CHAPTER 4
WORK ENVISAGED
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The proposed research work for fulfillment of the objectives is:

4.1 Updated literature review and Patent search

4.2 Selection of drugs and excipients

4.3 Physical characterization and identification of the drug

4.3.1 Physical properties:

- Appearance
- Colour
- Melting point
- Loss on drying

4.3.2 Identification

- UV spectral analysis
- FTIR Spectral analysis
- Differential Scanning Calorimetry (DSC) analysis

4.3.3 Analytical Methodology

- Determination of absorption maxima ($\lambda_{max}$) in different media
- Preparation of calibration curves in different solvents

4.4 Development and Validation of Analytical Method

4.4.1 Development and validation of UV method

4.4.2 Development of HPLC method

- Optimization of mobile phase
- Preparation of calibration curve for curcumin

4.4.3 Validation of developed HPLC method for following parameters as per ICH guidelines.

- Linearity
- Precision
- Accuracy
- Limit of detection (LOD)
- Limit of quantification (LOQ)
4.4.4 Stability indicating method
In order to determine that the method was stability indicating, following forced degradation study parameters were studied:
- Acid degradation
- Base degradation
- Dry heat degradation
- Oxidative degradation
- Photolytic degradation

4.5 Development and validation of bioanalytical method

4.5.1 Development of HPLC method
- Sample preparation
- Optimization of mobile phase
- Preparation of calibration curve for curcumin

4.5.2 Validation of developed bioanalytical HPLC method for the following parameters:
- Linearity
- Precision and accuracy
- Sensitivity
- Limit of detection (LOD)
- Limit of quantification (LOQ)
- Recovery studies
- Stability

4.6 Preformulation studies

4.4.1 Solid state stability at high temperature and high humidity

4.4.2 Partition coefficient

4.4.3 Effect of pH on the stability of curcumin

4.4.4 Solubility profile
4.4.5 Excipient compatibility studies

4.7 Formulation Development and Characterization of Nanoemulsion

4.5.1 Formulation of Nanoemulsion
- Excipient selection
- Construction of pseudoternary phase diagrams
- Formulation selection from phase diagram
- Formulation of curcumin loaded nanoemulsions.
- Physical stability studies of nanoemulsions.
- Dispersibility studies

4.5.2 Characterization of Nanoemulsion
- Globule size, polydispersity index and Zeta potential
- Refractive index
- Viscosity
- Robustness to dilution
- Centrifugation test
- Solubility characteristics
- Surface morphology by Transmission Electron Microscopy
- Surface topography by Atomic Force Microscopy
- In vitro release studies
- Ex vivo release studies
- In vitro lipolysis studies (pH stat method)
- Bioaccessibility determination
- Ex vivo everted gut sac method (permeability)

4.8 Pharmacokinetic studies

4.9 Cytotoxicity studies in human cancer cell line

4.10 Stability studies