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Research Article

Formulation & Evaluation of Ketoconazole Antifungal Nanocream

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ABSTRACT

When it comes to delivering active ingredients to and through the skin for a variety of medicinal uses, nanoformulations have a certain position. These provide notable delivery advantages over coarse emulsions and are attractive, reasonably easy to manufacture, and reasonably inexpensive. A key technology opening the door for cutting-edge goods is nano technology. By using materials on a microscopic scale, nanotechnologies can give them new qualities not found in their bigger form. Further more, a vast range of consumer goods that are now available on the market and used in daily life can be altered by this technology. Nano cosmetics is one such fascinate in gareasince nano material can be used to createin nov active products. On the other hand, the manufacturing of UV filters for sunscreens in because they behave differently than larger forms, nanoforms may be more dangerous than larger ones. Numerous studies conducted in the last few decades have shown how successful these delivery technologies are. Furthermore, the creation of novel excipients with prospective applications in nanoformulations keeps opening up new possibilities for formulations with high distribution capacities and low toxicity and irritation. In order to assess the durability of nano-cream preparation, droplet size, electrical conductivity, drug content, pH, and rheological characteristics have all been investigated at various temperatures. Thus, the extraordinary behavior and features of nanomaterials have the potential to significantly alter both industry and human life. In addition to develop an effective, long lasting antifungal Nanocream and examine its antifungal activity and physico chemical properties.

Keywords: FungalInfections, Nanocosmetics, Nanomaterials, Nanoemulsions.

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INTRODUCTION

Recent years have drawn increasing attention to the use of topical vehicle systems to help in drug permeation through the skin. Drugs of choice are usually those that are problematic when taken orally, such as piroxicam, a highly effective anti-inflammatory, antipyretic, and analgesic. Nano-cream/semi-solid emulsion falls under the category of topical preparations that are applied on the outer surface.^[1-2] Nanocream can be prepared by high-energy techniques like ultrasound generators, high-pressure homogenizers or high shear stirring.^[3] As a result, they are very useful in composing cosmetics and personal care

products due to the small droplets having a particle size in the range of nanoparticle (100–600nm) thereby permitting uniform and smooth deposition of the cream onto the skin surface. This increases the effective release of active drug ingredient on the skin surface on tainedin the cream in a semisolid base for the purpose of healing several diseases. Moreover, the semisolid base can be of either nature namely hydrophilic or hydrophobic.^[4] Nanotechnology is nothing but the fundamental study about how materials or particles reactor works at the nano scale (be it at the atomic, molecular or subatomic level) in the development and use of structures, devices, and systems having unique characteristics and

purposes. ^[5] Nanotechnology entered in the field of cosmetics and health products nearly 40 years ago with liposome moisturizing creams. Rising usage of the technology substantiates the enormous future it has for both the industry as well as the consumers. In fact, there are currently a variety of nanomaterials in practice such as nanoemulsions and nanoparticles of naturally occurring minerals namely copper, silver, titanium dioxide, silicon dioxide, alumina, zinc oxide, and calcium fluoride. ^[6] It is well known that when the drug molecules are transported through the skin, they undergo two processes, starting with the drug penetration through the stratum corneum followed by the drug diffusion method into the deeper tissues. However, various factors such as size, log P, ionic strength, the ability of hydrogen bonding, and physicochemical characteristics of the vehicle govern the rate as well as the degree of the transport of drug through the stratum corneum. ^[7] Nanomaterials have secured extensive use in the composition hair repairing shampoos, serums and conditioners, creams to heal wrinkles, moisturizing and skin whitening creams. ^[8] Microemulsions and nano emulsions have many advantages owing to their potential to act as delivery systems for topical drugs. Out of all perceived benefits, the fact that a huge amount of drug can be incorporated in to the composition is the most significant advantage of these dosage forms owing to their high potential to solubilize leading to increased thermodynamic activity into the skin. Moreover, the rate at which the drug penetrates could be improved by using micro/nanoemulsion on account of the synergistic effect of different substances to increase

drug delivery across the skin. Further more, the main ingredients, i.e., oil, water, and surfactant mixtures, or surfactant-co surfactant mixtures, can be combined with synergistically to enhance drug flux. ^[9] Consisting of water or volatile substances to a proportion of more than 20% and hydrocarbons, polyols, or waxes as mediums, these dosage forms are termed as creams. ^[10] Moreover, such forms can comprise of drug substances in an appropriate base.

