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Development and Validation of HPLC Method for Estimation of Etodolac in Matrix Formulation

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Abstract: *Analytical chemistry plays a pivotal role in characterizing the composition of matter, encompassing both the identification of components (qualitative analysis) and the determination of their quantities (quantitative analysis). Its applications span diverse scientific and industrial domains, underscoring the need for robust and reliable analytical techniques. 1−6 high-performance liquid chromatography (hplc) has emerged as a powerful tool in pharmaceutical analysis due to its versatility, sensitivity, and applicability to a wide range of analytes, including non-volatile and thermally labile compounds.*

Keywords: HPLC

I. INTRODUCTION

Analytical chemistry plays a pivotal role in characterizing the composition of matter, encompassing both the identification of components (qualitative analysis) and the determination of their quantities (quantitative analysis). Its applications span diverse scientific and industrial domains, underscoring the need for robust and reliable analytical techniques. 1−6 high-performance liquid chromatography (hplc) has emerged as a powerful tool in pharmaceutical analysis due to its versatility, sensitivity, and applicability to a wide range of analytes, including non-volatile and thermally labile compounds. 13−18

Tacrolimus (tac), a potent immunosuppressant drug, is crucial in preventing organ rejection following transplantation. Its therapeutic efficacy necessitates accurate and reliable methods for its quantification in pharmaceutical formulations to ensure patient safety and drug quality. While some analytical methods for tac exist, there is a continuous need for simple, efficient, and validated techniques for routine quality control. This research focuses on the development and validation of a reverse phase high-performance liquid chromatography (rp-hplc) method for the analysis of tacrolimus in its tablet formulation. The method aims to be accurate, precise, specific, robust, and economical for routine use in pharmaceutical quality control laboratories.

II. RATIONALE OF SELECTED WORK

There are very few hplc methods reported for analysis of etodolac. The methods include analysis of etodolac in various matrixes such as plasma and pharmaceutical formulations such as cream formulation. The methods suffer disadvantage of utilizing concentrated buffers like phosphate buffer and acetate buffers. Literatures reveled that there are few methods involved in analysis of recently approved tablet formulation of etodolac. The work was undertaken to develop a hplc method involving simple mobile phase for analysis of etodolac in matrix tablet formulation.

Analytical challenges:

Chemicalvariability of excipients for tablet formulation.
Complexity informulationswithexcipients of tablet formulation.
Demandofsimpleandshortmethodforroutineanalysis of etodolac.

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III. OBJECTIVE AND PLAN OF WORK

Objective

Analysis is important in every product but it is vital in medicines as it involveslife. The assurance of quality is achieved through analysis of the drug product. Nowdays, newer pharmaceutical dosage form are evolving for assuring better bioavailability and for getting good therapeutic response from available drugs.

etodolacisa nonsteroidal anti-inflammatory drug (nsaid) used to treat mild to moderate pain. Etodolacis usedto treat acute pain, in moderate-to-severe cases.

Literaturesurveyrevealedthatthere fewanalytical methods are reported for estimation ofetodolacsingly or in combination. The available hplc methods suffer disadvantage of using highly concentrated buffer solutions decreasing the column life.

The present work was undertaken with an objective to develop an accurate,simple, precise and reliable method for estimation of etodolacinits matrix tablet formulation.

Plan of work

Literaturesurvey.

Procurementofpureetodolacanditsmarketed tabletformulation.

Trial of instrumental method on pure drug samples which includes followingsteps-

Reversephase-highperformanceliquidchromatography(rp-hplc):

Selectionofcolumn.

Selectionandoptimizationofmobilephase.

Selectionofchromatographicconditions.

Systemsuitabilityparametersstudy.

Analysisof standard laboratorymixturetosee feasibilityof proposed method

Toadoptselectedmethodonmarketed formulation.

Recoverystudies.

Validationofproposed method for

System suitability

Linearity

Accuracy

Precision

Robustness

Experimental work

Material and Instruments:

Materials:

Thedrugsusedforthe presentinvestigationwereobtainedfromarrow chem mumbai.

Details of pure drug:

Drug	Suppliedby	Quantity	Purity(assay)
Etodolac	Arrow chem mumbai.	10g	99.8% w/w

Table : details of api

Marketed preparation:

Brand name	Mfdby	Content	Quantity
Etogesic er tablets	Zydus cadila	400 mg	10 tablets

Table : details of marketed preparation

The marketed preparation was obtained from local marketand is refer redhereafterinthis thesis by the name a ssuch.

