

**PREPARATION AND *EX-VIVO* EVALUATION OF CLINDAMYCIN
PHOSPHATE DENTAL FILMS FOR PERIODONTITIS**

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For the Degree of

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In

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By

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Problem statement: Periodontitis is a inflammatory gum disease. It can affect one or more of the periodontal tissues/structures (e.g. alveolar bone, periodontal ligament, cementum and gingiva). The common symptoms of periodontitis include redness and bleeding of gums while brushing teeth, gum swelling, splitting out blood after brushing the teeth, lose teeth in last stage, halitosis or bad breath, gingival recession, resulting in apparent lengthening of teeth, deep pockets formation between teeth and gum. The proportion of the population above the age of 15 years with this disease could be 80–90%. Periodontitis associated with diabetes, chronic obstructive pulmonary disease, Atherosclerosis, Kidney disease.

Purpose: The objective of this study was to resolve the problems arise in different dosage forms which are given by systemic root. Topical site specific delivery of clindamycin phosphate would reduce the side effect occurs by systemic drug delivery like hypersensitivity, gastrointestinal intolerance and bacterial resistance. Clindamycin phosphate has 60% susceptibility against oral pathogens. Periodontal film having potential to deliver small amount of drug with prolong action.

Methods: The site specific dental films of clindamycin phosphate was formulated by solvent casting method using ethyl cellulose as a polymer, Eudragit RL 100 as a copolymer, Dichloromethane: Methanol (1:1) as a solvent and Dibutyl phthalate as a plasticizer. The films were evaluated for thickness uniformity, folding endurance, weight uniformity, surface pH, Surface morphological study with Scanning electron microscopy, In-situ antibacterial study, *In-vitro* drug release study, *Ex-vivo* and *In-vitro* antibacterial study, comparison study with marketed formulation and kinetic

model study and Gas chromatography study for the measurement of residual solvent amount.

Results: The best film was selected as a one which is prepared by ethyl cellulose and eudragit RL 100 is C₈ since, give maximum drug release with 77.26% which is above the Minimum inhibitory concentration. The formulation follows the krosmeier peppas model and release was done via fickian diffusion mechanism. The Concentration of drug was found to be 75% from the *in-situ* release study. *In-vitro* antibacterial study shows that the the formulated polymeric films of clindamycin phosphate have a similar activity as compare to standard drug sample. *Ex-vivo* antibacterial study shows better activity against standard drug sample. In compare to marketed formulation (Chlorhexidine Mouth- wash) Fabricated Clindamycin Phosphate containing films have better antibacterial activity. The surface morphological study by scanning electron microscopy shows that the drug molecules are uniformly distributed with polymers in the formulation. The amount of residual solvent was found to be 221ppm in the formulation by gas chromatography study.

Conclusions: Ethyl cellulose - eudragit RL 100 combination is the batter carrier among the others for the preparation of Clindamycin phosphate dental films for prolonging the drug action up to 6 days.

Keywords: Clindamycin phosphate, Dental film, Periodontitis, Eudragit RL 100, Local delivery.