Materials and Methods:

Formulation of Nanoemulsion:

Preparation of Ketoconazole nanoemulsion The ingredients of the oil phase, namely, oleic acid are added with Ketoconazole stirred with magnetic stirrers to homogeneous. Mean while, the aqueous phase including sodium meta bi sulfite and Water. was mixed and stirred with a stirring bar until homogeneous. In a separate container, an emulgator comprising Tween 80 and PEG 400 is mixed and stirred with a magnetic stirrer up to homogeneous. Next, the oil phase is added to the water phase while the addition of the emulsifier mixture is piecemeal and stirred using a magnetic stirrer. After all the ingredients are mixed, then the mixture of the material homogenized using a homogenizer which is set at 1000 rpm for 60 min, after it was sonicated using sonicator for 30 min until it was formed the clear nanoemulsion ^[11,12]

Table 1: Formula for preparation of nanoemulsion

Sr.no.	Ingredients	Quantity
1.	Ketoconazole	200mg
2.	Oleic acid	3ml
3.	PEG 400 (%)	2ml
4.	Sodium meta bi sulfite	200mg
5.	Distilled Water	12ml
6.	Tween 80	1.5ml
7.	Span 20	1.5ml

Preparation of Nanocream:

Preparation of Ketoconazole cream all necessary materials are weighed. The materials are separated into two groups: The oil phase and the water phase.

The oil phase consists of Vaseline, stearic acid, and cetyl alcohol melted over a water bath with a temperature of 70–75°C. After a perfect melt was added, Ketoconazole into it.

In a separate container, aqueous phases comprising a quadeast, polyethylene glycol, and TEA are dissolved in hot water.

On a continuous phase, the water in a hot melt is then slowly added to the oil phase with a constant stirring at a temperature more or less 70°C, until a cream mass was obtained.

Table 2: Formula for the preparation of Nanocream

Cetyl alcohol	0.75gm
Stearic acid	0.75gm
Glycerol mono stearate	0.75gm
Propyleneglycol	1.25ml
TEA	0.25ml
Vaseline	1.15gm
Sodium meta bi sulfite	0.025gm
Sodium meta bi sulfite	0.025gm

The stored nanoemulsion was mixed with the cream properly using a hot plate magnetic stirrer. Phase separation, cracking, and creaming were all observed foramen that 5°C, 15°C, 25

°C, and 40 °C. After the formation of nanoemulsion cream, it was stored Medicina 2023, 59, 34 6 of 19 in a well-closed container at room temperature. ⁽¹³⁾



Figure 1: Nanocream

Optimization Studies:

Ketoconazole Nanocream Formulations were prepared according to a 3² factorial design. two-factor, 3-level 3^a factorial design was used for the optimization of the Nanocream formulations where the two factors were evaluated each at three different levels (low, medium, and high) and experimental trials were performed using all possible nine combinations using the Design Expert VR software ¹³.

The Independent variables chosen for Nanocream were the percentage of Glyceryl Monostearate (X1) and Propylene glycol (X2) whereas % Entrapment Efficiency (Y1), and Spreadability (g.cm/sec) (Y2) were selected as the dependent variable. The independent and dependent variables used in the 3^a factorial design approach for the formulation are shown.

