Chapter-3

Aims & Objectives

3. AIMS AND OBJECTIVES

The aim of the present study is to develop an HPLC for single method development for different classification of NRT and NRTIs of antiretroviral drugs Lamivudine, Zidovudine and Nevirapine

1. **Optimization of chromatographic conditions** will be proposed to be develop and optimize

a. Selection of Wavelength,

b. Selection of Initial Separation Conditions,

c. Nature of the Stationary Phase,

d. Nature of the Mobile Phase (pH, organic modifier, solvent strength, ratio and flow rate),

e. Sensitivity.

2. The developed method will be be validated as per ICH guidelines & USP,

a. Accuracy,

b. Precision,

c. Linearity and Range,

d. Limit of Detection (LOD)/ Limit of Quantitation (LOQ),

e. Selectivity /Specificity,

f. Robustness/ Ruggedness,

g. System Suitability.

3. **Comparison with marketed tablet dosage form with different brands**

4. **To perform stress studies so as to ensure the stability indicating nature of developed method by**

   a. Acid-induced degradation

   b. Base-induced degradation

   c. Hydrogen- peroxide induced degradation

   d. Photochemical degradation

   e. Thermal degradation

5. The developed method in animal plasma to make it suitable *in-vivo* study and *in-vitro* studies with different pH levels

The parameter of *in-vivo* studies is proposed to be calculated are:

a. C_{max} - Maximum Plasma Concentration

b. T_{max} - Time Of Maximum Plasma Concentration

c. AUC (0-t) - Area Under Plasma Concentration time curve

d. AUC(0-∞) - Area Under Plasma Concentration time curve 0 To ∞ hrs

e. t ½ - Elimination Half -Life

f. Vd - Volume of Distribution

g. CL - Clearance.