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Research Article

FORMULATION AND EVALUATION OF CLINDAMYCIN
PHOSPHATE EMULGELSaurabh Gupta*¹ Dilip Kumar Chanchal ² and Surabhi Rashi ¹¹Department of Pharmaceutics, Institute of Pharmacy, Bundelkhand University, Jhansi - 284128, Uttar Pradesh, India.²Department of Pharmacognosy, Institute of Pharmacy, Bundelkhand University, Jhansi - 284128, Uttar Pradesh, India.**Abstract:**

Introduction: Topical drug administration is simplest and easiest route of localized drug delivery anywhere in the body by routes as ophthalmic, rectal, vaginal and skin. These are applied as wide spectrum of preparations in case of both cosmetic and dermatological, to the healthy or diseased skin. Drugs are administered topically for their action at the site of application or for systemic effects. Clindamycin is a lincosamide antibiotic. It is usually used to treat infections with anaerobic bacteria, but can also be used to treat some protozoal diseases, such as malaria. It is a common topical treatment for acne and can be useful against some methicillin-resistant *Staphylococcus aureus* (MRSA) infections.

Objective and aim: 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 investigated using 2³ factorial design in addition, rheological properties were also evaluated.

Conclusion: The present work is to develop Clindamycin emulgel adaptable topical drug delivery systems which provide protection against oxidation, fast absorption, prolonged release and enables reduction in dose and evaluate the emulgel using an ideal topical drug candidate of Clindamycin by suitable method with its release.

Keywords: Clindamycin emulgel, Formulation, Evaluation.

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INTRODUCTION:

Topical drug administration is simplest and easiest route of localized drug delivery anywhere in the body by routes as ophthalmic, rectal, vaginal and skin. These are applied as wide spectrum of preparations in case of both cosmetic and dermatological, to the healthy or diseased skin [1]. Drugs are administered topically for their action at the site of application or for systemic effects [2]. Drug absorption is enhanced through the skin if the drug substance is in solution, if it has a favourable lipid/water partition coefficient and if it is a non electrolyte. Mostly, pharmaceutical preparations applied to the skin are expected to serve some local action and are formulated to provide prolonged local contact with minimal systemic drug absorption. Drugs applied to the skin for their local action include antiseptics, antifungal agent, skin emollients and protectants. Topical delivery system proves beneficial by passing first pass metabolism. Avoidance of the risks and inconveniences of intravenous therapy and of the varied conditions of absorption like pH changes, presence of enzymes, gastric emptying time are other advantages of topical preparations [3, 4]. The topical drug delivery system allows its usage where the others system of drug administration fails or it is mainly used in fungal infection.

Human skin is a uniquely engineered organ that permits terrestrial life by regulating heat and water loss from the body whilst preventing the ingress of noxious chemicals or microorganisms **Fig. 1** [2].

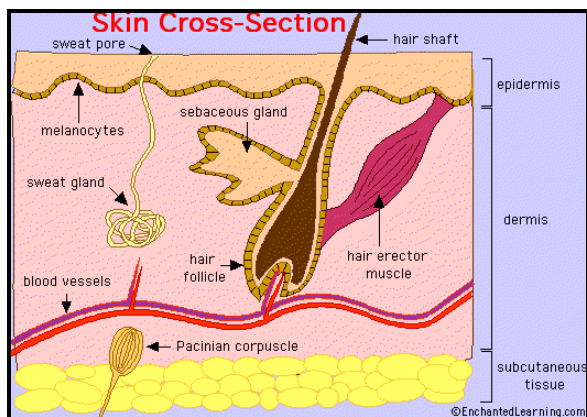


Fig. 1: Cross section of Skin

MATERIALS AND METHODS:

Clindamycin phosphate was kindly provided by curetech skin formulation Baddi, Himanchal Pradesh, carbopol 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 (Chandigarh, Punjab). Triethanolamine (TEA) was supplied from innova pharmaceutical chemicals (Chandigarh, Punjab). Cellulose membrane (M. Wt. cutoff 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 250c for 24 hours on Sabouraud's agar.

