

Analytical Method Development And validation for Simultaneous Estimation of Etofylline, Theophylline and Montelukast Sodium in Tablet Dosage Form

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ABSTRACT

A simple, rapid, precise, economical & accurate method development by RP-HPLC method for simultaneous estimation of etofylline, theophylline and montelukast sodium in tablet dosage form. High performance in liquid chromatographic. The separation was achieved by C18 (250 x 4.6mm, 5µ) column and Mobile phase A: Buffer Mobile phase B: ACN (gradient) Etofylline, Theophylline and Montelukast as mobile phase, flow rate of 1.0 ml / minute. Detection is carried out 286 nano meter. It can be applied in routine analysis and pharmaceutical dosage forms . It can be applied in commercial pharmaceutical dosage forms.

KEYWORDS: Etofylline, Theophylline , Montelukast , RP-HPLC method and validation

- Non allergic asthma
- Occupational asthma
- Exercise induced broncho-constriction
- Nocturnal asthma
- Cough – variant asthma

Causes:

- Genetics
- History of viral infections
- Hygiene hypothesis
- Early allergen exposures

Signs & Symptoms:

- Tightness in chest
- Shortness in breath
- Coughing especially at night
- Wheezing or whistling sound made when breathing.

Diagnosis:

There's no single test or exam to determine asthma but following can help to diagnose asthma

- Health history
- Physical examination
- Breathing test

I. INTRODUCTION

Asthma is an inflammatory disease of the airway to the lungs that makes breathing difficult. According to centre for disease control & prevention (CDC) approximately 27 million Americans have asthma.(1 child out of 12 child)

Types :

- Allergic asthma

II. MATERIAL AND METHODS

Trial	Mobile Phase	Retention time (minute)	Remark
1.	Buffer:Methanol(50:50) Etofylline	3.95 minutes.	Peak Observed
2.	Buffer:Methanol (50:50)- Theophylline	4.209 minutes	Peak Observed
3.	Buffer:Methanol (50:50) Montelukast	-----	No peak observed
4.	Buffer:Methanol (50:50) – Etofylline theophylline	3.952- Theophylline	Merged Peak Observed for

	and montelukast	4.202 - Etofylline	Etofylline and theophylline but no peak observed for montelukast
5.	Buffer:Methanol (20:80)- Montelukast	-----	No peak observed
6.	Buffer:ACN(22:78) Montelukast	8.708	Peak Observed
7.	Buffer:ACN (80:20)-Etofylline	2.51	Peak Observed earlier
8.	Buffer: ACN (80:20)- Theophylline	Etofylline 2.49	Peak Observed earlier
9.	Mobile phase A: Buffer Mobile phase B: ACN and Etofylline,Theophylline and Montelukast	3.945- Theophylline 4.292- Etofylline 10.611- Montelukast	Merged Peak Observed
10.	Mobile phase A: Buffer Mobile phase B: ACN and Etofylline,Theophylline and Montelukast	4.963-Theophylline 5.962- Etofylline 12.749 - Montelukast	Peak Observed

III. III EXPERIMENTAL WORK:

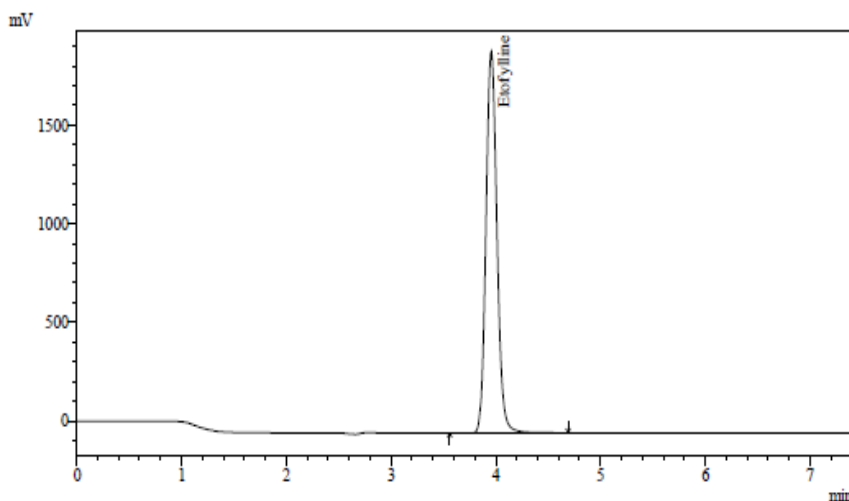


Figure 1: HPLC Chromatogram of Etofylline 231 ppm in Buffer:Methanol (50:50%v/v)

