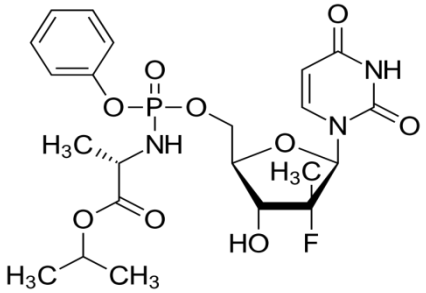
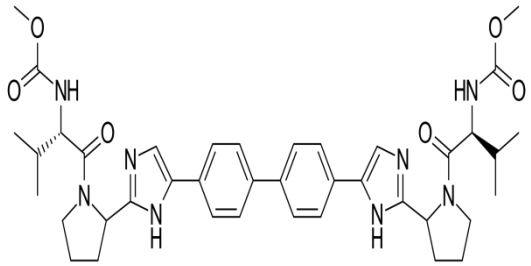
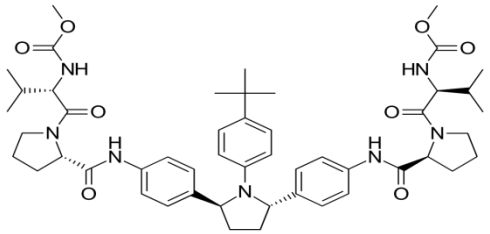
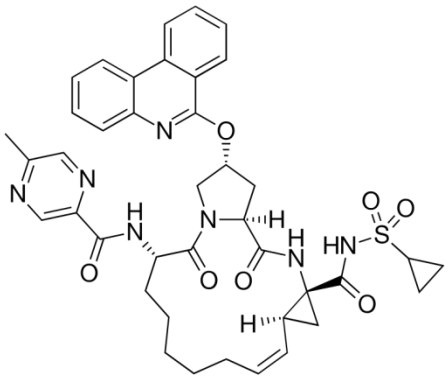
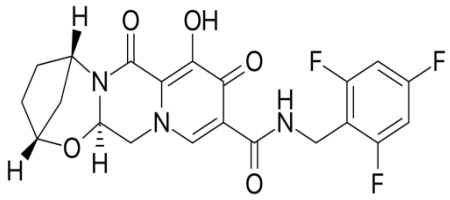
CHAPTER – 2

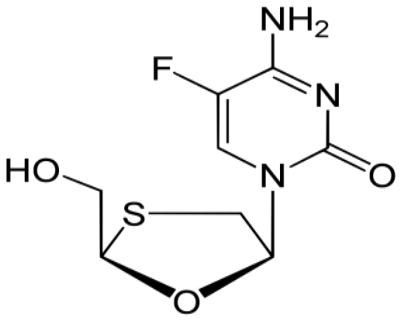
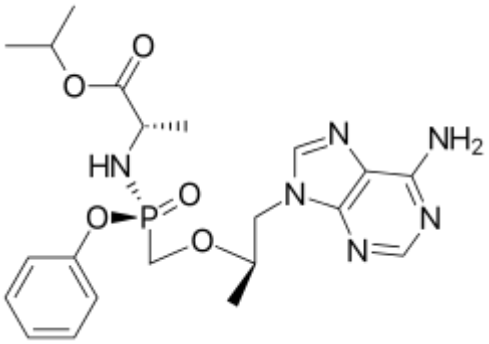
OBJECTIVE AND PLAN OF WORK

2.1 OBJECTIVES OF WORK

- ✓ To carry out an extensive literature survey before selecting a research problem (selection of drugs).
- ✓ To optimize chromatographic parameters, regression, extraction methods for selected drugs.
- ✓ To develop and validate a analytical method for quantitative determination of selected drugs like Sofosbuvir and Daclatasvir, Ombitasvir, Paritaprevir, Ritonavir and Abacavir, Dolutegravir, Lamivudine and Bictegravir, Emtricitabine, Tenofovir alafenamide in API's by using RP-HPLC, UV detection to explore the applicability of HPLC, the developed and validated methods have to be successfully applied to assess the purity of the marketed pharmaceutical formulation pharmaceutical formulations by using RP-HPLC with UV detection.

Table 2.1: List of drugs selected for research work

S. No.	Name of the Drug	Chemical Structure	Category
1.1	Sofosbuvir		Inhibitor of hepatitis C virus
1.2	Daclatasvir		Inhibitor of hepatitis C virus
2.1	Ombitasvir		Inhibitor of hepatitis C virus
2.2	Paritaprevir		Inhibitor of hepatitis C virus
3.1	Bictegravir		Treatment of HIV-1 and HIV-2 infection

3.2	Emtricitabine		Nucleoside reverse transcriptase inhibitor (NRTI) for the treatment of HIV infection
3.3	Tenofovir alafenamide		Hepatitis B virus (HBV) nucleotide reverse transcriptase inhibitor

2.2 PLAN OF WORK

A) To develop analytical method

1) Selection of solvent for solution preparation.

2) Selecting the HPLC separation mode and fixation of parameters like

   a) Selecting/optimizing the mobile phase and column for analyte and Internal analysis.

   b) Selecting appropriate gradient/ isocratic mobile phase medium, flow rate, column temperature and pH.

   c) Selecting the appropriate detector system.

3) Tuning of analyte and internal standard for fixation of mass parameters.

4) Selecting the extraction procedure for recovery of analyte.

B) To validate different parameters

1) System suitability

2) Specificity/selectivity

3) Linearity and range

4) Precision and accuracy

5) Accuracy (Recovery)

6) Ruggedness

7) Robustness

8) LOQ and LOD

C) To estimate the drug content in pharmaceutical formulations by RP-HPLC