International Journal of Recent Research and Review, Vol. XIX, Issue 2, June 2026

ISSN 2277 – 8322

DEVELOPMENT OF DEFLAZACORT TOPICAL GEL FOR LOCALIZED ANTI-INFLAMMATORY AND IMMUNOMODULATORY EFFECT

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Abstract- The present study focused on the development and evaluation of Deflazacort topical gel formulations for sustained topical drug delivery. Nine formulations were prepared using different polymers and oils and evaluated for physicochemical properties, drug content, spreadability, extrudability, in vitro drug release, antifungal activity, and stability. Compatibility studies confirmed no significant interaction between the drug and excipients. Among all formulations, F5 containing Carbopol-934 and coconut oil showed optimum performance with high drug content, controlled drug release, good spreadability, and enhanced antifungal activity. Stability studies demonstrated that the formulation remained stable under various storage conditions. The results suggest that the optimized Deflazacort gel is a promising and effective topical drug delivery system for prolonged therapeutic action.

Keywords: Deflazacort, Topical Gel, Carbopol-934, Sustained Release, Antifungal Activity, Stability Studies.

ISSN 2277 – 8322

I. INTRODUCTION

Deflazacort

Deflazacort is a synthetic glucocorticoid derived from prednisolone and is widely used for its potent anti-inflammatory and immunosuppressive properties. It belongs to the corticosteroid class of drugs and is considered to possess efficacy comparable to other glucocorticoids with relatively lesser adverse effects on bone metabolism and growth retardation. Deflazacort exhibits anti-inflammatory, antiallergic, and immunomodulatory activities and is commonly prescribed in autoimmune diseases, allergic disorders, inflammatory conditions, and organ transplantation therapy.

Mechanism of Anti-inflammatory Action

Inflammation is a protective biological response triggered by infection, injury, or irritation. However, excessive inflammation may lead to tissue damage and chronic diseases. Deflazacort exerts its anti-inflammatory action by inhibiting the synthesis and release of inflammatory mediators such as prostaglandins, leukotrienes, cytokines, histamine, and bradykinin.

The drug binds to intracellular glucocorticoid receptors and forms a steroid-receptor complex which translocates into the nucleus and regulates gene transcription. This action suppresses phospholipase A2 activity, thereby preventing the release of arachidonic acid, a precursor of inflammatory mediators. Deflazacort also reduces capillary permeability, leukocyte migration, edema formation, and fibroblast proliferation at the inflammatory site.

II. ANALYSIS OF DEFLAZACORT

1. Ultraviolet absorption

Ultraviolet spectroscopy analysis of the drug was carried out for wavelength maxima and absorbance determination and calibration of standard curve of the drug. It is performed by preparing various conc. Of solution (methanolic Sorensons Buffer, pH 6.8) of drug and run the spectroscopy in the range of 350 to 600 nm to obtained the absorbance for their relative concentration.

$$P_{o/w} = (C_{Oil} / C_{pH\ 6.8})_{equilibrium}$$

1.2.Calibration curve of Deflazacort

Preparation of Sorenson's Buffer pH 6.8

24.5 ml of 0.2 M dibasic sodium phosphate and 25.5 ml of monobasic sodium phosphate was placed in 100 ml volumetric flask, and then added water to make up the volume.

Determination of Absorption maxima

A UV absorption maxima was determined by scanning a 2 to 14 ug/ml solution of Deflazacort in 5% (v/v) methanolic Sorenson buffer pH 6.8 between 250-600nm.

1.3.Pre-formulation – Drug Excipient Compatibility Studies

Preformulation in the broadest sense encompasses all the activities and studies that are required to convert an active

pharmacological substance into a suitable dosage form. This term denotes "An investigation of the physical and chemical properties of a drug substance alone and also when combined with the excipients and polymers".The techniques that were employed are given as under.

