WJPMR, 2026, 12(5), 161-167

Research Article

Impact Factor: 7.555

WORLD JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

ISSN (O): 2455-3301
ISSN (P): 3051-2557
Coden USA: WJPMBB

FORMULATION DEVELOPMENT, CHARACTERIZATION AND IN-VITRO EVALUATION OF LULICONAZOLE AND CLOBETASOL PROPIONATE HYDROGEL

Lekhitha L.[1*], Gokul B.[2], Naveen Kumar M.[3], Heleena Jancy Rani R.[4], Dr. R. Caroline Jeba.[5], Dhanesh Kumar M. R.[6], Dr. Sathish A.[7]

[*1,2,3,4]Undergraduate Research Scholar, GRD College of Pharmacy, Thiruvallur.
[5]Professor, Dept. of Biotechnology, Dr. M.G.R. Educational and Research Institute, Chennai.
[6] Assistant Professor, GRD College of Pharmacy, Thiruvallur.
[7]Principal, GRD College of Pharmacy, Thiruvallur.
Affiliated to The Tamil Nadu Dr. M.G.R Medical University, Chennai.

***Corresponding Author: Lekhitha L.**
Undergraduate Research Scholar, GRD College of Pharmacy, Thiruvallur, Affiliated to The Tamil Nadu Dr. M.G.R Medical University, Chennai.

DOI: https://doi.org/10.5281/zenodo.19916269

How to cite this Article: Lekhitha L.[1*], Gokul B.[2], Naveen Kumar M[3], Heleena Jancy Rani R.[4], Dr. R. Caroline Jeba.[5], Dhanesh Kumar M. R.[6], Dr. Sathish A.[7]. (2026). Formulation Development, Characterization And In-Vitro Evaluation of Luliconazole and Clobetasol Propionate Hydrogel. World Journal of Pharmaceutical and Medical Research, 12(5), 161–167.

Article Received on 22/03/2026 **Article Revised on 11/04/2026** **Article Published on 01/05/2026**

ABSTRACT
The objective of this research was to develop and evaluate a hydrogel formulation containing a combination of Luliconazole (an antifungal) and Clobetasol Propionate (a corticosteroid) for the treatment of inflammatory skin conditions such as atopic dermatitis and psoriasis. Hydrogels were prepared using Carbomer 940 as the gelling agent. Pre-formulation studies, including FTIR and physical compatibility tests, confirmed the absence of drug-excipient interactions. Five formulations (F1–F5) were developed with varying concentrations of Carbomer 940. The optimized formulation (F2) exhibited excellent physical properties, including a pH of 6.90, spreadability of 5.35 cm, and superior extrudability. Drug content analysis showed high entrapment efficiency (100.69% for Luliconazole and 99.05% for Clobetasol Propionate). *In vitro* diffusion studies revealed a controlled release profile, with cumulative drug release reaching 96.19% for Luliconazole and 94.45% for Clobetasol Propionate over 8 hours. Stability studies for 45 days showed no significant changes in physical or chemical parameters, suggesting that the developed hydrogel is a stable and effective platform for the dual delivery of antifungal and anti-inflammatory agents.

KEYWORDS: Luliconazole, Clobetasol Propionate, Hydrogel, Carbomer 940, Topical Delivery, Controlled Release.

INTRODUCTION
A hydrogel is a unique type of soft biomaterial having a hydrophilic polymer network and have been the center of attraction for biomaterials scientists for many years. As we know, hydrogels available for clinical use are under continuous change due to their own limitations. Actually, each hydrogel system prepared by using selective preparation technique shows its own merits and demerits in terms of applications particularly regenerative medicines, being employed *in vitro* and *in vivo*. Hydrogels are water-swollen three-dimensional crosslinked polymer network, consisting of hydrophilic polymers and can be swollen with water up to 99% w/w of their dry weights.[1,2]

Hydrogels exhibit notable swelling properties, responding rapidly to changes in environmental conditions such as pH, temperature, and ionic species, which alter their physical texture. Their mechanical properties can be adjusted through variations in crosslinking and heating, depending on the desired application. Hydrogels are composed of both natural polymers (like chitosan and gelatin) and synthetic polymers (such as acrylic acid and methacrylate). Biocompatibility is crucial, involving bio-functionality for specific tasks and bio-safety ensuring a safe response from the host and surrounding tissue.[3,4]