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Reagents and chemicals:

Allreagentsand chemicalsusedwereofargrade andhplcgrade.

Methanol (hplcgrade).

Acetonitrile (hplcgrade)

Disodiumhydrogenphosphate (argrade).

Distilledwater (hplcgrade).

Triethylamine (hplcgrade).

Orthophosphoricacid (hplcgrade).

Instruments:

Table: instruments used

Sr.no	Instruments	Make	Model
1	**Uv-visiblespectrophotometer**	Shimadzu	Uv1900i
2	**Hplc**	Waters 600	996 pdadetector
3	**Ph meter**	Hanna	-
4	**Balance**	Citizen	Cy104 (microanalytical balance)
5	**Ultrasonicator**	-	1.5 l50

Study of functional group by using infrared spectroscopy:

Etodolacapi:-accuratelyweighed3mgof**etodolac**apiwasmixedproperly with 300 mg of dried kbr, then carefully triturated in a mortar pestle. Keep this mixture in a die and ir spectrum was taken using the diffused attenuatedreflectancemode.

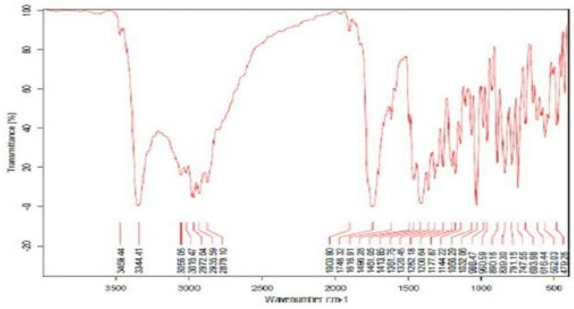

Fig.:irspectra of etodolac

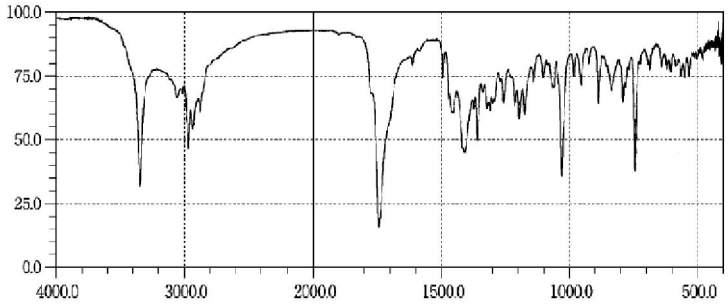

Fig :referenceirspectraof etodolac

Conclusion:

Theirspectraofthegiventestdrugsis matcheswiththeir spectraofstandarddrugs.

Determination of wavelength maxima Etodolac standard stock solution:

An accurately weighed quantity of**etodolac**(eto)5 mg was transferred to the 10 mlvolumetric flask and dissolved in hplc grade acn. The volume was made up to the mark with the same to make (500µg/ml).

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The aliquot portions of stock standard solutions were diluted appropriately with hplc grade acn to obtain concentration 5µg/ml of eto. The solutions were scanned in the range of 400–200 nm in 1 cm cell against blank. The uv absorbance spectrum of etowere recorded and found to be 280 nm.

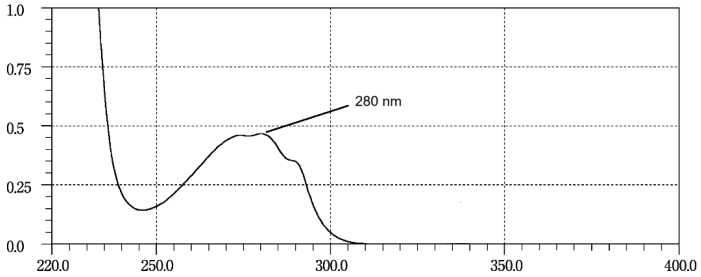

Fig.: wavelength maxima foretodolac

Development of hplc method for estimation of etodolac

Method development tstrategy:

Selection of common solvent(diluents):

Acn of hplc grade was selected as common solvent for preparation ofstock solution and developing spectral characteristics of drugs, further dilutions fromstock solutions were made in mobile phase. The selection was made after assessing thesolubilityof etoin different solvents i.e acetonitrile and water.

Preparationofstandardstocksolution:

Accurately weighted eto400mgwas dissolved in100ml acn.this solutionwasused as standard stocksolution.

