INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA):IJPS00]
Journal Homepage: https://www.ijpsjournal.com

Review Article

Determination Of Etoricoxib By Analytical And Bioanalytical Methods: A Review

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ARTICLE INFO

Received: 04 May 2024
Accepted: 08 May 2024
Published: 16 May 2024

Keywords:
Etoricoxib, Analytical method, High-performance liquid chromatography, liquid chromatography-mass spectroscopy, Bioanalytical methods.

DOI:
10.5281/zenodo.11203913

ABSTRACT

Etoricoxib is a selective COX-2 inhibitor. The way non-steroidal anti-inflammatory drugs (NSAIDs) function is by blocking the COX enzyme, which is an inflammatory mediator. Osteoarthritis, rheumatoid arthritis, and primary dysmenorrhea are all treated with etoricoxib. Therefore, the main objective of this work is to examine etoricoxib in pharmaceutical and biological formulations using both qualitative and quantitative methods. In this review paper, we have compiled the methodologies for estimating etoricoxib based on liquid chromatography-mass spectroscopy (LC-MS), high-performance liquid chromatography (HPLC), and UV/Vis spectroscopy. Furthermore, we have discussed the bioanalytical methods for ETX analysis. To sum up, this review article will assist researchers in developing new methods for estimating drug concentrations in biological fluids and pharmaceutical dose forms.

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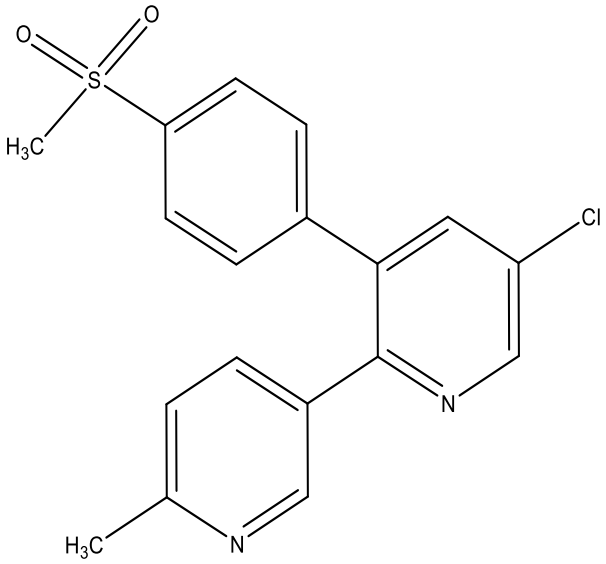
Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

INTRODUCTION

Rheumatoid arthritis pain and inflammation are frequently managed using non-steroidal anti-inflammatory medications (NSAIDs). Their suppression of cyclooxygenase (COX) enzymes, which convert arachidonic acid into prostaglandins, is responsible for their analgesic and anti-inflammatory properties as well as part of their chemopreventive actions.(1) Etoricoxib, 5-chloro-3-(4-methanesulfonylphenyl)-6-methyl-[2,3]-bipyridinyl is a highly selective cyclooxygenase–2 (COX-2) inhibitor.(2) The two types of the enzyme are cyclooxygenase-1 (COX-1) and cyclooxygenase-2 (COX-2). COX-1 regulates normal physiological prostaglandin-mediated functions such gastric cytoprotection and platelet aggregation. Nonselective NSAIDs' suppression of COX-1 has been connected to both platelet inhibition and gastric injury. It is well known that prostanoid mediators of pain and inflammation are produced in large part by COX-2.(2) Etoricoxib is used to treat osteoarthritis, rheumatoid arthritis, chronic low back pain, acute pain, dysmenorrheal, acute gouty arthritis and ankylosing spondylitis.(3)



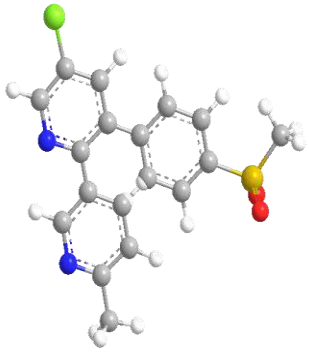


Figure 1: Chemical Structure of Etoricoxib

Mechanism of Action :

One possible explanation for the anti-inflammatory, analgesic, and antipyretic effects of NSAIDs is the inhibition of prostaglandin synthesis. The exact mechanism of action is yet unknown, but it appears that these effects are produced by blocking the COX-2 isoenzyme at the sites of inflammation, which in turn causes a reduction in the production of several prostaglandins from their precursors, arachidonic acid. Etoricoxib particularly inhibits the COX-2 enzyme, which is essential for the control of pain and inflammation. In contrast to non-selective NSAIDs, it does not stop platelet aggregation. Moreover, affinity for COX-1 is minimal to nonexistent.(4)

