3.1 Objectives of the study

The objective of the present study is to formulate, design and evaluate drug delivery system of anti hypertensive drug, which provide continuous dosing of drug at constant and controlled rate up to predetermined period. Also it belief that anti hypertensive drugs in form of transdermal drug delivery system will provide better therapy with minimum side effect such as GI irritation, degradation in GIT or by the liver, more frequent administration, extensive first pass metabolism and variable bioavailability. In developing the transdermal drug delivery system, the major aim is to overcome the barrier property of the skin that retards the penetration of molecule across it so, as to provide constant therapeutic level for prolong period of time and greater therapeutic efficacy in the treatment of hypertension.

3.2 Plan of the Experimental Work

1. To select suitable antihypertensive drug candidates having suitable criteria for the preparation of transdermal patch.

2. To perform permeability study of selective drug candidates using wistar rat skin for finding out release profile of pure drug through the skin.

3. To select suitable film forming polymers for the preparation of transdermal matrix patch.

4. To perform preformulation studies for the identification of physicochemical properties of selective drug candidates and excipients.

5. To perform incompatibility study between selective drug candidates and polymers using FT-IR spectroscopy.

6. To perform photo stability study for light sensitive drug.

7. To perform DSC study of light sensitive drug and final optimized formulation of light sensitive drug.

8. To prepare transdermal patches using solvent evaporation technique.
9. To evaluate transdermal patches for the optimization of polymer and plasticizer concentration.

10. To prepare preliminary trial batches of transdermal matrix patches containing selective drug candidates to ensure the controlled release of drug from the matrix.

11. To apply Design of experiment using $3^2$ full factorial design batches for the final optimization of transdermal matrix patch containing anti hypertensive agents.

12. To evaluate prepared factorial batches for the physicochemical properties such as flatness, thickness, weight variation, tensile strength, folding endurance, adhesion study, moisture uptake, moisture content and drug content.

13. To carry out ex-vivo permeation studies of transdermal patches through the wistar rat skin for 16 hrs to check the permeation of drug into different layers of skin.

14. To optimize final formulation using $3^2$ full factorial experimental design by performing checkpoint validation.

15. To perform skin irritation study of optimized batch of both the drugs on wistar rat skin for 24 hrs.

16. To carry out ex-vivo release studies of optimized batch of both the drugs for 16hrs through the wistar rat skin and compare with in-vitro dissolution study of extended release marketed product of both the drugs.

17. To carry out stability studies of optimized batch of both the drugs as per ICH guidelines for 6 months.