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# Design And Evaluation of Propranolol Loaded Bio Flexi Ocusert Using Musa Acuminate Biopolymer

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#### **ABSTRACT**

The objective of the study was to develop an ocular insert of Propranolol & evaluate for sustained ocular delivery of drug. Physical characterization, stability studies, invitro release studies were done. Solvent casting technique was used to prepare the ocuserts. Ten formulation were prepared by using propranolol drug, musa acuminate as biopolymer. The ocuserts were physically examined for colour and various other physical parameters were evaluated. Based on the physical parameters further studies were carried out like stability, invitro release studies. The ocuserts were evaluated for thickness and diameter, weight variation test, folding endurance, moisture absorption, stability studies, invitro release studies

Key words: propranolol, musa acuminate biopolymer, ocuserts

#### I. INTRODUCTION

Many people suffer from a wide variety of ocular diseases, many of which lead to irreversible blindness. The leading causes of irreversible blindness in the elderly--age-related macular degeneration and glaucoma--will continue to affect more individuals as the worldwide population continues to age. Although there are therapies for treating glaucoma, as well as ongoing clinical trials of treatments for age-related macular degeneration, there still is a great need for more efficacious treatments that halt or even reverse ocular diseases. The eye has special attributes that allow local drug delivery and non-invasive clinical assessment of disease, but it is also a highly complex and unique organ, which makes understanding disease pathogenesis and ocular drug discovery challenging. As we learn more about the cellular mechanisms involved in age-related macular degeneration and glaucoma, potentially, new drug targets will emerge. This study provides insight into some of the new approaches to therapy. "Ophthalmic disorder" refers to physiologic abnormalities of the eye. They may involve the retina, the vitreous humor, lens, cornea, sclera or other portions of the eye, or physiologic abnormalities which adversely affect the eye, such as inadequate tear production. Most ocular preparations like eye drops and suspensions call for the topical administration of active drugs to the tissues around the ocular cavity. These dosage forms are easy to instill but suffer from the inherent drawback that the majority of the medication they contain is immediately diluted in the tear film as soon as the eye drop solution is instilled into the cul-desac and is rapidly drained away from the precorneal cavity by constant tear flow and lacrimonasal drainage. Ophthalmic inserts are defined as sterile preparations, with a solid or a semi solid consistency, whose size & shape are especially designed for ophthalmic application. They are essentially composed of a polymeric support containing or not drug(s), the latter being incorporated as dispersion or a solution in the polymeric support. The inserts can be used for topical or systemic therapy. This invention is a medical treatment for ophthalmic conditions which are associated CDDS.

Propranolol is a sympatholytic non-selective beta blocker. Sympatholytics are used to treat hypertension, anxiety and panic and glucoma. It was the first successful beta blocker developed.

Propranolol is rapidly and completely absorbed, with peak plasma levels achieved approximately 1-3 hours after ingestion. The main metabolite 4-hydroxypropranolol, with a longer half-life (5.2–7.5 hours) than the parent compound (3–4 hours), is also pharmacologically active. Propranolol is a highly lipophilic drug achieving high concentrations in the brain. Propranolol is a non-selective beta blocker, that is, it blocks the action of epinephrine and norepinephrine on both  $\beta_1$ - and  $\beta_2$ -adrenergic receptors. It has little intrinsic sympathomimetic activity (ISA) but has strong membrane stabilizing activity.

Bananas are rich in vitamin B6 and they are a good source of fiber, vitamin C, magnesium and potassium. Lack of B6 in a diet can cause weakness, irritability and insomnia. The potassium found in bananas helps to regulate blood pressure and may reduce the risk of high blood pressure and stroke. Potassium is also

essential for helping muscles to contract properly during exercise and reduces cramping up. A medium-sized banana provides 400 mg of potassium -11% of daily value- and contains 110 calories and 4 grams of fiber.