Optimization Analysis:

Table 3: Optimization Analysis

Runs	Factor 1A Glycerol monostearate Mg	Factor 2B Propylene glycol Ml	Response1 Entrapment efficiency %	Response 2 Spreadability %
1	1.5	2	85	830.46
2	1.25	1.5	75	27.26
3	1.5	1	82	28.56
4	1.25	2.2	78	27.66
5	1	1	68	23.54
6	1.6	1.5	87	31.56
7	1.25	0.7	72	26.26
8	0.8	1.5	67	22.56
9	1	2	70	23.54

Composition of different formulation batches

Table 4: Composition of different batches

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
CetylAlcohol	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75
Stearic Acid	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75
Glyceryl Monostearate	1.5	1.25	1.5	1.25	1	1.6	1.25	0.8	1
Propylene glycol	2	1.5	1	2.2	1	1.5	0.7	1.5	2
TEA	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Vaseline	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15	1.15
Sodium Metabisulphite	0.025	0.025	0.025	0.025	0.025	0.025	0.025	0.025	0.025
Nanoemulsion	20ml	20ml	20ml	20ml	20ml	20ml	20ml	20ml	20ml

Evaluation of Nanocream- Physical Appearance^(14,15)

The prepared topical cream was visually inspected for homogeneity, colour, odour, state, consistency, and texture.

pH of Creams-

For pH determination, 5 gm of the formulated cream was mixed in 50 ml distilled water and measured by using pH meter at 27 °C. 2.7.7

Spreadability^(16,17).

For the spreadability determination wooden block with a pulley at one end consisting of apparatus was used. On the ground slide, 2g of the formulated cream was placed. Another slide which has dimension, provided with the hook was placed on the fixed ground slide. 1kg weight was poured on the two slides to create a consistent film of cream. After wards, a30gm pull was applied to the top slide. The top slide's time (measured in seconds) to travel 7.5 cm was calculated with the aid of a thread fastened to the hook. Better spreadability is indicated by a shorter interval. The equation used for calculating

Spreadability was: $S = M \times L/T$ Where, M =Weight (gm) taken, L= Length of the slide, T= Time (s) taken.

Anti-Fungal Study:

The anti-fungal activity of optimized Ketoconazole-loaded nanocream with conventional Ketoconazole cream was evaluated against Candida albicans by bore well method and compared.

Sabouraud dextrose agar medium was prepared, autoclaved at pressure 15lb/inch² and temperature of 121°C.

The prepared dextrose agar was poured into sterile petri plates and allowed to stay on a leveled surface at 37°C for 30min.

Result and Discussion

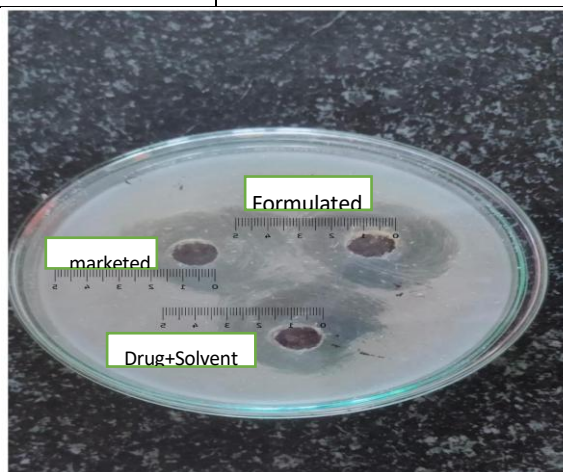
Table 7: Evaluation of the physicochemical properties

Test	F1	F2	F3	F4	F5	F6	F7	F8	F9
Homogeneity	Homogenous	Homogenous	Homogenous	Homogenous	Homogenous	Homogenous	Homogenous	Homogenous	Homogenous
Colour	White	White	White	White	White	White	White	White	White
State	Semisolid	Semisolid	semisolid	Semisolid	Semisolid	semisolid	semisolid	semisolid	Semisolid
Odor	Odorless	Odorless	odorless	odorless	Odorless	odorless	odorless	odorless	Odorless
Touch	Not even	Not even	Not even	Not even	Not even	Not even	Not even	Not even	Not even

Anti-Fungal Study:

Table 8: Antifungal Activity against Candida Albicans

1	3mm
2	3.5mm
3	3.5mm



For *C.albicans*

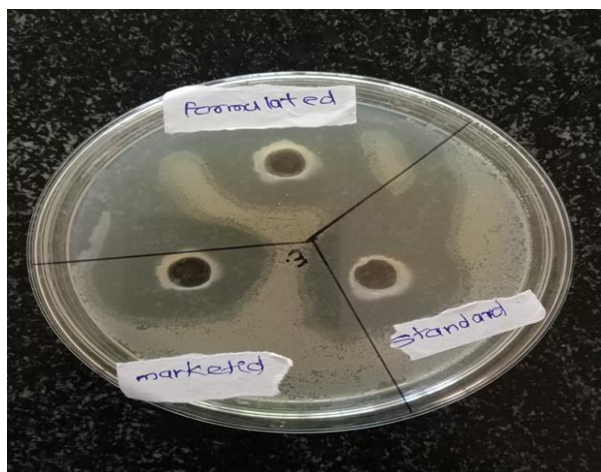
Once the medium gets solidified, fungi were spread with the help of sterile loop and a well of 4mm diameter was cut out of the agar using a sterile borer and test formulation was placed into the well.

The assay plates were incubated for 24hr.at 37°C followed by measurement of diameter of zone of inhibition.⁽¹⁸⁾

In vitro Diffusion Study^(19,20).

For the in-vitro diffusion study, the Franz Diffusion Cell was used; the base of the cell was covered with overnight wetted cellophane membrane. The 5gm of cream is transferred into the Franz Diffusion Cell. This cream-containing cell is tied on a stand and dipped in to the 1000ml

7.4 pH Phosphate buffer and that solution is continuously stirred using a magnetic stirrer. The moment the stirrer is started 5ml of sample is withdrawn which is further replaced by adding 5ml of fresh 7.4 pH Phosphate buffer to the solution. The withdrawn sample's absorbance is measured at λ_{max} 226nm and recorded as zero mins absorbance. The process is repeated after each 5mins interval and absorbance is taken by using a UV spectrophotometer. The marketed formulation was used for comparative studies with the prepared formulations.

Antimicrobial activity:For *E.Coli*

Sr.no	Zone Of Inhibition
1	3.8mm
2	3mm
3	2.8mm

Particle Size and Zeta Potential:

The particle size is one of the most important parameter for the characterization of nanocream. Particle size was found to be 185.4 nm and PDI value is 0.271.

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Measurement Results

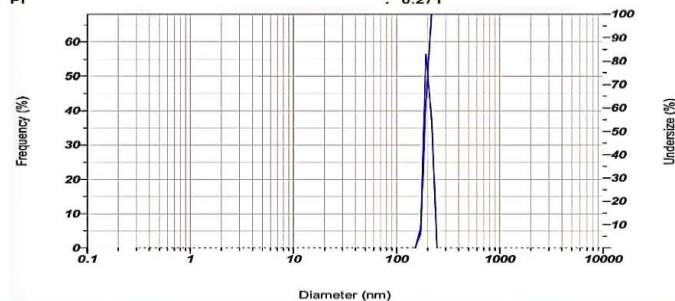
Date : 04 May 2024 02:57:52
 Measurement Type : Particle Size
 Sample Name : Naonocream
 Scattering Angle : 90
 Temperature of the Holder : 25.0 °C
 Dispersion Medium Viscosity : 0.895 mPa·s
 Transmission Intensity before Meas. : 32785
 Distribution Form : Narrow
 Distribution Form(Dispersity) : Polydisperse
 Representation of Result : Scattering Light Intensity
 Count Rate : 27 KCPS

Calculation Results

Peak No.	S.P.Area Ratio	Mean	S. D.	Mode
1	1.00	189.6 nm	13.3 nm	188.3 nm
2	--	-- nm	-- nm	-- nm
3	--	-- nm	-- nm	-- nm
Total	1.00	189.6 nm	13.3 nm	188.3 nm

