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Research Paper

Formulation and Evaluation of Topical Emulgel of Clascoterone

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ABSTRACT

The present study aimed to develop and evaluate a topical emulgel formulation of clascoterone for enhanced skin permeation and localized treatment of acne vulgaris. A 3^2 full factorial design was employed to optimize the formulation by studying the effect of oil concentration and gelling agent concentration on drug release and viscosity. Preformulation studies including UV spectrophotometric analysis and FTIR compatibility studies confirmed drug-excipient compatibility. Solubility studies were conducted to select suitable oil, surfactant, and co-surfactant, and a pseudo-ternary phase diagram was constructed to identify the microemulsion region. The optimized emulgel was prepared using Carbopol 940 as a gelling agent. The formulation was evaluated for physicochemical parameters such as color, homogeneity, consistency, phase separation, pH, viscosity, spreadability, extrudability, drug content, swelling index, and % drug release. Among all batches, formulation F5 showed optimal performance with 94.72% drug release in 6 hours, viscosity of 8988 cps, particle size of 247.9 nm, and zeta potential of −23.53 mV. The formulation also demonstrated good stability over one month. It is concluded that emulgel of Clascoterone was formulated successfully. It showed acceptable outcomes with respect to homogeneity, consistency, pH, viscosity, spreadability, extrudability, swelling index, % drug release, % drug content, particle size & zeta potential.

INTRODUCTION

One common chronic inflammatory skin disorder in young adults is acne vulgaris. According to the Global Burden of Disease (GBD) study, it affects about 85% of people aged 12–25 years, with nearly four out of five adolescents experiencing it at some point. Acne involves the pilosebaceous units and appears as inflammatory or non-inflammatory lesions.

This study introduces emulgel based topical drug delivery system, providing uniform & improved patient compliance.

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2. MATERIALS AND METHODS

- Isoproyl myristate, Tween 80, PEG 400, Carbopol-940.
- A 3^2 factorial design was applied to optimize formulation variables.

RESULTS AND DISCUSSION

3.1 Evaluation of Optimized Batch (F5):

Sr. no.	Evaluation Parameter	Result
1.	Colour	Milky white
2.	Homogeneity	Homogeneous
3.	Consistency	Smooth
4.	pH	6.3
5.	Viscosity (cps)	8988
6.	Spreadability (gm.cm/sec.)	19.8 ± 0.2
7.	Extrudability (gm/cm^2)	18.5 ± 0.5
8.	Swelling Index (%)	64.5 ± 0.6
9.	% Drug Release at 6 hr	94.72
10.	% Drug Content	98.5 ± 0.2

- These values confirm suitability for Topical delivery.

3.2 In-vitro Drug Release:

Sr. no.	Time (min)	% Drug Release
1.	0	0
2.	30	14.25
3.	60	32.72
4.	120	47.92
5.	180	66.73
6.	240	74.65
7.	300	86.97
8.	360	94.72

3.3 Statistical Analysis (ANOVA):

- Y_1 Model p-value = 0.0053 (< 0.05) → significant
- Y_2 Model p-value = 0.0010 (< 0.05) → significant
- Confirms model validity and optimization process.

3.4 Stability Study:

- % Drug Release = 94.72 → 93.48
- No significant change

CONCLUSION

- The developed topical emulgel of Clascoterone showed excellent homogeneity,good consistency, skin compatible, viscosity, spreadability, extrudability, drug content, swelling index, % drug release, particle size & zeta potential.
- The formulation offers promising alternative to conventional cream.

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