OBJECTIVE: The objective of preformulation testing is to generate information useful to the formulator in developing stable and bioavailable dosage forms. Following preformulation studies are carried out:-

- Physical appearance
- Identification of drug.
- IR spectra of drug sample.
- Solubility studies.

Physical Appearance:

The prepared Clotrimazole emulgel erwe 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.

Identification of Drug:

Clindamycin phosphate was kindly provided by curetech skin formulation Baddi, Himanchal Pradesh, carbopol 934 (shree Chemicals New Delhi, Hydroxypropyl methyl cellulose, (HPMC 2910) was kindly supplied by atlis pharmaceuticals Baddi Himanchal Pradesh. identified and characterized as per requirement of official standards. Clindamycin phosphate was identified by ultraviolet spectroscopy.

Drug excipient interaction study (FTIR spectra):

Drug Excipient Interaction Study was carried out to check the interaction between the drug and excipient by using FT-IR spectrophotometer (Perkin-Elmer, Model-1600, USA). Accurately weigh 50 mg each of Clindamycin phosphate, Carbopol-934, Carbopol-940, HPMC-5 and HPMC-15. The mixtures of Clindamycin phosphate and Carbopol-934, Clindamycin phosphate and Carbopol-940, Clindamycin phosphate and HPMC-5, Clindamycin phosphate & HPMC-15 were placed separately on the sampling plate of FT-IR spectrophotometer. Then scanning of the sample was performed and IR spectra were obtained as shown in **Fig. 2, 3, 4, 5** and **6** respectively. The data of the interaction study is shown in **Table 1**.