Preparationofdiluent:

Acn of hplc grade was selected as common solvent for preparation ofstock solution and developing spectral characteristics of drugs, further dilutions fromstocksolutions weremadein the mobile phase.

Procedure:

The mobile phase was allowed to equilibrate with stationary phase until steadybaselinewasobtained.thestandardsolutioncontainingetowas injected in different combinations of solvents, to get astable peak with good peak characters. Each solution was filtered through membrane filter(size0.15µ). To achieve peaks with good symmetryvariousmobilephasecompositionswereevaluated to achieve acceptable separation using selected chromatographic conditions.the following chromatographic conditions were established by trial and error and werekeptconstant throughout themethod.

Chromatographi parameters:

Column: c_{18} (thermo hypersil gold) /4.6x250 mm, 5µ particle size

Flow rate: 1.0ml/min

Wavelength: 280 nm

Injectionvolume: 20µl

Columnoven temperature: ambient(25^0c)

Runtime: 10 minutes

Mobilephase:10mm phosphate buffer (ph 3.5) and acn**(**50:50)

Preparation of 10mm phosphate buffer: weigh accurately 1.36 g of potassium dihydrogen phosphatein dissolve it in 1000 ml of hplc grade water. The ph was modified to 3.5 using 1 m opa solution.

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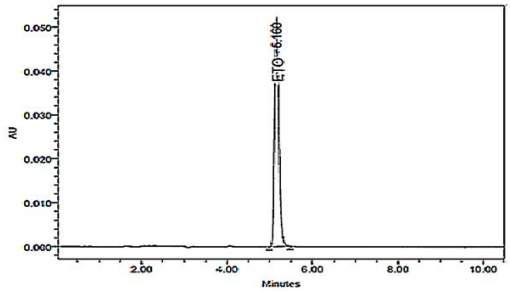

Fig **: separation of eto in selected mobile phases how ingretention time at 5.16 min.**

system suitability studies

System suitability is a pharmacopeial requirement and is used to verify, whether the resolution and reproducibility of the chromatographic system are adequate for analysis to be done. The test was performed by collecting data from 5 replicate injections of standard solutions.

The mobile phase was allowed to equilibrate with the stationary phase until steady baseline was obtained. Standard working solution of eto was injected five times under optimized chromatographic conditions. System suitability parameters were recorded and reported.

B) procedure:

Filtered mobile phase was allowed to equilibrate with stationary phase until steady baseline was obtained. A 20 µl std. Drug solution was injected which was made infivereplicatesand the system suitability parameters were recorded.

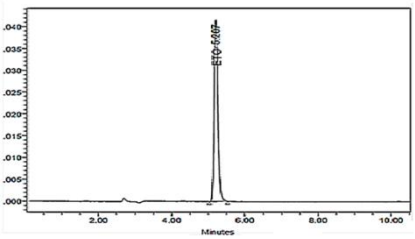

Fig : separation of etoin selected mobile phase showing retention time at 5.20min.

Sr.no	Peak area	Retention Time	Symmetry	No.of theoretical Plates
	Eto	Eto	Eto	Eto
1	240220	5.16	1.20	9520
2	248925	5.22	1.22	9590
3	245815	5.31	1.22	9545
4	242633	5.10	1.20	9500
5	247831	5.15	1.15	9550
Mean	245084	5.188	1.19	9541
S.d	3622	0.08	0.02	33.98
%r.s.d.	1.47	1.55	2.39	0.35

Table : result of system suitability test

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application of proposed method for estimation of etoin matrix tablet formulation:

Standard stock solution:

Preparation of standard solutions

Etodolacstandard stock solution: accurately weighed quantity of 400 mg eto was dissolved in acn and volume was made up to 100 ml mark by same to obtain 4000µg/ml stock solution.

Etodolac standard working solution: pipette out 1 ml from standard stock solution and dilute it with 10 ml acn to obtain 400 µg/ml of eto.

Sample solution preparation:

Entire content of **etogesic er® tablets**(400 mg) was transferred to a 100 ml volumetric flask, the volume was made upto the mark with acn, the resultant concentration was 4000 µg/ml. The whole content was centrifuged at 5000 rpm for 10 min followed by passing through 0.45µ membrane filter. 1 ml of resultant was transferred to a 10 ml volumetric flask and the volume was made upto the mark with acn, the concentration of working sample solution was 400 µg/ml.

