CHAPTER 2
LITERATURE REVIEW

2.1 Literature study of Rimantadine.

Rimantadine is represented as RMT in this chapter.

RMT is an antiviral drug used in the treatment of influenza virus. It is a closely related derivative of Adamantane with similar biological properties.

Past work reveals that RMT analysis included its determination in human urine by HPLC online post column derivatization [11]. Amantadine and its relative compound RMT in rat plasma was also reported [12].

RMT was analyzed in rat plasma by liquid chromatography or electrospray mass spectrometry. The results of this study were applied in pharmacokinetic study [13].

RMT hydrochloride determination in RMT 100 Tablets by capillary zone electrophoresis and its validation was also reported [14].

RMT was analyzed in chicken muscle by ultra HPLC and tandem mass spectrometry was also reported[15].There were not many earlier methods reported related to RP-HPLC method development and its validation in Flumadine Tablets. Hence in the present research work Flumadine tablets were selected for study.

2.2 Literature study of Cidofovir

Cidofovir is represented as CDF in this chapter**.**

Earlier research studies related to CDF included CDF quantification in human serum by LC -MS/MS method [16]. HPLC determination of CDF in skin layers and percutaneous penetration sample [17]. Past works included CDF determination in human plasma using HPLC–tandem mass spectrometry [18]. A sensitive and selective RP HPLC method was developed for the determination of three process impurities in CDF drug substance [19]. In the present research work, experiment was conducted to develop a new and simple RP – HPLC method and its validation in Vistide dosage form of CDF.

2.3 Literature study of Pranlukast.

Pranlukast is represented as PLK in this chapter**.**

Thorough literature study revealed that the physiochemical and crystal structure analysis of PLK pseudopolymorphs [20], studies on oral bioavailability and drug delivery system of PLK were reported [21].

Determination of PLK and its metabolites in human plasma by LC/MS/MS was also reported[22]. Not many methods have been reported for RP–HPLC analysis of PLK. Hence a study has been made to develop a novel RP – HPLC method and its validation for estimation of PLK in ONON capsules.

2.4 Literature study for Simultaneous estimation of Sofusbuvir and Velpatasvir tablets by RP-HPLC method.

The following were the previous works related to SOF and VEL.

Table 2.1 Previous works related to SOF and VEL

S. No.	Author/ Ref.No	Column Used	Mobile phase (% v/v)	λ_{max} (nm)	RT (min)	Linearity (µg/mL)	Recovery (%)
1	V.Swetha (SOF,VEL) [23]	C18	Acetonitrile : Water (50:50)	235	2.079 4.045	5-25 20-100	98-100
2	Dr.Gandla Kumaraswamy (SOF,VEL) [24]	C18	Acetonitrile : Water (50:50)	262	4.256.05	25-150 100-600	99.6 99.40
3	D.Vanaja (SOF, VEL) [25]	C18	Methanol: Triethylamine (40:60)	272	2.781 4.048	7.5-37.5 5-25	100.46
4.	U.Jyothi (SOF,VEL) [26]	C18	Trifluoro Acetic acid: Methanol (42:58)	269	3.444.68	80-240 20-60	97-103

SOF: Sofusbuvir VEL: Velpatasvir

In the present research work experiments were conducted to develop a new, economical and faster RP –HPLC method with less retention times than the earlier reported methods.

2.5. Literature study for Simultaneous estimation of Montelukast, Acebrophylline and Desloratadine tablets by RP-HPLC method.

Literature survey revealed that there were few methods reported for simultaneous estimation of double drug combinations of these drugs which are presented below.

Table 2.2 Previous works related to MON, ACE and DES

S. No.	Author/ Ref.No	Column used	Mobile phase (% v/v)	λ_{max} (nm)	RT (min)	Linearity (µg/mL)	Recovery (%)
1	Rima M Banker (MON,DES) [27]	ACE 5 C18	Acetonitrile : Methanol: Water: (15:80:5)	283	2.20 55.70	5-50 5-50	100.12 100.01
2	Bonthu Mohan Gandhi (MON, DES) [28]	Hypersil BDS C18	Orthophosph oric acid :Water (20:80)	280	2.929 4.439	10-30 5-15	99.59 99.60
3	Neha Mistry (MON, DES) [29]	ODS Hypersil C18	Trifluoroacetic acid (0.3%) :Acetonitrile (20:80)	230	6.12 4.19	80-120 40-60	99.55 99.56
4	Kalyankar M Tukaram (MON, DES) [30]	Hypersil C18	Acetonitrile :Phosphate Buffer (65:35)	210	12.76 2.12	10-60 10-60	98-100 100-102

MON: Montelukast DES: Desloratadine.

So far no HPLC method was available in literature for simultaneous estimation of MON, ACE and DES in ACMON –DM tablets by RP-HPLC method. Hence in the present research work ACMON –DM tablets were selected for study.

2.6. Literature study for Simultaneous estimation of Pantoprazole, Chlorzoxazone and Diclofenac capsules by RP-HPLC.

Literature survey revealed that there were no RP-HPLC method reported for the simultaneous estimation of above three drugs in its dosage form. Double drug combination of these drugs reported earlier are listed below.

Table 2.3 Previous works related to PAN. CHL and DIC

S. No.	Author/ Ref.No	Column Used	Mobile phase (% v/v)	λ_{max} (nm)	RT (min)	Linearity Range (µg/mL)	Recovery (%)
1	Madhukar .A (Paracetomol, CHL,DIC) [31]	C18	Phosphate buffer: Acetonitrile : Methanol (25:25:50)	220	2.8 4.2 6.4	50-150 50-150 5-15	100.29 99.88 99.27
2	Chakraborty Mithun (Paracetomol, CHL, DIC) [32]	C 18	Phosphate buffer: Acetonitrile (45:55)	220	1.8 2.9 4.5	30-90 20-80 6-14	99.14 98.88 99.31
3	Jigar Patel (Tramadol,CHL, DIC) [33]	C 18	Acetonitrile : Phosphate buffer (50:50)	220	2.11 3.82 12.39	15-75 100-500 20-100	99.4 99.30 99.6

PAN: Pantoprazole CHL: Chlorzoxazone DIC : Diclofenac.

Hence ALLDEX –DT capsule which is the combination capsule [34-36] form of PAN, CHL and DIC was selected for RP-HPLC method development and its validation [37- 40].

From the extensive literature survey the authors were interested to carry out the analytical method development and validation of the selected dosage forms by RP-HPLC technique.

Plan of the work includes

1. Selection of new marketed dosage form and its literature Review.
2. Analytical Method development by RP-HPLC technique.
3. Method validation as per ICH Q2 (R1) guidelines.
4. Future scope of the present investigation inclusion.