Peak	Ret. Time	Name	Area	Area%	Resolution	T.Factor	T. Plate
1	3.952	Etofylline	14261873	100.00	0.000	1.18	6160
Total	----	-----	14261873	100.00	----	----	----

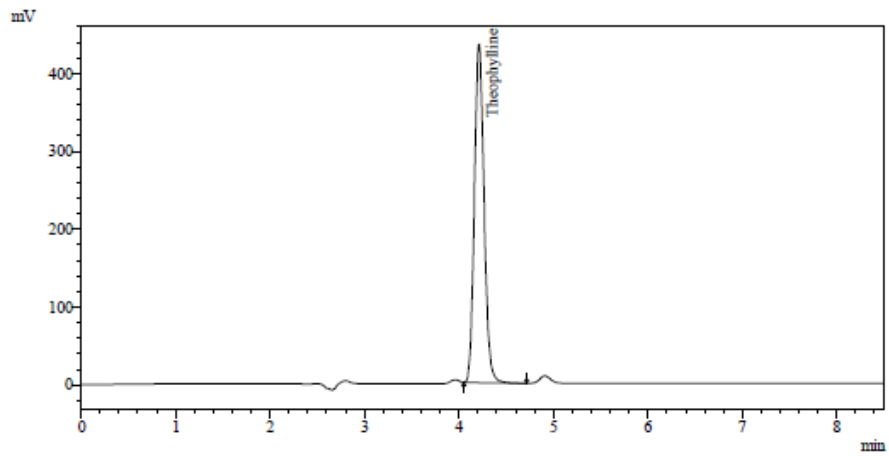


Figure 2: HPLC Chromatogram of Theophylline 69 ppm in Buffer:Methanol (50:50% v/v)

Peak	Ret. Time	Name	Area	Area%	Resolution	T.Factor	T. Plate
1	4.209	Theophylline	3101503	100.00	0.000	1.18	7286
Total	----	-----	3101503	100.00	----	----	----

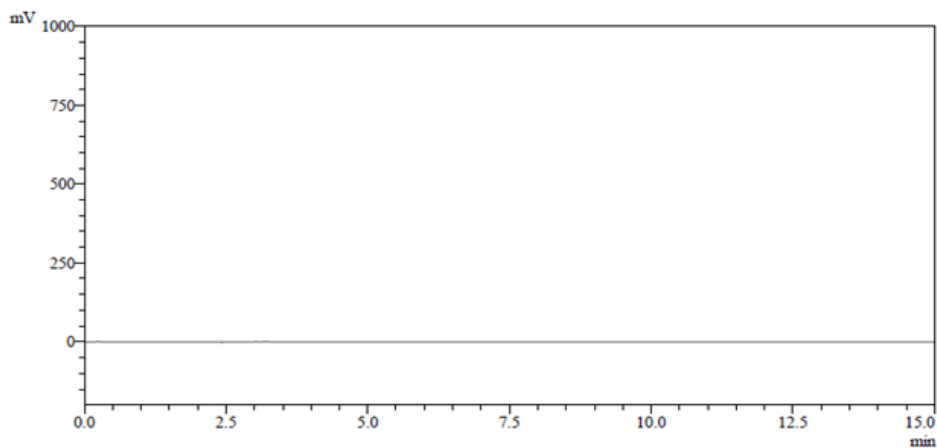


Figure 3 : HPLC Chromatogram of Montelukast 10 ppm in Buffer:Methanol (50:50% v/v)

