungal Activity of Formulation of all formulations

Sr. No.	Formulation code	Aspergillus Niger	
		Zone of inhibition (mm)	% Efficacy
1.	F1	13	69.99
2.	F2	11	64
3.	F3	19	95
4.	F4	15	72.99
5.	F5	12	67
6.	F6	23	98
7.	F7	16	82
8.	F8	14	74.99
9.	F9	17	88
10.	Ethanol	5	20
11.	Drug Suspension	22	96
12.	Marketed formulation	18	78.20

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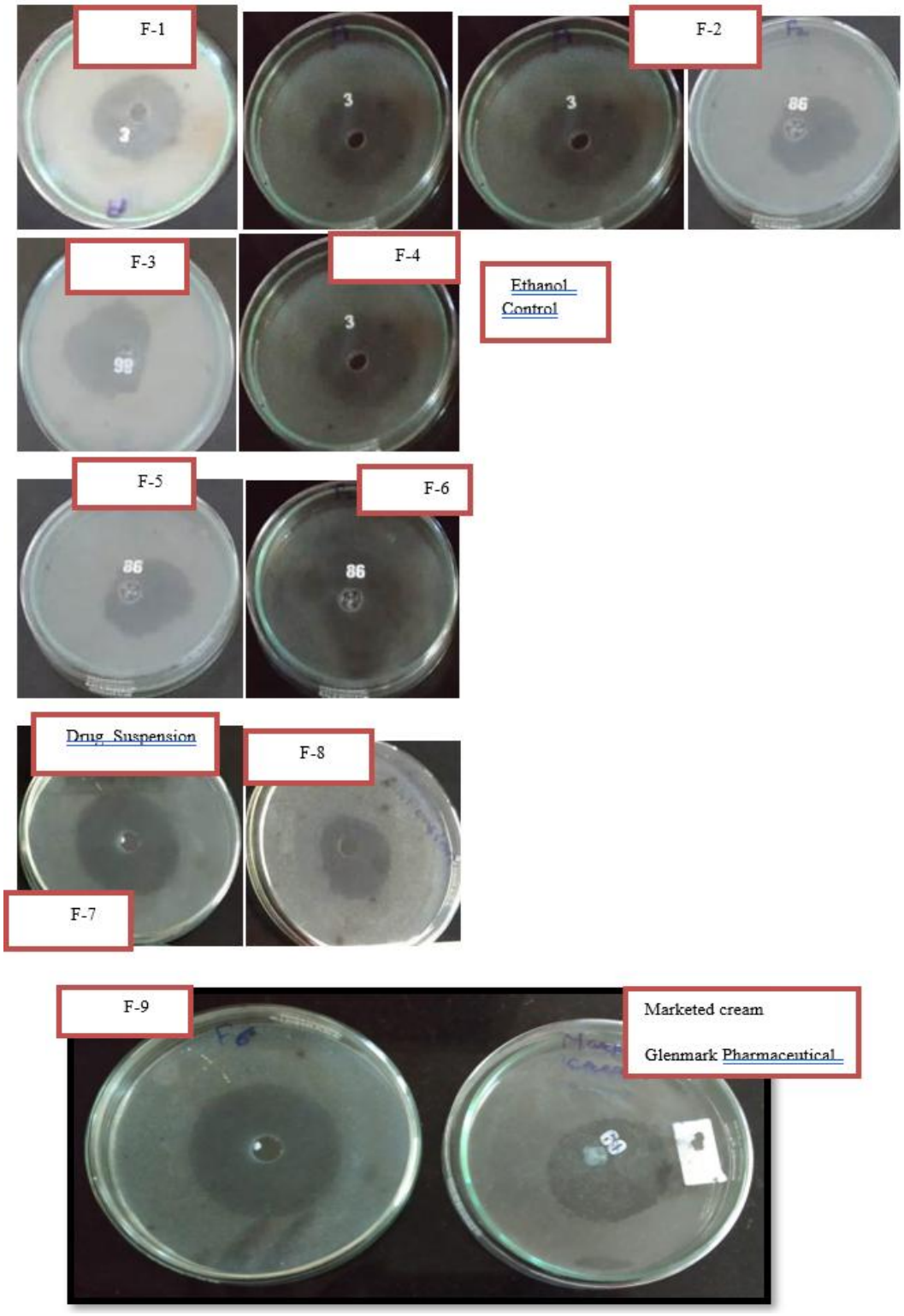

