WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 5.990
Volume 4, Issue 12, 913-918. Research Article ISSN 2277– 7105

# FORMULATION AND CHARACTERIZATION OF CLINDAMYCIN PHOSPHATE EMULGEL

**Gupta Saurabh*, Niranjan S.K.[2], Dr. Prajapti S.K[1]**

*Institute of Pharmacy, B.U. Jhansi.

[1]Head of Department, Institute of Pharmacy, B.U. Jhansi.

[2]Assistant Professor, Institute of Pharmacy, B.U. Jhansi.

Article Received on
21 Sept. 2015,

Revised on 12 Oct. 2015,
Accepted on 03 Nov. 2015,

***Correspondence for Author**
**Saurabh Gupta**
Institute of Pharmacy,
B.U. Jhansi

## ABSTRACT

**AIMS:** The aim of present study was to develop an emulgel formulation of clindamycin phosphate using Carbopol 934 or HPMC 2930 as a gelling agent. The influence of the type of gelling agent and the concentration of both the oil phase and emulsifying agent on the release of the drug and its microbial activity were investigate using $2^3$ factorial design in addition, rheological properties were also evaluated.

**KEYWORDS:** emulgel, Carbopol 934 or HPMC 2930.

## 1. INTRODUCTION

Topical formulations apply a wide spectrum of preparation both cosmetic and dermatological, to healthy or diseased skin. These formulations range in consistency from solid through semisolid to liquid. When gels and emulsion are used in a combined form, the dosage forms are referred to emulgel. As the name suggests they are the combination of emulsion/microemulsion and gel.

Novel polymer with complex functions as emulsifiers and thickness have been widely used due to their gelling capacity which allows the formulation of stable emulsion by decreasing surface and interfacial tension and also by increasing the viscosity of aqueous phase. Oil/water and water/oil emulsions are used as vehicles to deliver various drugs to the skin. Emulsion gels are gaining importance due to many reasons; they have better application properties in comparison to classical formulation as cream and ointments, they have faster and more complete release of the from vehicles to the skin, also they are convenient to apply on hair skin due to absence of greasiness and lack of residue upon application. They permit

the incorporation of both aqueous and oleaginous ingredients, so hydrophobic or poor water soluble drugs as antifungal agents are easily incorporated in such type of vehicle through the proper choice of the oily phase.

Clotrimazole is an antifungal agent which inhibits the growth of pathogenic dermatophytes. It shares with econazole, miconazole, first choice status for topical treatment of Tania pedis, Tineacruris and tineacorporis due to candida albicans. It is effective for topical treatment of vulvovaginal and oropharyngeal candasis, for skin care and the topical treatment of dermatological diseases, a wide choice of vehicles including solid, semisolid and liquid preparation is available to physician and patients. Within the major groups of semisolid preparation, the use of transparent emulgels has expended, both in cosmetics and pharmaceutical. Emulgel or gelified emulsion is stable one and better vehicle for hydrophobic or water insoluble drugs as Clotrimazole. Also emulgels have a high patient acceptability since they possess the advantages of both emulsions and gels. Therefore, they have been recently used as vehicles to deliver various drugs to the skin.

## 2.MATERIALS AND METHODOLOGY

### 2.1 Materials

Clindamycin phosphate was kindly provided by curetech skin formulation Baddi, Himanchal Pradesh, carbpol 934 (shree Chemicals new Delhi, Hydroxypropyl methyl cellulose, (HPMC 2910) was kindly supplied by atlis pharmaceuticals Baddi Himanchal Pradesh. Tween 20, Span 20, methyl and propyl parabens, light liquid paraffin, propylene glycol, Dimethyl Formamide (DMF), hydrochloric acid and ethyl alcohol were purchased from innova pharmaceutical chemicals (Chandigand, panjab). Triethanolamine (TEA) was supplied from innova pharmaceutical chemicals (Chandigand, panjab).Cellulose membrane (M. Wt. cut-off 10-000-14-1000) was supplied from Sigma Chemical Company (Saint Louis, MO). C. albicans ATCC NO10231 was kindly provided by the Department of Microbiology, October University for Science and Modern Arts (MSA) clinical isolate growth at $25^0$c $^{for}$ 24 hours on Sabouraud's agar.

### 2.2 METHODOLOGY

#### 2.2.1 Preparation of Emulgel

The detailed composition for the prepared emulgel formulations is given in Table 1. The gel in formulations F1, F3, F5 and F7 was prepared by dispersing Carbopol 934 in purifying water with continuous stirring using overhead stirrer for 5 min at 2000 rpm. The gel in

formulations F2, F4, F6 and F8 was prepared by dispersing HPMC in hot purified water ($70^0$C); the gel was cooled and left overnight. The oil phase of the emulsion was prepared by dissolving span 20 in purified water. Methyl and propyl parabens were dissolved in propylene glycol while Clotrimazole was dissolved in ethanol; both were then mixed with the aqueous phase. The aqueous and the oily phases were separately heated to $70^0$C, and then the oily phase was added to the aqueous phase with continuous stirring till cooled to room temperature. The emulsion and the gel were both mixed together in equal ratio with gentle stirring till obtaining the emulgel.[9,10]

