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RESEARCH ARTICLE

Analytical Method Development and Validation for the Simultaneous Estimation of Ephedrine and Theophylline by RP- HPLC Method

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ABSTRACT

Another technique was set up for concurrent assessment of Theophylline and Etofylline by RP- HPLC strategy. The chromatographic conditions were effectively created for the partition of Theophylline and Etofylline by utilizing Xterra C18 5µm (4.6*250mm) section, stream rate was 1ml/min, portable stage proportion was Phosphate support (0.05M) pH 4.6: ACN (55:45%v/v) (pH was changed with orthophosphoric corrosive), location frequency was 255nm. The % virtue of Theophylline and Etofylline was discovered to be 100.7% and 101.4% individually. The framework reasonableness boundaries for Theophylline and Etofylline, for example, hypothetical plates and following element were discovered to be 1.3, 5117.5 and 1.4, 3877.3 the goal was discovered to be 8.0. The diagnostic strategy was approved by ICH rules (ICH, Q2 (R1)). The linearity concentrate for Theophylline and Etofylline was found in focus scope of 1µg-5µg and 100µg-500µg and relationship coefficient (r²) was discovered to be 0.999 and 0.999, % mean recuperation was discovered to be 100% and 100.5%, %RSD for repeatability was 0.2 and 0.4, % RSD for middle accuracy was 0.5 and 0.1 individually. The exactness study was exact, vigorous, and repeatable. LOD esteem was 2.95 and 3.04, and LOQ esteem was 9.87 and 10 separately.

Keywords: Xterra C18, Theophylline and Etofylline, RP-HPLC

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1. Introduction

ETO is practically white translucent powder and is primarily utilized as bronchodilator. The compound name is 7-(2-hydroxyethyl)- 1,3-dimethyl-3, 7dihydro-1H-purine-2, 6-dione1. THEO demonstrated for the persistent obstructive

maladies of the aviation routes, ongoing obstructive pneumonic illnesses (COPD) bronchial asthma, baby apnea2. Artificially THEO is 1, 3- dimethyl-7H-purine-2, 6- Dione. Numerous methods3-6 were depicted in the writing

for the assurance of ETO independently and in blend with different medications.

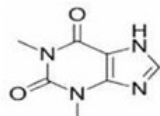


Fig.1 Theophylline

IUPAC Name: 1,3-dimethyl-2,3,6,7-tetrahydro-1H-purine-2,6-dione

Chemical formula: C₇H₈N₄O₂

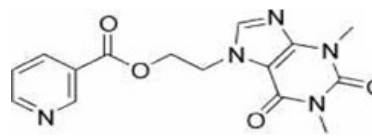


Fig.2 Etofylline

IUPAC Name: 7-(2-hydroxyethyl)-1,3-dimethylpurine-2,6-dione

Chemical formula: C₉H₁₂N₄O₃

2. Experimental

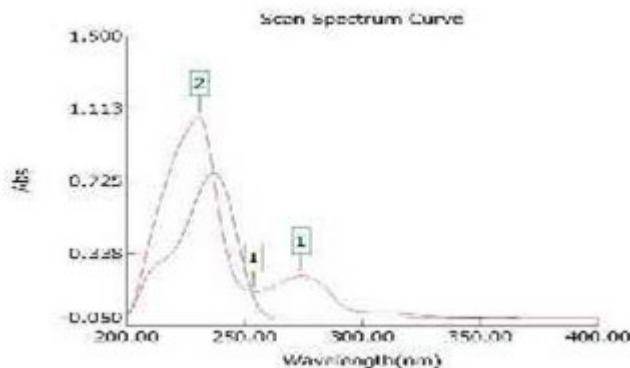


Fig.3 Overlay Theophylline and Etofylline

Table 1: Trial-1

Column	Agilent C18 (4.6*150mm) 5μm
Mobile phase ratio	Water: Methanol (40:60%v/v)
Detection wavelength	255nm
Flow rate	1ml/min
Injection volume	10μl
Column temperature	Ambient
Auto sampler temperature	Ambient

