CHAPTER 2

LITERATURE SURVEY

This chapter includes a literature review of the work done for the analysis of impurities in drugs by various analytical methods.

2.1 Literature survey on erlotinib and its impurities

The literature review revealed that some spectrophotometric methods, HPLC methods and LC/MS/MS were developed for the determination of erlotinib in different combinations of formulations and biological matrices as per the details given below. The literature survey revealed that no stability indicating impurity methods has been developed for the determination of impurities in erlotinib tablets dosage forms.

Table 2.1. Literature review on various methods for erlotinib and its impurities

S.No	Technique	Analytes	Author/s	Ref
1	Spectrofluorimetric method	Pure and pharmaceutical formulations	Rajesh et al.	48
2	Spectrophotometric method	Pure and pharmaceutical dosage forms	Padmalatha et al.	49
3	Spectrofluorimetric method	Erlotinib in spiked human plasma	Mandal et al.	50
4	RP-HPLC Assay method	Bulk drug and its pharmaceutical formulations	Chakravarthy et al.	51
5	RP-HPLC Assay method	Pharmaceutical formulation	Latha et al.	52
6	RP-HPLC Assay method	Bulk and tablet dosage form	Ravi kumar et al.	53
7	Stability indication assay method	Active pharmaceutical ingredient	Pujeri et al.	54
8	RP-HPLC method	Tablet dosage forms	Geetha et al.	55
9	RP-HPLC method	Process-related impurities	Karunakara et al.	56
10	HPLC-UV method	Gefitinib and erlotinib in human plasma	Faivre et al.	57
11	HPLC	Erlotinib protein binding studies	Soheila et al.	58
12	HPLC method	Erlotinib in Rat Plasma	Hou et al.	59
13	HPLC method	Erlotinib a tablet dosage form	Mohammed Ishaq et al.	60

14	HPLC-UV method	Vemurafenib and erlotinib in plasma from cancer patients	Zheng et al.	61
15	UPLC method	Erlotinib in pharmaceutical formulations	Naveen Kumar Reddy et al.	62
16	LC-MS/MS method	Erlotinib in spraguedawley rat serum, pharmacokinetic study	Raju et al.	63
17	Liquid chromatography tandem mass spectrometry	Celecoxib, erlotinib, and its metabolite dimethyl-erlotinib in rat plasma with positive/negative ion-switching	Satheeshmanikandan et al.	64
18	Liquid chromatography - Tandem mass spectrometry	Erlotinib (OSI-774) and OSI-420in human plasma	Andrea et al.	65
19	Liquid chromatography tandem mass spectrometry	Erlotinib, gefitinib, and imatinib in human plasma	Chahbouni et al.	66
20	LC-MS/MS method	Erlotinib in rat plasma sample	Zhang et al.	67
21	LC and LC-MS/MS method	Separation, identification, and characterization of degradation products	Mahajan et al.	68

2.2 Literature survey on raloxifene and its impurities

The literature survey revealed that many researchers focused their research on the quantification of raloxifene in different combinations of formulations and biological matrices using spectrophotometry, HPLC and LC/MS techniques and no stability indicating impurity method has been reported for the determination of impurities in raloxifene tablet dosage forms.

Table 2.2. Literature review on various methods for raloxifene and its impurities

S.No	Technique	Analytes	Author/s	Ref
1	Spectrofluorimetric method	Spectrophotometric determination of raloxifene hydrochloride in raloxifene hydrochloride in tablets	Pavithra`et al.	70
2	Spectrophotometric method	Determination of raloxifene hydrochloride by oxidative coupling reaction in pharmaceutical formulations	Kalyanaramu et al.	71
3	Spectrofluorimetric method	Validated spectrophotometric methods for the determination of raloxifene hydrochloride in pharmaceuticals	Basavaiah et al.	72
4	RP-HPLC Assay and purity method	Gradient RP-HPLC method for the determination of purity and assay of raloxifene hydrochloride in bulk drug	Sathyaraj et al.	73
5	RP-HPLC Assay method	Development of alternative methods for the determination of raloxifene hydrochloride in tablet dosage form	Fernanda et al.	74
6	RP-HPLC Assay method	Validated stability indicating liquid chromatographic method for the determination of raloxifene (anti-osteoporotic agent) in tablets,	Phaniet al.	75
7	RP-HPLC Assay method	Validated stability indicating liquid chromatographic method for the determination of raloxifene (anti-osteoporotic agent) in tablets	Sowjanya et al.	76