**Table 1.composition and codes of Clotrimazole emulgel formulations (%w/w)**

| COMPONENTS | Formulas Code | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | $F_1$ | $F_2$ | $F_3$ | $F_4$ | $F_5$ | $F_6$ | $F_7$ | $F_8$ |
| Clotrimazole | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Carbopol 934 | 1 | - | 1 | - | 1 | - | 1 | - |
| HPMC2910* | - | 2.5 | - | 2.5 | - | 2.5 | - | 2.5 |
| Liquid paraffin | 5 | 5 | 7.5 | 7.5 | 5 | 5 | 7.5 | 7.5 |
| Tween 80 | 0.6 | 0.6 | 0.6 | 0.6 | 1 | 1 | 1 | 1 |
| Span 80 | 0.9 | 0.9 | 0.9 | 0.9 | 1.5 | 1.5 | 1.5 | 1.5 |
| Propylene glycol | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Ethanol | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 |
| Methyl paraben | 0.03 | 0.03 | 0.03 | 0.03 | 0.03 | 0.03 | 0.03 | 0.03 |
| Propyl paraben | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 |
| Purified water to | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |
| *HPMC Hydroxypropyl methyl cellulose | | | | | | | | |

**Table 2. Variables and observed response in $2^3$ factorial design for emulgel Formulation**

| Formulation | Independent variables | | | Dependent variables | |
|---|---|---|---|---|---|
| | $X_1$ | $X_2$ | $X_3$ | $Y_1$ | $Y_2$ |
| F1 | -1 | -1 | -1 | 27.53 | 34.4 |
| F2 | 1 | -1 | -1 | 31.56 | 42.3 |
| F3 | -1 | 1 | -1 | 26.43 | 32.4 |
| F4 | 1 | 1 | -1 | 29.88 | 35.7 |
| F5 | -1 | -1 | 1 | 38.58 | 48.5 |
| F6 | 1 | -1 | 1 | 42.54 | 56.4 |
| F7 | -1 | 1 | 1 | 30.23 | 39.7 |
| F8 | 1 | 1 | 1 | 34.67 | 46.3 |

### 2.2.2 Experimental design and analysis

Eight clindamycin phosphate emulgel formulations were prepared according to $2^3$ full factorial designs to optimize the formulation factors and evaluate the main effects. The independent variables were the type of gelling agent ($X_1$) and emulsifying agent % ($X_3$). The

two levels of gelling agent type were used Carbopol and HPMC, denoted the value (-1) and (1) in the above design respectively. Two level of liquid paraffin concentration were chosen to be 5% and 7.5% denoted -1 and 1 respectively. Finally the emulsifying agent concentration were 1.5 and 2.5% denoted -1 and 1 respectively. The eight experimental trials and the respective observed responses are given in table 2.

**Evaluation of emulgel**

**Physical appearance and p$^{h.}$ determination**

The prepared Clotrimazole emulgel were inspected visually of their colour, homogeneity consistency and ph. The ph values of 1% aqueous solutions of the prepared emulgel were measured by a ph meter. Experiments were carried out in triplicate.

**Drug content determination**

the drug content of Clotrimazole emulgel was measured by dissolving a known weight of the emulgel formulation(one gram) in 100 ml methanol, appropriate dilution were made and the resulting solution was then filtering using Millipore filter (0.45 um). Absorbance was measured at 260 nm using UV- spectrophotometer (shimadzu UV 1700, japan). Drug content was calculated using the slope and the intercept obtained by linear regression analysis of standard calibration curve. Experiments were carried out in triplicates.

**In-vitro release of clindamycin phosphate from different emulgel**

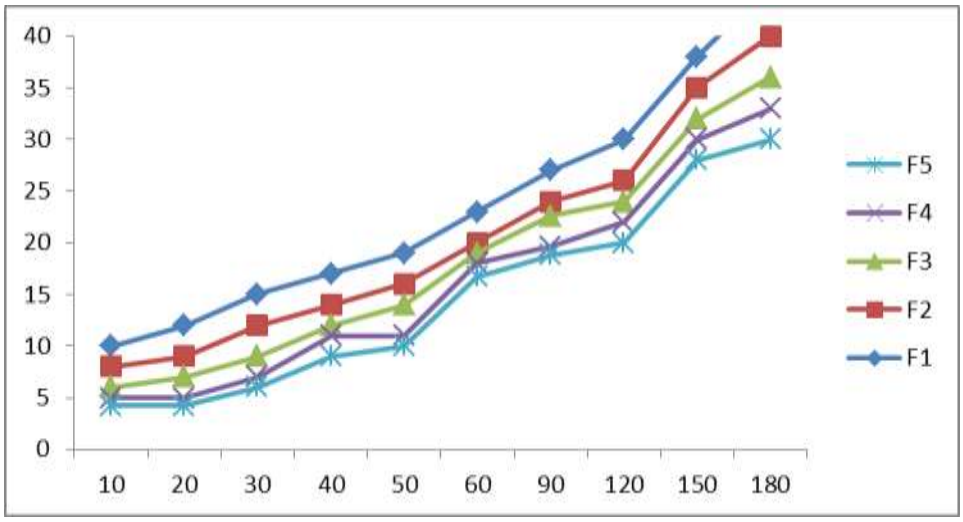
The test was done by using modified USP dissolution test apparatus. A glass cylindrical tube (6 cm in length and 2.25 cm in diameter) containing the emulgel was hinged in place of the basket and tightly covered with a semipermeable membrane (100 um pore size).