Figure 13: Zone of inhibition of Topical Hydrogel formulation

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Optimization

The Experimental Design in Correlation with Optimization Study has been outlined in table 16 X1 and X2 are the amount of Aloe Vera Gel and Carbopol 940 respectively, and Y1 and Y2 are % Drug Release and Antifungal Activity in terms of % efficacy respectively.

Table 17 shows ANOVA for the dependent variables % Drug Release and Table 18for Antifungal Activity. The Values of X1 and X2 were found to be significant at .p <0.05, hence it can be confirmed that both the variables have a significant effect on the selected responses.

From this data optimum concentration of aloe vera gel was found to be 3 %w/v and that for Carbopol 940 was found to be 0.9 %w/v.

Final Equation in terms of actual Factors

Y1 (Drug release) = +118.4222-21.01512*(A)-41.00000*(B)

Y2 (Antifungal Activity) = +121.61111-22.43024*(A)-41.66667*(B)

Table 16:
Experimental Design and optimization Study

Formulation Code	Factor X1 (Aloe Vera Gel)	Factor X2 (Carbopol 940)	Response Y1 (%Drug Release)	Response Y2 (%Efficacy)
F1	1	0.2	70	69.99
F2	2	0.2	64.69	64
F3	3	0.2	96	95
F4	1	0.8	74.25	72.99
F5	2	0.8	68.85	67
F6	3	0.8	98.99	98
F7	1	1.6	82.7	82
F8	2	1.6	75	74.99
F9	3	1.6	80.66	88

Table 17:
Analysis of variance for % Drug Release

Source	Sum of Squares	df	Mean Squares	F value	P value	Model Significant/Non-significant
Model	978.21	3	326.07	10.57	0.0132	Significant
A-Aloe Vera Gel	9.58	1	9.58	0.3105	0.6014	
B-Carbopol 940	24.60	1	24.60	0.7978	0.4127	
AB	944.03	1	944.03	30.61	0.0026	
Residual	154.20	5	30.84			
Cor Total	132.40	8				

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Standard Deviation Standard Deviation =5.55

R-Squared=0.8638

Factor coding is coded.

Sum of squares is Type III - Partial

Table 8.18.
Analysis of variance for Antifungal Activity

Source	Sum of Squares	df	Mean Squares	F value	P value	Model Significant/Non-significant
Model	1018.72	3	339.57	8.91	0.0189	Significant
A-Aloe Vera Gel	37.55	1	37.55	0.9853	0.3665	
B-Carbopol 940	20.17	1	20.17	0.5291	0.4996	
AB	961.00	1	961.00	25.22	0.0040	
Residual	190.56	5	38.11			
Core Total	1209.08	8				

Standard Deviation=6.17

R-Squared=0.8424

Factor coding is coded.
Sum of squares is Type III - Partial

The variance Inflation Factor measure the extent to which the variance of the model coefficient was inflated by the lack of orthonality in the design and was calculated for % drug release. It was found to be near to one, this indicated a good estimation of the coefficient. Similarly R-Squared near to zero which led to a good model. The value of P Where less than 0.05, which indicate model term significant.

The linear model obtained from the regression analysis where used to build a 3-D graph in which the responses were represented by curvature surface as a function of independent variables.

The relationship between the response and independent variables can be directly visualized from response surface plots. The response surface plots presented Figure 29 was generated using design expert 11 software. It can be used to observe the effects of independent variables on the response studied. From response surface methodology as a 3 level factorial design was chosen using linear design model. The range was set from a minimum value of 64.69% to a maximum of 98.99 for % in vitro drug release and 64 to a 98% for antifungal activity. The 9 runs performed for the response % *in vitro* drug release and antifungal activity were found to be linear.