Procedure:

Equal volume (20µl) of standard and sample solution were injected separately after equilibrium of stationary phase. The chromatograms were recorded and the response i.e. Peak area of major peaks were measured. The content of eto was calculated by comparing a sample peak with that of standard.

Amount of drug in tablet was calculated using following formula-

$$\% \text{ estimation} = \frac{a_t}{A_s} X \frac{d_s}{D_t} X \frac{w_s}{W_t} X\ 100$$

Where,

At = area count for sample solution.

as = area count for standard solution.

ds = dilution factor for standard.

Dt = dilution factor for sample.

Ws = weight of standard (mg)

Wt = weight of sample (mg)

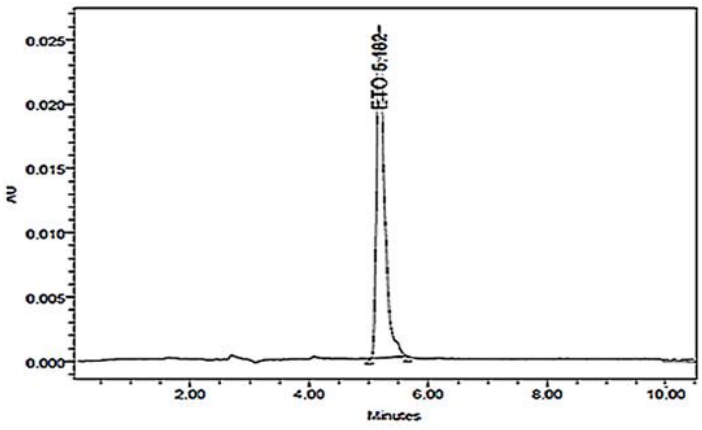

Fig : chromatogram of marketed formulation showing retention time 5.182 min.

Brand name : etogesic er® tablet

Sr.no.		
	Assay (mg)	**% purity**
1	399.95	99.9875
2	399.89	99.9725
3	399.95	99.9875
4	399.96	99.99

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5	399.98	99.995
Average	399.95	99.98
Sd	0.03	0.008
% rsd	0.008	0.008

Table : results and statistical data for estimation of etoin marketed formulation

Validation parameters:

2. Accuracy
3. Precision
4. Ruggedness
5. Robustness
6. Linearity and range
7. Specificity
8. Placebo interference study

accuracy:

The accuracy samples were prepared by spiking the standard into the pre-analyzed formulation sample at different concentrations (80%,100% and 120%) and injected each in triplicate. The resultant mix was injected and recovery of standard spiked was calculated.

The % recovery was then calculated by using formula

% recovery = a-b x 100/ c

Where- a = total amount of drug estimated.
B = amount of drug found on pre analyzed basis.
C = amount of pure drug added.

Calculate the amount recovered, % recovery, average recovery, % rsd of triplicate sample preparation, overall recovery and overall % rsd. Record the observation into the following table.

	Eto		
	Levels		
	80%	100%	120%
Amt added (µg/ml)	320	400	480
	320	400	480
	320	400	480
Amt taken (µg/ml)	320	400	480
	320	400	480
	320	400	480
Amt recovered (µg/ml)	319.95	399.95	479.95
	319.98	399.97	479.95
	319.96	399.79	479.92
% recovery	99.98	99.98	99.98
	99.99	99.99	99.98
	99.98	99.94	99.94
Mean % recovery	99.98	99.97	99.96
% rsd	0.15	0.02	0.02

Table : accuracy studies by standard addition method

Acceptance criteria:

1) the % rsd for the triplicate at each spike level shall be nmt 2.0.

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2) the overall % rsd for % recovery for all spike levels shall be nmt 2.0.
3) the % recovery at each spike level shall be nlt 98.0 and nmt 102.0 of the addedamount.

precision:

system precision

Prepared the standard solution as per test method and inject into the hplc system in three replicates. Calculate the % rsd for the area responses and record the observations into the following table

Sr. No.	Parameter	Observations	Limits
1	The % rsd of peak area response for three replicate injections of standard	1.10	Nmt 2.0
2	Theoretical plates	9560	Nlt 2000
3	Tailing factor	1.24	Nmt 2.0