1 gm of emulgel contain 2% clindamycin phosphate was placed in the cylindrical tube covered with the semipermeable membrane. The glass tube dipped in a 500 ml 0.2M phosphate buffered saline ($P_H$ 7.4). The test was carried out at 37 $^0$C+0.5$^0$C, and rotation speed of 50 r.p.m.

Aliquots of 2ml were withdrawn from the dissolution medium at 5, 15, 30, 60, 90, 120 and 150 minute time intervals, replaced at each time with 2ml of buffer to maintain a constant volume.

The sample diluted with equal volume with buffered and the absorbance of the collected samples was measured spectrophotometrically at L max 365 nm using phosphate buffered

saline as blank. For compression a commercially available product namely clindamycin phosphate was also tested.




**Stability studies**

The prepared clindamycin phosphate were packed in temperature resistant plastic tubes and subjected to stability studies at 25$^{o}$C/60% relative humidity (RH) and 40$^{0}$C/75% RH for a period of 3 month. Samples were withdrawn at time intervals of 15 days and evaluate for physical appearance, ph, rheological properties, drug content and drug release.

## RESULT AND CONCLUSION

The prepared clindamycin phosphate emulgel formulations were inspected visually for colour homogeneity, phase separation, consistency and ph. All formulations showed white formulations prepared using Carbopol 934 as gelling agent showed glossy appearance, No phase separation was noticed Formulation show suitable homogeneity and consistency.

From the above result be can conclude that emulgel will be a solution for incorporating hydrophobic drugs in water soluble gel bases. Clindamycin phosphate emulgel formulations prepared using either Carbopol 934 or HPMC 2910 showed acceptable physical properties, ph, drug content, viscosity and antibacterial activities

## REFERENCES

1. Jain A, Deveda P, Vyas N, Chauhan J, Khambete H, Jain S, Development of antifungal emulsion based gel for topical fungal infection(s). Int J Pharm Res Dev 2011; 2(12).

2. Kasiwal N, Derle D, Negi J, Ghoil J. Effect of permeation enhancers on the release and permeation kinetics of meloxicam gel formulation through rat skin.Asn J pharmsci 2008; 3(5): 193-199.
3. Mohamed MI. Topical emulsion gel composition comprising diclofenac sodium. AAPS J 2004; 6(3): 26.
4. Khullar R, Saini S, Sethi N, R ana AC. Emulgel A surrogates approaches for topically used hydrophobic drugs. Int J Pharma Biol Sci 2011; 117-128.
5. Stan- posthumd JJ, Vink J, Lecessies, Bruijn JA, Topical tertinoin under oocclusion on a typical navei. Asn J Pharm Clnl Res 1988; 548(3).
6. Rieger MM, Lachman L, Lieberman HA, Kaing JL. The theory and practice of industrial pharmacy. 3rd ed. PA Lea and Febiger (Philadelphia); 1986; 502- 533.
7. Stanos SP. Topical agent for the management of musculoskeletal pain. J Pain symptoms manage 2007; 33.
8. Gupta A, Mishra AK, Singh AK, Gupta V, Bansal P. Formulation and evaluation of topical gel of diclofenac sodium using different polymers. Drug invention Today 2010; 2: 250-253.
9. Cevec G. Preclinical characterisation of NASIDS in ultra deformable carriers or conventions topical gels. Int J Pharm 2008.
10. Banker GBS, Rhodes CT. Modern pharmacist. 2nd ed. Marcel Dekker New York; 1979.p.263-273,283.286-287,299-311.
11. 12. Lembereg AP. A hand book of non-prescription drug. American Pharmaceutical Association 5th ed. Washington; 1973; 161.
12. Wilkes GL, Brown IA, Wilanaver RH. CRC Crit rev, Bioeng; 1973; 453.
13. Rushmer RF, Buttner KJK, Short JM. Odland science; 1996; 154: 343.
14. Chien YW. Transdermal drug delivery and delivery system. Marcel Dekker, Inc. New York; 1992; 50: 301-381.
15. Lachman L, Lieberman HA: The Theory and practice of industrial pharmacy. 3rd ed. Mumbai; Varghese publishing house; 1990; 534.
16. Gibson M. Pharmaceutical formulation and preformulation. Interpharm 2004.