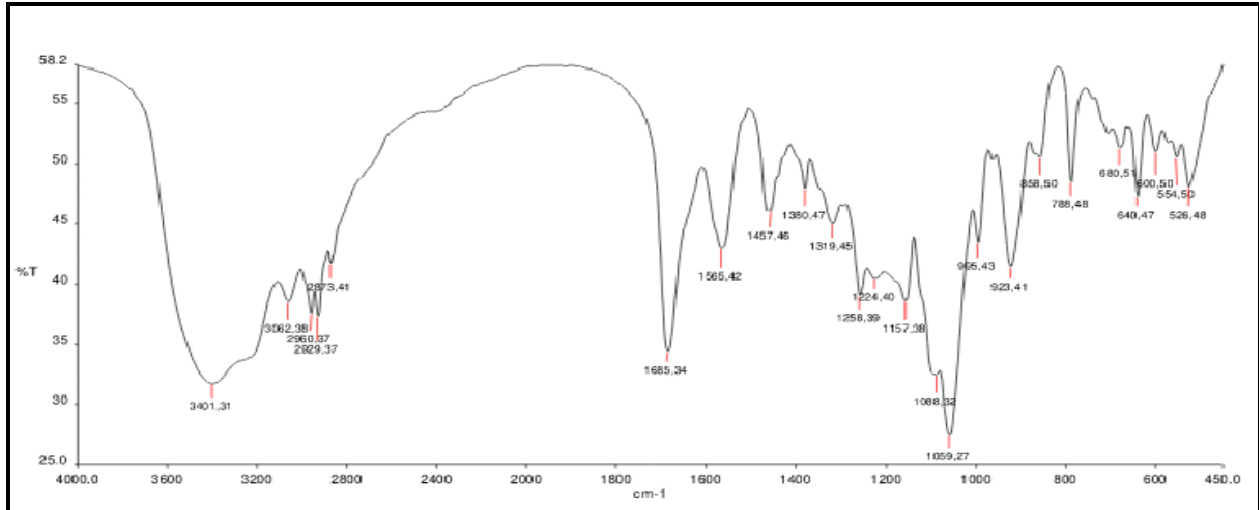


Fig. 2: FTIR Spectra of Clindamycin phosphate

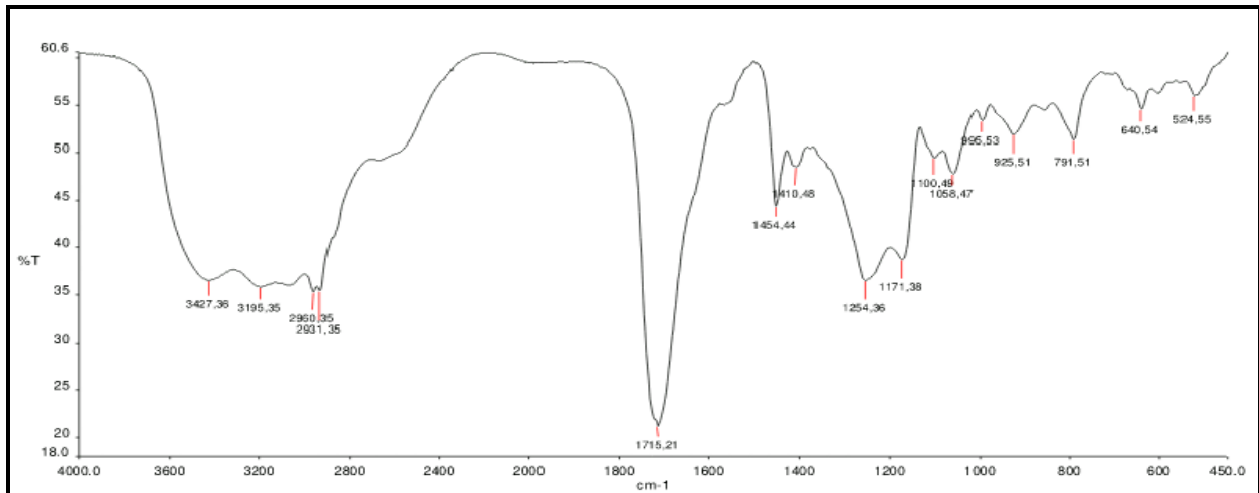


Fig. 3: FTIR Spectra of mixture of Clindamycin phosphate and Carbopol-934

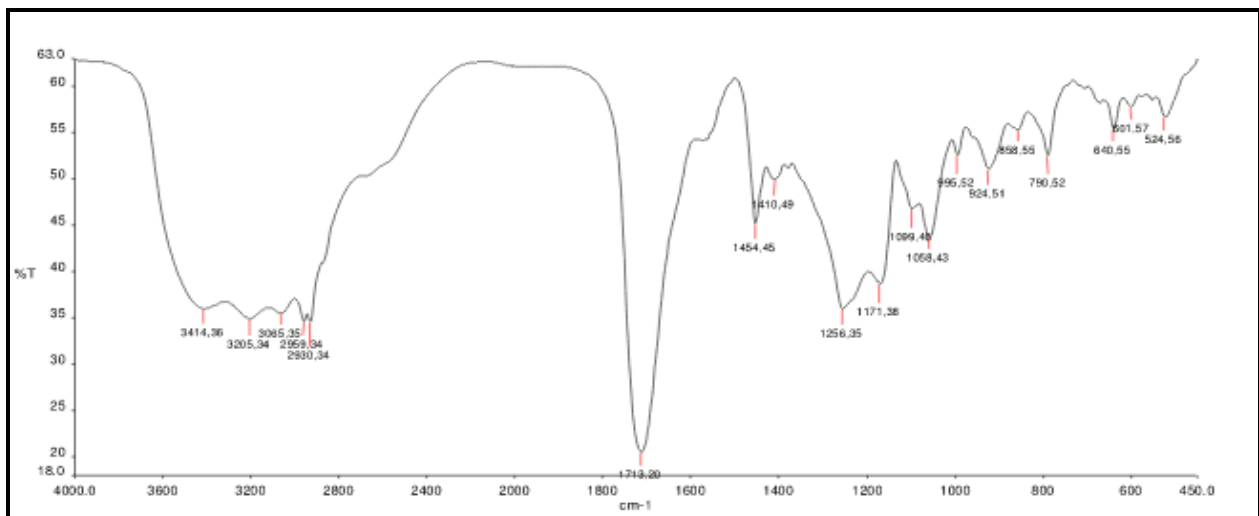


Fig. 4: FTIR Spectra of mixture of Clindamycin phosphate and Carbopol-940

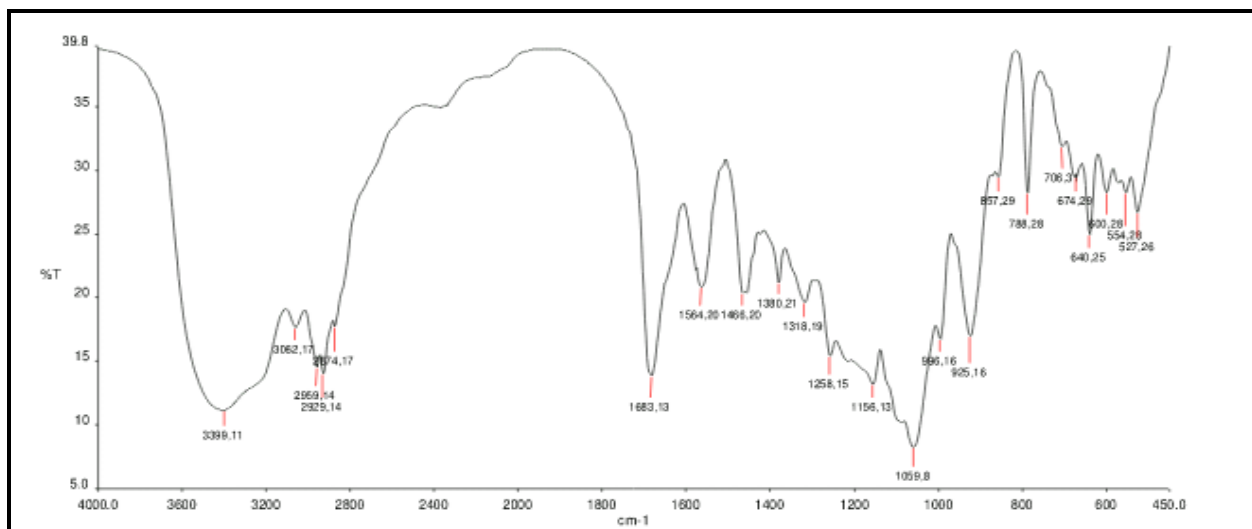


Fig. 5: FTIR Spectra of mixture of Clindamycin phosphate and HPMC-5

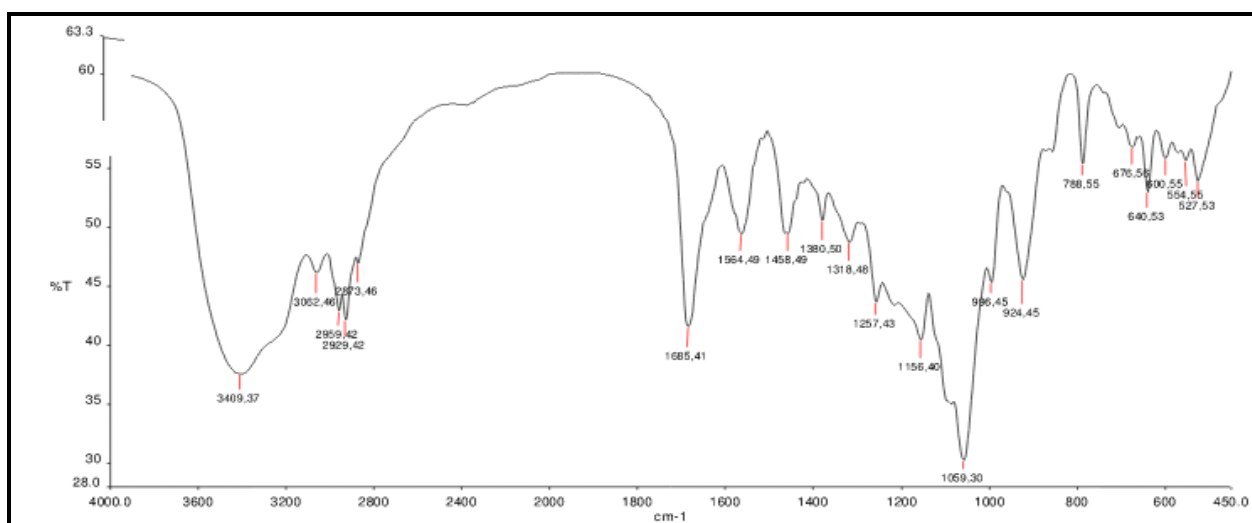


Fig. 6: FTIR Spectra of mixture of Clindamycin phosphate and HPMC-15

Table 1: Comparison between Peaks Obtained In Drug and Drug-Polymer Mixture

S. no.	Peaks Obtained in drug (frequency cm^{-1})	Description	Peak obtained in mixture of drug and Carbopol-934	Peak obtained in mixture of drug and Carbopol-940	Peak obtained in mixture of drug and HPMC-5	Peak obtained in mixture of drug and HPMC-15