Table : results for system precision showing system suitability

Where, nmt - not more than nlt – not less than

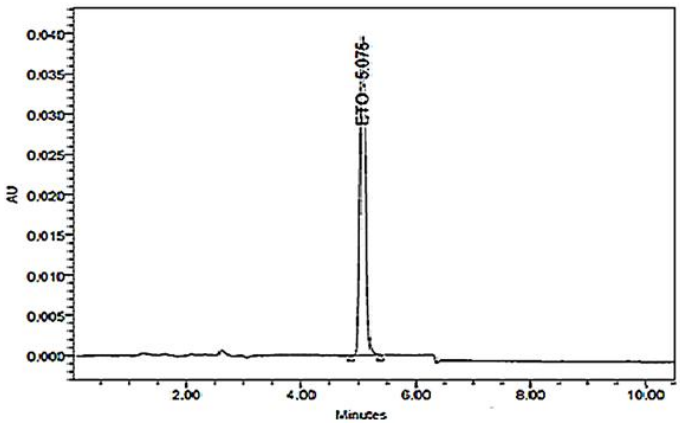

Fig : chromatogram system precision showing repeatability

Injection no.	Area response
	Eto
1	240520
2	241780
3	240250

Average	240850
Sd	816
% rsd	0.39

Table : system precision showing repeatability

Acceptance criteria:

% rsd for replicate injections shall be nmt 2.0

Method precision:

Prepared three samples solutions as per the test method and injected into the hplc system by following the conditions prescribed in the test method.

Procedure:

Sample solution was prepared and injected into the hplc system, the chromatograms were recorded for peak area response for the eto. The assay and % label claim for eto was calculated.

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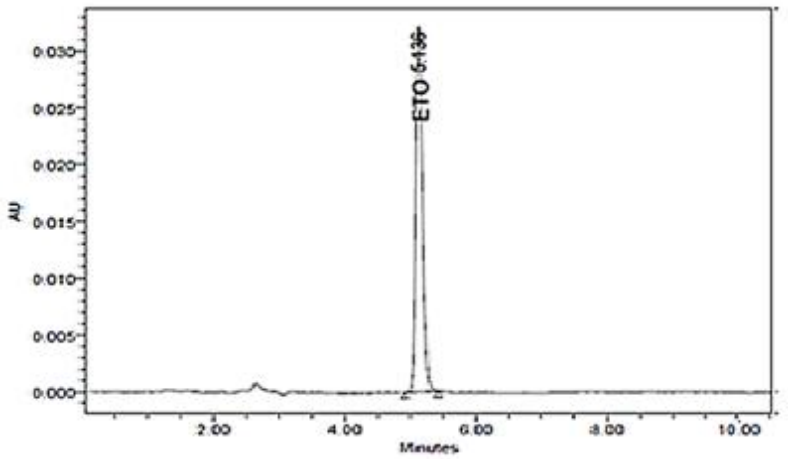

Fig: chromatogram of method precision

Sr.no.	Eto	
	Assay (mg)	Assay % of lc
1	399.98	99.99
2	399.91	99.97
3	399.80	98.95
Average	399.89	99.97
Sd	0.09	0.02
% rsd	0.02	0.02

Table : method precision studies set – i

Acceptance criteria: the% rsd for the three determinations shall be nmt 2.0

Ruggedness: intermediate precision

Prepared three sample solutions as per the test method. Injected into the different hplc system (preferably with different manufacturer or same manufacturer with different configuration) by using the different column and by the different analyst at different date.

Sr.no.	Eto	
	Assay (mg)	Assay % of lc
1	99.97	99.97
2	99.97	99.97
3	99.96	99.96
Average	99.65	99.65
Sd	0.03	0.03
% rsd	0.04	0.04

Table : intermediate precision studies (ruggedness) set – ii

Acceptance criteria: the % rsd for the three determinations shall be nmt 2.0

Ddata analysis between method precision and intermediate precision:

Compared the data obtained in this section verses the data obtained in method precision and evaluate the overall average, overall sd and overall % rsd and recorded the observation into the following table

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Sr.no.	% assay of lc	
	Eto	
	Set – i	Set - ii
1	99.99	99.97
2	99.97	99.97
3	98.95	99.96
Average	99.98	
Sd	0.55	
% rsd	0.55	

Table : intermediate precision (ruggedness) evaluation of data

Set – i: method precision data **, set – ii:** intermediate precision data

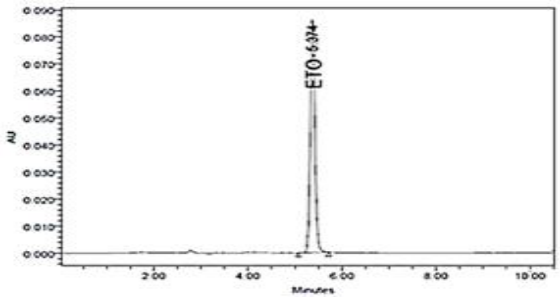
Acceptance criteria:the overall % rsd for the twelve determinations shall be nmt 2.0

