Scope and Plan
SCOPe AND PLAN OF THE STUDY

As mentioned in the review of literature, though numerous studies have been carried out with *Piper longum*, no detailed studies have been carried out to study all aspects of its role in the treatment of tuberculosis. Since *Piper longum* fruits have been suggested for use as a tonic, it was planned to evaluate the role of fruits as such also apart from isolating compounds and testing their activity as done in some previous studies. The use of fruits as such for study is also beneficial since the stability of isolated compounds is of concern. Moreover, the fruit when used as such may also contain other similar compounds which may give a cumulative effect. So aqueous extract of *Piper longum* was used for study.

The main aspects to be studied were checking the antimycobacterial activity of the aqueous extract of fruits of *Piper longum* as well as isolated compounds, evaluating the bioenhancer effect of the aqueous extract of fruits when administered with anti TB drugs *in vitro*, assessing the hepatoprotective effect of the aqueous extract of the fruits when administered with anti TB drugs *in vivo* in uninfected and infected experimental animals. The fruits were used as such to study its role as a bio availability enhancer when administered
with anti TB drugs \textit{in vivo} and to ascertain whether the adminisration of \textit{Piper longum} fruits does not cause any adverse change in various biochemical and hematological parameters in healthy human volunteers.

The above mentioned studies would serve the purpose of deciding whether the administration of fruits of \textit{Piper longum} along with anti TB drugs will be effective in the treatment of tuberculosis.

Since the antimycobacterial activity of the essential oil and amides from \textit{Piper longum} has only be studied , it was planned to separate mixtures of compounds or isolate new pure compounds , characterize them and test their antimycobacterial activity.

The bio enhancing effect of piperine with rifampicin \textit{in vitro} has been reported recently. It was therefore planned to study the bioenhancing effect of aqueous extract of fruits of \textit{Piper longum} with different anti TB drugs.

In the previous study on hepato protective effect of \textit{Piper longum} fruits when administered with anti TB drugs , the dosage of drugs used was higher and level of lipid peroxides and reduced
glutathione was not assessed. In the study planned normal dosage of drugs was used and the above mentioned parameters were also assessed apart from levels of liver enzymes and the hepato protective effect of aqueous extract of fruits of *Piper longum* was compared with that of piperine. The study was also extended to infected experimental animals.

The use of piperine as a bioavailability enhancer of anti TB drugs has been reported. It was therefore planned to study the bioavailability enhancing effect of fruits of *Piper longum* in healthy human volunteers. It was also planned to study the effect of administration of *Piper longum* fruits on various biochemical and hematological parameters because though 15-20g of the fruit powder was prescribed for rasayana (immunomodulatory) therapy, there is no documented evidence of its effect on various biochemical and hematological parameters.