1.4.Fourier Transform Infrared Spectroscopy (*Perkin Elmer, Japan***)**

FTIR spectra of excipients – carbopol 934 polymer(C 934), hosphatidylcholine (P90)and cholesterol (CHL) were recorded using KBr pellet technique (2 mg sample in 180 mg KBr) on an IR spectrophotometer (Perkin Elmer, Japan) over a range 400-4000 cm-1.

Drug methanol dissolved added to the formulation before homogenization.

Table 1: Deflazacort Gel

Ingredients (mg)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Deflazacort	2	2	2	2	2	2	2	2	2
Carbopol	2	2	2	2	2	2	2	2	2
Methanol	10	10	10	10	10	10	10	10	10
Tween-80	2	4	6	-	-	-	-	-	-
Coconut Oil	-	-	-	2	4	6	-	-	-
Lemmon Oil	-	-	-	-	-	-	2	4	6
Polyethylene glycol	1	1	1	1	1	1	1	1	1
Methyl Paraben	2	2	2	2	2	2	2	2	2
Propyl Paraben	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Water	80	78	74	80	78	74	80	78	74

III. RESULTS

In the present study Organogel of Deflazacort were prepared and evaluated for their use to obtain Local onset release and to prevent first pass metabolism.

1.2. Analytical Profile of Deflazacort:

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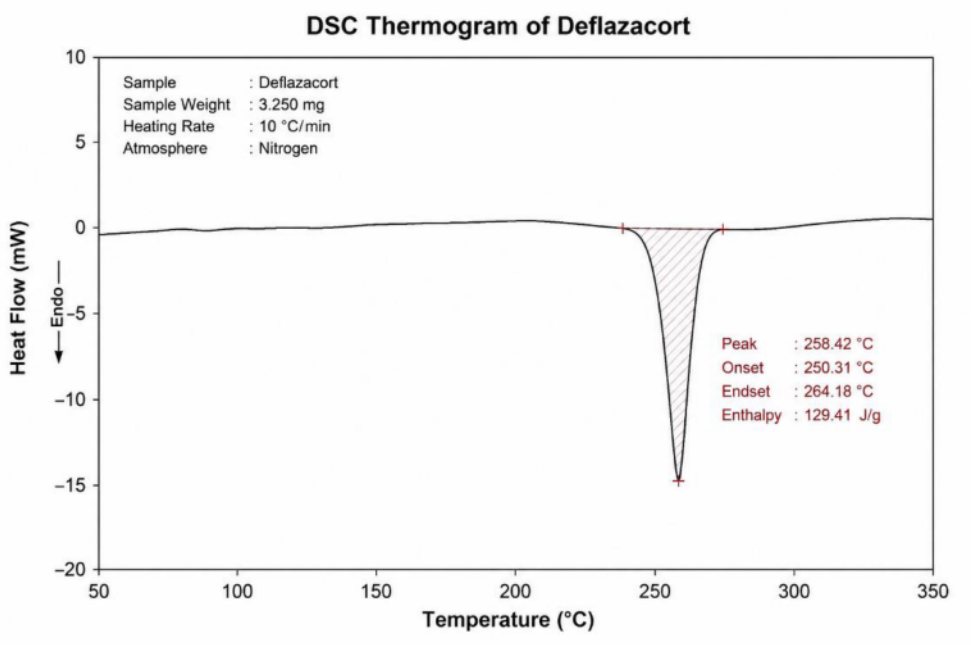