Hydrogels have diverse applications in various medical fields. They are used in wound healing for their ability to retain moisture and drug delivery, especially in the colon due to polysaccharide enzymes. In gastrointestinal drug delivery, hydrogels demonstrate tissue specificity based on pH changes. Transdermal delivery systems exploit hydrogels for enhanced drug permeation, while gene delivery benefits from modified hydrogels to target specific cells effectively. Additionally, micronized hydrogels are important in tissue engineering for delivering macromolecules, and they are extensively utilized in ocular drug delivery systems for controlled release, improving drug effectiveness and reducing dosing frequency.[5]

Methods of preparation for hydrogels include several polymerization techniques: (i) Bulk Polymerization: Involves a single or multiple monomer types and a small quantity of cross-linkers. Initiation occurs via UV radiation or catalysts, producing various physical forms like films or rods. (ii) Solution Polymerization: Utilizes neutral or ionic monomers reacted with multifunctional cross-linking agents, where the solvent acts as a heat sink. Requires washing to remove impurities. (iii) Suspension Polymerization: Also known as inverse suspension polymerization, it allows for formulations as powders or microspheres, with monomers and initiators suspended in a non-polar phase. (iv) Grafting to Support: Enhances mechanical strength by polymerizing monomers onto support material through covalent bonding. (v) Polymerization by Irradiation: Uses high-energy radiation like gamma rays to create radicals in the polymer solution, leading to a cross-linked structure. (vi) Physical Cross-Linking: Employs physical interactions like hydrogen bonding and polyelectrolyte complexation for hydrogel formation. (vii) Complex Coacervation: Forms gels by mixing oppositely charged polyanions and polycations, resulting in both soluble and insoluble complexes based on concentration and pH.[6,7]

Atopic dermatitis (AD) is a chronic inflammatory skin disease that typically manifests in early childhood and may precede the development of other atopic disorders, including asthma, allergic rhinitis, and food allergies.[3] The onset of AD most commonly occurs between 3 and 6 months of age, with approximately 60% of children with AD presenting symptoms in the first 12 months. Consensus guidelines indicate that AD is characterized by essential features such as pruritus and eczema (acute, subacute, or chronic), with eczema lesions displaying typical morphology or age-specific patterns and having a chronic or relapsing history.[8,9]

Clobetasol Propionate may be used to treat moderate-to-severe eczema, plaque psoriasis, and some other skin conditions, such as lichen sclerosis. Luliconazole is a potent, broad-spectrum imidazole antifungal agent primarily used to treat superficial fungal infections like tinea corporis and cruris. It acts by disrupting the fungal cell membrane, with some studies showing high efficacy in treating fungal complications. Topical drug delivery is the preferred treatment for superficial fungal infections due to its direct application and minimized systemic exposure. Traditional forms like creams and ointments have drawbacks, including greasiness and poor patient acceptance. Hydrogel formulations address these issues by enhancing spreadability, absorption, and aesthetic appeal while providing cooling relief.[10] A hydrogel-based formulation combining luliconazole, a potent antifungal, and clobetasol, a strong corticosteroid, offers dual benefits: infection control and inflammation reduction. This combination accelerates healing and improves patient outcomes, demonstrating superior efficacy compared to conventional treatments. This study is aimed to formulate and evaluate hydrogel of Luliconazole and Clobetasol Propionate for the treatment of acute dermatitis.

MATERIALS

Luliconazole and Clobetasol Propionate Hydrogel was prepared using Clobetasol propionate (SGS Formulations), Luliconazole (SGS Formulations), Carbopol 940 (Tristar formulations), Isopropyl Alcohol (SGS Formulation), Propylene Glycol (SGS Formulation), Methyl paraben (Lab chemicals), Propyl paraben (Lab chemicals) and Triethanolamine (Lab chemicals).

