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Original Article

Formulation and Evaluation of Eye Drop for Dry Eye Syndrome

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ABSTRACT

The ophthalmic formulation was prepared considering the essential requirements for the healthy eye. Sodium Carboxy Methyl Cellulose (Na-CMC) dissolve in the distilled water. The pH was adjusted to make the solution isotonic by using NaCl and other buffer solutions. The formulation was evaluated for viscosity and eye irritation test. The formulation was made in concerned with dry eye syndrome and associated disease due to old age. The formulation was observed for sterility test and finally stability test.

Key words: Sodium CMC, Eye Drop, Method of Preparation.

1. INTRODUCTION

Some of these are easily identified, such as decreased use of artificial tears or reduced office visitutilization that stems from poor patient satisfaction and compromised lifestyle due to dry eye symptoms. [1] Until very recently, practitioners have been able to offer patients only palliative therapy; many of these individuals jump from physician to physician in search of relief from their progressively debilitating condition. [2] In their modest way, these patients chronically and unnecessarily tax the health care system. Other overutilization costs are more suitable. The more than 3 million elective eye procedures each year in the United

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States often involve patients who are predisposed to dry eye; cataract patients, for instance, tend to be older, while some LASIK patients dislike their contact lenses — often because their dry eyes make wearing contacts irritating or unbearable. Some of these elective procedures can, in fact, be avoided altogether by controlling the dry eye. [3] Yet another group of potential savings is in *opportunity costs* outside the health care system. These include indirect costs, such as loss of productivity attributed to morbidity, and reduced comfort and convenience to patients. Bacterial keratitis may result in permanent scarring. Without a corneal transplant, these patients can suffer the loss of effectiveness relative to areas such as work performance, night driving, caring for family members, or engaging in a favorite activity. The projections can playout in various ways a prospective fiscal analysis of this nature would hinge on the variables selected for the study. [4]

Nevertheless, when opportunity costs are factored in, the overall costs to the health care system and to society are logarithmically accelerated. Finally, *intangibles* include a satisfied patient population being offered a first-in-class drug therapy that represents a new paradigm in dry eye treatment. Contented patient clients reflect well on any health care organization, creating goodwill, an open dialog, new patient referrals, less confrontation, and more personable and appropriate access patterns. [5]

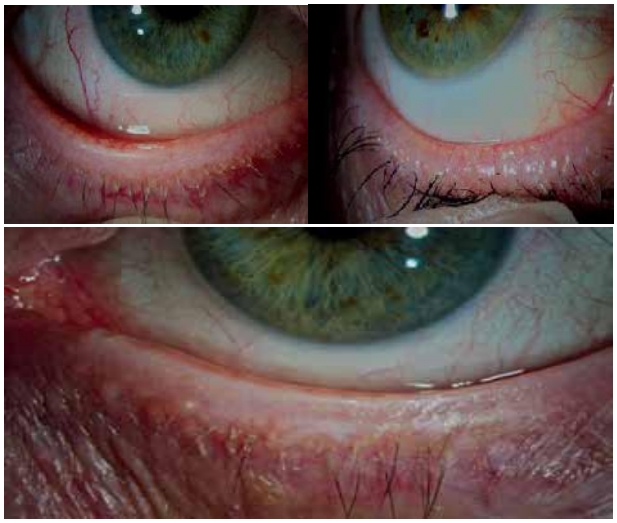


Fig 1: Picture of dry eye syndrome

2. MATERIAL AND METHODS

To prepare vicious eye care solution, different concentrations of Na-CMC as per were used. To obtain clear viscous solutions, accurately weighed Na-CMC were dispersed and thoroughly hydrated in about 30 ml of the required amount of WFI. The dispersion was vigorously stirred and heated to 40–50°C until the solution became clear. Then add weighed the quantity of Sodium Chloride, Sodium Hydroxide and at last add weighed the quantity of drugs in about 40-50% of the required amount of WFI. Add this mixture to the dispersion of polymers while stirring. Adequate WFI was then added to obtain the required volume. The viscous solutions prepared with the excipients were sterilized at 121°C in an autoclave for20 min. Afterward, aqueous solutions were sterilized by filtration through 0.22 µm sterile filter. The same formulation was prepared into simulated tear fluid in place of WFI.