Figure 1: DSC Thermogram of Deflazacort

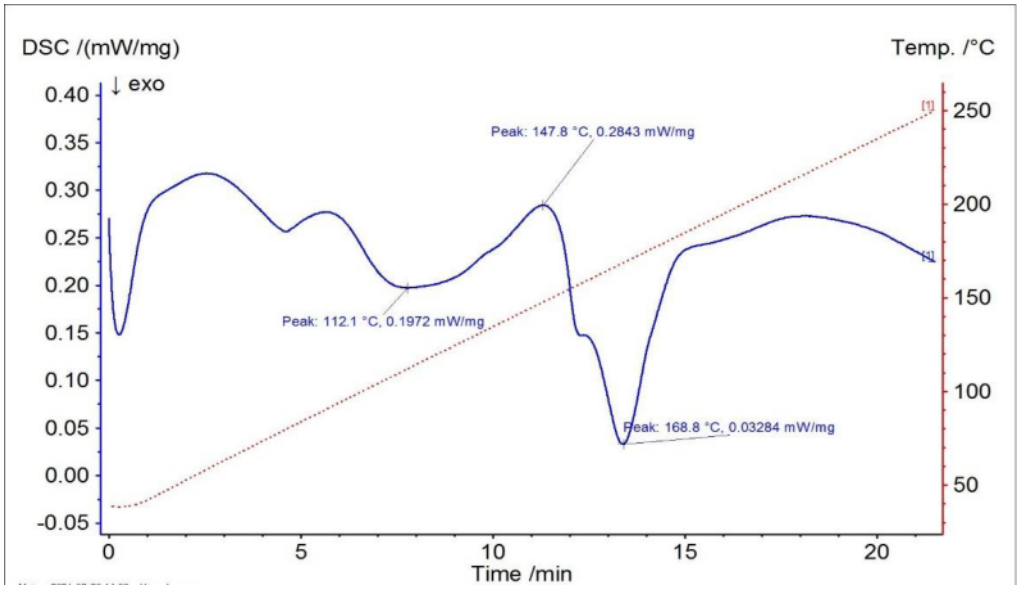

Fig. 2: DSC Thermogram of Deflazacort+ Carbapol+Oils

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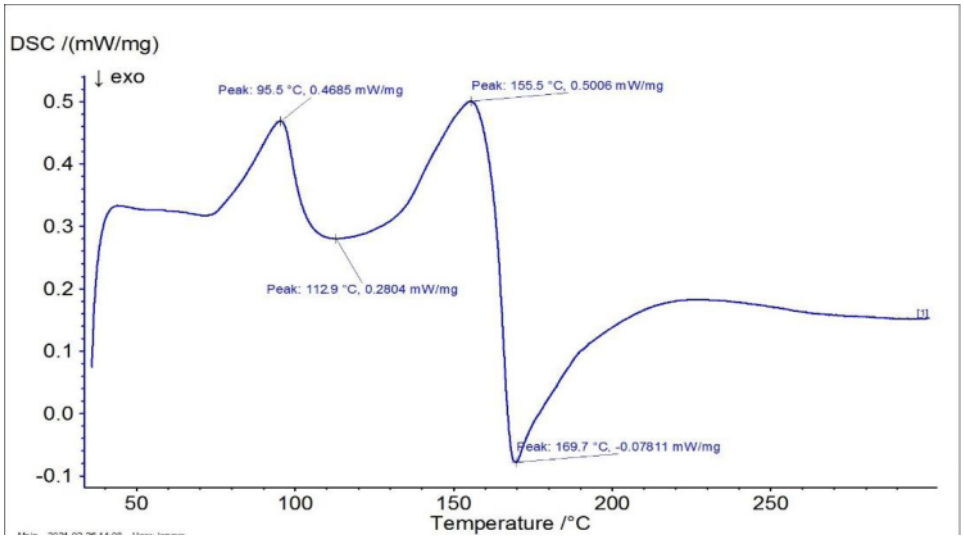