## II. MATERIALS AND METHODS

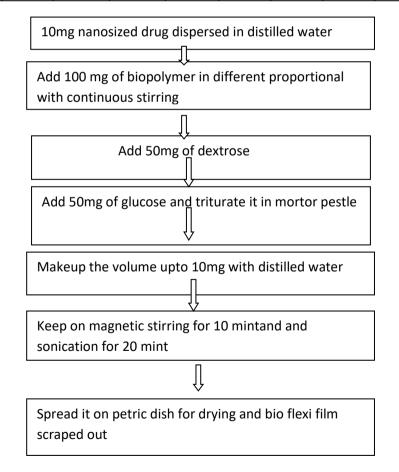
Material- banana bio-polymer were collected.

## I. Preparation of Ocuserts

The various formulations of bio flexi ocusert were prepared by solvent casting method. Different bioflexi ocusert (1:1 to 1:10) were prepared with varying concentration of the biopolymer. Biopolymer was taken in mortar pestle and triturated properly for the fine powder. After that 50 mg of dextrose & 50mg of glucose was added along with 100 mg of nanosized drug (propranolol). Then 10 ml of distill water was added and triturated properly in uniform direction.. After that magnetic stirring was done for 45 minutes and sonication was performed (3cycle). After that the mixture was uniformly spreaded on a petri-dish and dried at room temperature. Bio-flexi film was obtained.

#### Formulation detail

formulation	FB1(1:1)	FB2(1:2	FB3(1:3)	FB4(1:4)	FB5(1:5)	FB6(1:6)	FB7(1:7)	FB8(1:8)	FB9(1:9)	FB9(1:10)
Propranolo(mg)	10	10	10	10	10	10	10	10	10	10
musa acuminate biopolymer	1%	2%	3%	4%	5%	6%	7%	8%	9%	10%
dextrose	50	50	50	50	50	50	50	50	50	50
glucose	50	50	50	50	50	50	50	50	50	50
Distilled water	10	10	10	10	10	10	10	10	10	10



## **EVALUATION PARAMETER**

The ocuserts were evaluated for thickness, folding endurance, drug content uniformity, surface pH, and in-vitro diffusion studies

**Thickness-** Insert thickness was measured by a Vernier caliper at five different points on the film. The mean thickness and standard deviation (SD) were calculated.

s.no	formulation	Thickness
1	FB1	0.17
2	FB2	0.21
3	FB3	0.24
4	FB4	0.28
5	FB5	0.32
6	FB6	0.24
7	FB7	0.52
8	FB8	0.43
9	FB9	0.29
10	FB10	0.48

**Weight uniformity** - Weight uniformity of bio-flexi ocusert determined by taking weight of ten bio-flexi ocusert of sizes 1 square cm diameter from every batch and weight individually on electronic balance. The avg. weight was calculated.

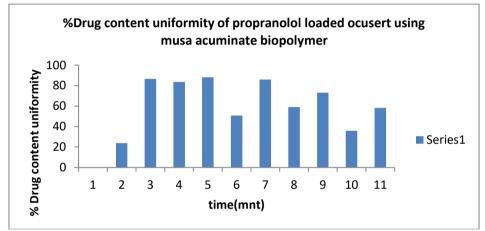
s.no	formulation	Weight uniformity
1	FB1	16.7
2	FB2	16.7
3	FB3	18.6
4	FB4	16.5
5	FB5	19.6
6	FB6	21.5
7	FB7	17.4
8	FB8	17.6
9	FB9	15.6
10	FB10	18.5

**Folding Endurance**- Folding Endurance of the film was determined by repeatedly folding the inserts at the same place till it breaks. The ocuserts was folded in the center, between finger and thumb and then opened. This was one folding. The number of times, the film could be folded at the same place without breaking gave the value of folding endurance

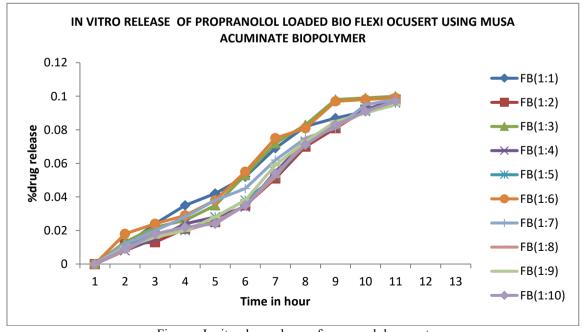
s.no	formulation	Folding indurance
1	FB1	132
2	FB2	138
3	FB3	148
4	FB4	156
5	FB5	132
6	FB6	178
7	FB7	138
8	FB8	164
9	FB9	148
10	FB10	157