METHOD

(i) Preformulation Studies

Preformulation studies explore the physical and chemical properties of a drug substance, both alone and with excipients, serving as the first step in developing stable and bioavailable drug dosage forms. Key goals include establishing physical characteristics, compatibility with excipients, and determining kinetic rate profiles. Compatibility studies are crucial for selecting suitable excipients by examining both physical mixtures and using infrared (IR) spectroscopy to detect potential chemical interactions. Physical compatibility is assessed visually, while chemical compatibility is evaluated through FT-IR analysis of drug-excipient mixtures prepared via the potassium bromide pellet technique. Additional studies done includes determining the melting point and absorption maxima of drugs like Luliconazole and Clobetasol Propionate, as well as conducting solubility studies in various media. Polymers like HPMC K4M and CMC are screened for further formulation development.[11]

(ii) Development and Formulation of Luliconazole with Clobetasol Propionate Hydrogel

Hydrogels were formulated using different concentrations of polymeric dispersions. Different concentrations of Carbopol 940 colloidal dispersions were prepared with distilled water by using magnetic stirrer (500rpm). After complete dispersion, the polymer solutions were kept in dark for 24 h for complete swelling. Aqueous drug solution was added to the polymeric dispersion. Methyl paraben and propyl paraben were added. Finally, the remaining distilled water was added to obtain a homogeneous dispersion of gel under magnetic stirring.[12] Different formulation trials were made using different concentrations of hydrophilic and hydrophobic polymers along with sodium bicarbonate summarized in the Table 1.

Table 1: Formulation of Luliconazole with Clobetasol Propionate Hydrogel.

S.NO	INGREDIENTS	FORMULATION CODE DRUG				
		F1	**F2**	**F3**	**F4**	**F5**
1.	Luliconazole	10 mg	10 mg	10 mg	10 mg	10 mg
2.	Clobetasol Propionate	500 mcg	500mcg	500 mcg	500 mcg	500 mcg
3.	Carbomer 940	0.5mg	1.0mg	1.5mg	2.0mg	2.5mg
4.	Methyl Paraben	0.1mg	0.1mg	0.1mg	0.1mg	0.1mg
5.	Propyl Paraben	0.01mg	0.01mg	0.01mg	0.01mg	0.01mg
6.	Triethanolamine	0.001ml	0.001ml	0.001ml	0.001ml	0.001ml
7.	Isopropyl Alcohol	0.05ml	0.05ml	0.05ml	0.05ml	0.05ml
8.	Poropylene Glycol	0.1ml	0.1ml	0.1ml	0.1ml	0.1ml
9.	Purified Water	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.

(iii) Characterization of Luliconazole with Clobetasol Propionate Hydrogel

Evaluation parameters like pH, Swelling index, Extrudability, Spreadability, Viscosity and Drug content were performed. (**Table 3**).[13,16]

***In-Vitro* Drug Diffusion Study**

The *in vitro* drug release studies were performed by using diffusion cell with cellophane paper. The water jacketed recipient compartment had total capacity of 20 ml. The donor compartment was placed in such a way that it just touches the diffusion medium in receptor compartment. The receptor compartment contained phosphate buffer saline (PBS) that was maintained at 37°C ± 1°C. The membrane was equilibrated before application of the hydrogel onto the donor side. Samples were periodically withdrawn from the receptor compartment, replacing with the same amount of fresh PBS solution, and assayed by using a spectrophotometer at 237 and 240 nm for Luliconazole and Clobetasol Propionate respectively.[17]

Accelerated Stability Studies

Stability studies were carried out as per ICH guidelines. The Hydrogel were kept at 40±2ºC and relative humidity 75±5% for period of 45 days in stability chambers. After 30 and 45 days, samples were taken out and analyzed for their physical appearance and drug content.[18]

RESULTS AND DISCUSSION

(i) Preformulation Studies

Physical Compatibility

The evaluation was carried out for 10, 20 and 30 days at room temperature and at 40°C ± 2°C and RH 75% ± 5%. There was no change in colour. Therefore, the drug and excipients are physically compatible with each other.

Chemical Compatibility

The peak observed in the FT-IR spectrum of Luliconazole, Clobetasol Propionate and Carbomerl-940 (Fig. 1) admixture showed no shift and no disappearance of the characteristic peaks of drug. This suggests that there is no interaction between the drugs and Carbomer-940.

