Review Article

Methods for Estimation of Celecoxib Singly and in Combined Dosage Forms Using Analytical and Bioanalytical Evaluation: An Extensive Review

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ABSTRACT

This is a collective data for Celecoxib from previously published methods either in alone or in combination. Many analytical methods such as HPLC, UV, HPTLC etc, were reported for biological fluids and pharmaceutical formulations. The method proposed was validated statistically. All of the suggested techniques are straightforward, precise, repeatable, delicate, and exact with a high degree of accuracy. This succinct review article can help an analyst decide on the best technique to build and validate an analytical method for Celecoxib alone or in combination with other formulations.

Keywords: Celecoxib, HPLC, UV, HPTLC, Analytical Method, Biological Fluids.

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INTRODUCTION

Every day in human health a revolution found as pharmaceuticals developing. These pharmaceuticals can show best activity if these are free from impurities and pure. Various chemical and instrumental techniques were regularly developed to produce drugs free of impurities. Starting from manufacturing of bulk drug to packaging of finished product and further up to storage the impurities may develop at any stage. Transportation and storage are the two stages where impurities may occur frequently. Impurities must be detected and quantitated in the condition. For detection and measurement purposes, analytical instrumentation and techniques are crucial. Various methods are available to validate bulk drugs and pharmaceuticals such as, HPLC, GC, Titration, UV-Visible spectrophotometry, IR, NMR, Polarimetry, Fluorimetry, AAS, Polarography, Microbiological assay, etc.[1] To be capable of testing bulk drugs, intermediate products, drug formulations, and degradation products, chemical stability makes pharmaceutical analysis a valuable tool.

Celecoxib works by decreasing hormones that cause irritation and inflammation throughout the body. Celecoxib is used to treat pain or areas affected by a range of disorders, including menstrual discomfort, ankylosing spondylitis, and arthritis. Celecoxib can be used to treat children with juvenile rheumatoid arthritis who are at least two years old. It belongs to the nonsteroidal anti-inflammatory drug class (NSAID). NSAIDs work differently from steroids (such as prednisone), another type of drug used to treat pain. At present, the more commonly used NSAIDS drugs in clinical are Ansaid, Oruvail, Advil, Proprinol, Celecoxib and Celebrex. Among them, Celecoxib is used more. The chemical name for Celecoxib is 4-[5-(4-Methylphenyl)-3- (trifluoromethyl) pyrazol-1-yl] benzenesulfonamide, which describes its analgesic and antiinflammatory effect by selectively inhibiting the enzyme cyclooxygenase-2. All nonsteroidal anti-inflammatory drugs (NSAIDs) block the cyclooxygenase (COX) enzymes that the body uses to produce the inflammatory and uncomfortable prostaglandins.

The enzyme COX is in charge of producing a variety of prostaglandins (PGs). The two well-known isozymes of COX are COX-1 and COX-2. Nearly every tissue contains COX-1, including blood arteries, the stomach, and the kidney. PGs have important physiological role in many tissues. COX-2 is induced during inflammation by cytokines and endotoxins and is responsible for the production of prostanoid mediators of inflammation.

Most of the NSAIDs inhibit both COX-1 and COX-2 isoforms; thereby decrease PGs and thromboxane synthesis. The anti-inflammatory effect of NSAIDs is mainly due to inhibition of COX-2.

Chemical Structure

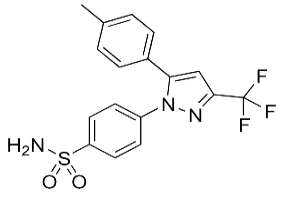


Figure 1: (4-[5-(4-Methylphenyl)-3- (trifluoromethyl) pyrazol-1-yl] benzenesulfonamide)

Table 1: Details of COX inhibitors.