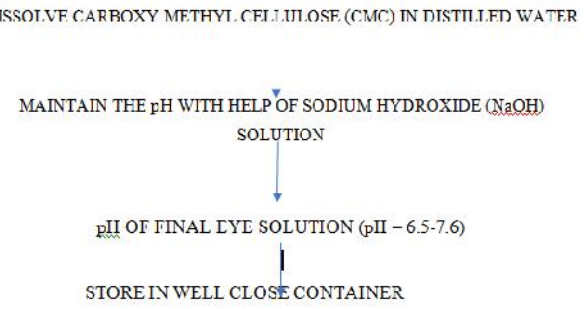
Table 1: Material used in dry eye drop

S No	Ingredient	Company
1	Sodium hydroxide,Na-CMC	CDH, NEW DELHI
2	Distilled water	DISTILLATION UNIT OF IFTM

Table 2: Composition of Dry Eye Drop

S. No	Name of Component	F1 (gm)	F2	F3
1	Sodium Carboxy methyl Cellulose (Na-CMC)	0.075	0.1125	0.15
2	Distilled Water	q.s	q.s	q.s
3	Sodium Hydroxide		1ml	
4	Hydrochloric Acid	——	1 ml	——

The method of Preparation- (in house procedure)



EVALUATION PARAMETERS:

i. Clarity:

Clarity test was done by visual inspection of each container and by measuring the refractive index using refractometer at 25°c. [6]

ii. pH:

pH of prepared viscous eye care solution was measured with pH meter. [7]

iii. Viscosity:

The viscosity of batches F1-F3 by Brook field viscometer at different RPM. By plotting graph of RPM vs. viscosity, flow pattern was checked. [8]

iv. Stability

To assess the drug and formulation stability, stability studies were done according to ICH guidelines. Optimized formulation was kept in the stability chamber at specified temperature and humidity (40°±10°C and75%RH) for one month. The chemical stability of the formulation was assessed by the estimation of the percentage drug remaining in the formulation and physical stability was evaluated by monitoring any change in pH, viscosity, and appearance. [9]

3. RESULT AND DISCUSSION

1. pH: It is negative log value of hydrogen ion concentration. pHof prepared vicious eye care solution was measured using the pH Meter.

Table 3: pH value of different formulations

S. No	Formulation code	Ph
1	F1	7.8
2	F2	6.8
3	F3	6.7

2. Viscosity: The viscosity of different formulation (F1-F3) by Using Brookfield viscometer, flow pattern was checked.

Table 4: Viscosity for Different Formulation

S. No	Formulation	VISCOSITY (cp)
1	FI	3.56
2	F2	4.45
3	F3	5.21

3. Clarity test: Clarity test was done by using clarity apparatus of each formulation

Table 5: Clarity of viscous eye drop solution of different formulations

S. No	Formulation code	Observation
1	**F1**	Clear
2	**F2**	Clear
3	**F3**	Clear

4. Stability-To assess the drug and formulation stability, stability studies were done according to ICH guidelines. Optimized formulation was kept in the stability chamber at specified temperature and humidity (40°±10°C and 75%RH) for one month. The chemical stability of the formulation was assessed by the estimation of the percentage drug remaining in the formulation and physical stability was evaluated by monitoring any change in pH, viscosity, and appearance.

Table 6: Stability data of eye drop solution of different formulations

FORUMAUTION	pH	VISCOCITY(cp)	CLEARITY
F1	7.3	3.56	Clear
F2	6.4	4.45	Clear
F3	6.3	5.21	Clear

In the present study about eye drop solution, the pH was found of F1,F2 and F3 formulation

4. CONCLUSION

Thus, based on all the studies we can conclude that the different formulation having Na-CMC in distilled Water, the viscous solution may be considered as a promising for ophthalmic drug delivery. If the formulation will scale-up to manufacturing level, it will be used for the treatment of the dry eye syndrome.

Social Economic goals-In the present study, Na-CMC loaded Eye drop (Solution) were prepared by the mixing method. These formulations were prepared to achieve the following goals,

1. Development of eye solution
2. Prevent eye irritation
3. To overcome the bioavailability related problem.
4. To stabilize the formulation.
5. To minimize the side effects.

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