Peak	Ret. Time	Name	Area	Area%	Resolution	T.Factor	T. Plate
No peak observed							

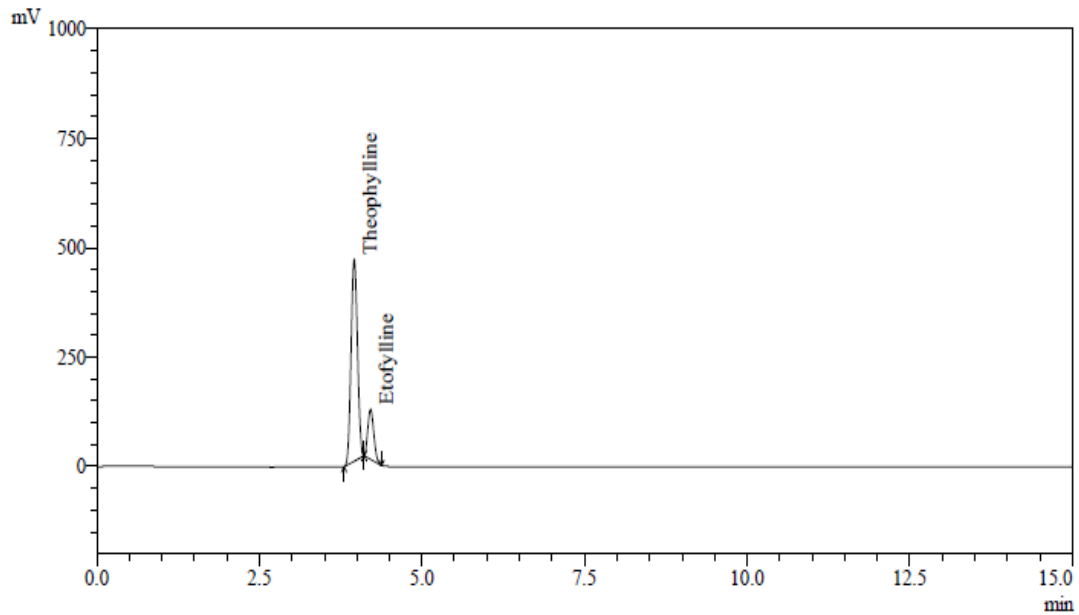


Figure 4: HPLC Chromatogram of Etofylline 231 ppm + Theophylline 69 ppm + Montelukast 10 ppm in Buffer:Methanol (50:50%v/v)

Peak	Ret. Time	Name	Area	Area%	Resolution	T.Factor	T. Plate
1	3.952	Theophylline	13119838	81.48	0.000	1.10	6513
2	4.202	Ethofylline	2982294	18.52	1.335	1.22	8807
Total	----	---	16102132	100.00	--	--	---

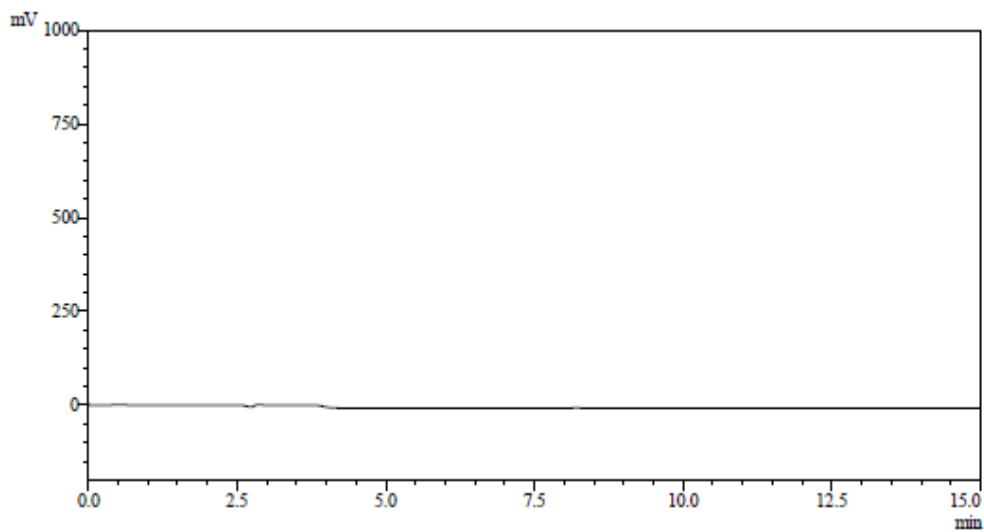


Figure 5: HPLC Chromatogram of Montelukast 10 ppm in Buffer:Methanol (20:80%v/v)