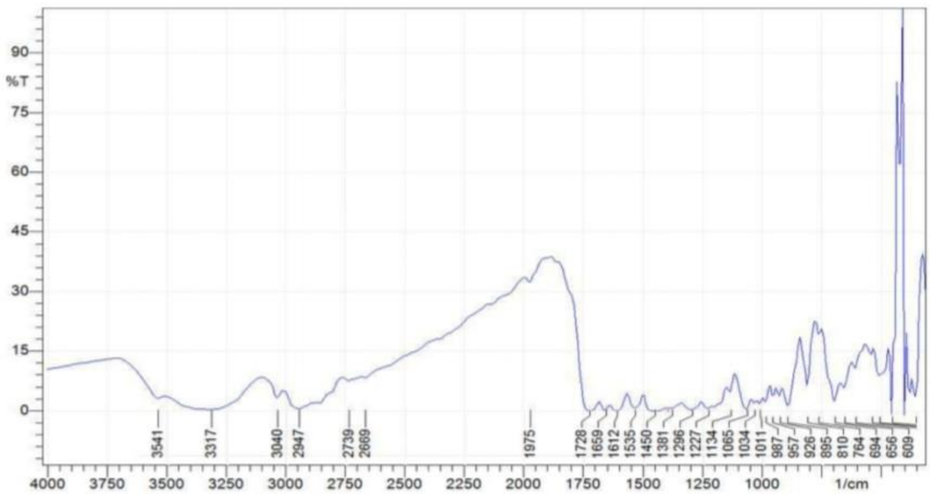

Fig. 1: FT-IR Spectrum of Luliconazole + Clobetasol propionate + Carbomer 940.

Table 2: FT-IR spectral interpretation of Luliconazole + Clobetasol propionate + Carbomer 940.

Wave number (cm-1)	Types of vibrations
1535.0	C=C Stretching
1728.0	C=O Stretching
1065.0	C=F Stretching
3317.0	COOH Stretching
3541.0	OH Stretching
3040.0	C-H Stretching (Aromatic)
1381.0	C-N Stretching
694.0	C=CI Stretching
1065.0	C=O Stretching

Melting Point

The melting points of Luliconazole and Clobetasol Propionate were determined to be 151°C and 198°C, respectively, which align with their standard values of 150 to 154°C and 196 to 198°C, indicating quality consistency.

Solubility Studies

The solubility studies of Luliconazole and Clobetasol Propionate were conducted in various solvents. Luliconazole exhibited a solubility of 0.001 mg/ml in water, 11.5 mg/ml in methanol, 24.2 mg/ml in ethanol, 0.001 mg/ml in phosphate buffer (pH 6.8), and 52.5 mg/ml in propylene glycol. Clobetasol Propionate showed slightly higher solubility, with 0.002 mg/ml in water, 15.5 mg/ml in methanol, 25.6 mg/ml in ethanol, 0.001 mg/ml in phosphate buffer (pH 6.8), and 35.7 mg/ml in isopropyl alcohol. Both compounds were determined to be soluble in methanol and ethanol.

(ii) Development and Formulation of Luliconazole with Clobetasol Propionate Hydrogel

Luliconazole and Clobetasol propionate loaded hydrogel were prepared by solvent casting method using Carbomer 940, MethyIparaben, Propyl paraben, Triethanolamine,Isopropyl alcohol, Propylene Glycol.

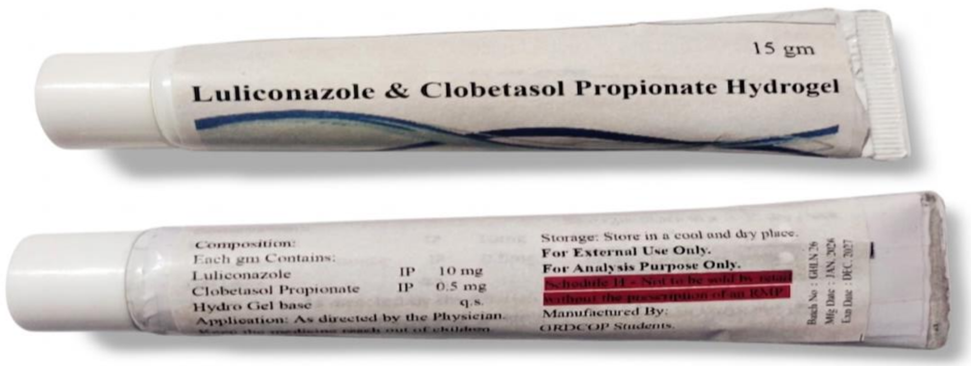

Fig. 2: Finished product of Luliconazole with Clobetasol Propionate Hydrogel.