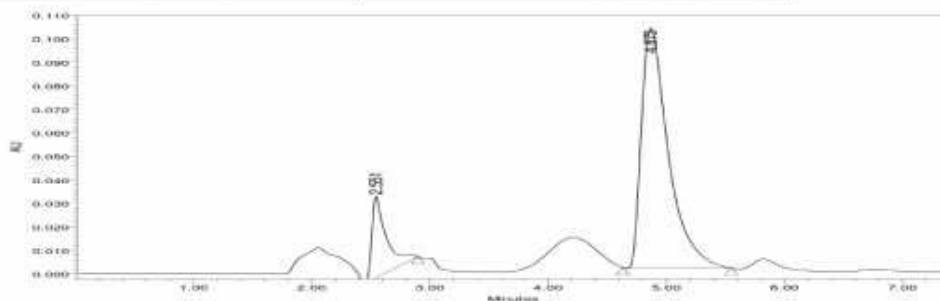


Table 2: Trial-2

S.No	Peak name	R _t	Area	Height	USP Plate	USP Tailin	USP Resolutio
1	Theophylline	2.551	8671924	460798	745	2.19	
2	Etofylline	4.879	2283694	179357	1911	2.79	1.45

Table 3

Column	Thermosil C18 (4.6*150mm)
	5µm
Mobile phase ratio	Water: Methanol (40:60%v/v)
Detection wavelength	255nm
Flow rate	1ml/min
Injection volume	10µl
Column temperature	40 ^o
Auto sampler temperature	Ambient

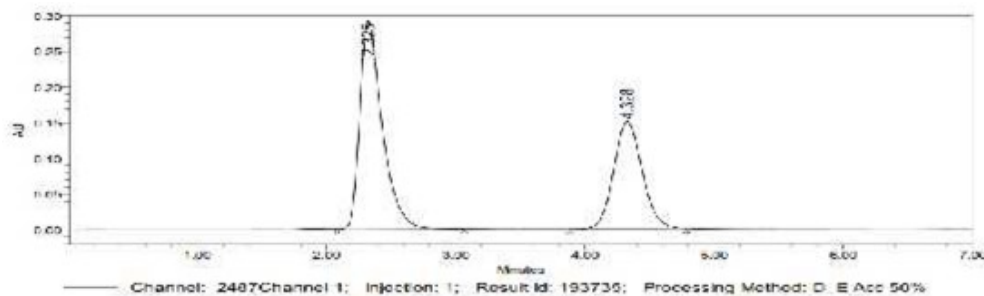


Fig.4 Accuracy 50%inj-1

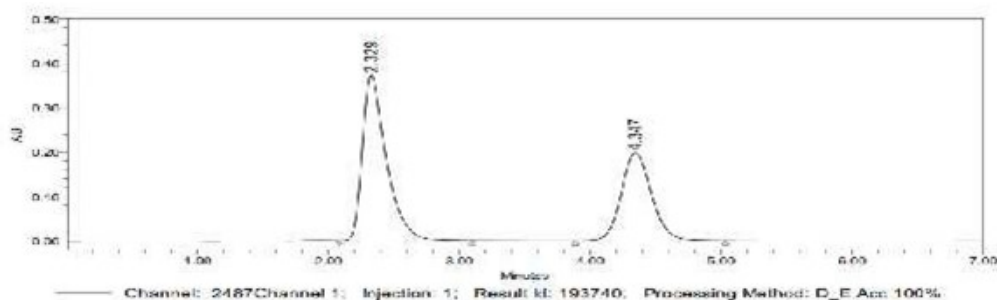


Fig.5 Accuracy 100%inj-1

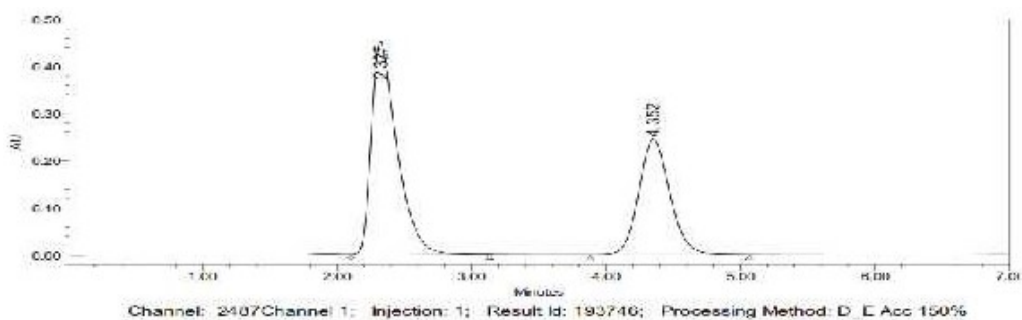


Fig.6 Accuracy 150%inj-1

Table 4 Etofylline

%Concentration (at specification Level)	Area	Amount added(mg)	Amount found(mg)	% Recovery	Mean Recovery
50%	2332744	5	5.10	101.8%	100.5%
100%	3132697	10	9.99	99.9%	
150%	3918997	15	14.9	99.1%	