Peak	Ret. Time	Name	Area	Area%	Resolution	T.Factor	T. Plate
No peak observed							

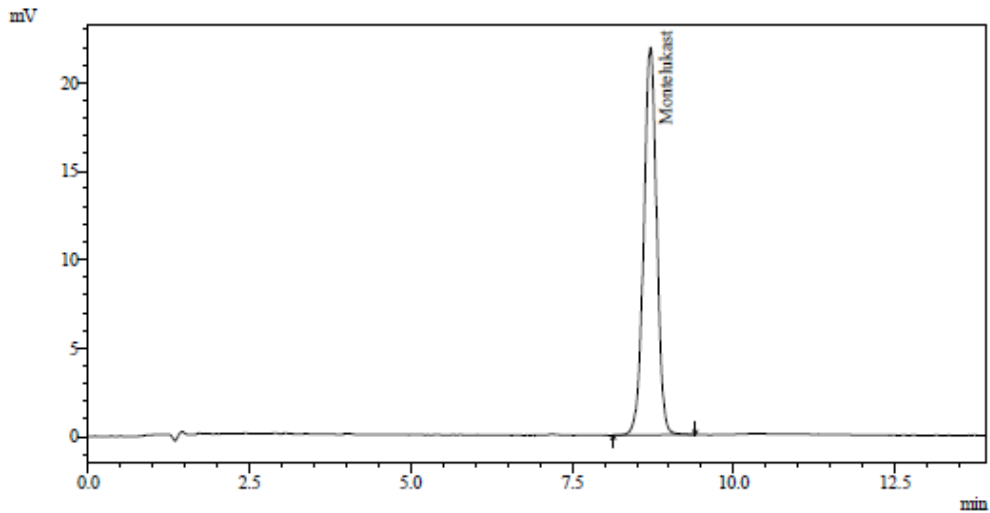


Figure 6: HPLC Chromatogram of Montelukast 10 ppm in Buffer:ACN (22:78%v/v)

Peak	Ret. Time	Name	Area	Area%	Resolution	T.Factor	T. Plate
1	8.708	Montelukast	295160	100.00	0.000	0.99	8827
Total	----	---	295160	100.00	--	--	---

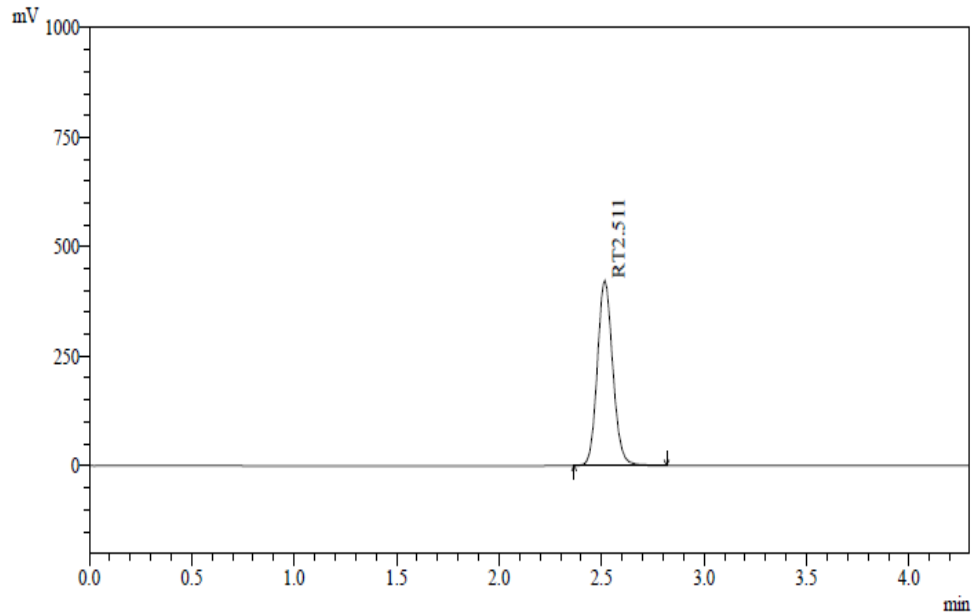


Figure 7 : HPLC Chromatogram of Etofylline 231 ppm in Buffer:ACN (20:80%v/v)