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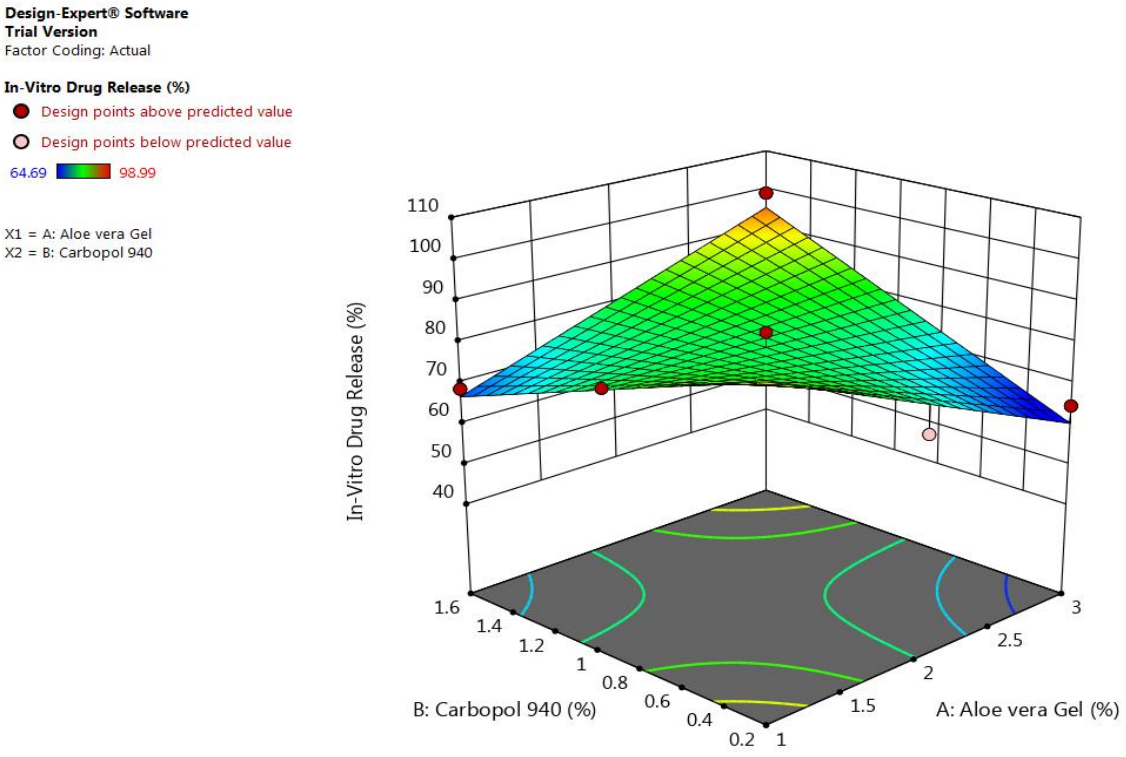

Figure 14: Surface Response Plot showing effect of Aloe Vera Gel and Carbopol 940 on Drug Release

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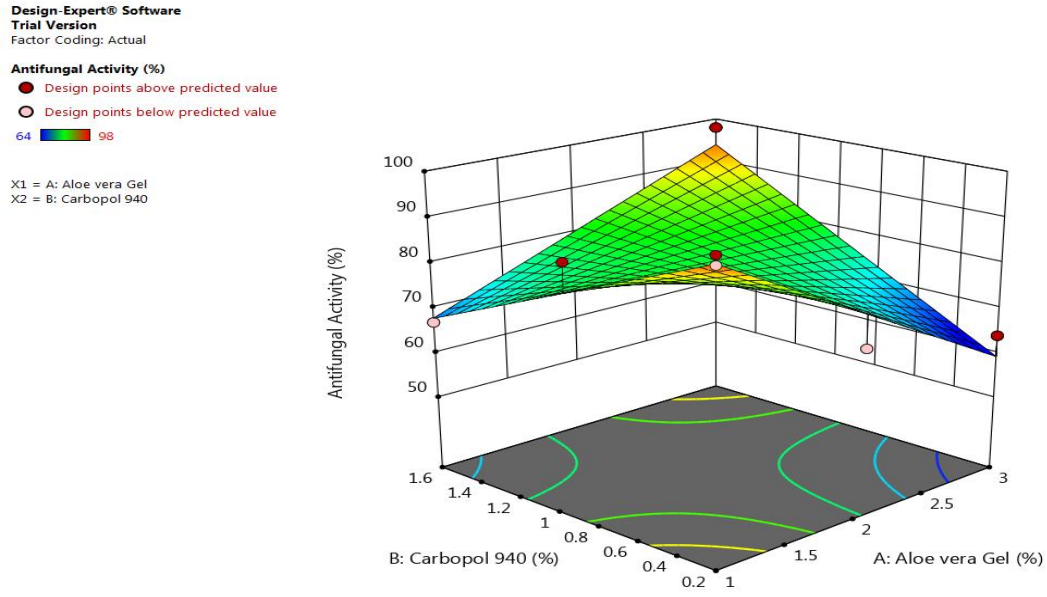

