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Stability-indicating RP-HPLC method for simultaneous quantitation of tramadol and aceclofenac in presence of their major degradation products: Method development and validation (Article)

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Abstract

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Primary objective of this study was to develop a stability-indicating reverse-phase high-performance liquid chromatography (HPLC) method for simultaneous quantitation of tramadol and aceclofenac in presence of their degradation products. The drugs were subjected to various International Conference on Harmonization recommended stress conditions, such as acid hydrolysis, alkaline hydrolysis, peroxide oxidation, thermolysis, and photolysis. The major degradation products got well resoluted from the analytes in HPLC analysis with a mobile phase composed of a mixture of 0.01 M ammonium acetate buffer (pH 6.5) and acetonitrile (65:35, v/v) through a Phenomenex Gemini C18 (250 mm × 4.6 mm, 5 µm particle size) column. The method was linear over a range of 15–60 µg/mL for tramadol and 40–160 µg/mL for aceclofenac concentration. The analytes were detected at a wavelength of 270 nm. The method was validated and found to be specific, accurate, precise, stable, and robust for its intended use. The method can be recommended for its future use in routine quality control, accelerated and real-time stability analysis of the formulations containing tramadol and aceclofenac combination. © 2017 Taylor & Francis.

Reaxys Database Information

View Compounds

Author keywords

Aceclofenac forced degradation HPLC stability-indicating method tramadol validation

Indexed keywords

Engineering controlled terms: Alkalinity Chromatography Degradation High performance liquid chromatography Hydrolysis Liquid chromatography Particle size Particle size analysis Photolysis Stability

Compendex keywords: Aceclofenac Forced degradation HPLC Stability indicating method Tramadol validation

Engineering main heading: Quality control

EMTREE drug terms: aceclofenac acetic acid acetonitrile ammonium acetate buffer peroxide tramadol triethylamine

EMTREE medical terms: accuracy Article chemical reaction drug degradation hydrolysis limit of detection limit of quantitation oxidation particle size pH photolysis process development quantitative analysis reversed phase high performance liquid chromatography software thermolysis validation study

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Chemicals and CAS Registry Numbers:

aceclofenac, 89796-99-6; acetic acid, 127-08-2, 127-09-3, 64-19-7, 71-50-1; acetonitrile, 75-05-8; ammonium acetate, 631-61-8; peroxide, 14915-07-2; tramadol, 27203-92-5, 36282-47-0; triethylamine, 121-44-8

Device tradename:

Gemini C18, Phenomenex, Spinchrom software

Manufacturers:

Drug manufacturer:

Intas, India

Device manufacturer:

Phenomenex;

Shimadzu, Japan

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	International Islamic University Malaysia	IIUM	See opportunities by IIUM

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1 Sawant, S., Ghante, M.
A Validated Stability Indicating RP-HPLC Method for Simvastatin, Identification and Characterization of Forced Degradation Products of Simvastatin using LC-ESI-MS/MS
(2015) *Adv. Anal. Chem.*, 5, pp. 8-16. Cited 3 times.

2 Blessy, M., Patel, R.D., Prajapati, P.N., Agrawal, Y.K.
Development of forced degradation and stability indicating studies of drugs - A review
(2014) *Journal of Pharmaceutical Analysis*, 4 (3), pp. 159-165. Cited 123 times.
doi: 10.1016/j.jpha.2013.09.003
View at Publisher

3 (2003)
ICH guidelines, November, 25

4 Baertschi, S.W., Alsante, K.M., Tønnesen, H.H.
A critical assessment of the ICH guideline on photostability testing of new drug substances and products (Q1B): Recommendation for revision

(2010) *Journal of Pharmaceutical Sciences*, 99 (7), pp. 2934-2940. Cited 34 times.
http://www3.interscience.wiley.com/cgi-bin/fulltext/123274955/PDFSTART
doi: 10.1002/jps.22076

View at Publisher

5 (2003) *Regul. EMA*
EMA-stability, December, 1–18

6 Stability Guidelines
(1998) *Cent. Drug Eval. Res.*, 22, pp. 1-30.
FDA

7 Guidance for Industry
(2015) *Cent. Drug Eval. Res.*, pp. 1-15.
FDA, July

8 Chakole, R.D., Charde, M.S., Kumar, J., Welankiwar, A.S.
Review: Development of Forced Degradation Studies of Drugs
(2013) *Int. J. Adv. Pharm.*, 2, pp. 34-39. Cited 9 times.