Fig. 3: DSC Thermogram of Deflazacort+ HPMC +Oils

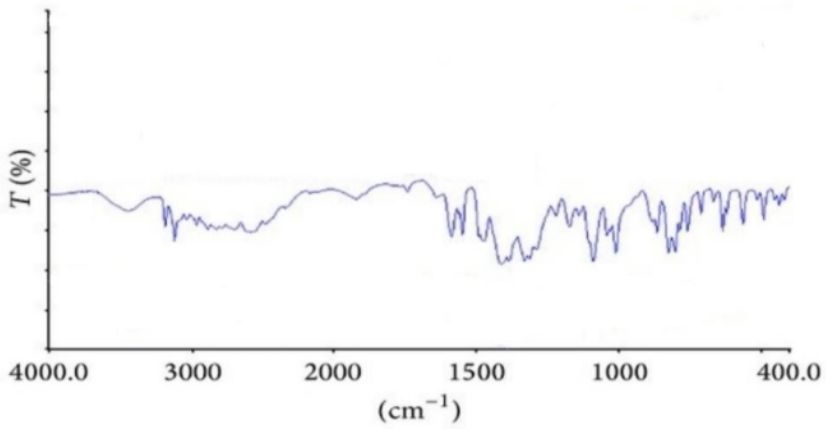

Figure 4: IR Spectra of Deflazacort

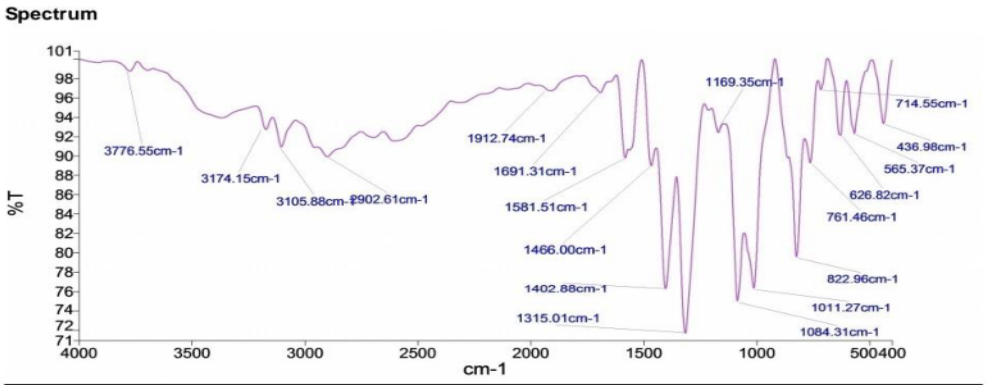

Figure 5: IR Spectra of Deflazacort+ Carbopol + oils

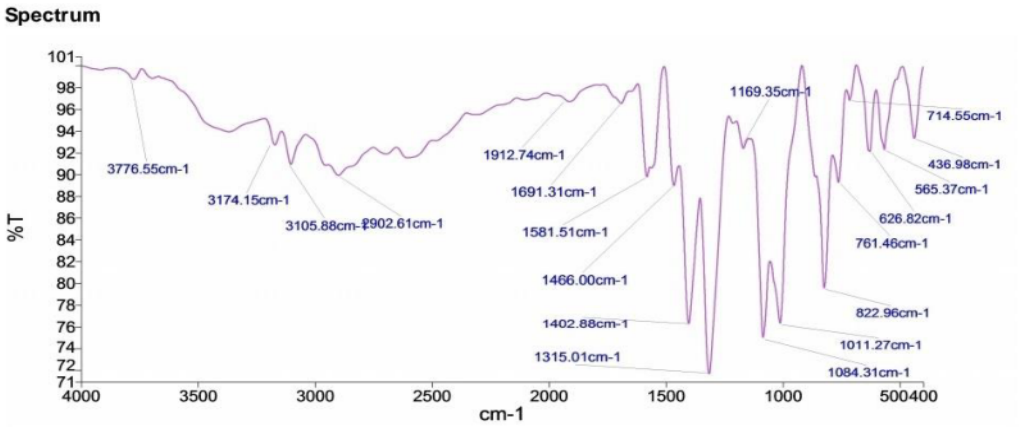

Figure 6: IR Spectra of Deflazacort+ HPMC + oils

The absorption maxima (λ_{max}) of Deflazacort in methanol was found to be 244 nm as shown in Table 2.