Figure 15: Surface Response Plot showing effect of Aloe Vera Gel and Carbopol 940 on Antifungal Activity

The above figure shows that effect of concentration of Aloe Vera Gel and Carbopol 940 on % Drug Release and Antifungal Activity.

It is shown that both the independent variables have a significant effect on the dependent variable and, drug release and antifungal activity decreases as concentration of polymers increases.

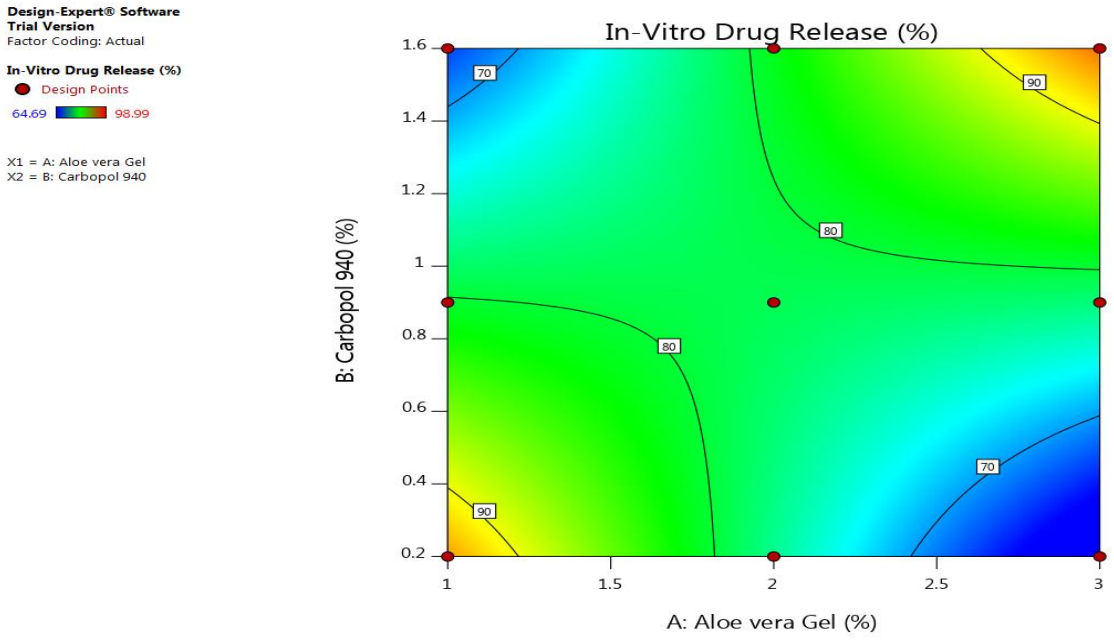

Figure 16: Contour Plot showing effect of Aloe Vera Gel and Carbopol 940 on Drug Release