Table 5: Theophylline

%Concentration(at specification level)	Area	Amount Added(mg)	Amount Found(mg)	% Recovery	Mean Recovery
50%	353867	5	5.0	101.3%	100.0%
100%	4735088	10	9.94	99.4%	
150%	5911798	15	14.8	99.2%	

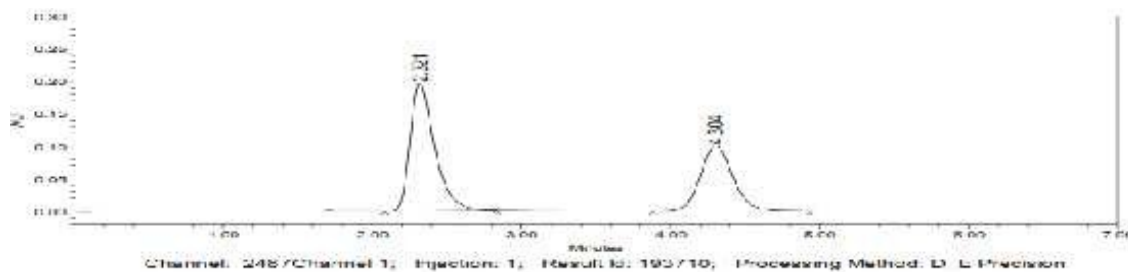
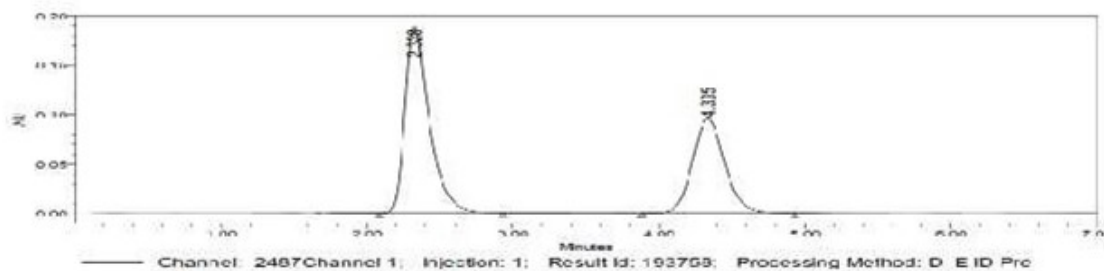


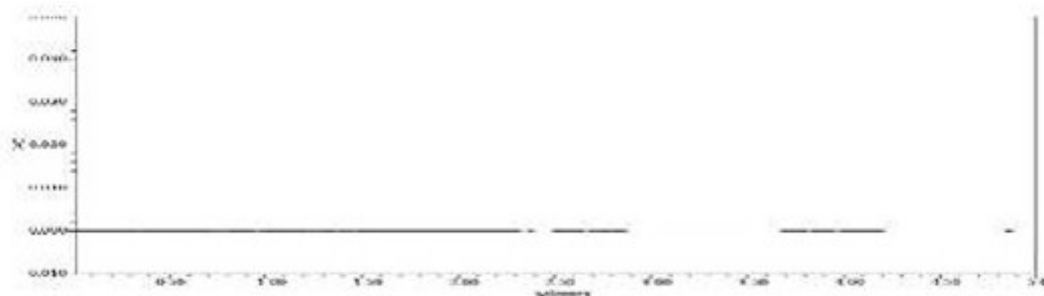
Fig.7 Repeatability

Table 6: Theophylline & Etofylline.

Injection	Area
Injection-1	2235319
Injection-2	2240678
Injection-3	2249490
Injection-4	2245822
Injection-5	2251694
Average	2244601
Standard Deviation	6656.8
%RSD	0.32