1	788	C-H (Aromatics)	791	790	788	788
2	1059	C-N (Amine)	1058	1058	1059	1059
3	1258	C-O	1254	1256	1258	1257
4	1457	C-O-H bonding	1454	1454	1465	1458
5	2929	C=C (stretch)	2931	2930	2929	2929
6	2960	C=C (stretch)	2960	2959	2959	2959
7	3401	N-H (stretch)	3427	3414	3499	3404

Solubility Studies:

It affects the bioavailability of drug, the rate of drug release into dissolution medium and consequently, the therapeutic efficacy of pharmaceutical product. The solubility of the molecules in various solvent is determined as the first step. This information is valuable in developing a formulation. The solubility of material is usually determined by the equilibrium solubility method, which employs a saturated solution of the material, obtained by stirring an excess of material in the solvent for a prolonged until equilibrium obtained.

Clindamycin phosphate are soluble in:

- Methanol

- Ethanol
- Dimethyl sulfoxide

Evaluation:**Drug Content Determination:**

Weigh accurately 1 gm of Emulgel and it was dissolved in 100 ml of methanol. The volumetric flask was kept for 2 hours and shaken well in a shaker to mix it properly. The solution was passed through the filter paper and filtered. The absorbance was measured spectrophotometrically at 210 nm after appropriate dilution against corresponding Emulgel concentration as blank. The drug content was determined using following formula. The results have been reported in Fig. 7.

Drug content = (concentration × dilution factor × volume taken) × conversion factor