Robustness:

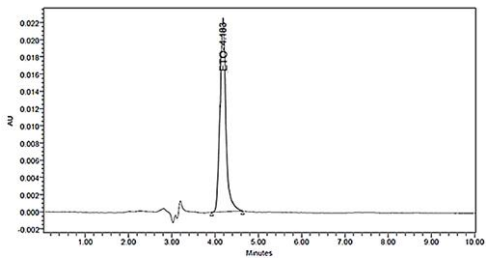
Effect of variation in flow rate of mobile phase by ± 10%:

Prepared the system suitability solution (standard preparation) and inject into the hplc system at –10% flow rate (0.9ml/min) and +10% flow rate (1.1ml/min) when compared with the test method flow rate

Procedure: injected standard solution into the hplc system in normal conditions and followed by the robust conditions. Measured the peak response for the major peaks.



0.9 ml/min



1.1 ml/min

Fig. : chromatograms of change in flow rate

System suitability parameters were recorded and the resultsare presented in the table below.

Sr. No.	System suitability parameter		Observations for flow rate			Limits
			Unchanged	0.9 ml	1.1 ml	
1	The % rsd of peak area response for five replicate injections	Eto	1.15	1.16	1.35	Nmt 2.0
2	Theoretical plates	Eto	9590	9538	9557	Nlt 2000

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3	Tailing factor	Eto	1.18	1.59	1.56	Nmt 2.0
4	Retention time (min)	Eto	5.50	5.37	4.26	

Table : system suitability of change in flow rate

Observation: the allowable variation in flow rate of the method is from 0.9ml/min to 1.1 ml/min

Acceptance criteria: all the system suitability parameters shall pass

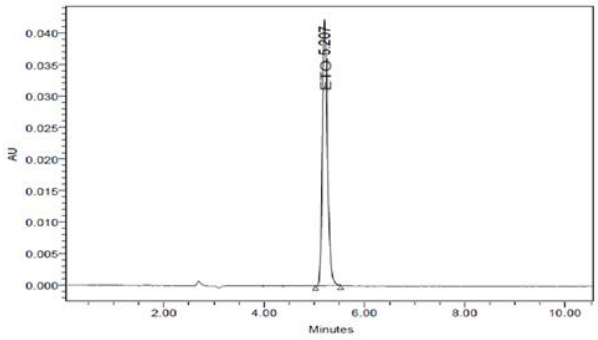
10mm phosphate buffer (ph 3.5) and acn **(**50:50)

change in organic composition+10%

System suitability dilution was prepared and injected into the hplc system at –10% and + 10 % acn (organic phase) compared with the optimized method mobile phase concentration

Procedure:injected standard solution into the hplc system in normal conditions and followed by the robust conditions. Measure the peak response for the major peaks. Check the system suitabilityand record the resultsin the table.

-10% acn:- (phosphate buffer ph 3.5:acn45:55 % v/v)



+10% acn: (phosphate buffer ph 3.5: acn 55:45)

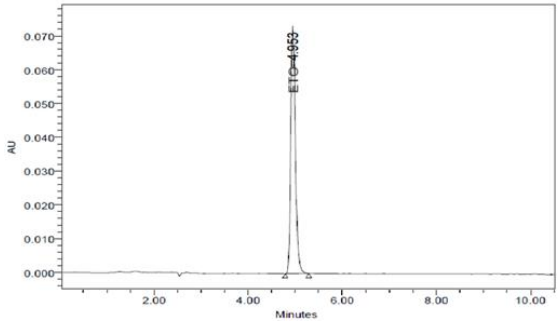


Fig. : chromatograms of change organic composition of mobile phase

Sr. No.	**System suitability parameter**		**Observations**			**Limits**
			Unchanged	**- 10%**	**+ 10%**	
1	The % rsd of peak area response for five replicate injections	Eto	1.26	1.22	1.36	Nmt 2.0
2	Theoretical plates	Eto	9597	9516	9447	Nlt 2000
3	Tailing factor	Eto	1.20	1.22	1.25	Nmt 2.0
4	Retention time (min)	Eto	5.52	5.20	5.15	

Table : system suitability of change in organic composition

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Observation: the allowable variation in acn composition of method is from 90% to 110%.**acceptance criteria:** 1. All the system suitability parameters shall pass.