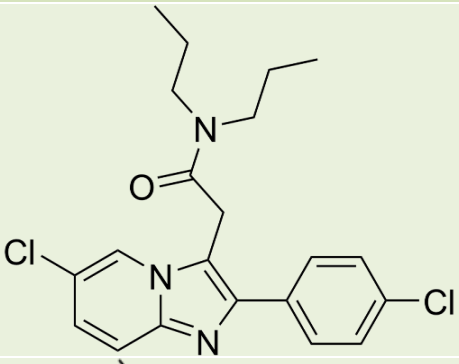
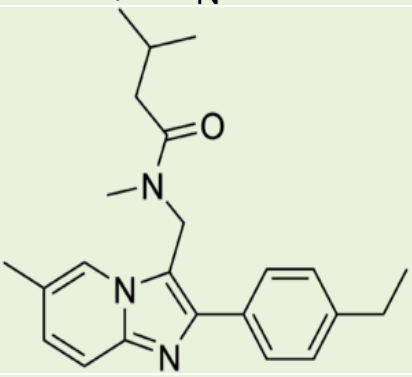
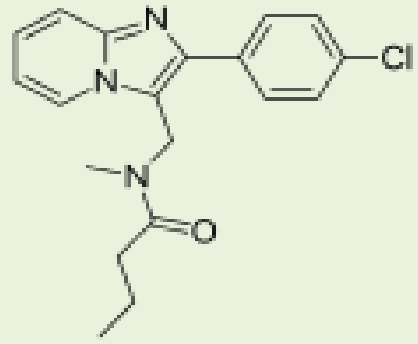
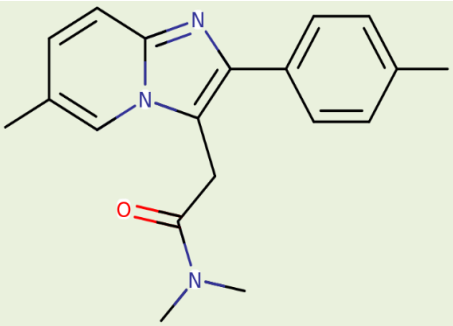
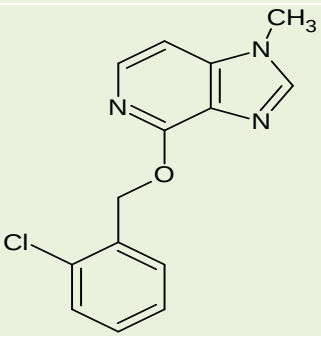
Sr. No.	Drug	Structure	IUPAC Name	Molecular wt.	Solubility
1	Etoricoxib		2-(6-chloro-2-(4-chlorophenyl) imidazole [1,2-a] pyridin-3-yl)-N, N-dipropylacetamide	404.1 g/mol	Slightly soluble in MeOH, Chloroform,
2	Celecoxib		N-[[2-(4-ethylphenyl)-6-methylimidazole [1,2-a] pyridin-3-yl] methyl]-N-3-dimethylbutanamide	363.5 g/mol	Slightly soluble in Chloroform, MeOH.
3	Firocoxib		N-[[2-(4-chlorophenyl) imidazole [1,2-a] pyridine-3-yl] methyl]-N-methyl butanamide	341.8 g/mol	Very Soluble in Dimethyl Sulfoxide
4	Cimicoxib		N, N-Dimethyl-2-[6-methyl-2- (4-methylphenyl) imidazole [1,2-a] pyridin-3-yl] acetamide	307.4 g/mol	Sparingly soluble in MeOH, Slightly soluble in H_2O
5	Robenacoxib		4-[(2 chlorophenyl) methoxy]-1-methyl imidazole [4,5-c] pyridine	273.71 g/mol	Very Soluble in Dimethyl Sulfoxide

Table 2: Summary of methods related to HPLC technique.

Sl. No.	Stationary Phase (Column)	Mobile Phase (with ratio)	pH	Wave length	Flow Rate	Reference
1	RP-18	Mixture of Ammonium acetate buffer & methanol (30:70, v/v)	5.0	243nm	0.5mL/min	2
2	C18 column (250×4.6mm i.d.,5µm)	Mixture of Isocratic mode Methanol & acetonitrile (50:50, v/v)	---	293nm	1.0 mL/min	3
3	C18 column	Mixture of Acetonitrile-ammonium acetate (60:40 v/v)	8.0	245nm	1.0 mL/min	4
4	C18 column (100×3.9mm)	Mixture of Acetonitrile-sodium dihydrogen phosphate (35:65 v/v)	7.0	245nm	2.5 mL/min	5
5	C18 column	Mixture of Acetonitrile-monopotassium phosphate (40:60 v/v)	3.5±0.1	245nm	1.2 mL/min	6
6	Silica-gel 6- F254	Mixture of Ethyl acetate-methanol-ammonia solution (8.5:2.0:1.0, v/v/v)	---	254nm	0.78 mL/min	7
7	Silica gel 60 F254 plates	Mixture of Toluene-n-butanol-glacial acetic acid-water (1:4:2:2 v/v/v/v)	---	254nm	0.59±0.01 mL/min	8
8	C18 reversed phase column	Mixture of Acetonitrile-potassium dihydrogen phosphate (50:50 v/v)	7.0	254 & 390nm	1.5 mL/min	9
9	Reversed phase Kromasil C18 column (150mm & 5µm)	Mixture of Acetonitrile-ammonium acetate	8.0	---	1.0 mL/min	10
10	I.D. RP OD-5-100 C18 column (2.1 mm; 5µ m)	Mixture of Methanol-acetonitrile-tetrabutylammonium phosphate (13:10:77 v/v/v)	2.0	240nm	0.07 mL/min	11