Fig. 7: Percentage drug content of different formulations F1-F12

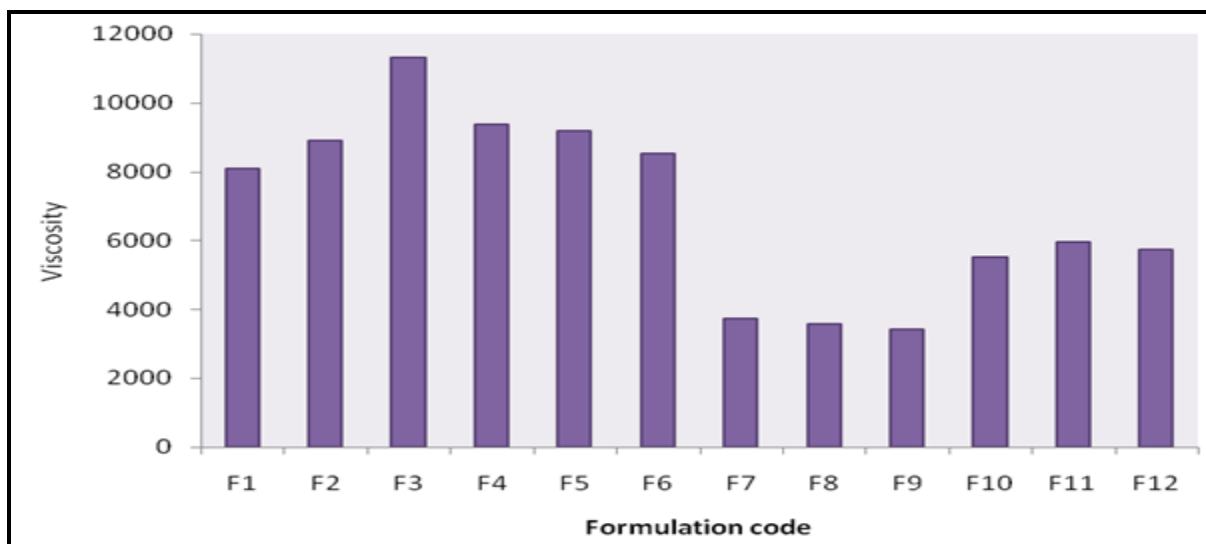


Fig. 8: Viscosity of different formulations F1- F12

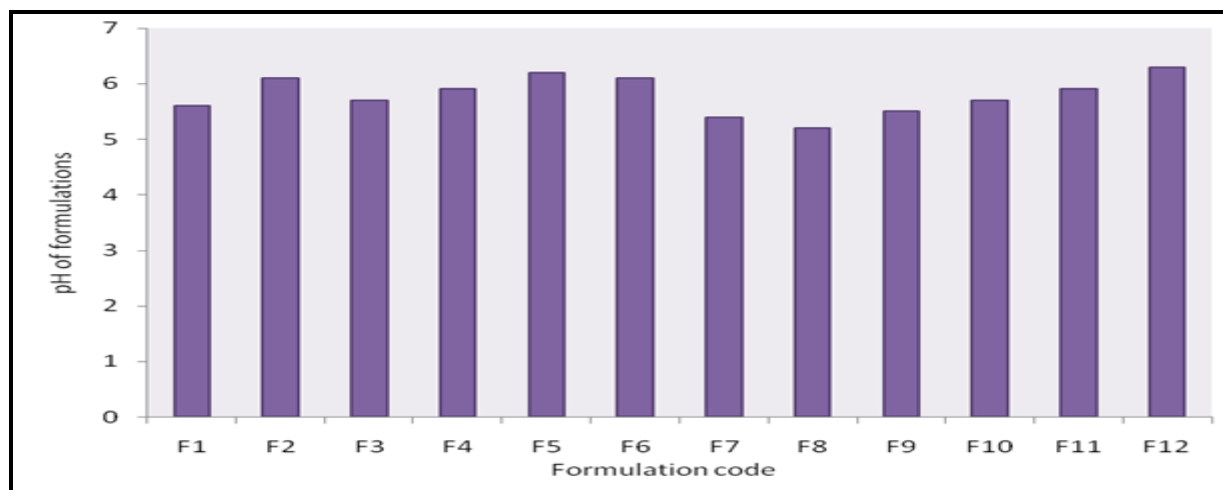


Fig. 9: pH of different formulations F1-F12

pH Determination:

The pH of Emulgel formulations was determined by using digital pH meter. One gram of gel was dissolved in 100 ml of distilled water and it was placed for two hours. The measurement of pH of each formulation was done in triplicate and average values were calculated. The pH of the Emulgel formulations was in range of 5.5 ± 0.54 to 6.4 ± 0.43 , which lies in the normal pH range of the skin and would not produce any skin irritation. There was no significant change in pH values as a function of time for all formulations. The data is reported in **Fig. 9**.

