CHAPTER-10

CONCLUSION

The data obtained from the study of development and evaluation of starch based hydrotropic gels, the following conclusions were made.

It was observed that hydrotropic starch gels offer a suitable vehicle for topical delivery of Terbinafine HCL.

The hydrotropic salts Urea was observed to improve the solubility of Terbinafine HCL as compared to Mannitol.

The hydrotropic starch gels were found to be white opaque to white translucent in appearance and have good homogeneity.

The drug content, pH, spreadability, was found to be within acceptable range.

The starches (corn & potato) showed an impact on the viscosity of gel formulations. Gels prepared using potato starch was more viscous than gels prepared using corn starch.

Hydrotropic salts has also showed an impact on the viscosity of gels Gels containing Mannitol were more viscous than that containing Urea.
The in vitro release of hydrotropic starch gels containing Terbinafine HCL were found to be in the following order TCU-III>TCU-II>TCM-III>MP1.

Formulation TCU-III containing 15% Urea, 10% corn starch and 1% w/w of drug. Showed highest drug release of 57.94% as compared to other formulation and marketed preparation.

IR spectra showed that there is no interaction between the drug and additives, and hence the drug remains intact without undergoing any chemical reaction during the preparation and after its storage.

Skin irritation study was conducted on white rabbits and guinea pigs for a period of 3 days, and was observed regularly. The results of the study concludes that there was no (erthrema & edema) found after 3 days on the skin of rabbit and guinea pig on application of prepared gel. The obtained results were confirmed on application of formulations in healthy human volunteers in clinical studies.

The antifungal activity manifested that the mean zone of inhibition of the hydrotropic starch gel (TCU-III) was larger than that of the reference and marketed cream (MP1).

The experiment was reproduced with another drug ketoconazole and the results obtained were reproducible.