Chapter 5

Conclusion
5. CONCLUSION

A new HPTLC method has been developed for the identification and quantification of TTO in formulations. The method was found to be simple, sensitive, precise, accurate and specific for estimation and can be conveniently employed for studies on TTO formulations.

Antimicrobial studies proved that TTO formulated at the right pH showed significant promise as a potential therapeutic agent for the treatment of acne vulgaris. *In vitro* results indicate susceptibility at low concentration and products containing TTO maintained their *in vitro* efficiency.

This work further demonstrated that the microemulsion and liposomal formulations were more efficient for the delivery of TTO through the follicular route. With delivery of formulations into hair follicle, a reduction of either the applied dose or the frequency of administration is a possibility. A clinical study will have to be performed in order to compare the efficacy and safety of different formulations of TTO. More detailed studies of the effects of formulation composition, on the extent and kinetics of drug deposition have to be carried out in the future to gain insight as to the mechanism by which formulation factors can increase and control drug delivery. Drug delivery targeting the follicles may represent a promising and valuable therapeutic approach for pathologies associated with the sebaceous glands.
The *in vitro* release of TTO from the formulations into artificial sebum made one assume that *in vivo* the drug will be released in the hair follicles in a much shorter period than the time corresponding to sebum excretion and hence pharmacologically more effective.

Skin irritation studies showed that the optimized TTO formulation was well tolerated.

Clinical studies showed the optimized TTO formulation to be more effective than the marketed formulation.

The fundamentals of a successful pharmaceutical formulation are to enable delivery of active substances to the target organ at therapeutically relevant levels, with negligible discomfort and side effects to the patient. The research work carried out fulfilled the objectives of the present study which was to develop a HPTLC method for the quantification of TTO; examine the *in vitro* antimicrobial activity of TTO and TTO formulations against *S. aureus*, *S. epidermidis* and *P. acne*; study the role of pH in the antimicrobial activity against these microorganisms; determine the follicular concentrations of TTO; study the skin tolerability of the optimized TTO formulation and to clinically evaluate efficacy of the optimized formulation.