9 Srinivasulu, K., Naidu, M.N., Rajasekhar, K., Veerender, M., Suryanarayana, M.V.
Development and Validation of a Stability Indicating LC Method for the Assay and Related Substances Determination of a Proteasome Inhibitor Bortezomib
(2012) *Chromatogr. Res. Int.*, 2012, pp. 1-13. Cited 3 times.

10 Bakshi, M., Singh, S.
Development of validated stability-indicating assay methods - Critical review

(2002) *Journal of Pharmaceutical and Biomedical Analysis*, 28 (6), pp. 1011-1040. Cited 460 times.
doi: 10.1016/S0731-7085(02)00047-X

View at Publisher

11 Qiu, F., Norwood, D.L.
Identification of pharmaceutical impurities

(2007) *Journal of Liquid Chromatography and Related Technologies*, 30 (5-7), pp. 877-935. Cited 62 times.
doi: 10.1080/10826070701191151

View at Publisher

12 Keskinbora, K., Aydinli, I.
An atypical opioid analgesic: Tramadol

(2006) *Agri*, 18 (1), pp. 5-19. Cited 22 times.

13 Glavanović, S., Glavanović, M., Tomišić, V.

Simultaneous quantitative determination of paracetamol and tramadol in tablet formulation using UV spectrophotometry and chemometric methods

(2016) *Spectrochimica Acta - Part A: Molecular and Biomolecular Spectroscopy*, 157, pp. 258-264. Cited 8 times.
doi: 10.1016/j.saa.2015.12.020

View at Publisher

14 Subrahmanyam, V., Renwick, A.B., Walters, D.G., Young, P.J., Price, R.J., Tonelli, A.P., Lake, B.G.

Identification of cytochrome P-450 isoforms responsible for cis-tramadol metabolism in human liver microsomes

(2001) *Drug Metabolism and Disposition*, 29 (8), pp. 1146-1155. Cited 140 times.

View at Publisher

15 Perez, T.E., Mealey, K.L., Grubb, T.L., Greene, S.A., Court, M.H.
Tramadol Metabolism to O-desmethyl Tramadol (M1) and N-desmethyl Tramadol (M2) by Dog Liver Microsomes: Species Comparison and Identification of Responsible Canine Cytochrome P-450s (CYPs)
(2016) *Drug Metab. Dispos.*, 44, pp. 1963-1972. Cited 4 times.

16 Overholser, B.R., Foster, D.R.

Opioid pharmacokinetic drug-drug interactions.

(2011) *The American journal of managed care*, 17 Suppl 11, pp. S276-287. Cited 46 times.

17 Smith, H.S.

Opioid metabolism

(2009) *Mayo Clinic Proceedings*, 84 (7), pp. 613-624. Cited 243 times.
http://www.mayoclinicproceedings.com/content/84/7/613.full.pdf+html
doi: 10.4065/84.7.613

View at Publisher

18 Ravisankar, P., Rao, G.D., Saibabu, S., Devadasu, C., Babu, P.S., Sricharitha, P., Kumar, K.V.S.S.
Development and Validation of a Reverse Phase HPLC Method for the Determination of Aceclofenac in Bulk and Pharmaceutical Dosage Forms
(2013) *Int. J. Res. Pharm. Chem.*, 3, pp. 483-494. Cited 2 times.

19 Chandra, P., Rathore, A.S., Lohidasan, S., Mahadik, K.R.

Application of HPLC for the simultaneous determination of aceclofenac, paracetamol and tramadol hydrochloride in pharmaceutical dosage form

(2012) *Scientia Pharmaceutica*, 80 (2), pp. 337-351. Cited 14 times.
http://www.scipharm.at/download.asp?id=1133
doi: 10.3797/scipharm.1108-04

View at Publisher

20 Pavithra, P., Dhanraj, M., Sekhar, P.

Analgesic effectiveness of Ibuprofen and Aceclofenac in the management of acute pulpitis - A randomized double blind trial

(2015) *International Journal of Pharmaceutical Sciences Review and Research*, 35 (2), pp. 70-74.
http://globalresearchonline.net/journalcontents/v35-2/14.pdf

21 Cho, H., Walker, A., Williams, J., Hasty, K.A., Shuang, Y.
Study of osteoarthritis treatment with anti-inflammatory drugs: Cyclooxygenase-2 inhibitor and steroids

(2015) *BioMed Research International*, 2015, art. no. 595273. Cited 11 times.
http://www.hindawi.com/journals/biomed/
doi: 10.1155/2015/595273

View at Publisher

22 Vinay, K.B., Revanasiddappa, H.D., Xavier, C.M., Ramesh, P.J., Raghu, M.S.
Stability Indicating UPLC Method for the Determination of Tramadol Hydrochloride: Application to Pharmaceutical Analysis
(2012) *Chromatogr. Res. Int.*, 2012, pp. 1-9. Cited 2 times.