8	RP-HPLC Assay method	Validated RP-HPLC method for the estimation ofraloxifene in pure and tablet dosage form	Suneetha et al.	77
9	RP-HPLC Assay method	Development and validation of RP-HPLC method for determination of raloxifene Hydrochloride from pharmaceutical preparation	Vijay Kumar et al.	78
10	HPLC impurity method	Systematical approach in evaluation of LC method for determination of raloxifene hydrochloride and its impurities employing experimental design	Stojanovic et al.	79
11	UPLC method	Development and validation of stability indicating method for the quantitative determination of Raloxifene hydrochloride and its related impurities using UPLC.	Srinivas et al.	80
12	UPLC method	Raloxifene hydrochloride in pharmaceutical dosage form	Deepa et al.	81
13	HPLC- method	Identification and characterization of potential impurities in raloxifene hydrochloride	Buchireddy et al.	82
14	LC/ESI-MS and NMR methods	Structural elucidation of potential impurities of raloxifene hydrochloride by LC/ESI-MS and NMR	Jagadeesh et al.	83
15	LC-MS/MS method	Determination of raloxifene and its glucuronides in human urine by liquid chromatography–tandem mass spectrometry assay	Trdan et al.	84

2.3 Literature survey on fampridine and its impurities

The literature review revealed that some pharmacology studies, spectrophotometric methods, HPLC methods and LC/MS/MS were developed for the determination of fampridine in different combinations of formulations and biological matrices as per the details given below. No stability indicating impurity method was found in the literature for the determination of impurities in fampridine tablets dosage forms.

Table 2.3. Literature review on various methods for fampridine and its impurities

S.No	Technique	Analytes	Author/s	Ref
3	pharmacology, pharmacokinetics, clinical trials	Pharmacology, pharmacokinetics, clinical trials, and adverse effects of sustained-release (SR) fampridine in patients with multiple sclerosis	Korenke et al.	87
4	Spectrophotometric method	Development and validation of spectrophotometric method for the estimation of dalfampridine in tablets	Madhumathi et al.	88
5	Spectrofluorimetric method	Validated spectrophotometric methods for the determination of dalfampridine in its synthetic mixture and spiked human plasma	Fatatry et al.	89
6	RP-HPLC method	RP-HPLC stability indicating method for estimation of dalfampridine in its bulk and formulation	Dharani et al.	90
7	UV–HPLC method	Determination of potential impurities in fampridine active pharmaceutical ingredient by stability indicating method	Thomas et al.	91
8	HPLC method	HPLC method was developed for identification and quantification of five potential genotoxic impurities in dalfampridine drug substance	Mohitet al.	92

9	RP-HPLC method	RP-HPLC) method for the quantitative estimation of impurities which are present in dosage form of tiapride Hydrochloride	Jwal et al.	93
10	RP-HPLC method	Simultaneous estimation of organic impurities, enantiomer and assay of dexlansoprazole	Balamurugan et al.	94
11	LC-MS method	Simultaneous determination of fampridine, paroxetine, and quinidine in rat plasma	Suneetha et al.	95
12	LC–MS/MS method	Simultaneous determination of fingolimod, fampridine and prednisone in rat plasma	Suneetha et al.	96
14	RP-HPLC	4-aminopyridine in serum by solid-phase extraction	Van der Horst et al.	97

2.4 Literature survey on lamivudine and tenofovir disoproxil fumarate and their impurities

The literature review revealed that most of the studies were aimed to develop HPLC and LC/MS/MS methods for the quantification of lamivudine or/and tenofovir disoproxil fumarate in the dosage forms and biological matrices through spectrophotometric, HPLC and LC/MS/MS techniques. The literature survey revealed that no stability indicating impurity methods has been developed for the impurities quantification in lamivudine and tenofovir disoproxil fumarate tablets dosage forms.

Table 2.4. Literature review on various methods for lamivudine and tenofovir disoproxil fumarate and their impurities

S.No	Technique	Analytes	Author/s	Ref
1	Spectrophotometric method	Estimation of tenofovir disoproxil fumarate and lamivudine in three component tablet formulation containing efavirenz	Sharma et al.	99
2	Spectrophotometric method	Development and validation of emtricitabine and tenofovir disoproxil fumarate in pure and dosage forms	Anandakumar et al.	100
3	Spectrophotometric method	Degradation study of tenofovir disoproxil fumarate	Sutar et al.	101
4	Spectrophotometric method	Estimation of emtricitabine and tenofovir disoproxil fumarate in bulk and tablet dosage form	Anindita et al.	102
5	HPTLC- method	Analysis of lamivudine, tenofovir disoproxil fumarate, and efavirenz (LTE) in tablets	Nyamweru et al.	103
6	RP-HPLC Method	Stability-Indicating method for the estimation of efavirenz, tenofovir and emtricitabine Pharmaceutical Formulations	Varma et al.	104
7	HPLC Method	Simultaneous estimation of lamivudine, tenofovir and nevirapine in extended release tablets	Prasad et al.	105