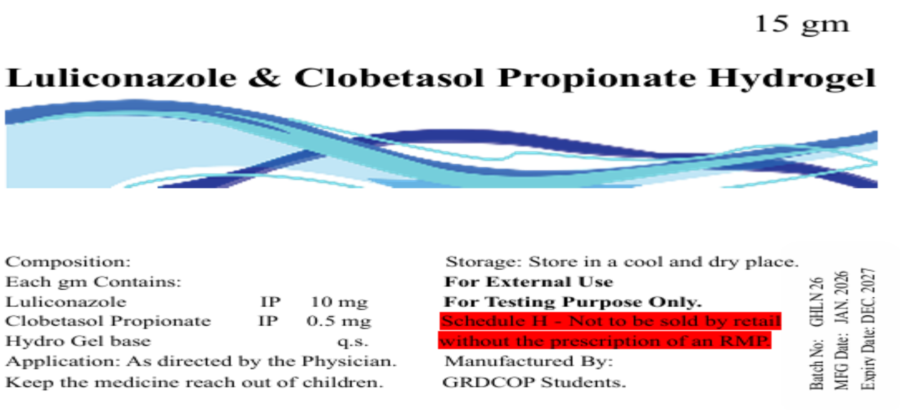

Fig. 3: Label for Luliconazole and Clobetasol Propionate Hydrogel.

(iii) Characterization of Luliconazole with Clobetasol Propionate Hydrogel

All the formulations were evaluated for their various parameters like pH, Swelling index, Spreadability, Extrudability, Viscosity and Drug content (**Table 3**).

Table 3: pH, Swelling index, Spreadabilty, Viscosity and Drug Content of Luliconazole and Clobetasol Propionate Hydrogel.

Formulation Code	pH	Swelling Index (%)	Spread ability (cm)	Extrud Ability	Viscosity (cps)	Drug Content (%)	
						Luliconazole	Clobetasol Propionate
F1	7.02	19.4	5.32	Good	1432	86.7	90.23
F2	6.90	22.8	5.13	Excellent	1523	100.69	99.05
F3	6.89	25.5	5.35	Good	1493	91.5	93.51
F4	6.98	21.8	5.53	Good	1502	89.16	88.25
F5	7.07	24.3	5.24	Good	1482	90.16	95.67

***In-Vitro* Drug Diffusion Study**

The *in-vitro* drug profile of Luliconazole and Clobetasol Propionate from different formulations was carried and the results are depicted in Table 4 & 5**.** The highest drug release was found in the formulation F2 i.e. 94.45% (Clobetasol Propionate) and 96.19% (Luliconazole) within 8 hrs. F2 was found to be optimized formulation based on the dissolution and other evaluation parameters.

Table 4: *In Vitro* Drug Release profile of formulation (Luliconazole).

Time (hours)	Cumulative percentage drug release				
	F1	**F2**	**F3**	**F4**	**F5**
1	4.70	9.72	8.43	8.90	6.50
2	10.45	21.35	16.93	18.38	11.72
3	26.34	38.23	27.51	29.08	23.87
4	36.78	47.97	37.97	40.75	38.23
5	42.63	59.68	44.61	45.74	48.98
6	52.87	71.87	59.32	54.78	53.68
7	64.78	83.45	71.89	69.78	63.89
8	72.04	96.19	89.03	78.50	74.12