23 Kamble, R.M., Singh, S.G.
Stability-indicating RP-HPLC method for analysis of paracetamol and tramadol in a pharmaceutical dosage form

(2012) *E-Journal of Chemistry*, 9 (3), pp. 1347-1356. Cited 13 times.
doi: 10.1155/2012/732506

View at Publisher

24 Karunakaran, K., Navaneethan, G., Elango, K.P.
Development and validation of a stability-indicating RP-HPLC method for simultaneous determination of paracetamol, tramadol HCL and domperidone in a combined dosage form

(2012) *Tropical Journal of Pharmaceutical Research*, 11 (1), pp. 99-106. Cited 10 times.
http://www.tjpr.org/vol11_no1/2012_11_1_13_Karunakaran.pdf
doi: 10.4314/tjpr.v11i1.13

View at Publisher

25 Azhlwar, S., Ravi, T.K.
Stability indicating HPLC method for simultaneous determination of drotaverine and aceclofenac

(2011) *International Journal of Pharmacy and Pharmaceutical Sciences*, 3 (1), pp. 245-250. Cited 9 times.
http://www.ijppsjournal.com/Vol3Issue1/1056.pdf

26 Hossain, M.F., Bhadra, S., Kumar, U., Rouf, A.S.S.
The ICH guidance in practice: Stress degradation studies on aceclofenac and development of a validated stability-indicating reversed-phase HPLC assay in tablet dosage form

(2013) *Der Pharma Chemica*, 5 (4), pp. 131-146.
http://derpharmachemica.com/vol5-iss4/DPC-2013-5-4-131-146.pdf

27 Bhinge, J.R., Kumar, R.V., Sinha, V.R.
A simple and sensitive stability-indicating RP-HPLC assay method for the determination of aceclofenac

(2008) *Journal of Chromatographic Science*, 46 (5), pp. 440-444. Cited 36 times.
http://docstore.ingenta.com/cgi-bin/ds_deliver/1/u/d/ISIS/44139192.1/pres/jcs/2008/00000046/00000005/art00014/7F94F25B56840E1C121039793109D95A41376C60FB.pdf?link=http://www.ingentaconnect.com/error/delivery&format=pdf
doi: 10.1093/chromsci/46.5.440

View at Publisher

28 (2003) *Int. Conf. Harmon.*
ICH., February, 24

29 (2006) *ICH Harmon. Tripart. Guidel.*
International Conference on Harmonisation B, June, 12

30 (1996) *Int. Conf. Harmon. Tech. Requir. Regist. Tripart. Guidel.*
ICH., November, 13

31 (1995) *Food Drug Adm.*, pp. 1-9.
U.S. Food and Drug Administration/Center for Biologics Evaluation and Research, March

32 (2005) *Int. Conf. Harmon.*, 1994, p. 17.
ICH

33 Bakshi, M., Singh, S.
Development of validated stability-indicating assay methods - Critical review

(2002) *Journal of Pharmaceutical and Biomedical Analysis*, 28 (6), pp. 1011-1040. Cited 460 times.
doi: 10.1016/S0731-7085(02)00047-X

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34 Rawat, T., Pandey, I.P.
Forced degradation studies for drug substances and drug products- scientific and regulatory considerations

(2015) *Journal of Pharmaceutical Sciences and Research*, 7 (5), pp. 238-241. Cited 4 times.
http://www.jpsr.pharmainfo.in/Documents/Volumes/vol7Issue05/jpsr07051501.pdf

35 Sehrawat, R., Maithani, M., Singh, R.
Regulatory aspects in development of stability-indicating methods: A review

(2010) *Chromatographia*, 72 (1-2), pp. 1-6. Cited 15 times.
doi: 10.1365/s10337-010-1612-z

View at Publisher

36 Ngwa, G.
Forced degradation as an integral part of HPLC stability-indicating method development

(2010) *Drug Delivery Technology*, 10 (5), pp. 56-59. Cited 23 times.
http://d-cdn.dashdigital.com/drugdelivery/201006/data/drugdeliverytech201006-dl.pdf?lm=1275458668000

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