Table 3: Summary of analysis of Celecoxib by UV-Spectroscopy methods

SL. No.	Drug	Method	Description	Reference
1	Determination of Celecoxib Tartrate in pharmaceutical dosage form	Spectrophotometric method	Detection wavelength: 230.95nm-254,25nm in phosphate buffer & 231.07nm-254.76 nm in borate buffer Linearity range: 1-30 µg/ml Co-relation Co-efficient: 0.9999 in phosphate buffer and 0.999 in borate buffer % Recovery range: 99.7-99.88 & 99.46-99.91 %RSD: <2%	12
2	Determination of Celecoxib Tartrate in pure and pharmaceutical formulations	New RP-HPLC method	Detection wavelength:300nm Linearity range:20-60 µg/ml Co-relation Co-efficient:0.999 % Recovery range: 98.90-100.87 %RSD: 0.14%(intra-day), 0.18%(inter-day), 0.46% (intra-day)	13

Quality By Design

For pharmaceuticals, several analytical methods are available to enhance the quality.[14-19] But currently, the Quality by Design technique is widely used to improve the analytical method. For the development and production of pharmaceuticals, quality by design (QbD), which is covered in ICH Q81, Q9, and Q2, is well-established.[20]

Benefits of Quality

By Design Method It supports the growth of a reliable methodology. Variability sources can be better controlled according to the design setup. Method When a method is transferred from the quality control department to the research level, the success of the transfer is higher. Through ongoing improvement throughout the lifecycle, this technique creates a space for the development of new techniques.[21]

CONCLUSION

This review depicts the analysis methods; developed for determination of Celecoxib. According to this review it was concluded that for Celecoxib different analytical methods are available for a single component as well as in combination and it was also found that mobile phase of acetonitrile was common for most of the chromatographic methods. For the most spectroscopic methods common solvent id methanol. All of the methods were discovered to be concise, precise, cost-effective, and repeatable.

