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RESEARCH ARTICLE

DESIGN OF MEDICATED TOOTH PASTE FOR DENTAL DISORDERS.

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Abstract

In the present work, it was planned to prepare therapeutic medicated dental pastes for treatment of periodontitis and oral thrush, which provides effective treatment. Stress was given on local action of the drug and to treat initial stages of periodontitis and oral thrush. Beclomethasonedipropionate was chosen model drug which was a corticosteroid which has a wide range of anti-inflammatory activity. The prepared dental pastes were subjected for various physicochemical parameters like PH, Spreadability, tube extrudability, uniformity of drug content and IR studies. For this study periodontal infective pus sample of a patient collected from a patient under the supervision of dental professor of a local dental college. In-vitro drug release studies were carried out in P^H 6.4 phosphate buffer. Stability studies of selected formulations were also done at ambient temperature (30°C) for the period of six months as per ICH guidelines. The formulations were subjected for primary skin irritation test in healthy human volunteers for 72 hours. In-vitro diffusion study showed good results in formulation F₂, which showed more retentive time in oral cavity. During physicochemical studies significant results were obtained and found to be within the limits of official standards. The present work is being focused on designing of medicated tooth pastes to protect the gums, teeth and oral cavity from periodontal infections and oral thrush resulting from improper fixation of artificial dentures. The present study revealed that the prepared Beclomethasonedipropionate dental paste formulations will be useful in the treatment of oral thrush and periodontal diseases of all age groups of patients.

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Introduction:-

Oral diseases continue to be a major health problem worldwide. Dental caries and periodontal diseases are among the most important global oral health problems, although conditions such as oral and pharyngeal cancers and oral tissue lesions are also significant health concerns (Petersen PE, 2003). Despite general advances in the overall health status of the people living in industrialized countries, including oral and dental health, the prevalence of dental caries in school aged children is up to 90% and the majority of adults are also affected (Bourgeois D et. al. 2005). Oral

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health is integral to general well-being and relates to the quality of life that extends beyond the functions of the craniofacial complex. There is considerable evidence linking poor oral health to chronic conditions, for example, there is a strong association between severe periodontal diseases and diabetes (Petersen PE, 2005).

There is also evidence linking poor oral health and systemic diseases, such as cardiovascular diseases, rheumatoid arthritis and osteoporosis (Rautemaa R et. al.2007), while periodontal diseases may also contribute to the risk of pregnancy complications, such as preterm low-birth weight (Yeo BK et. al. 2005). Tooth loss, caused by poor periodontal health (which affects up to 20% of the adult population worldwide) can lead to significant morbidity and premature death. The economic impact of oral diseases is an important consideration with up to 10% of public health expenditure in developed countries related to curative dental care.

Material and Methods:-

Beclomethasonedipropionate was a gift sample from Alkem pharmaceuticals, Mumbai., Sodium carboxy methylcellulose (Sol Fine Chemicals Pvt. Ltd., Mumbai.), Precipitated chalk, Glycerin and Alcohol (Qualigens Fine Chemicals, Mumbai.), Methyl salicylate and Acacia (SD Fine Chemicals, Mumbai.), Sodium lauryl sulfate (Himedia Laboratories Ltd., Mumbai.), Methyl parahydroxy benzoate (Loba Chemicals, Mumbai.), Empty aluminium collapsible tubes (Digvijay containers and closures, Mumbai.), Cellophane paper (Local market).

Preparation Of Formulation:-

Medicated dental paste were prepared by conventional trituration method. The formulations were prepared containing mucoadhesive polymer. The formulations were transferred and stored in collapsible tubes for further studies. (Cooper & Gunn, 1987).

Characterization Of Prepared Beclomethasone Dipropionate Medicated Pastes:-

Spreadability:-

About 1 g of tooth paste was weighed at the centre of glass plate (10x10 cm) and another glass plate is placed over it carefully. At the centre of the plate a 2 kg weight is placed. After 30 min, the diameter of the paste was measured in cm. The experiment was repeated thrice and average diameter is determined.

Determination of pH:-

A weighed quantity of tooth paste (10 g) was taken in a 150 ml beaker and 10 ml of freshly boiled and cold water (at 27° C) is added, stirred well to make thorough suspension and the pH of the suspension is determined within 5 min using pH meter.

Tube extrudability:-

The method adopted for evaluating paste formulation for extrudability was based upon the quantity in percentage paste extruded from tube on application of finger pressure. More quantity extruded better was extrudability. The formulation under the study was filled in a clean, aluminum collapsible tube with a nasal tip of 5 mm opening and applied the pressure on the tube by the help of finger. Tube extrudability was then determined by measuring the amount of paste extruded through the tip when a pressure was applied on the tube.

Determination of drug content uniformity:-

5 gm medicated dental pastes (prepared formulation) was taken and dissolved in 50 ml vol. flask with small quantity of ethanol and volume is made up to 50 ml with ethanol after that solution is filtered with Whatman filter paper which gives 1000 mcg/ml concentration. From this solution 1 ml solution was transferred in 10 ml vol. flask and volume was made to 10 ml with ethanol which gives 100 mcg/ml concentration. From this different concentration of solution was taken in 10 ml vol. flask and volume was made to 10 ml with methanol and absorbance was measured by UV spectrophotometer at 238 nm against blank. All the formulations were found within the specified limit of drug content.