Measurement of Viscosity:

The viscosity of the formulated batches was determined using a Brookfield Viscometer (RVDV-1 Prime, Brookfield Engineering Laboratories, USA) with spindle 07. The formulation whose viscosity was to be determined was added to the beaker and was allowed to settle down for 30 min. at the assay temperature ($25^\circ \pm 1^\circ\text{C}$) before the measurement was taken. Spindle was lowered perpendicularly in to the centre of the Emugel, taking care that spindle does not touch the bottom of the beaker and rotated at a speed of 50 rpm for 10 min. The viscosity reading was noted down. The average of three readings was taken in 10 minutes was noted as the viscosity of Emulgel. The viscosity of the formulations increases as the concentration of polymer increases. The data is reported in **Fig. 8**

RESULTS:

- The purity of the drug carried out by FTIR spectrum of the drug sample, which is in agreement with standard IR spectrum of Clindamycin. The FTIR spectrum of drug sample has been shown in **Fig. 2**.
- The physical and chemical interaction between drug and the excipients were studied using FTIR

technique. No significant shifts in the peaks corresponding to the drug or the polymer were observed as shown in **Table 1**. It has been observed that there is no chemical interaction between the Clindamycin phosphate and the polymers used. Hence, there was no interaction between the drug and the polymers. So they can be successfully incorporated in the Emulgel. The FTIR spectrums of the drug and polymers are shown in **Fig. 3, 4, 5 and 6** respectively.

- The solubility of material is usually determined by the equilibrium solubility method, Clindamycin phosphates are soluble in Methanol, Ethanol and Dimethyl sulfoxide.
- The drug content was determined for all the formulations by UV spectrophotometer method. The result of the drug content varies between 77.50 % and 93.30% as shown in **Fig. 7**. The results indicated that the drug dispensed uniformly throughout the Emulgel.
- The viscosity of the formulation batches were checked by using Brookfield viscometer. The results are shown in **Fig. 8**. According to the results, the viscosity differs in accordance to the concentration of the gelling agent used in different formulations. From the data it has been revealed that the formulations with Carbopol-934, Carbopol-940 are more viscous than those with HPMC-5 and HPMC-15 gelling agents.
- The pH of the Emulgel formulation was in the range 5.3 ± 0.5 to 6.2 ± 0.5 , which lies in the normal pH range of the skin and would not produce any skin irritation. The results are shown in **Fig. 9**.

CONCLUSION:

Acne vulgaris is a common skin disease of pilosebaceous unit that affects 85% to 100% of people mostly affecting face. Severest form occurs in

boys but it tends to persist longer in girls. The incidence peaks at teenage but also affects men and women between 20-40 years of age. Patients often have problems with self-esteem, self-confidence, social withdrawal, depression, anger and higher unemployment rate. Morbidity in acne is primarily emotional. If left untreated it leaves physical and emotional scar that can be devastating. There are many drugs that can be used in the treatment of acne, some of them are; Antibiotics (tetracycline, Doxycycline, Minocycline, Clindamycin, Erythromycin, Clarithromycin), Retinoids (tretinoin, isotretinoin), Benzoyl peroxide and miscellaneous.

Clindamycin is a lincosamide antibiotic. It is usually used to treat infections with anaerobic bacteria, but can also be used to treat some protozoal diseases, such as malaria. It is a common topical treatment for acne and can be useful against some methicillin-resistant *Staphylococcus aureus* (MRSA) infections.

The present work is to develop Clindamycin emulgel adaptable topical drug delivery systems which provide protection against oxidation, fast absorption, prolonged release and enables reduction in dose and evaluate the emulgel using an ideal topical drug candidate of Clindamycin by suitable method with its release.

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CONFLICT OF INTEREST: The author declares there is no conflict of interest.

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