Table 2: Determination of maxima wavelength (λ_{max})

Wavelength (nm)	Absorbance
244	0.998
295	1.286
260	0.359
285	0.557
240	0.092
220	0.207

The calibration curve of Deflazacort was prepared in Sorenson's Buffer pH 6.8 at 244 nm and the absorbance values of different concentrations of Deflazacort solutions in Sorenson's Buffer pH 6.8 are shown in Table 3. The Beers law was found to obey in the range of 2.0-14.0 µg/ ml.

Table 3: Calibration Curve Data of Deflazacort

Concentration	Absorbance (244 nm)
0.0	0
2.0	0.176
4.0	0.306
6.0	0.498
8.0	0.639
10.0	0.809
12.0	0.920
14.0	0.998

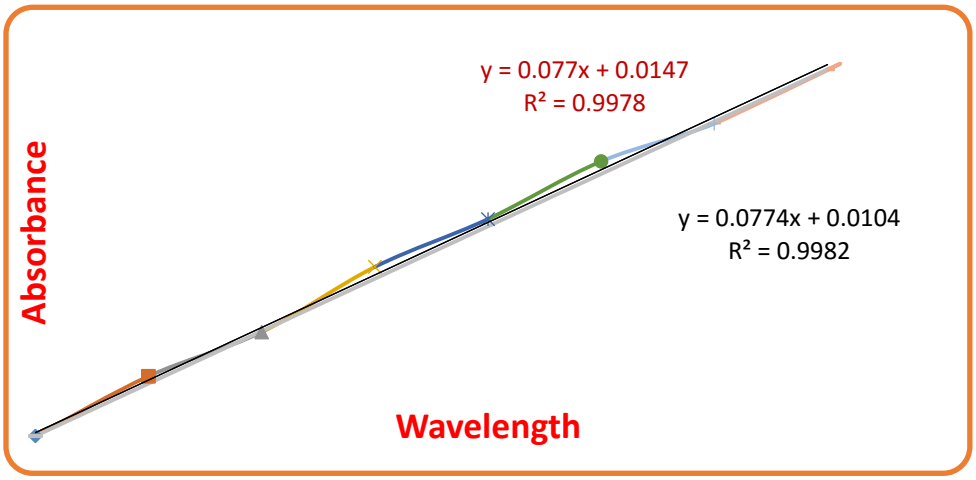

Figure7: Calibration Curve of Deflazacort

Solubility of Deflazacort was determined in different solvents and the observations are shown in Table 4. The maximum solubility was found in Methanol and least in water. Partition coefficient of Deflazacort in n-octanol and sorensons buffer pH 6.8 was found to be 4.

Table 4: Solubility Profile of Deflazacort

S.No.	Solvents	Solubility
1.	Distilled water	+
2.	0.1N Hydrochloric acid	+++
3.	methanol	++++
4.	Ethyl ether	++
5.	Dichloro methane	++
6.	Chloroform	++
7.	DMSO	+++

Practically insoluble + Slightly soluble ++ Soluble ++++

1.3 Characterization of gel

X-ray diffraction spectra of drug and physical mixture of drug and polymer were obtained for investigating the purity of the drug and its crystallinity in physical mixture. X-ray differactometer consist of three basic elements : an X-ray tube, a sample holder, and X-ray differactor.