8	RP-HPLC method	Development and validation of lamivudine and tenofovir in tablet dosage form	Goud et al.	106
9	HPLC method	Simultaneous determination of tenofovir disoproxil fumarate and lamivudine in bulk and dosage forms.	Sonawane et al.	107
10	RP-HPLC method	Simultaneous estimation of lamivudine and tenofovir disoproxil fumarate in pure and tablets.	Anandakumar et al.	108
11	RP-HPLC method	Estimation of tenofovir disoproxil fumarate in bulk and pharmaceutical formulation	Sharma et al.	109
12	RP-HPLC method	Estimation of tenofovir disoproxil fumarate, lamivudine and efavirenz in combined tablet dosage form	Dhara et al.	110
13	Stability-indicating LC method	Determination of tenofovir disoproxil fumarate in pharmaceutical formulation	Shweta et al.	111
14	RP-HPLC method	Simultaneous estimation of lamivudine, tenofovir and efavirenz in combined tablet	Srinath et al.	112
15	RP-HPLC method	Simultaneous estimation of Lamivudine, Tenofovir Disoproxil Fumarate and Efavirenz in tablet formulation	Anandakumar et al.	113
16	LC Method	Determination of related Substances and assay of tenofovir disoproxil fumarate	Dunge et al.	114
17	Stability-indicating HPLC method	Determination of lamivudine, tenofovir, and dolutegravir in bulk and their tablet dosage form	Rao et al.	115
18	UPLC method	Estimation of lamivudine, tenofovir and efavirenz	Madeesh et al.	116
19	RP-UPLC method	Estimation of assay of emtricitabine and tenofovir disoproxil fumarate in bulk and dosage forms	Purnima et al.	117

20	mass spectrometry	Characterization of interaction products of emtricitabine and tenofovir disoproxil fumarate	Kurmi et al.	118
21	LC-MS/MS method	Quantification of tenofovir and lamivudine in human plasma and its application to a pharmacokinetic study	Krishna et al.	119
22	LC-MS method	Quantitation of lamivudine, zidovudine and nevirapine in human plasma	Krishna et al.	120

2.5 Literature survey on emtricitabine, tenofovir disoproxil fumarate, efavirenz and their impurities.

The literature review revealed that some spectrophotometric methods, HPTLC method, HPLC methods and LC-MS/MS were developed for the determination of efavirenz, tenofovir disoproxil fumarate and emtricitabine in different combinations of dosage forms and biological matrices as per the details given below. The literature survey revealed that no stability indicating impurity methods has been developed to quantify the impurities in the combined dosage forms of efavirenz, tenofovir disoproxil fumarate and emtricitabine drug substances.

Table 2.5: Literature survey on emtricitabine, tenofovir disoproxil fumarate, efavirenz and their impurities

S.No	Technique	Analytes	Author/s	Ref
1	UV Spectrophotometric method	Estimation of lamivudine and efavirenz in the pharmaceutical dosage form	Kumar et al.	127
2	Spectrophotometric method	Determination of emtricitabine in pharmaceutical dosage forms	Narendra et al.	128
3	Spectrophotometric method	Simultaneous estimation of tenofovir disproxil fumarate and emtricitabine in tablet dosage form	Sasikala et al.	129
4	Spectrophotometric Method	Determination of tenofovir and emtricitabine	Kulsum et al.	130
5	Spectrophotometric method	Emtricitabine and tenofovir disoproxil fumarate in bulk and tablet dosage	Behera et al.	131
6	UV-spectrophotometry	Estimation of tenofovir disproxil fumarate, emtricitabine and rilpivirine hydrochloride	Madhuri et al.	132
7	RP-HPLC	Estimation of emtricitabine and tenofovir disoproxil fumarate in pure and tablet dosage form	Deepthi et al.	133
8	RP-HPLC method	Simultaneous estimation of	Koteswara	134

		emitricitabne, tenofovir and efavirenz in pharmaceutical dosage form	Rao et al.	
9	RP-HPLC method	Estimation of emtricitabine and tenofovir disoproxil fumarate in a tablet dosage form	Rajesh et al.	135
10	RP-HPLC method	Estimation of emtricitabine, tenofovir and efavirenz in tablet dosage forms.	Palavan et al.	136
11	RP-HPLC Method	Simultaneous estimation of impurities from emtricitabine and tenofovir disoproxil fumarate tablet	Mali et al.	137
12	UPLC method	Estimation of emtricitabine, tenofovir and efavirenz in pharmaceutical preparation	Tiwariet al.	138
13	UPLC method	Analysis of emtricitabine, tenofovir, cobicistat and elvitegravir from their degradation products	Revathi et al.	139
14	UPLC method	Estimation of emtricitabine impurities in formulated drug product	Sreekanthet al.	140
15	RP-UPLC method	Estimation of emtricitabine , rilpivirine, tenofovir disoproxil fumarate and its pharmaceutical dosage forms	Kavitha et al.	141