

CHAPTER 4

CONCLUSION

The stability study of antituberculosis drugs, ethambutol tablets in aluminum foil, isoniazid tablets, pyrazinamide tablets and rifampicin capsules in blister pack was performed by the non-isothermal and the isothermal stability methods. The sampling time of non-isothermal stability could not be determined *a priori* and the kinetic parameters derived from this method were not acceptable (Vyazovkin *et al.*, 1999 and Galway, 2003). However, the non-isothermal stability method could be completed in a short time and not costly therefore it was used to design for isothermal stability sampling times. The study suggested sampling time at 30, 60, 90, 120, 150 and 180 days. The isothermal stability study, classical method, showed that high temperature and humidity significantly affected antituberculosis drug stability ($p < 0.001$). Therefore antituberculosis drugs should be stored at low temperature and controlled humidity. Shelf-life of ethambutol, predicted by the Arrhenius and the Yoshioka, was less than three years while that of isoniazid was longer. Shelf-lives of pyrazinamide and rifampicin by the Arrhenius method were more than five and three years, respectively. However the Yoshioka gave shorter shelf-lives.

The quality of ethambutol should be monitored intermittently during their storage, while isoniazid stability is reliable. For pyrazinamide and rifampicin, both methods, the Arrhenius and the Yoshioka methods gave different shelf-lives so they should be monitored intermittently during their storage.

The study suggests that if the non-isothermal stability be used for solid dosage form, it should be powdered to be more homogenous system and decreased tablet/capsule variation. It suggested that the Arrhenius method could perform well. Stability is often a function humidity and temperature, and the Yoshioka method could predict stability testing simultaneously both factors. So the Yoshioka method is useful for solid dosage form.