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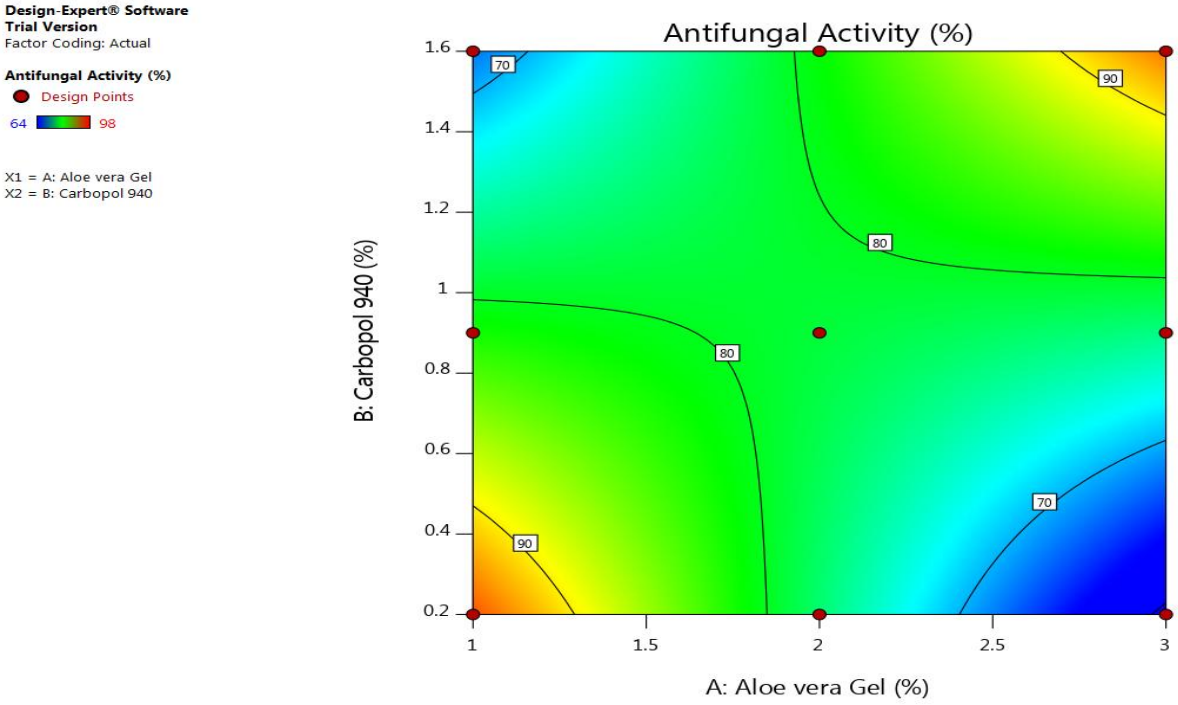

Figure 17: Contour Plot showing effect of Aloe Vera Gel and Carbopol 940 on Antifungal Activity

In the figure above show the effect of concentration of Aloe vera gel and Carbopol 940 on drug release and antifungal activity. It is also shown that both independent variables have a significant effect on the dependent variables.

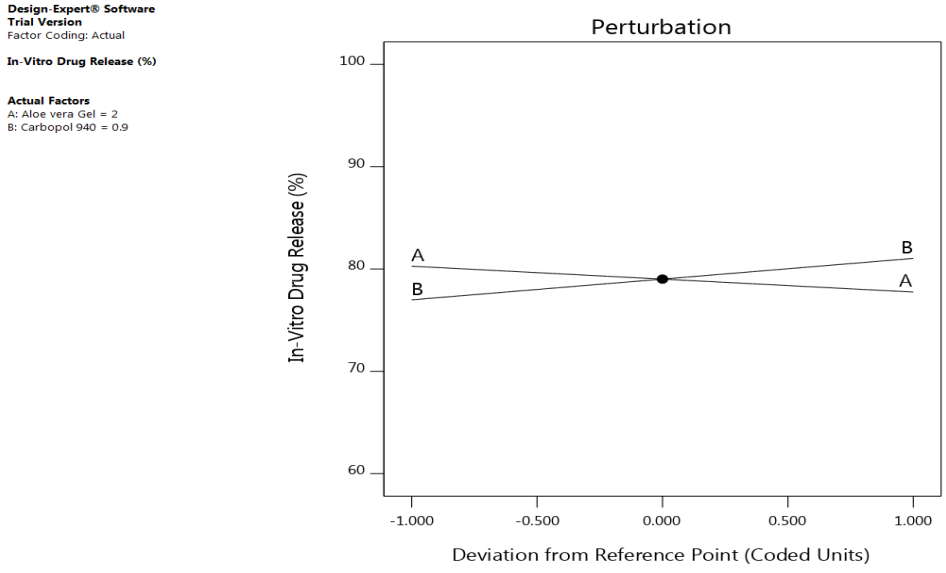

Figure 18: Perturbation Plot showing effect of Aloe Vera Gel and Carbopol 940 on Drug release