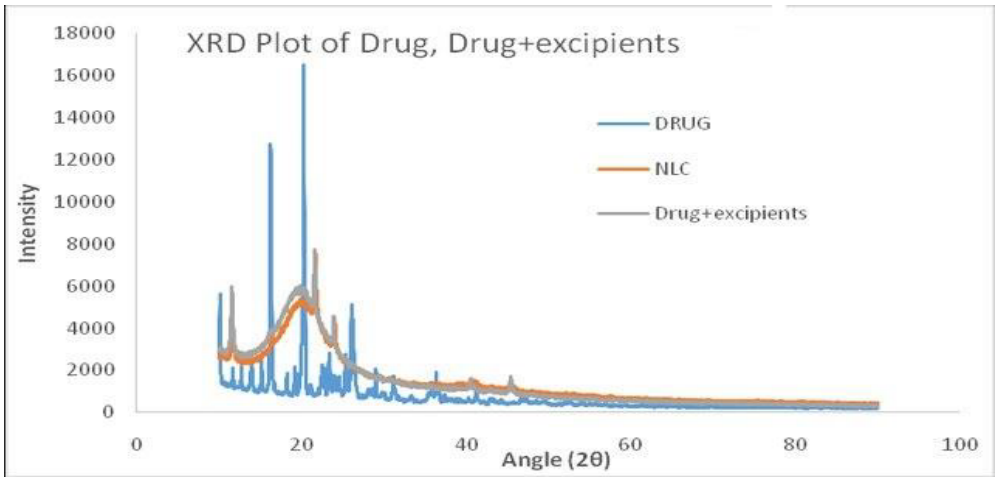

Fig: 8 XRD of (a) Deflazacort nitrate (b) Carbapol and EN mixture

Table 5: Extrudability of gel formulations

Formulation	Extrudability
F1	++++
F2	++++
F3	+
F4	++
F5	++
F6	++
F7	++
F8	+
F9	++

++++Excellent, ++Good, +Not satisfactory

Table 6: Spreadability of gel formulations

Formulation	Time taken (min.)	Spreadability (cm)
F1	30	8.0
F2	30	7.8
F3	30	5.4
F4	30	4.7
F5	30	5.5
F6	30	6.3
F7	30	5.4
F8	30	5.6
F9	30	5.2

Table no. 7 characterization of formulation of Deflazacort Gel

Characterization	F1	F2	F3	F4	F5	F6	F7	F8	F9
Ph	7.2	7.1	7.3	7.1	7.1	6.9	7.0	7.3	7.1
Viscosity (cP)	43k	43.5k	43.1k	43k	43.5k	43.2k	43.1k	43.2k	43.1k
Gelling capacity	++	++	++	++++	++++	++++	+++	++++	++++
Content Uniformity (% w/w)	96.09 ±0.38	97.54 ±0.70	96.17 ±0.81	98.51 ±0.34	99.03 ±0.21	98.97 ±0.54	96.63 ±0.87	98.68 ±0.21	97.74 ±0.18

Table 8: In-vitro release data of Deflazacort gel

Time (Hrs)	**% cumulative drug release from various batches**				
	F1	F2	F3	F4	F5
0	0	0	0	0	0
1	16.50	17.40	21.40	12.24	21.32
2	25.30	24.20	20.42	12.46	22.31
3	44.25	46.13	43.16	26.21	33.45
4	64.23	60.41	62.12	38.29	46.56
5	72.27	77.46	76.33	40.09	60.01
6	87.42	85.03	83.14	53.46	69.21
7	92.02	92.46	93.33	75.63	74.91
8	97.98	98.72	98.04	89.32	84.12
9	16.50	17.40	21.40	12.24	21.32
10	25.30	24.20	20.42	12.46	22.31
11	44.25	46.13	43.16	26.21	33.45
12	64.23	60.41	62.12	38.29	46.56