Pharmacokinetics :

Absorption :

Bioavailability is 100% following oral administration.(4)

Protein binding :

92%(4)

Metabolism :

Hepatic, primarily via CYP3A4. (4)

Pharmacodynamics :

Etoricoxib is a COX-2 selective inhibitor (approximately 106 times more selective for COX-2 inhibition over COX-1). (4)

Analytical Account of ETX

An extensive literature search revealed a variety of analytical methods, including UV/Visible Spectrophotometry, HPLC, HPTLC, UPLC, LC-

MS/MS, and bioanalytical approaches, for the determination of RFX in bulk and pharmaceutical formulations. Celecoxib (CXB), Paracetamol (PCT), Salicylic acid (SCA), Ketoprofen (KPF), Nimesulide (NMS), Riluzole (RLZ), Drotraverine (DRT), Thiocholchicoside (THC), Pregabalin (PGBN), Tolperisone (TOP) are all evaluated alone as well as in conjunction with ETX.

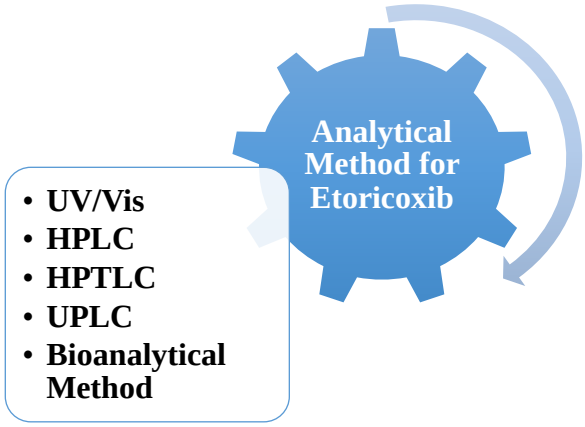


Figure 2 shows different analytical methods implemented for the estimation of ETX

Bio-analytical method for ETX

A branch of analytical chemistry known as "bio-analysis" deals with the quantitative measurement of biotics (macromolecules, proteins, DNA, large-molecule drugs, metabolites) and xenobiotics (drugs and their metabolites) in biological systems. The summary of the reported bioanalytical methods is shown in Table 1

Table 1: Bioanalytical determination of ETX

Sr. No.	Drug	Sample Matrix	Method	Column	Detection	Internal Standard	Ref
1	ETX	Human plasma	HPLC	Hypersil BDS, C18 column	235 nm	Valdecoxib in acetonitrile	5
2	ETX	Human plasma	HPLC	Waters symmetry® C18 column	284 nm	Zaleplon	3
3	ETX	Human plasma	HPLC	Waters symmetry® C18 column	284 nm	Rofecoxib	6
4	ETX	Rat Plasma	HPLC	Novapak-C8 column	245 nm	Flurbiprofen	7
5	ETX	Human plasma	LC-APCI/MS/MS	Luna C18 column	***	Antipyrin	8
6	ETX	Human plasma	LC–MS–MS	Narrow bore RP C column	***	Phenazone	9
7	ETX	Human plasma	LC-MS/MS	Thermo Hypurity, C18 column	***	Etoricoxib D3	10
8	ETX	Spiked Human plasma	LC-MS/MS	C18 analytical column	234 nm	Piroxicam	11
9	ETX and VDX	Human plasma	RP-HPLC	Nucleosil C8 guard column	***	TO FIND IT	12
10	ETX, SCA, VDX,	Human plasma	HPLC	Kromasil KR 100-5C18 column	235 nm	DRF-4367	13

	KPF, NMS, CXB						
11	ETX	Human plasma	UPLC-MS/MS	ACQUITY UPLC HSS T3 column	***	Etoricoxib-d3	14
12	RLZ and ETX	Rat plasma and brain tissue	LC-MS/MS	ACQUITY UPLC BEH C18 column	***	Etoricoxib D4	15

***** Not Provided**

UV-Visible spectroscopy method for ETX

The spectrophotometric methods have been accounted for the determination of ETX. The details of Spectrophotometry determination of basic principle, sample matrix, lambda max, solvent linearity range and the correlation coefficient are summarized in Table 2.