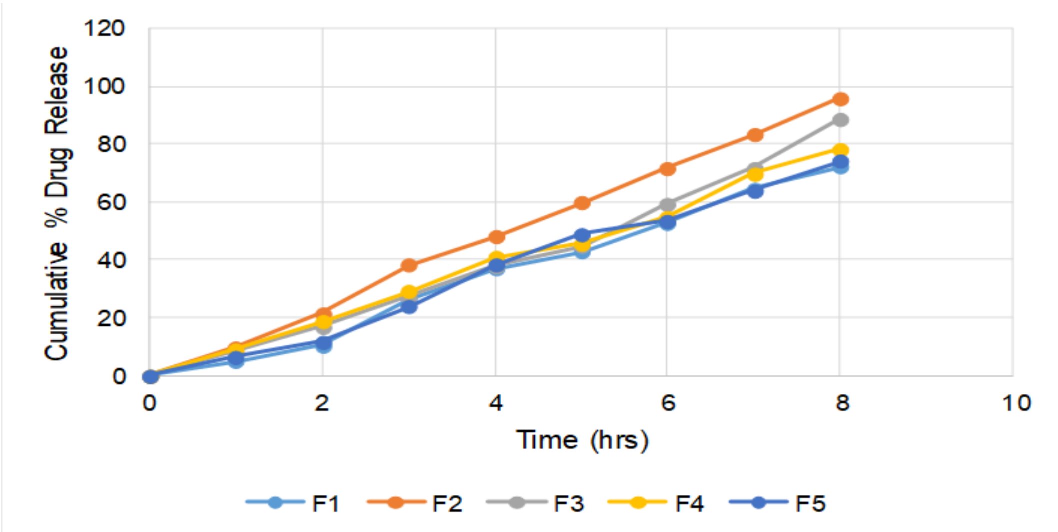

Fig. 4: *In Vitro* Drug Release profile of formulation (Luliconazole).

Table 5: *In Vitro* Drug Release profile of formulation (Clobetasol Propionate).

Time (hours)	Cumulative percentage drug release				
	F1	**F2**	**F3**	**F4**	**F5**
1	7.02	9.68	7.98	8.50	8.80
2	17.97	17.97	16.77	17.23	10.4
3	23.67	28.25	25.44	28.06	25.73
4	41.43	41.12	39.06	38.97	40.6
5	50.68	54.90	53.64	44.08	53.56
6	57.45	67.64	68.12	54.76	59.44
7	65.82	82.48	77.87	68.09	67.90
8	70.09	94.45	91.72	77.03	75.57

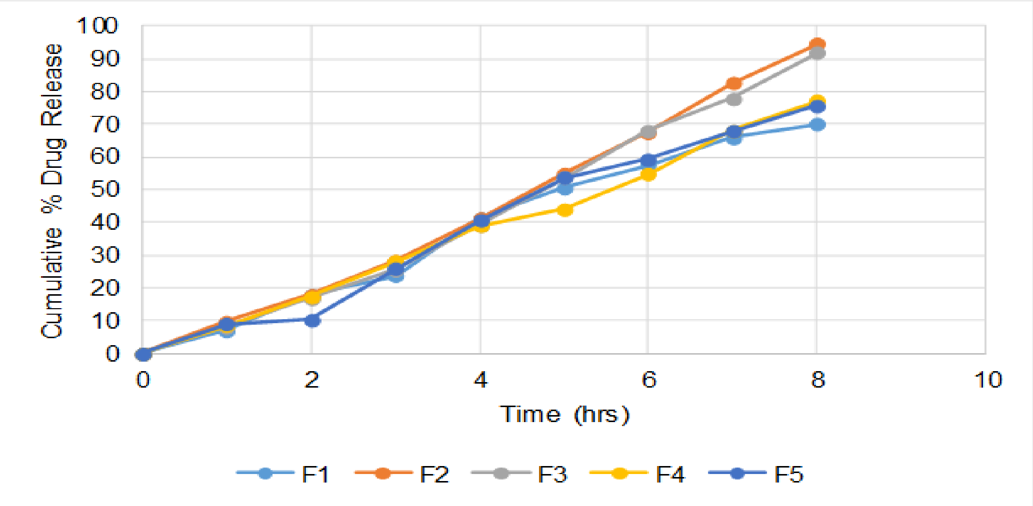

Fig. 5: *In Vitro* Drug Release profile of formulation (Clobetasol Propionate).

Accelerated Stability Studies

Optimized formulation F2 was selected for stability studies on the basis of high cumulative % drug release. Short term stability studies were conducted according to ICH guidelines. From the results it was concluded that, There is no significant changes in physical appearance, drug content and drug release at the storage conditions of 4ºC±2ºC / 75±5%RH, 40ºC±2ºC and at room temperature after the end of 30 days.

CONCLUSION

The study investigates the incorporation of Luliconazole and Clobetasol propionate into hydrogel for controlled drug release, enhancing dosage accuracy and patient comfort. Physical compatibility tests confirmed the drugs and excipients were compatible, while FTIR analysis showed no chemical interactions. Drug content ranged from 86.7% to 100.69% for Luliconazole and 88.25% to 99.05% for Clobetasol propionate. The hydrogel demonstrated a cumulative drug release of 96.19% and 94.45% over 8 hours, highlighting its efficiency compared to traditional formulations. F2 was stable and retained their original properties with minor differences. Future work includes *in-vivo* studies on skin irritation, drug deposition, and bioequivalence in humans.