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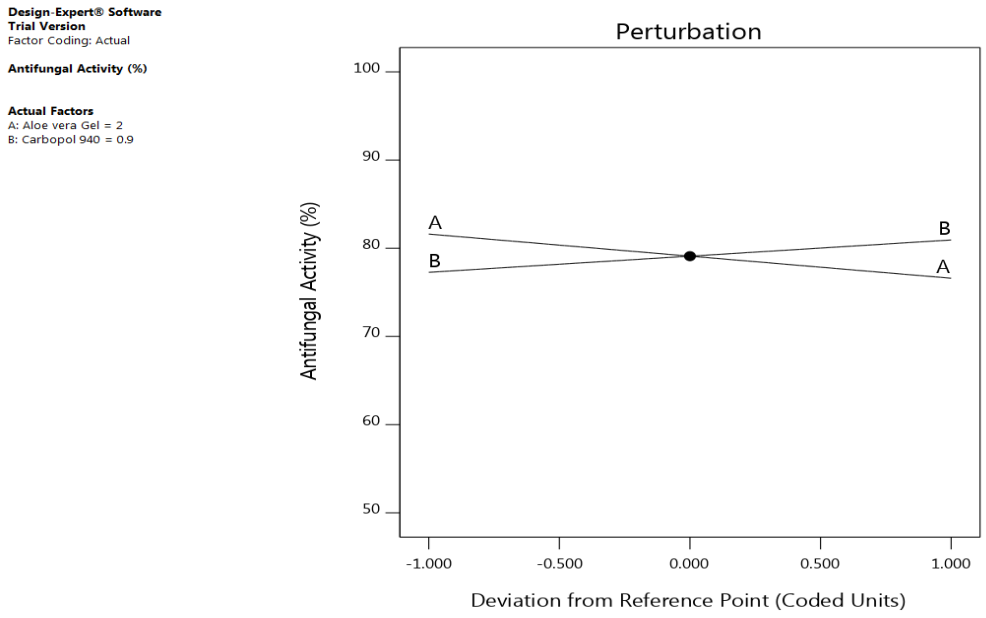

Figure 19: Perturbation Plot showing effect of Aloe Vera Gel and Carbopol 940 on Antifungal Activity

It can be seen from the above figure, that the effect of Aloe vera gel on % Drug Release and Antifungal Activity is more pronounced than that of Carbopol 940.

Table 19 shows design summary for % Drug Release, table 20 shows response summary for % Drug Releaseand Table 21 shows response summary for antifungal activity.

Table 19:
Design summary

Factor	Name	Units	Type	Min	Max	-1	+1	Mean	SD
A	Aloe vera Gel	%w/v	Numeric	1	3	1	3	2	0.8660
B	Carbopol 940	%w/v	Numeric	0.2	1.6	0.2	1.6	0.9	0.6062

Table 20:
Response summary for % Drug Release

Response	Name	Units	Obs	Analysis	Minimum
Y1	Drug Release	%	9	Polynomial	64.69
Maximum	Mean	SD	Ratio	Trans	Model
98.99	79.02	11.90	1.53	None	Linear

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Table 21:
Response summary for Antifungal Activity

Response	Name	Units	Obs	Analysis	Minimum
Y2	Antifungal Activity	%	9	Polynomial	64
Maximum	Mean	SD	Ratio	Trans	Model
98	79.11	12.29	1.53	None	Linear

The Design Expert Version 11 Thirty nine solutions were found. The batch with Aloe Vera Gel 3%w/v and Carbopol 940 0.9 %w/v with desirability 1 where found to be optimum formulation.

The classical Zero order release curve and Higuchi release model where found to be linear.