Cumulant Operations

Z-Average : 185.4 nm
 PI : 0.271



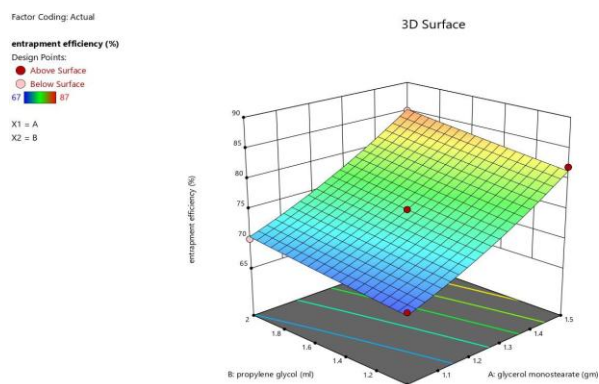
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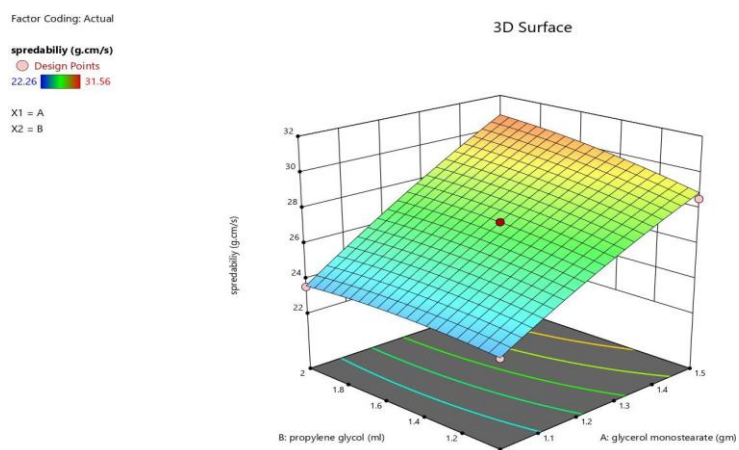
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Concentration of Entrapment Efficiency:

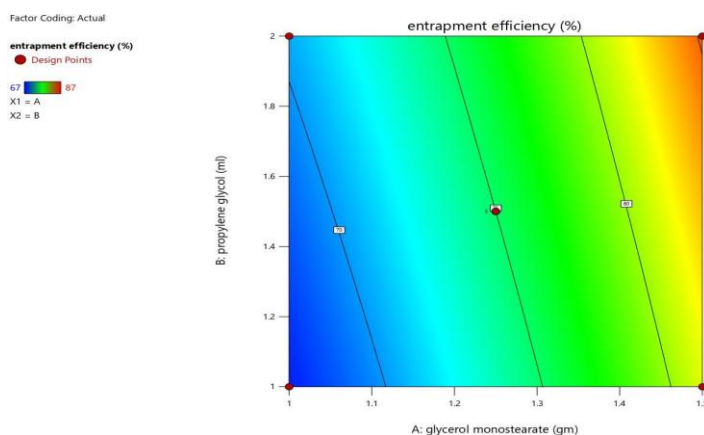


3D Response surface plot showing effect of entrapment efficiency

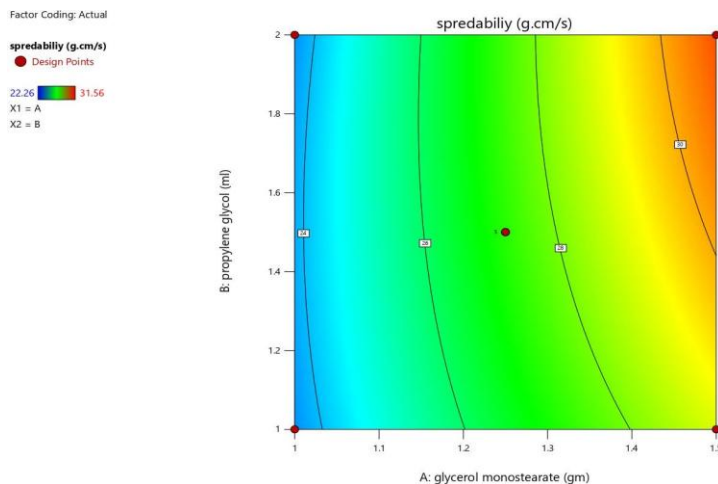
Concentration on Spreadability:



3D Response surface plot showing effect of spreadability



Counter graph showing effect of independent variables on entrapment efficiency



Counter graph showing effect of independent variables on spreadability

Rheological Study:

A brook field viscometer was used to measure the prepared nano cream viscosity

Table 9: Viscosity of formulated batches

Formulation Code	Viscosity
F1	3380±0.03
F2	3268±0.01
F3	3459±0.04
F4	3501±0.07
F5	3340±0.02
F6	3595±0.08
F7	3340±0.02
F8	3577±0.01
F9	3367±0.03

pH of Creams:

It is a crucial parameter to consider. The Cream's should be appropriate for the skin. The prepared cream formulations were found to have pH ranging 6.2 to 7.4.

Table 10: pH of Formulated Batches

Sr. No.	Formulation	pH
1	F1	6.4±0.01
2	F2	6.0±0.08
3	F3	6.6±0.07
4	F4	7.0±0.05
5	F5	7.4±0.03
6	F6	6.2±0.02
7	F7	6.2±0.08
8	F8	6.3±0.08
9	F9	6.1±0.09

Entrapment Efficiency:

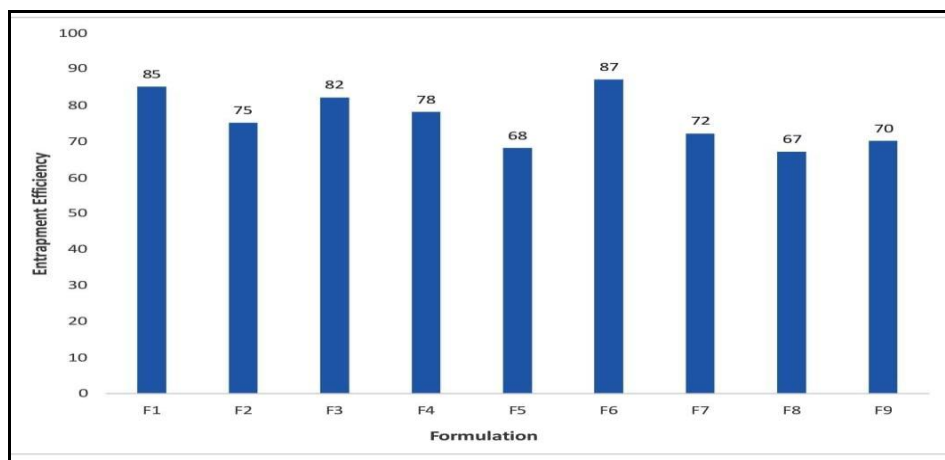
The % entrapment efficiency of all formulations was found to be 65-90%. Among all formulation, F6 shows highest drug entrapment efficiency given in following table.

The receptors compartments 1ml of sample was removed at specified intervals and refilled with an equal volume of HCl

buffer by using UV spectrophotometer at 229nm, the aliquots were examined. The F6 batches total drug release after 6 hours was determined to be 89% which is better percentage of drug release when compared to other formulation.

Table11: Entrapment Efficiency

Formulations	% Entrapment Efficiency
F1	85±0.03
F2	75±0.01
F3	82±0.02
F4	78±0.04
F5	68±0.02
F6	87±0.08
F7	72±0.03
F8	67±0.02
F9	70±0.01

**Figure 2:** Entrapment Efficiency**Table 12:** In-Vitro drug release of ketoconazole nano cream

Time	F1%	F2%	F3%	F4%	F5%	F6%	F7%	F8%	F9%
0	0	0	0	0	0	0	0	0	0
1	3.5	8.8	10.6	8.6	11.1	30.2	10.2	11.5	8.1
2	10.8	24.5	19.9	20.8	23.3	38.8	26.5	27.6	17.6
3	24.7	40.6	29.3	46.5	33.8	41.5	45.3	32.8	30.2
4	45	50.9	42.1	55.2	52.7	51.8	55.8	46.4	38.8
5	60	66.9	56.6	61.9	73.8	78	50.5	50.2	63.3
6	78±0.01	74±0.02	64±0.01	68±0.09	85±0.01	89±0.02	66±0.09	58±0.08	77±0.05