REFERENCES

1. Reddy KV, Nagabhushanam MV, Naik ER. Swellable hydrogels and cross linking Agents-Their role in drug delivery system. Research J. Pharm. and Tech. 2017 Mar 28; 10(3): 937-43.
2. Mohite PB, Adhav SS. A hydrogels: Method of Preparation and applications International Journal of Advances in Pharmaceutics 2017; 06(03): 79-85.
3. Chirani N, Yahia LH, Gritsch L. et al. History and Applications of Hydrogels Jumal of Biomedical Science 2016; 4: 2.
4. Garg S, Garg A. Hydrogel, classification, Properties, Preparation and Techosal Features. Asian Journal of Biomaterial Research, 2016; 2(6): 163-170.
5. Devi A. Nautiyal U, Kaur S, Komal. Hydrogel: a smart drug deliver device. Asas Pacific Journal of Health Sciences, 2014; 1(45): 92-105.
6. Sing A, Sharma PK, Garg VK, Garg G. Hydrogels: a review. International journal of Pharmaceutical Sciences Review and Research, 2010; 4(2).
7. Abbas K, Amin A, Mudassir J, Abdullah Alzahrani AY, Saher T, Manzoor R. Aleem A. Khan MA, Wazir MA, Rana SJ, Abdul khaliq H. Preparation, characterization and evaluation of hydrogels from different fractions of diverse medicinal plants for management of pain and inflammation. International Journal of Food Properties. 2023 Sep 22: 26(1): 2532-52.
8. Berke R. Singh A, Guralnick M. Atopic dermatitis: an overview. American family physician. 2012 Jul 1; 86(1): 35-42.
9. Frazier W. Bhardwaj N. Atopic dermatitis: diagnosis and treatment. American family physician. 2020 May 15; 101(10): 590-8.
10. Biswal B, Karna N, Nayak J, Joshi V. Formulation and evaluation of microemulsion hased topical hydrogel containing lomoxicam. Journal of Applied Pharmaceutical Science. 2014 Dec 29; 4(12): 077-84.
11. Bachhav, Ashwini & Ahire. Satish & Jadhav, Anil. (2019). PREFORMULATION STUDY OF PIROXICAM. International Journal of Pharmaceutical Sciences and Research. 10. 811-818. 10.13040/IJPSR.0975-8232. 10(2): 811-18.
12. Gulrez SK, Al-Assaf S, Phillips GO. Hydrogels: methods of preparation, characterisation and applications. Progress in molecular and environmental bioengineering-from analysis and modeling to technology applications. 2011 Aug 1; 117150.
13. Kumari K, Sara UVS, Sachdeva M. Formulation and Evaluation of Topical Hydrogel of Mometasone Furoate using different polymers. International Journal of Pharmaceutical and chemical sciences. 2013; 2(1).

14. Khapare SS, Bhandare MG, Talele SG, Jadhav A. An Emphasis on Hydrogels for Pharmaceutical Applications. American Journal of Pharmatech Research. 2016; 6(3).
15. Bindu SM, Ashok V, Chatterjee A. As a Review on Hydrogels as Drug Delivery in the Pharmaceutical Field. International Journal of Pharmaceutical and Chemical Science. 2012; 1(2).
16. Chaturvedi K, Ganguly K, Nadagouda MN, Aminabhavi TM. Polymeric hydrogels for oral insulin delivery. J Control Release. 2013 Jan 28; 165(2): 129-38. doi: 0.1016/j.jconrel.2012.11.005.
17. Bettini R, Colombo P, Massimo G, Catellani PL, Vitali T. Swelling and drug release in hydrogel matrices: polymer viscosity and matrix porosity effects. Eur J Pharm Sci. 1994; 2(3): 213-9.
18. ICH. International Conference On Harmonisation Of Technical Requirements For Registration Of Pharmaceuticals For Human Use Ich Harmonised Tripartite Guideline Stability Testing Of New Drug Substances And Products Q1A (R2) [Internet]. 2003 Feb. Available from: https://database.ich.org/sites /default/files/Q1A%28R2%29%20Guideline.pdf