Table 2: Spectrophotometric methods used for determination of ETX

Sr. No.	Drug	Matrix	Solvent	Lambda Max (nm)	Linearity (µg/mL)	Correlation coefficient (R2)	Ref.
1	ETX	Bulk and tablet Formulation	0.1N HCl	233 nm	2-24 µg/ml	0.9996	16
2	ETX	Tablet dosage form	0.1 N HCl	271.6 nm	1-25µg/ml	0.9981	17
3	ETX	Bulk and Tablet Formulation	Methanol	234nm	1 to 11 µg/ml	0.9986	18
4	ETX	Pharmaceutical formulations	0.1 M HCl	233 nm	0.1–0.5 µg/ml	0.997	19
5	ETX and DRT	Combined tablet dosage form	Methanol	274nm and 351 nm	4.5-22.5 µg/ml and 4-20 µg/ml	***	20
6	ETX and THC	Bulk and combined tablet dosage form	0.1N HCl	240 nm and 260 nm	2.5–30 µg/ml	0.9999	21

***** Not Provided**

Liquid-Chromatography-Mass Spectroscopy methods (LC-MS) for ETX:

In recent years, the combination of LC/MS has gained a lot of attention for the analysis of interest analytes in complex samples with improved performance. In brief, after a thorough examination, LC/MS interfaces are divided into two categories namely interfaces for indirect and direct input of column effluent. A mechanical mechanism is employed to transmit the column effluent to the MS vacuum at an indirect introduction interface. A classic example of an indirect introduction type of interface is the transportation system. In the case of the direct introduction system, the column effluent flows directly into the mass spectrometric vacuum system via a tube. Mainly, the most straightforward method of linking LC and MS appears to be the direct introduction. In this section, we have discussed the LC-MS methods for the determination of ETX in a dosage form Table 3.

Table 3. Summary of LC-MS methods for the determination of ETX in a dosage form

Sr. No	Drug	Matrix	Stationary Phase	Mobile Phase	Internal Standard	Linearity (µg/mL)	Ref.
1	ETX	Pharmaceutical dosage forms	Synergi fusion C18 column	0.01M phosphoric acid – acetonitrile (62 + 38, v/v)	Piroxicam	0.02–150 µg/ml	22

HPLC method for ETX

The specificity of the HPLC method is excellent and simultaneously sufficient precision is also attainable. However, it has to be stated that the astonishing specificity, precision, and accuracy are attainable only if wide-ranging system suitability tests are carried before the HPLC analysis. For this reason, the expense to be paid for the high specificity, precision, and accuracy is also high. The summary of the reported HPLC methods is shown in Table 4.

Table 4: Summary of HPLC methods for the determination of ETX in a single and combined dosage form

Sr No	Drug name	Column	Mobile phase	Lambda max (nm)	Linearity (µg/mL)	Retention time (min)	Flow rate (mL/m)	Detector	Ref
1	ETX	Hyper ODS 2 C18 column	Methanol	233 nm	20-55 µg/ml	3.28 min	1 ml/min	UV-Visible	23
2	ETX	Reverse phase C18 column	Acetonitrile : Ammonium Acetate buffer (50:50)	235 nm	20-75 µg/ml	5.337 min	1 ml/min	UV-Visible	24
3	ETX	Inertsil ODS-4 column	0.01M sodium perchlorate monohydrate and acetonitrile (48:52v/v)	235 nm	34.44-63.96 µg/ml	4.299 min	1.5 ml/min	UV detector	25
4	ETX	Reverse phase C18 column	Methanol: phosphate buffer (90:10 v/v)	235 nm	10-200 µg/ml	3.428 min	1ml/min	UV detector	26
5	ETX	Kromasil 100, RP-C18 Column	Acetonitrile : methanol : 10mm potassium dihydrogen phosphate (35:35:30 v/v)	234 nm	25 to 400 ng/injection	***	1 ml/min	UV/VIS detector	27
6	ETX	Phenomenex ODS 2 C18 column	Methanol : 10mM Potassium Dihydrogen Phosphate (75:25 % v/v)	287 nm	4.99–99.70 µg/ml	3.2 min	0.8 ml/min	UV detector	28
7	ETX	BDS-Hypersil C-8 column	Water : acetonitrile : methanol (50:25:25v/v/v)	284 nm	5 -50 µg/ml	4.8 min	1.25 ml/min	UV detector	29