IR spectral analysis:-

Infrared spectroscopy is one of the most powerful analytical techniques which offer the possible chemical identification. In the present work, IR spectra of Beclomethasone and hydrocolloids were obtained by KBr pellet method.

In-vitro drug diffusion studies:-

A glass cylinder with both ends open, 10 cm height, 3.7 cm outer diameter and 3.1 cm inner diameter was used as permeation cell. A cellophane membrane soaked in distilled water (24 hrs. before use) was fixed to the one end of the cylinder with the side of an adhesive to result in permeation cell. One gram of semisolid formulation was taken in the cell (donor compartment) and the cell was immersed in beaker containing 100 ml of drug free P^H 6.4 phosphate buffer as receptor compartment. The cell was immersed to a depth of 1 cm below the surface of receptor fluid. The medium in the receptor compartment was agitated using a magnetic stirrer and temperature of 37±1°C was maintained. Samples (5 ml) of the receptor compartment were taken at various intervals over a period of 90 minutes with replacement of equal amount of free receptor fluid. The samples were estimated by measuring the absorbance at 238 nm in 1800 UV Shimadzu spectrophotometer.

Evaluation for antimicrobial activity of formulations:-

Antimicrobial activity of the formulations was evaluated according to the standard agar cup plate method in brain heart infusion agar media. In present media work, antibacterial activity of BeclomethasoneDipropionate was tested for against causative microorganism of periodontitis in brain heart infusion agar plates, by taking pus sample of oral cavity of diseased patient suffering from periodontitis under the supervision of a dentist. Inoculated in peptone broth and streaked in brain-heart infusion agar using cup and plate method and incubated at 37°C. The diameter of the zone of inhibition was measured and compared with marketed formulation (MF) as well as pure drug (Cruickshank, 1968).

Stability studies:-

The prepared 0.025% Beclomethasonedipropionate dental paste formulations were filled in the collapsible tubes and stored at room temperature (27±2°C) for the span of six months. Known amount of cream formulation were taken out at different time intervals (one month interval) and analyzed for drug content, physical appearance, P^H and rheological properties.

Table-1:- Formulae used to prepare dental pastes

Sl. No.	Ingredient	Without hydrocolloid (F ₁)	With hydrocolloid (F ₂)
1.	Beclomethasonedipropionate	25 mg	25 mg
2.	Precipitated chalk	56 gm	52 gm
3.	Acacia	1.2 gm	1.2 gm
4.	Glycerin	20 ml	20 ml
5.	Sodium carboxymethylcellulose	-	4 gm
6.	Sodium lauryl sulfate	0.8 gm	0.8 gm
7.	Methyl paraben	0.216 gm	0.216 gm
8.	Alcohol	5 ml	5 ml
9.	Methyl salicylate	0.76 ml	0.76 ml
10.	Distilled water	Q.S. to 100 gm	Q.S. to 100 gm

Table-2:- Characterization of prepared formulations

Formulation code	Appearance	Spreadability (cms)	Tube extrudability (%)	pH	Drug content (%)
F ₁	White	7.1	98.15	7.2	98.63
F ₂	White	6.6	92.88	6.7	98.34

* Each reading is a mean of three replicates.

Table-3:- Comparative *In vitro* drug release studies of F₁ and F₂ Dental Formulations

Time in mins	Cumulative % drug release	
	Without hydrocolloid (F ₁)	With hydrocolloid (F ₂)
0	0.00	0.00

15	25.58±0.63	22.01±0.63
30	38.75±0.84	34.87±0.42
45	51.38±0.42	46.13±0.33
60	64.05±0.62	54.31±0.84
75	72.03±0.50	63.45±0.62
90	81.43±0.33	74.12±0.50

* Each reading is a mean of three replicates

* Each sample of 1 gm. paste contains 250 mcg of drug.

Figure-1:- Comparative studies of Beclomethasonedipropionate dental pastes with hydrocolloid (F₁) and without hydrocolloid (F₂)

