4. PLAN OF WORK AND METHODOLOGY

4.1. PLAN OF WORK
1. Literature survey and patent search (3 Months)
2. Preformulation studies (3 Months)
3. Trial Batches for Formulation and Development of Microsponges- (2 Months)
4. Optimization and Evaluation of the formulated Microsponges (6 Months)
5. Formulation & Evaluation of Microsponges loaded gel (1 Months)
6. Accelerated stability studies of optimized batch of Microsponges gel (3 Moths)
7. Thesis Writing (3 Months)

4.2. METODOLOGY
4.2.1. Literature survey and Patent Search.
4.2.2. Selection of Drug, Polymer and methodology for the formulation & development of Microsponges and its subsequent topical delivery system
4.2.3. Preformulation study of Drug.
   ✓ Organoleptic characteristics of drug
   ✓ Melting Point.
   ✓ Solubility.
   ✓ Wavelength Maxima ($\lambda_{\text{max}}$)
   ✓ Identification of drug by $\lambda_{\text{max}}$, FT-IR and DSC study.
   ✓ Calibration Curve of Drug
   ✓ Compatibility study of drug & polymer by FT-IR and DSC
4.2.4. Preparation of Microsponges.

4.2.5. Preliminary Trial Batches for selection of

- Polymer Type,
- Drug: polymer Concentration,
- Stabilizer type,
- Stabilizer concentration,
- Internal phase type and internal phase concentration,
- External phase type and external phase concentration,
- Speed (RPM) and Speed with Time.

4.2.6. Risk assessment for Critical Quality Attribute to develop Quality by Design Approach (to identify variables affecting drug product quality as per Preliminary trial batches)

4.2.7. Formulation of Microsponges Using Factorial Design

4.2.8. Characterization of Drug loaded microsponges

- Mean Particle Size:
- Drug Content:
- Percentage Yield:
- Entrapment Efficiency:
- *In vitro* drug release study of microsponge
- Particle Morphology by SEM
- Porosity study
- Solvent Residual Analysis
- Kinetics of drug release
- Statical analysis:
- Validation batches (Check Point Analysis) and its characterisation of drug loaded microsponges for its subsequent topical drug delivery system

4.2.9. Preparation of Topical Gel
4.2.10. Characterization of Fluconazole Microsponges loaded Topical Gel

✔ Physical evaluation
✔ Measurement of pH
✔ Viscosity study
✔ Spreadability
✔ Homogeneity and grittiness
✔ Drug content
✔ *In vitro* diffusion studies
✔ Anti-microbial study
✔ Primary skin irritancy studies
✔ Comparison with conventional topical gel
✔ Accelerated stability studies