The curve plotted according to first order and Korsemeyer peppas model where found to be linear. The r square value where found to be >0.75 for the optimized formulation which indicates that formulation show anomalous (non-Fickian release i.e. swellable matrix). The drug release occurs probably by diffusion and erosion.

Release kinetics of selected formulations

Table 22:
Release kinetics of selected formulations

Sr.No	Formulation	Kinetic Model			
		Zero order	First order	Higuchi model	Korsmeyer peppas
		R^2	R^2	R^2	R^2
1.	F6	0.993	0.661	0.941	0.661

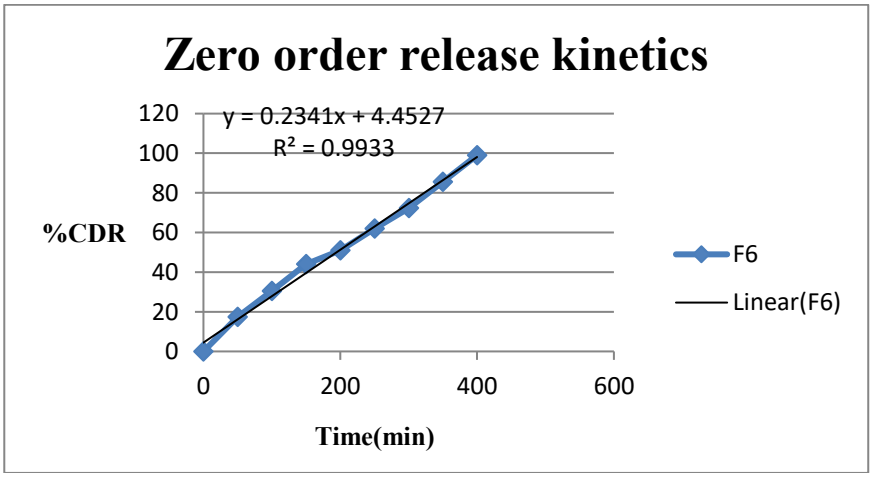

Figure 20:Model Graph For Comparative Evaluation Of Zero Order Release

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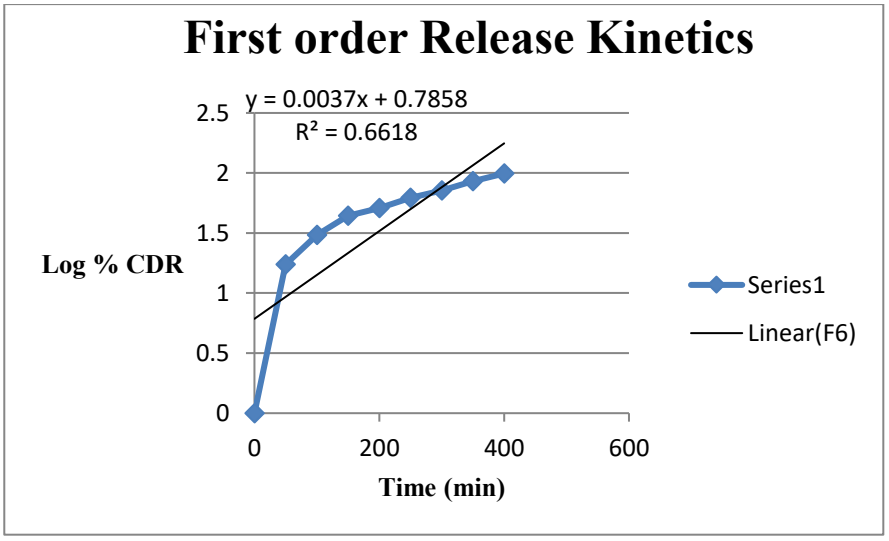

