NEED AND OBJECTIVE
5.1. Aim of the study

Nowadays one of the basic tasks of drug formulation is to develop an already existing dosage form in a way which makes drug release the best possible under the given circumstances, that is to enhance bioavailability in this way. The other important aim is to widen the choice of products with respect to dosage that is to make a given drug available in as many dosage forms as possible. The need for delivering drugs to patients efficiently has prompted formulation scientists to engage in the development of new drug delivery systems. Incorporating an existing medicine into a new drug delivery system can significantly improve its performance in terms of safety, efficacy and improved patient compliance. One important innovation in this regard is the development of aqua triggered w/o phase transition ophthalmic microemulsion.

Conventional eye drop formulations are the most suitable ones used since decades for treatment of most of the ocular diseases. Drugs administered in the form eye drops produces local action without causing systemic side effects as compared to the oral route. However the eye drops are rapidly washed away from the eye, and the dose administered do not reach the interior tissues of eye.

The reason for the poor bioavailability from the eye drop formulation is
1) Short residence time in the cul-de-sac.
2) Poor penetration from the corneal membrane.
3) Rapid washout of applied drug due to reflex lachrymation.

To solve the problems of eye drops, it would be desirable to develop a microemulsion eye drop formulation which:
1) Increases the residence time of drug in the cul-de-sac.
2) enhances the corneal permeation of drug.
3) Prevents the washout of applied drug with of reflex lachrymation.

In view of the above; the future objective of research can be to formulate a microemulsion based eye drop formulation for treatment of glaucoma, which is currently missing from the pharmaceutical trade in spite of the fact that internists expressed a concrete therapeutic need for the formulation of an ocular preparation containing antiglaucoma drug.
5.2 Objectives

The major objective of the study are listed below:

1) To evaluate the physical compatibility of the formulation excipients and with the drug used, by Fourier transform Infra Red Spectroscopy (FTIR) and High Performance Thin Layer Chromatography (HPTLC) techniques.
2) To design the ternary phase diagram of non ionic surfactants tween 80, span 20, ethyl oleate (oil) and water and demarcation of microemulsion region in the phase diagram.
3) Determination of drug solubility in the various aqueous and oily phase
4) Evaluation of the microemulsion
   - Determination of droplet size and distribution of the formulation by photon correlation spectroscopy (Dynamic light scattering).
   - Determination of zeta potential of the colloidal solution by photon correlation spectroscopy (Dynamic light scattering).
   - Characterization of the phase behavior of the microemulsion by small angle neutron scattering technique (SANS).
   - Determination of location of Timolol maleate molecules in the microemulsion domain by $^1$H-Nuclear magnetic resonance spectra ($^1$H-NMR)
   - Determination of conductivity by conductivity meter.
   - Determination of pH by pH meter.
   - Rheological Measurements
   - Osmolality study
   - Surface tension study
   - To determine the in-vitro drug release characteristics of the formulations and study the mechanism and drug release kinetics of the formulation.
   - Ex-vivo transcorneal Permeation, calculation of flux values and permeation coefficients
5) In vivo evaluation

   - In-vivo evaluation of formulation in comparison with aqueous eye drop formulation
CHAPTER-6

PREFORMULATION STUDY