Peak	Ret. Time	Name	Area	Area%	Resolution	T.Factor	T. Plate
1	2.511	Etofylline	2208117	100.00	0.000	1.18	4463
Total	----	---	2208117	100.00	--	--	---

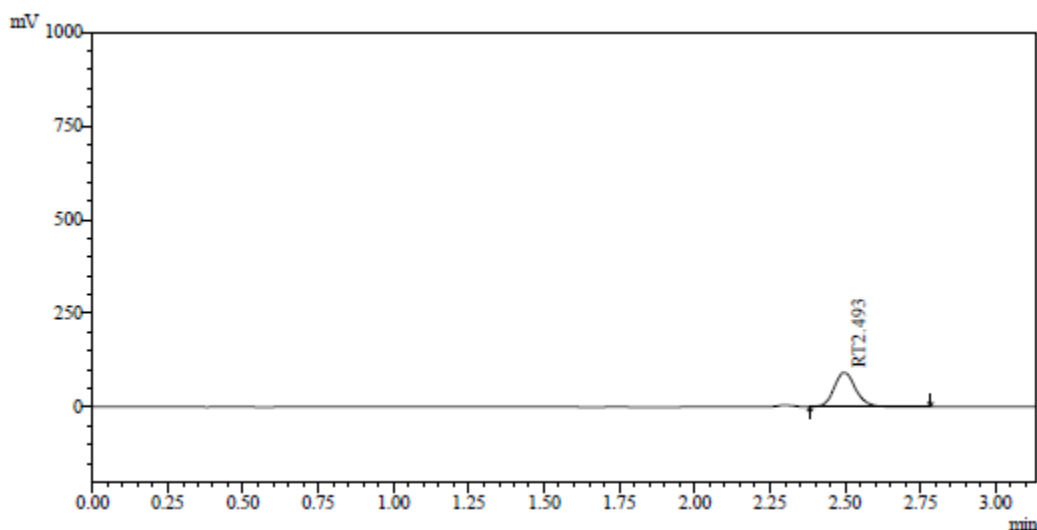


Figure 8 : HPLC Chromatogram of Theophylline 69 ppm in Buffer:ACN (20:80%v/v)

Peak	Ret. Time	Name	Area	Area%	Resolution	T.Factor	T. Plate
1	2.49	Theophylline	454258	100.00	0.000	1.23	4788
Total	----	---	454258	100.00	--	--	---

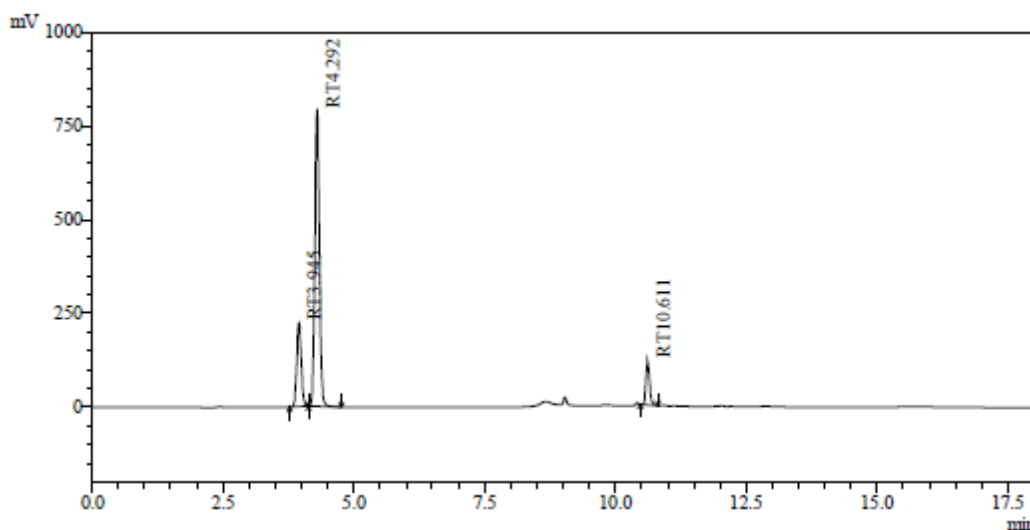


Figure 9 : HPLC Chromatogram of Etophylline 231 ppm + Theophylline 69 ppm + Montelukast 10 ppm
 Mobile phase A: Buffer Mobile phase B: ACN