8	ETX	ODS Hypersil C18 column	Acetonitrile: water (55:45v/v)	269 nm	10 to 60 µg/ml	5.03 min	0.9ml/min	UV/VIS detector	30
9	ETX	Hypersil ODS C-18 column	Acetonitrile and potassium dihydrogen phosphate buffer (46:54%v/v)	280 nm	0.5-85.0 µg/ml	3.083 min	1.2 ml/min	UV detector	31
10	ETX	Zorbax SB CN column	Disodium hydrogen orthophosphate (0.02 M) : acetonitrile (60:40)	235 nm	***	11.510 min	0.8 ml / min	***	32
11	THC and ETX	BDS Hypersil C18 column	Acetonitrile : Buffer (75:25)	220nm	***	3.97 min and 7.46 min	1.5 ml/min	***	33
12	THC and ETX	Zorbax C-18 analytical column	Methanol and water (60:40)	283 nm	2 to 20 µg/ml and 10 to 200 µg/ml	3.523 min and 9.627 min	0.7 ml/min	UV detector	34
13	PCT and ETX	Kromasil C18 column	Buffer : Acetonitirile	220 nm	48 to 146 µg/ml and 6 to 19 µg/ml	8.34 min and 18.45 min	1.0 ml/min	UV-VIS detector	35
14	THC and ETX	BDS Hypersil C-18 column	Trifluoroacetic acid buffer and acetonitrile (75:25, v/v)	220 nm	2 to 16 ppm and 20 to 160 ppm	3.1 min and 6.6 min	1.5 ml/min	UV detector	36
15	PCT and ETX	Phenomenex Luna C18 column	Methanol : water (70:30 v/v)	235 nm	5-30 µg/ml	3.07 min and 5.72 min	1.0 ml/min	UV detector	37
16	PGBN and ETX	Thermo C18 column	Orthophosphoric acid (0.1%) : methanol (60:40 v/v)	236 nm	37.5 to 112.5 µg/ml and 30 to 90 µg/ml	2.636 min and 5.607 min	1.0 ml/min	Waters photodiode detector	38
17	THC and ETX	Hypersil BDS C18 column	Phosphate buffer(ph-3.4) and acetonitrile (35:65v/v)	260nm	2.5-15 µg/ml and 5.0-30 µg/ml	2.83 min And 6.92min	1.0 ml/min	UV detector	39
18	PGBN and ETX	Hypersil ODS, C18 column	Methanol: acetonitrile: phosphate buffer (pH5) (40:20:20)	215 nm	12.5–37.5 µg/ml and 150–450 µg/ml	3.523 min and 4.702 min	1.0 ml/min	UV-VIS detector	40
19	ETX and PCT	Hypersil ODS, C18 column	0.05 M sodium dihydrogen phosphate buffer : acetonitrile (35:65 v/v)	235nm	50-150% of the working standard solution concentration	1.889 min and 2.460 min	1.0 ml/min	UV-VIS detector	41

20	KPF, ETX and DIC	C18 column	50% Cetrimide and 50% acetonitrile for KPF and ETX 30% Cetrimide and 70% acetonitrile for DIC	254 nm, 234 nm, and 254 nm	0.03- 0.50 mg/ml , 0.007-0.11 mg/ml and 0.016 - 0.250 mg/ml	9.41 min, 7.34 min, and 6.66 min	1.0 ml/min	UV detector	42
21	PCT and ETX	Inertsil ODS, C8-3 column	Methanol: acetonitrile: phosphate buffer (40:20:40 v/v)	242 nm	50 to 150 µg/ml and 6-18µg/ml	3.27min, 6.12 min	1.0 ml/min	***	43
22	THC and ETX	Inertsil C18 column	Acetonitrile: ph 3 phosphate buffer (70:30% v/v)	254nm	25-125 µg/ml and 15-75 µg/ml	2.325 min and 4.296 min	1.0 ml/min	UV detector	44
23	ETX and PCT	PURITAS ™ EXIMIUS C18 analytical column	Acetonitrile and 0.1 percent acetic acid in water (70:30V/V)	235nm	20-120ppm and 20-200ppm	4.2 min and 2.1 min	1.0 ml/min	PDA detector	45
24	ETX and PCT	Phenomenex® C18 column	Acetonitrile, methanol and water 60:15:25 (v/v/v)	236 nm	8.3-41.5 µg/ml and 1-5 µg/ml	5.472 min, 7.650 min	1.0 ml/min	UV detector	46
25	TOP and ETX	Eclips plus C18 column	0.035M triethylamine and acetonitrile (70:30 v/v)	290nm	5-15 µg/ml	2.826 min and 7.566 min	1.0 ml/min	PDA detector	47
26	PGBN and ETX	Ascentis C18 column	Acetonitrile and 0.01N potassium dihydrogen phosphate (50: 50)	228nm	***	2.313 min and 2.840 min	0.8 ml/min	PDA detector	48

HPTLC method for ETX

Thin-layer chromatography is a popular technique for the analysis of a wide variety of organic and inorganic materials, because of its distinctive advantages such as minimal sample clean-up, a wide choice of mobile phases, flexibility in sample distinction, high sample loading capacity and low cost. The summary of the reported HPTLC methods is shown in Table 5.