**Drug content uniformity-** Uniformity of drug content was determined by assaying the individual inserts. Three inserts from each batch were powdered individually and each was dissolved in 100 ml of purified water by stirring on a magnetic stirrer for 2 hours. The absorbance of each of these solutions was then measured on UV-visible spectrophotometer at 290 nm.

s.no	formulation	%drug content uniformity
1	FB1	72.64
2	FB2	97.76
3	FB3	95.23
4	FB4	94.77
5	FB5	93.28
6	FB6	88.80
7	FB7	94.77
8	FB8	71.64
9	FB9	86.56
10	FB10	88.80



**In-vitro diffusion studies** The in-vitro drug release studies were carried out using diffusion cell. 0.7 ml of isotonic phosphate buffer of pH 7.4 was placed in the donor chamber, which acted as tear fluid. Ocusert was placed in the donor compartment over a egg shell membrane. 25 ml of isotonic phosphate buffer was taken as the receptor medium and the apparatus was maintained at  $37^{\circ} \pm 2^{\circ}$  C and was continuously stirred using magnetic stirrer. The samples were withdrawn at regular intervals and analyzed at 290 nm.



#### III. RESULT AND DISCUSSION

The prepared ocusert were evaluated for the thickness of each film using a micrometer . The average of five readings was taken. The mean thickness, standard deviation and percent coefficient of variation were calculated. All the eight formulations, measured thickness with low stan-dard deviation values ensured the uniformity of the films prepared by solvent casting technique.

The estimation of drug content uniformity was found to be al-most same with their low standard deviation value. Cumulative percentage drug release of each ocusert in the *in vitro* release studies was based on the mean content of the drug present in the respective films. The weight of all the ocusert was found to be uniform indicating good distribution of drug, polymer.

Thickness specifications may be set on an individual product basis. There were no marked variations in the thickness of ocuserts within each formulation indicating uniform behavior of ocusert throughout the sealing process. The thickness of the ocuserts of all formulation were tabled.

Drug release was carried out by M.S Diffusion apparatus . The mechanism of propranolol released from the bioflexi ocusert was studied by fitting the dissolution data in different kinetic models such as Zero order, First order, Higuchi Matrix, Peppas Korsmeyer and Hixon Crowell and determining the  $R^2$  values of the release profile corresponding to each model. Its % drug release,  $t_{50\%}$  and  $t_{80\%}$  were calculated on the basis of M.S diffusion apparatus.

The drug release pattern for formulations by *Musa acuminate(BANANA)* for FB1-FB10 based on t80 was found to be FB2 (1:2) > FB5 (1:5) > FB3 (1:3) > FB6 (1:6) > FB9 (1:9) > FB10 (1:10) > FB8 (1:8) > FB7 (1:7) > FB1 (1:1) > FB4 (1:4). In-vitro drug release was performed for all the formulations and the data indicate that drug loaded formulations show the sustained release behavior. Graph was plotted between % Cpr and time, theR² value, T50% and T80% was calculated from graph, the FB2 (1:2) formulation was found to be the best formulation showing an R² value of 0.9881, t50% of 4.6hrs and t80% of 22 hrs respectively. According to the release kinetics the best fit model was found to be Higuchi Matrix with SUPERCASE 11 TRANSPORT as the mechanism of drug release.

From each batch randomly five ocuserts were selected and weighed. It ranges from 15.6 to 21.5. The weight uniformity of ocuserts of all formulations were tabled. Use of less amount of plasticizer was observed to cause brittleness in the medicated discs, but use of greater amount of plasticizer (1ml plasticizer per 10 ml) displayed little opaqueness and good folding endurance.

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