Spreadability:

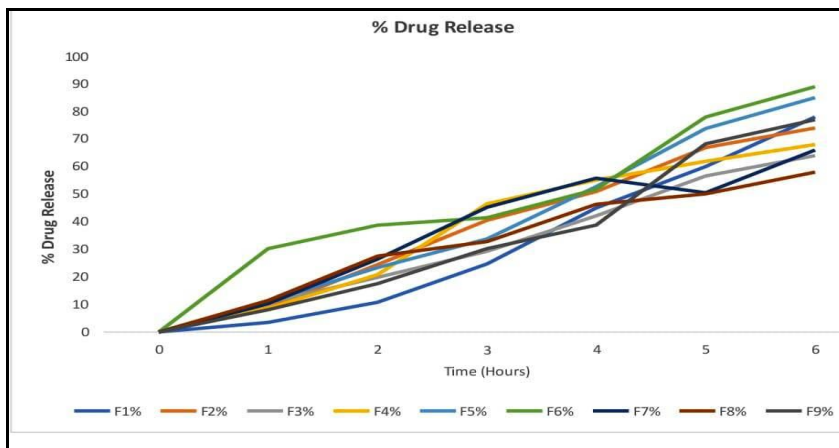
All developed nanocreams were tested for spreadability F1-F9.

Table13: Spreadability of Formulated Batches

Sr. No.	Formulations	Spreadability g.cm/s
1	F1	30.46±0.02
2	F2	27.26±0.03
3	F3	28.56±0.01
4	F4	27.66±0.04
5	F5	3.54±0.09
6	F6	31.56±0.07
7	F7	26.26±0.04
8	F8	22.56±0.03
9	F9	23.54±0.01

Table 14: Stability study

PARAMETR	0 DAYS	1 Month
Appearance	Clear, homogenous, white	Clear, homogenous, white
Spreadability	3.5 \pm 0.04	3.4 \pm 0.05
Ph	6.7 \pm 0.01	6.6 \pm 0.01
Extrudability	96.30 \pm 0.02	95.30 \pm 0.02
% Drug release	87%	90%

**Figure 3:** % Drug Release**Spreadability:**

All developed nanocreams were tested for spreadability F1-F9.

Table 13: Spreadability of Formulated Batches

Sr. No.	Formulations	Spreadability g.cm/s
1	F1	30.46 \pm 0.02
2	F2	27.26 \pm 0.03
3	F3	28.56 \pm 0.01
4	F4	27.66 \pm 0.04
5	F5	3.54 \pm 0.09
6	F6	31.56 \pm 0.07
7	F7	26.26 \pm 0.04
8	F8	22.56 \pm 0.03
9	F9	23.54 \pm 0.01

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Ph	6.7 \pm 0.01	6.6 \pm 0.01
Extrudability	96.30 \pm 0.02	95.30 \pm 0.02
% Drug release	87%	90%

CONCLUSION

Topical drug delivery system is an effective way for drug therapeutic response. In that drug reaches to site of action gives good therapeutic response. It avoids first pass

metabolism. It is easy to apply and convenient route of administration. Skin disease is very common and the need to prevent or treat the disease is in great. Demand. In the present scenario, people need remedy for skin disease

without side effects. It can be conducted that prepared formulation was found to be ideal with reference to evaluation. The prepared antifungal nanocream has best properties and having beneficial values.

In the present study, antifungal nanocream was formulated and evaluated by physical examination, spreadability, viscosity, antifungal studies, etc.

It can be concluded that the formulation of antifungal nanocream was found to be ideal according to evaluation parameters. It protects skin from fungal infections.

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