Table 5: Summary of HPTLC methods for the determination of ETX in a single and combined dosage form

Sr. No.	Drug	Stationary Phase	Mobile Phase	Detection	Linearity	Ref.
1	ETX	Precoated silica gel $60F_{254}$	Chloroform: methanol: toluene (4:2:4 v/v)	289 nm	100 to 600 ng/spot	49

2	ETX	Precoated silica gel $60F_{254}$	Toluene–1,4-dioxane–methanol 8.5:1.0:0.5 (v/v)	235 nm	100 to 1500 ng/spot	50
3	PCT and ETX	Precoated silica gel $60F_{254}$	Toluene: ethyl acetate: methanol in the ratio of 6: 4: 1 (v/v/v)	263 nm	60-360 ng/spot 50-300 ng/spot	51

UPLC methods for ETX

Ultra-performance liquid chromatography (UPLC) is a new category of separation based on well-established principles of liquid chromatography, which utilizes sub-2-mm particles for the stationary phase. The developed UPLC method is validated and therefore could be further used for quantitative analysis of Etoricoxib. Sanjay Shesha Shetgar, Ramadevi Dharmasoth, Bandlamudi Mallikarjuna Rao, Basavaiah Keloth established UPLC method development and validation for simultaneous estimation of Etoricoxib and Thiocolchicoside in tablets. UPLC was carried out in Hibar, C18 column of dimension 100 × 2.1 mm, 1.8 µm,at 30°C, by using mobile phase 0.1% orthophosphoric acid (pH 2.5) and acetonitrile in a ratio of 90:10 (v/v). The column effluents were monitored at 256 nm using a Acquity Tunable UV detector at a flow rate of 0.3 ml/minute. The linearity of the calibration curve ranged from 1–6 µg/ml of Thiocolchicoside and 15–90µg/ml of Etoricoxib and the regression coefficient (r2) was 0.999 for both Etoricoxib and Thiocolchicoside drugs.(53)

CONCLUSION

The current review article offers a thorough understanding of the many analytical and bioanalytical techniques both singular and combined developed for etoricoxib. Numerous novel analytical techniques, including as UV spectroscopy, UPLC, HPLC, and HPTLC, have been published for analysis purposes. The method has been tabulated and includes information regarding the mobile phase, stationary phase, retention time, etc. for the researchers' convenience. Future analytical techniques for the bio-analysis of etoricoxib in pharmacological and biological formulations can be developed using the information acquired. In conclusion, it offers an opportunity to gain additional insight into past achievements and prospective future initiatives and modifications aimed at expanding our understanding of etoricoxib.

CONFLICT OF INTEREST

The authors declare that no conflict of interest

ABBREVIATIONS

1. UV/VIS – Ultra violet/visible spectroscopy
2. HPLC – High-performance liquid chromatography
3. HPTLC – High-performance thin layer chromatography
4. LC-MS/MS – Liquid chromatography-mass spectroscopy-mass spectroscopy
5. UPLC – Ultra performance liquid chromatograpy
6. RP – Reverse phase
7. nm – Nanometer
8. µg/mL – Micro gram per Milliliter
9. PDA - Photo diode array
10. VDX – Valdecoxib
11. SCA – Salicylic acid
12. KPF – Ketoprofen
13. NMS – Nimesulide
14. CXB – Celecoxib
15. RLZ – Riluzole
16. DRT – Drotraverine
17. THC – Thiocholchicoside
18. PCT – Paracetamol
19. PGBN – Pregabalin

20. TOP – Tolperisone

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HOW TO CITE: Shweta V. Rane, Sapan K. Shah, Dinesh R. Chaple, Mayur A. Lohi, Pooja R. Denge, Sahil D. Gayakwad, Bhagyashri S. Patil, Vinay V. Sarode, Determination Of Etoricoxib By Analytical And Bioanalytical Methods: A Review, Int. J. of Pharm. Sci., 2024, Vol 2, Issue 5, 743-754. https://doi.org/10.5281/zenodo.11203913