REFERENCES

1. Jena D, Behera SR, Chintapalli GS, Kumar S, Mishra K, An Overview of Analytical and Bioanalytical Methods for Estimation of Cefaclor Alone and in the form of a Mixed Dosage, Asian Journal of Research in Chemistry and Pharmaceutical Sciences, 2022; 10(3): 172-178.
2. Kalkotwar RS, Vairal PS, Application of Quality by Design Approach for development and Validation of Analytical RP-HPLC Method for Celecoxib in Bulk and Marketed formulation, World Journal of Pharmacy and Pharmaceutical Sciences, 2017; 6(8): 1211-1222.
3. Nagamani P, Manjunath SY, Hemant Kumar T, Development and Validation of RP-HPLC Method for Estimation of Amlodipine Besylate and Celecoxib in Pharmaceutical Formulation, Journal of Drug Delivery and Therapeutics, 2020; 10 (6):31-36.
4. Krishnaveni G, Sathyannaryana PVV, A Novel RP-HPLC method for the Quantification of Celecoxib in Formulations, Research Journal of Pharmaceutical, Biological and Chemical Sciences, 2012; 3(1): 340-346.
5. Patel SNB, Patel BR, Sharda, Analytical Method Development and Validation of Stability Indicating RP-HPLC Method For Estimation of Amlodipine Besylate and Celecoxib in Synthetic Mixture, International journal of advanced Research, 2019; 7(3): 1066-1075.
6. Baboota S, Faiyaz S, Ahuja A, Ali J, Shafiq S, Ahmad S, Development and Validation of a Stability-Indicating HPLC Method for Analysis of Celecoxib (CXB) in Bulk Drug and Microemulsion Formulations, Acta Chromatographica, 2007; 18: 116-129.
7. Tadikonda YK, Dhanalakshmi M,RP-HPLC Method Development and Validation of Rofecoxib in Bulk and Dosage Form, International Journal of Advances in Pharmacy and Biotechnology, 2019; 5(2): 1-5.
8. Bapatu HR, Maram RK, Murthy RS, Stability-Indicating HPLC Method for Quantification of Celecoxib and Diacerein Along with Its Impurities in Capsule Dosage Form, Journal of Chromatographic Science, 2015; 53: 144-153.
9. Nekkala K, Kumar VSJ, Ramachandran D, Ramanaiah G, Development and Validation of Stability Indicating RP-LC Method for Estimation of Celecoxib (CXB) in Microemulsion Capsule Formulations, Journal of Chemical and Pharmaceutical Research, 2015; 7(7): 766-774.
10. Jadhav PS, Jamkar PM, Avachat AM, Stability Indicating Method Development and Validation for Simultaneous Estimation of Atorvastatin Calcium and Celecoxib in Bulk and Niosomal Formulation by RP-HPLC, Brazilian Journal of Pharmaceutical Sciences, 2015;51(3):653-661.
11. Chandana OSS, Ravichandra babu R, Assay Method Development and Validation for Celecoxib Dosage Forms by High Performance Liquid Chromatography, Research Journal of Pharmacy & Technology, 2017;9 (11):1951-1956.
12. Mishra K, Behera SR, Tripathy S, Biswal BR, Sankar CG, Analytical Techniques for the Estimation of Celecoxib in Capsule Dosage form by Spectrophotometric Method, International Journal of Pharmaceutical Research and Development, 2021;3(1):18-21.
13. Sharma T, Solanki NS, Statistical Assurance of Process Validation and Analytical Method Validation of Celecoxib Capsules, International Journal of Current Pharmaceutical Research, 2012;4(1): 80-83.
14. Pathak DS, Pradhan PK, Meshram DB, Patel HA, UV Spectroscopic Method for Simultaneous Estimation of Celecoxib and Amlodipine, Pharmawave, 2017; 10: 48-55.
15. Mishra K, Saragi B, Burala KK, Simultaneous Estimation of Sertraline and Alprazolam in its Bulk and Tablet Dosage form by RP-HPLC Method, Asian Pacific Journal of Pharmacy and Phytochemistry, 2016; 1(1): 25-32.
16. Mishra K, Prasanna KD, Behera SR, Simultaneous Estimation of Sacubitril and Valsartan bin Bulk and Pharmaceutical Dosage Form by Using RP-HPLC, Research Journal of Pharmacy and Life Sciences, 2020; 1(2): 25-32.
17. Balamurugan K, Mishra K, Suresh R, Simultaneous Estimation of Linagliptin and Metformin HCL in Human

Plasma by RP-HPLC Method, International Research Journal of Pharmacy, 2019; 10(1): 01-04.

18. Mishra K, Behera SR, Mishra SR, Somesu M, Kumar BK, A Validated Stability Indicating RP-HPLC Method Development for Platelet Aggregation Inhibitor Ticagrelor in Bulk and Tablet Formulation, Journal of Global Pharma Technology, 2019; 11(12): 12-18.
19. Mishra K, Kumar BK, Kumari MM, Subrahmanyam BSS, New Analytical Method Development and Validation of Chlorpheniramine Maleate by Using UV Visible Spectrophotometry, Indo American Journal of Pharmaceutical Sciences, 2016; 3(7): 767-772.
20. Mishra K, Behera SR, Sankar CG, Martha SK, Development and Validation of Stability Indicating Assay Method (SIAM) for Rabeprazole in Rabeprazole Sodium Delayed Release Tablets Using HPLC, Research Journal of Pharmacy and Life Sciences, 2020; 1(3): 89-97.
21. Sun L, Zhang W, Liu X, Sun J, Preparation and Evaluation of Sustained Release Azithromycin Tablets *in Vitro* and *in Vivo*, Asian Journal of Pharmaceutical Sciences, 2014; 9(3): 155-161.

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