Peak	Ret. Time	Name	Area	Area%	Resolution	T.Factor	T. Plate
1	3.945	Theophylline	1353665	20.05	0.000	1.14	8367
2	4.292	Etophylline	4824823	71.47	2.014	1.14	9970
3	10.611	Montelukast	572423	8.48	40.640	1.25	93239
Total	----	----	6750912	100.00	---	---	----

Time (Minutes)	MPA	MPB
0	88	12
5	75	25
8	10	90
13	10	90
15	88	12
18	88	12

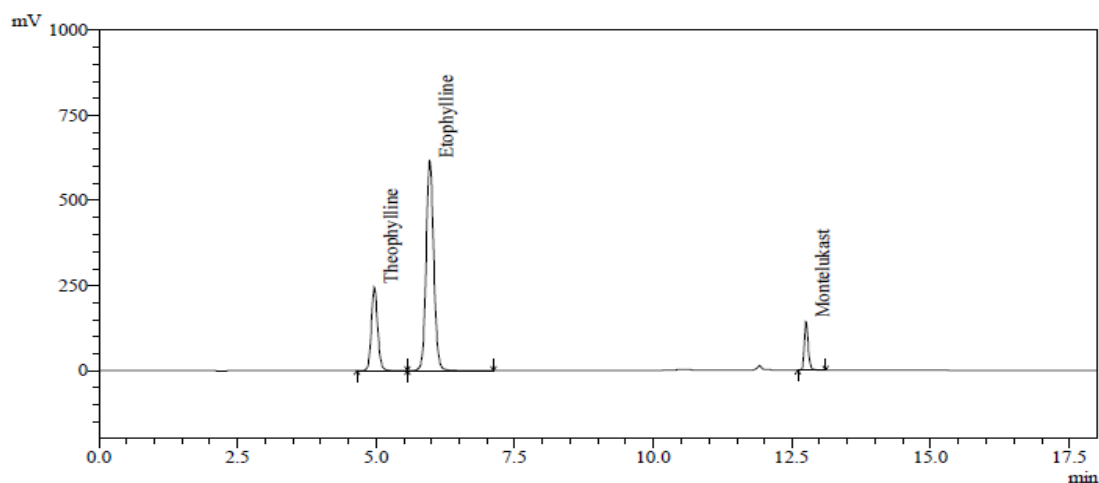


Figure 10 : HPLC Chromatogram of Etofylline 231 ppm + Theophylline 69 ppm + Montelukast 10 ppm
Mobile phase A: Buffer Mobile phase B: ACN

Peak	Ret. Time	Name	Area	Area%	Resolution	T.Factor	T. Plate
1	4.963	Theophylline	1956361	22.78	Resolution	1.15	8299
2	5.962	Etophylline	5945384	69.23	0.000	1.13	8504
3	12.749	Montelukast	686268	7.99	4.191	1.33	133131
Total	----	----	8588014	100.00	---	---	----

Time (Minutes)	MPA	MPB
0	90	10
6	90	10
10	15	85
13	15	85
14	90	10
18	90	10

IV. CONCLUSION:

- Literature review reveals that numbers of individual analytical methods available for estimation of etofylline, theophylline and Montelukast sodium.
- But no method has been reported for analytical method development and validation for simultaneous estimation of etofylline, theophylline and Montelukast sodium in tablet dosage form .
- So Aim of present work is to develop simple, accurate, precise, rapid, specific, sensitive method development and validation for simultaneous estimation of etofylline,

theophylline and Montelukast sodium in tablet dosage form

- To perform analytical method development and validation method.
- Applying the newly developed, validated analytical method for the estimation of etofylline, theophylline and Montelukast sodium in tablet dosage form .
- Analytical method development and validation for simultaneous estimation. of etofylline, theophylline and Montelukast sodium in tablet dosage form .

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