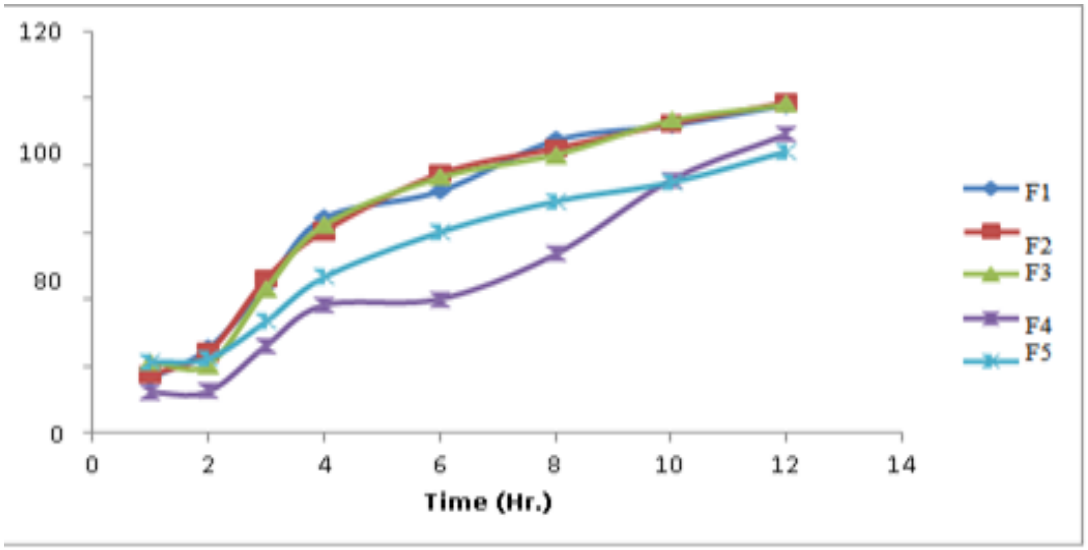

Figure 9: In vitro release curve of Deflazacort

Table 9: In-vitro release data of Deflazacort gel

Time (Hrs.)	% cumulative drug release from various batches			
	F6	F7	F8	F9
0	0.00	0.00	0.00	0.00
1	18.40	28.42	22.37	25.13
2	28.17	37.72	27.08	32.26
3	30.46	43.27	42.36	35.52
4	49.81	49.60	51.18	49.09
6	61.21	57.12	55.19	56.72
8	70.15	66.61	61.68	58.40
10	74.96	63.32	72.84	63.61
12	83.28	79.10	77.37	74.12

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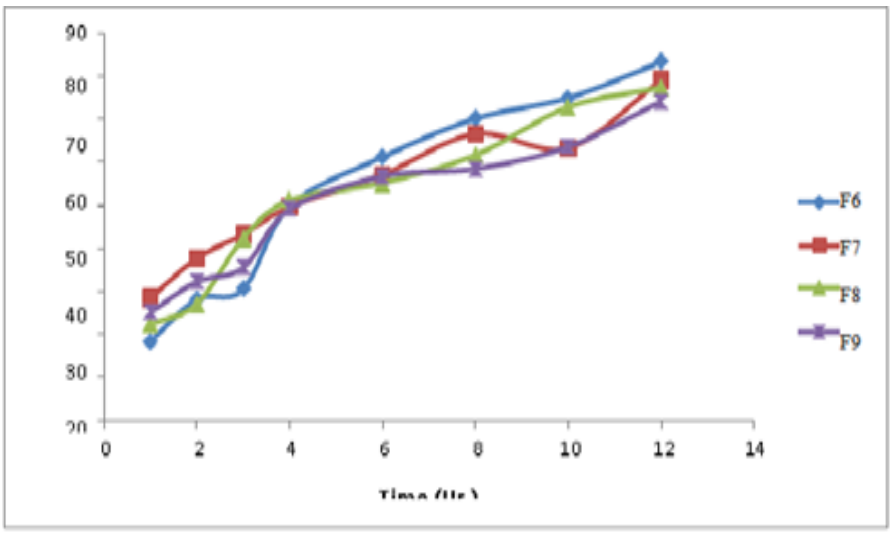

1.4.Antifungal sensitivity:

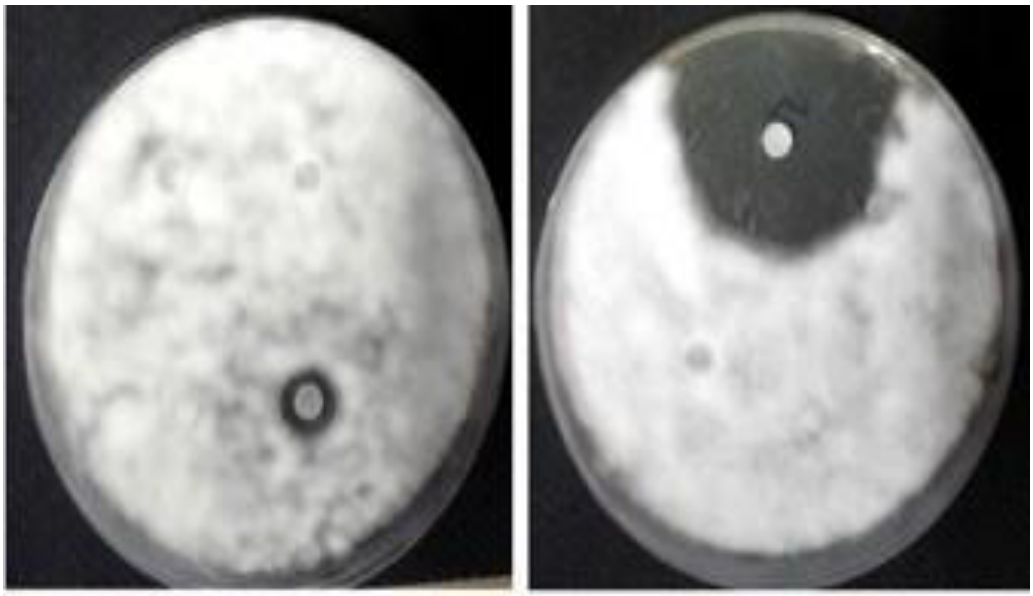

Figure 11: Antifungal Activity

Marketed Product F5

Table 10: Stability studies of formulation F5 (Carbopol-934 with coconut oil)

Parameters	**Room Temperature (25±2^{0}C)**	**40±2^{0}C**	**4-5±2^{0}C**
Visual appearance			
Initial	Transparent	Transparent	Transparent
Final	Transparent	Transparent	Transparent
Ph			
Initial	6.9	6.9	6.9
Final	7.1	7.0	6.9
Viscosity (cps)	43,000	43,000	43,000
Initial	43,000	43,500	43,000
Final			
Extrudability	**+++**	**+++**	**+++**
Initial	**+++**	**+++**	**+++**
Final			
Phase separation	Not found	Not found	Not found
Leakage	Not found	Not found	Not found
Nature			
Initial	Smooth	Smooth	Smooth
Final	Smooth	Smooth	Smooth

1.5. Chemical evaluation

The drug content of the formulation was estimated over a period of 3 months. The results were tabulated as follows.

Table 11: Drug content of formulation F5 (Carbopol-934 with coconut oil)

Storage condition	Withdrawal period (monthly)			
	0	1	2	3
4-5^{0}C	99.03	98.90	98.85	98.55
Room Temperature (25±2^{0}C)	99.03	98.95	98.85	98.80
40±2^{0}C	98.85	98.80	98.75	98.70

IV. CONCLUSION

The present investigation successfully developed and evaluated Deflazacort topical gel formulations using different polymers and oils for effective topical drug delivery. The study confirmed that topical gel formulations are capable of providing controlled and sustained release of Deflazacort with suitable physicochemical characteristics for topical application.

Among all formulations, formulation F5 containing Carbopol-934 with coconut oil was identified as the optimized formulation due to its superior viscosity, spreadability, gelling capacity, drug content uniformity, and sustained drug release profile. The optimized formulation also demonstrated better antifungal activity and satisfactory stability under various storage conditions.

The developed topical gel showed acceptable pH, good consistency, smooth texture, excellent extrudability, and enhanced patient applicability. The in-vitro release studies indicated prolonged drug release behavior, which may help maintain therapeutic drug concentration for longer durations and reduce the frequency of application.

Stability studies confirmed that the optimized formulation remained physically and chemically stable without significant changes in formulation properties during storage. The incorporation of suitable polymers and oils significantly contributed toward improved formulation performance and enhanced topical delivery of Deflazacort.

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