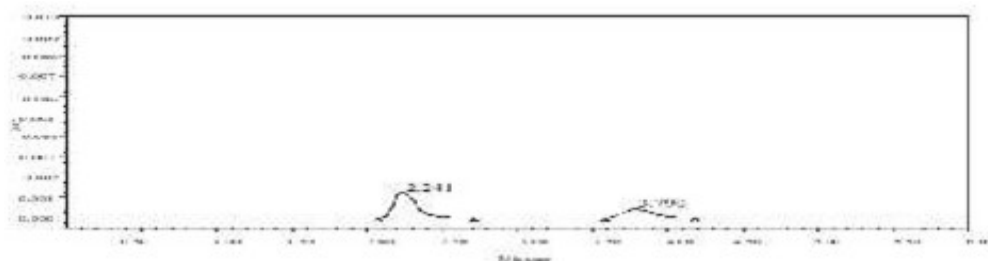
Intermediate precision/Ruggedness



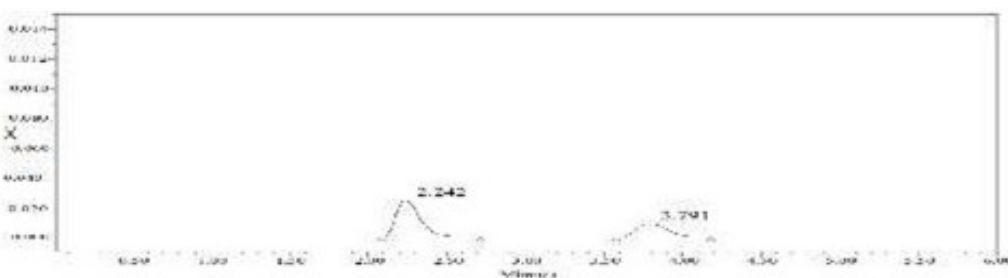
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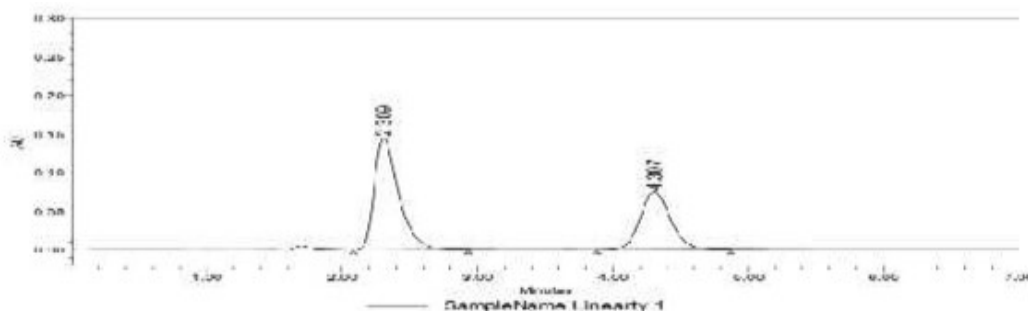
Standard Injection



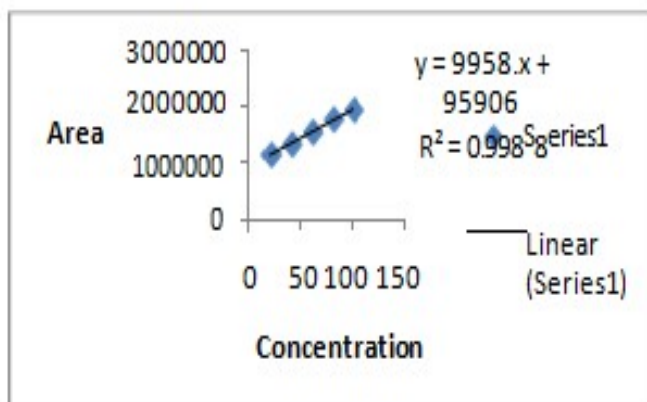
LOD



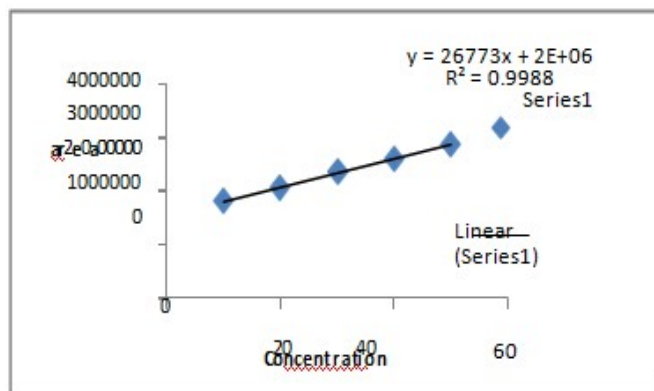
LOQ



Linearity



Etofylline



Theophylline

3. Conclusion

A straightforward, explicit, direct, exact and precise RP-HPLC technique has been created and approved for quantitative assurance of ETO and THEO in Pharmaceutical dose structure. The strategy is straightforward and explicit as the two pinnacles are all around isolated which makes it particularly appropriate for routine examination work.

4. References

- [1] Brij Bhushan, Uttam Singh Baghel, Ramandeep Singh, RP-HPLC technique advancement for the assessment of Etofylline and Phenylephrine hydrochloride in consolidated measurements structure. Global Journal of Pharmaceutical and Medicinal Research, 2013;1(2):85-90