Figure 21:Model Graph For Comparative Evaluation Of First Order Releas

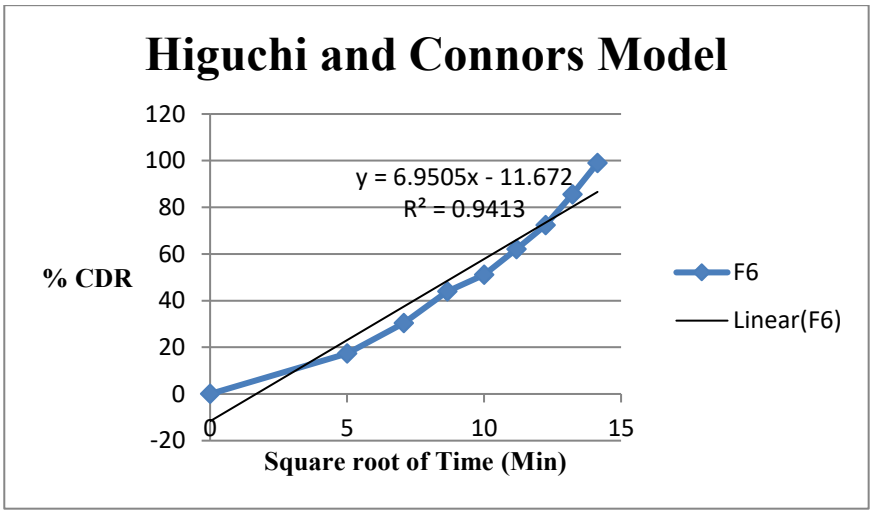

Figure 22:Model Graph For Comparative Evaluation Of Higuchi Release

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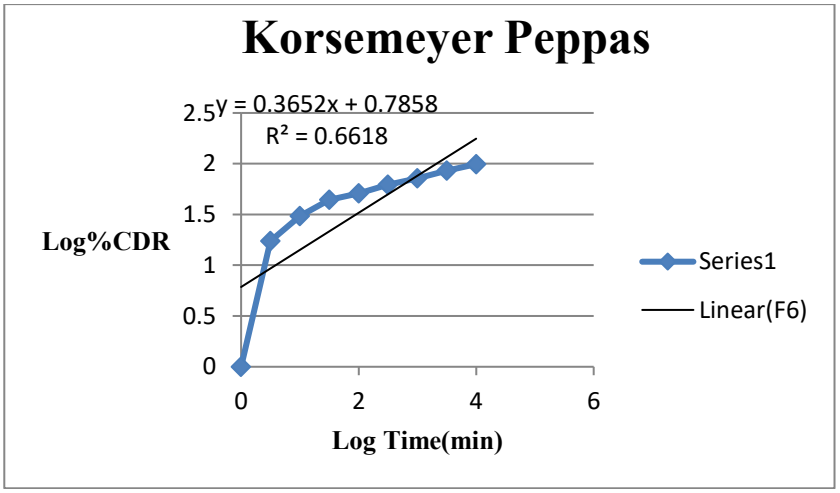

Figure 23:Model Graph For Comparative Evaluation Of Korsemeyer Peppas Release

The classical Zero order release curve and Higuchi release model where found to be linear. The curve plotted according to first order and Korsemeyer peppas model were also found to be linear.

The r square value was found to be >0.75 for the selected formulation which indicates that formulation show anomalous (non-Fickia release i.e. swellable matrix). The drug release occurs probably by diffusion and erosion.

Accelerated stability studies

Table 23:
Stability studies data for optimized formulation(F6) at room temperature

Sr.no	Observation	Before study	During study
			3th month
1.	Appearance	Transparent	Transparent
2.	pH (±S.D)	6.70±0.02	6.68±0.01
3.	Viscosity (± S.D)	12000	11950
4.	Drug content (± S.D)	98±0.5	99±0.5
5.	Spreadability (± S.D)	16.81± 0.012	16.81± 0.012
6.	Antifungal activity (± S.D)	98%	97.50%

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Table 24:
Stability studies data for optimized formulation (F6) at 45^0c ± 1^0c and 75 % ± 5 %RH

Sr.no	Observation	Before study	During study
			3th month
1.	Appearance	Transparent	Transparent
2.	pH	6.70±0.02	6.69±0.02
3.	Viscosity (± S.D	12000	11500
4.	Drug content (± S.D)	98±0.5	99±0.2
5.	Spreadability (± S.D)	16.81± 0.012	16.81± 0.012
6.	Antifungal activity (± S.D)	98%	97.99%

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