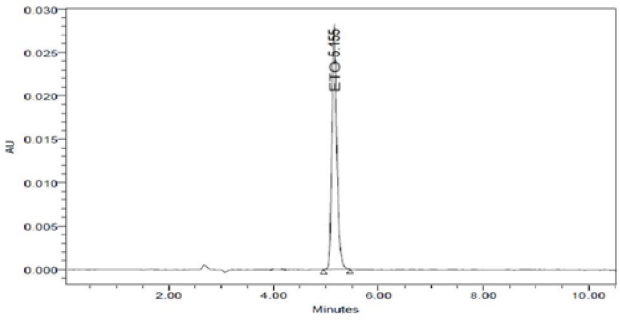
Effect of variation in wavelength by ± 2 units:

Prepared the system suitability solution (standard preparation) and inject into the hplc system. Measure the peak area response at different wavelengths at flow rate 1 ml/min.

Procedure:

Injected standard solution into the hplc system in normal conditions and followed by the robust conditions. Measure the peak response for the major peaks.

At 278nm wavelength



At 282 nm wavelength

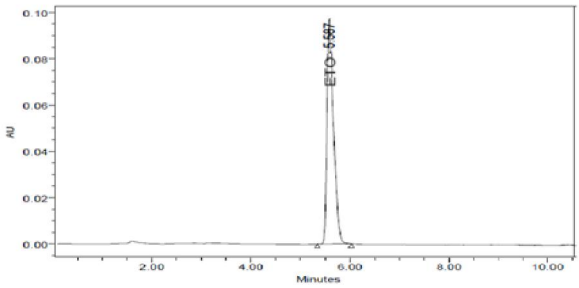


Fig : chromatograms of change in wavelength.

Sr. No.	System suitability parameter		Observations for wavelength			Limits
			Unchanged	278nm	282nm	
1	The % rsd of peak area response for five replicate injections	Eto	1.33	1.41	1.44	Nmt 2.0
2	Theoretical plates	Eto	9557	9598	9478	Nlt 2000
3	Tailing factor	Eto	1.25	1.15	1.10	Nmt 2.0
4	Retention time (min)	Eto	5.2	5.15	5.5	

Table : system suitability of change in wavelength

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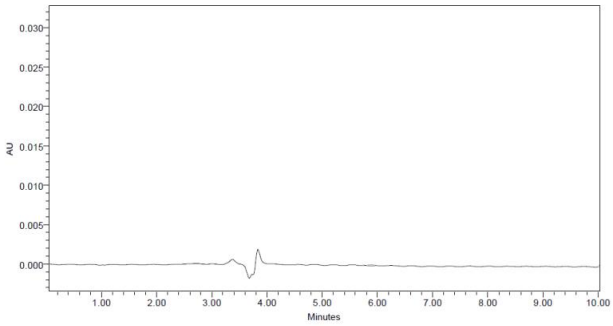
Specificity:

Placebo interference study:

Prepared the placebo solution by weighing equivalent amount of placebo present in the sample to be taken for assay preparation in triplicate, diluted it as per the test method and injected into the hplc system. Evaluate the % interference from placebo and recorded the observation.

Sample matrix



Placebo preparation

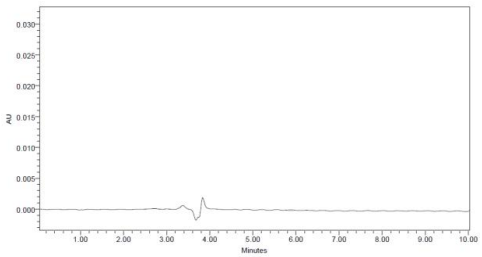


Fig : chromatograms of placebo interference study

Observation	Placebo prep.1	Placebo prep.2	Placebo prep.3
% interference	No interference	No interference	No interference

Table : placebo interference

Acceptance criteria:

No interference should observe from placebo at the retention time of eto.

Linearity and range:

Prepared the series of standard concentrations ranging from 50 % to 150 % of the targeted concentration of eto. Each of the linearity dilution was injected into the hplc system with optimized chromatographic parameters.

Procedure:

Separately inject standard preparation and linearity preparations into the hplc system, record the chromatograms and measure the peak responses for eto peaks.