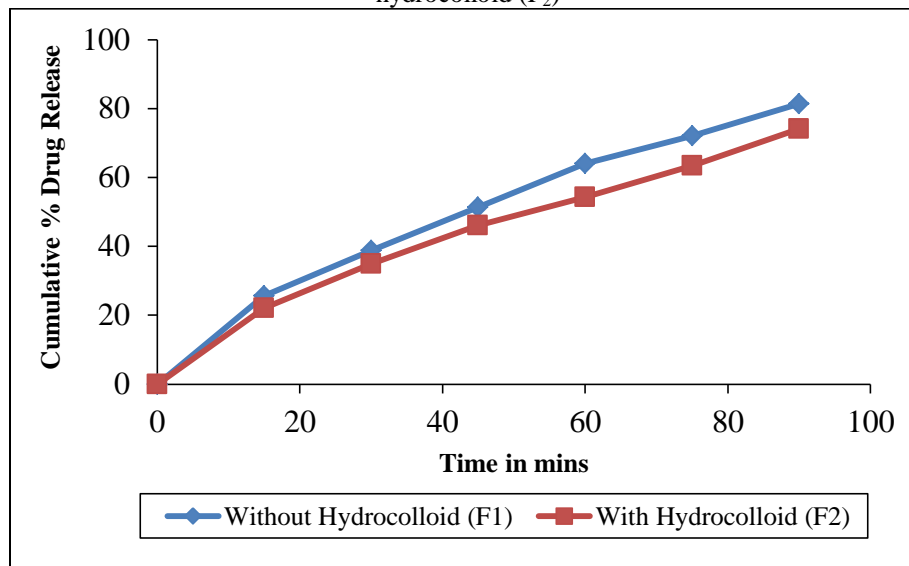
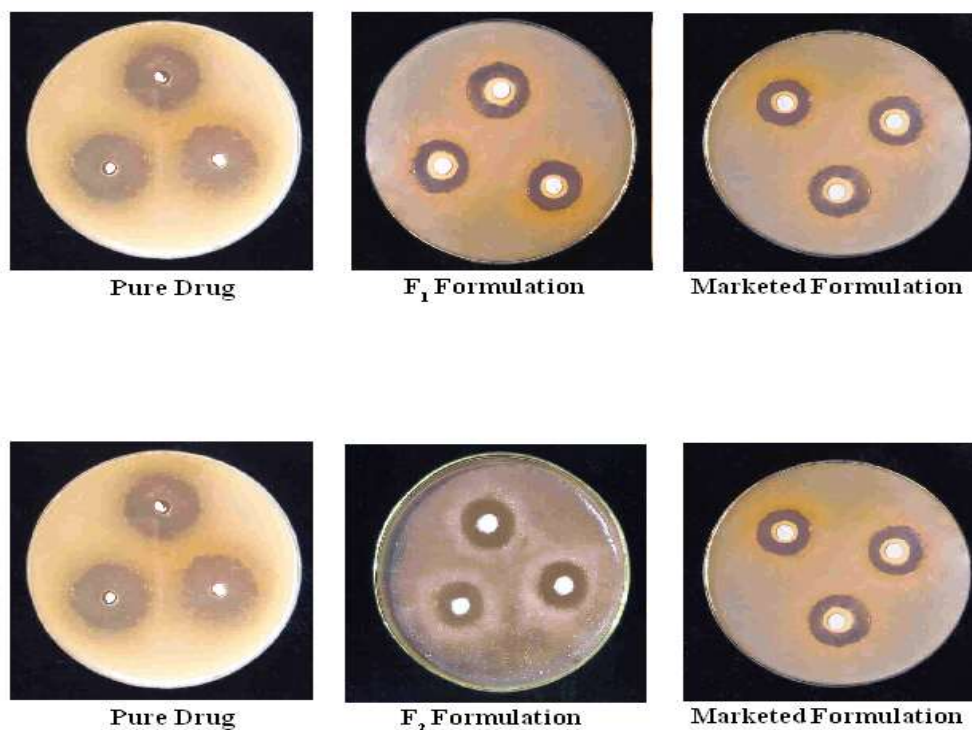


Figure-2:- Photographs showing the effects of treatment during the clinical study



Figure-2: Comparative zone inhibition studies of drug in the formulations with pure drug and marketed formulation



Results and Discussion:-

Results showed that all the formulations were shown good spreadability and extrudability and all formulations were within pH range (Table-2). Drug content estimation, drug present in the formulations F_1 and F_2 were found to be 98.63% and 98.34% respectively. Results showed that the drug content was uniform in all the formulations. In-vitro drug release from medicated pastes prepared revealed that, in F_1 and F_2 at the end of 90 min, percent cumulative drug release was 81.43% and 74.12% respectively. To know precisely, the basic in-vitro drug release data was plotted (Figure-1). During microbiological investigation against the organism collected from the pus sample of dental patient, all formulation showed equal zone of inhibition when compared with the pure drug and marketed formulations. In stability studies, all formulations are not segregate, ferment or physically deteriorated during normal condition of storage and use. When stored at $27 \pm 2^\circ\text{C}$ for period of 6 month all the formulation did not undergo phase separation or gassing formulation or otherwise deterioration aesthetically. The present study revealed that the prepared Beclomethasone Dipropionate mucoadhesive dental paste formulations with more retentive time in oral cavity will be useful for more effective drug action.

Conclusion:-

From our study it was revealed that Beclomethasone dipropionate dental paste formulation should be useful for treatment of periodontitis and oral thrush. The present work revealed that the prepared Beclomethasone dipropionate dental paste formulations with short retentive time also useful in dental disorders. The present work is being focused on designing of medicated tooth pastes to protect the gums, teeth and oral cavity from periodontal infections and oral thrush results from improper fixation of artificial dentures.

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