CHAPTER–2

OBJECTIVES OF THE WORK

Need of Study:

The skin often has been referred to as the largest of the body organs. An average adult’s skin has surface area of about 2m². Its accessibility and the opportunity it affords to maintain applied preparation intact for a prolonged time have resulted in its increasing use as a route of administration whether for local, regional or systemic effects.

The extensive studies on release properties have revealed that the active ingredients in gel based formulations are better percutaneously absorbed than cream or ointment bases. Terbinafine HCL is effective topically for the management of cutaneous candidiasis and tinea infection.

The major drawback of this drug is its low aqueous solubility. Increasing the water solubility of insoluble or slightly soluble compounds is a major concern for pharmaceutical researchers.

The techniques generally employed to enhance the solubility of poorly water soluble drugs are use of surface active agents, hydrates and solvates, polymorphism, complexation, hydrotrropic solubilization and conventional trituration and grinding. Among these techniques, hydrotrope solubilization is considered as easy method of solubilization. Hydrotropes are class of compounds that normally increase the aqueous solubility of insoluble solutes.
Starches when used with hydrotropic salts (solubilizing agents) such as urea and mannitol results in hydrotrope gels, which will serve as a vehicle for topical drug delivery and also improve stability, solubility and bioavailability of poorly insoluble drugs. Hydrotrope-gelled starch offers promise as a vehicle for topical drug delivery.

The solubility of terbinafine HCL can be enhanced by using hydrotropic salts; these are the solubilizing compound which will enhance solubility of poorly soluble drugs.

Hence, in the present investigation an attempt was made to develop terbinafine HCL hydrotropic starch gels using potato and corn starch along with urea and manitol as hydrotropic salts, which will be a potential vehicle for delivering topically the drug directly to the site of action.

**Objectives of the study**

The present work is aimed:

1. Utilization of commonly available starches to prepare hydrotropic gels to minimize cost factor than the marketed preparations.
2. To develop hydrotropic starch gels using various starches and hydrotropic salts in varying concentration.
3. physico-chemical characterization of prepared gels:
   a) Physical appearance
   b) pH
   c) Drug content
4. Rheological studies of prepared hydro tropic starch gels.
   - Viscosity
   - Spreadability
   - Extrudability
   - Gel strength
5. Stability studies
6. In-vitro drug release studies of the formulated gels using dialysis technique.
7. Anti-fungal studies of the prepared gels using microbiological assay.
8. Skin irritation studies of prepared formulation on rabbits and guinea pigs.