The details of mean peak areas for linearity concentrations are presented in following table and plot the graph of concentration verses average area response foreto, the correlation coefficient and equation of regression were recorded.

Sr. No.	% level	Eto	
		Conc. (µg/ml)	Mean peak area
1	80	320	194200
2	100	400	243220
3	120	480	293400
4	160	640	388520
5	180	720	436520

Table : observations of linearity and rangestudy for eto

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Acceptance criteria: the correlation coefficient shall be nlt 0.99

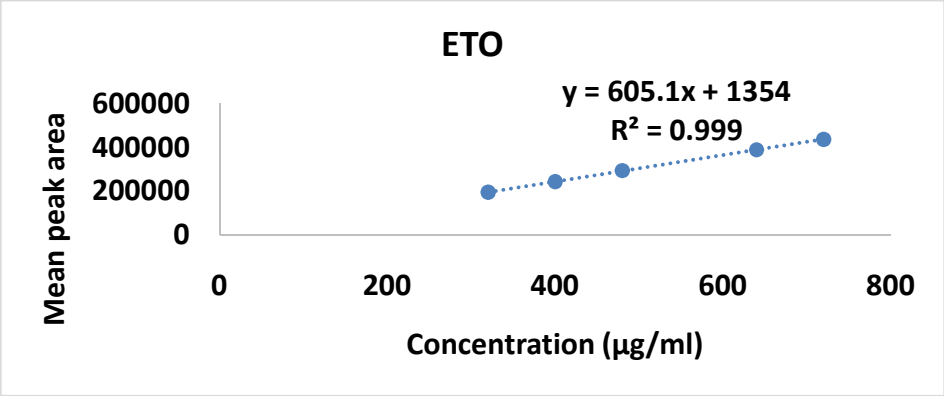

fig : plot of linearity and range study for eto

Result and discussion

Highperformanceliquidchromatographywhichisahighlysophisticatedtechnique, it is used for the determination of active molecules from their formulations. In the present study a hplc method was developed for analysis of eto from its matrix tablet formulation.

Recently matrix extended-release tablet formulation containing etois introduced in market, thedrugis used to manage pain, in moderate-to-severe cases.

Very few methodsare so far reported for estimation of **eto**. In the present investigation an attempt has been made to develop a simplehplcmethodforestimation of **eto** from its formulation.purestandardsof**eto** were procured from arrow chem mumbai.percentpurityofabove-mentioneddrugwasreportedbysuppliercompanyasfollows-

Tableno.24:detailsofapi

Drug	Suppliedby	Quantity	Purity(assay)
Etodolac	Arrow chem mumbai.	10g	99.8% w/w

These were not analyzed in our study and the % purity stated by the supplierswastaken as standardfor comparison studies.

II. SUMMARY AND CONCLUSION

Summary

Extended-release matrix tablet formulation containing eto is introduced in market, the drug is used to treat and manage pain. Literature survey revealed very few analytical methods for the estimation of eto.

The present study was undertaken with an objective of developing suitable,sensitiveandsimpleanalyticalrp hplcmethodforestimationofetointablet formulation.

In the developed rp-hplc method the analyte was resolved using mobile phase composedof10mm phosphate buffer (ph 3.5) and acn (50:50 %v/v).an isocratic program was developed contributin ga total run time of 10 min. Using hplc auto-sampler system containing pdadetectorwithempowersoftwareandc$_{18}$ (thermo hypersil gold) /4.6x250 mm, 5µ particle size column, the detection wavelength was 280 nm.the method gave the good resolution and suitableretentiontime.The results of analysis in all the method were validated in terms of accuracy,precision, ruggedness, linearity and range. The methods were found to be sensitive,reliable,reproducible,rapid and economicalso.

Conclusion

From the results of the study it can be concluded that the present rp-hplc technique was successfully used for the estimation of the eto in the extended-release matrix tablet formulation.

The method showed good reproducibility,it was accurate,precise,specific,reproducibleandsensitive.theanalysisoftablet formulationof eto was done by the developed and validated rp-hplc method.

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Therp-hplc method was also simple, accurate, precise, reproducible an deconomical too. It may be adopted for routine control analysis of eto alone intablet formulation.

No interference of additives ,matrix etc.is encountered in the se methods. further studies on other pharmaceutical formulations would throw more light on these studies.

Suitability of these method son biological samples needs to be studied.