

REFERENCES

- [1] International Conference on Harmonization (2000) Draft Revised Gui-dance On Impurities in New Drug Products. Federal Register Q3B(R) 65 (139): 44791.
- [2] International Conference on Harmonization: (1997) Impurities, Q3C- Guidelines for Residual Solvents, Q3C. Federal Register 62(247): 67377.
- [3] International Conference on Harmonization: (1999) Specifications, Q6A: Test Procedures and Acceptance Criterial for New Drug Substances and New Drug Products. Chemical substances 65 (146):67488.
- [4] S. Ahuja, S. Marcel Dekkar, Impurities Evaluation of Pharmaceuticals: (1998) 142.
- [5] S. Gorog, Identification and Determination of Impurities in Drugs, Elsevier Science Publishing Company, 4 (2000) 154.
- [6] K M. Alsante, T D. Hatajik, L. L. Lohr and T R. Sharp, Isolation and Identification of Process Related Impurities and Degradation Products from Pharmaceutical Drug Candidates, Part 1, American Pharmaceutical Review, 4 (2001) 70.
- [7] P. Bhat, V.S. Velingkar, Synthesis and Characterization of Degradation Products in Diclofenac-Na and Clotrimazole, Indian Drugs, 41 (2004) 396-400.
- [8] K.J. Volk, S.E. Hill, E.H. Kerns, M.S. Lee, Profiling degradants of paclitaxel using liquid chromatography-mass spectrometry and liquid chromatography-tandem mass spectrometry substructural techniques, J Chromatogr. B Biomed Sci Appl., 696 (1997) 99-115.
- [9] P. Jacobs, W. Dewe, A. Flament, M. Gibella, A.Ceccato, A new validation approach applied to the GC determination of impurities in organic solvents, J Pharm Biomed Anal., 40 (2005) 294-304.
- [10] Jack Yuk K Cheng, Man Fai Chan, Tai Wai Chan, Mei Yuen Hung, Impurity profiling of ecstasy tablets seized in Hong Kong by GC-MS, Forensic Sci Int., 162 (2006) 87-94.

- [11] P. Gimeno, F. Besacier, M. Bottex, L. Dujourdy, H. Chaudron-Thozet, A study of impurities in intermediates and 3,4-methylenedioxymethamphetamine (MDMA) samples produced via reductive amination routes, *Forensic Sci Int.*, 155 (2005) 141-157.
- [12] Food and Drug Administration for Immediate Release Consumer Media (1998) 888- Info- FDA. May 6, 45.
- [13] J. Roy, M. Mahmud, A. M. Sobhan., Aktheruzzaman, M. Al-Faoque and E. Ali, Marketed vitamin b-complex injectables: stability and mutual interaction, *Drug Dev Ind Pharm*, 20 (1994) 2157-2163.
- [14] S.L. Hoerle, K.D. Evans, B.G. Snider, HPLC Determination of Impurities in a 3rd Generation Cephalosporine, *Eastern Analytical Symposium*, 12 (1992).
- [15] M. Gazdag, M. Babjag, J. Brlik, S. Maho, Z. Tuba and S. Gorog, Estimation of impurity profiles of drugs and related materials Part 18. Impurities and degradation products of mazipredone, *J. Pharm Biomed Anal.*, 17 (1998) 1029-1036.
- [16] P. Skett, Low-level Measurement of Potent Toxins, in *Analysis of Drug Impurities*, R.S.A.M. Webb, Editor. 2007, Blackwell Publishing.
- [17] L. Muller, R.J. Mauthe, C.M. Riley, M.M. Andino, D. De Antonis, C. Beels, J. De George, A.G.M. De Knaep, D.J. Ellison, A. Fagerland, R. Frank, B. Fritschel, S. Gal-loway, E. Harpur, C.D.N. Humfrey, A.S. Jacks, N. Jagota, J. Mackinnon, G. Mohan, D.K. Ness, M.R. O'Donovan, M.D. Smith, G. Vudathala, L. Yotti, A rationale for determining, testing, and controlling specific impurities in pharmaceuticals that possess potential for genotoxicity, *Regul Toxicol Pharmacol.*, 44 (2006) 198-211.
- [18] www.fda.gov/cder
- [19] www.ich.org
- [20] Z.Y. Yuabova , D.R. Holschlag , S.A. Rodriguez , C. Qin , V.V. Papov, F. Qiu , J.F. McCaffrey , D.L. Norwood, Genotoxic Impurities: A Quantitative Approach”, *J. Liq. Chromatogr. Related Technol.*, 31(2008) 2318-2330.
- [21] S. Lindsay, High Performance Liquid Chromatography, ACOL Series (1992).
- [22] K. Robards, P.R. Haddad, and P.E. Jackson: Principles and Practice of Modern Chromatographic Methods, Academic Press (1994).

- [23] V.R. Meyer, Wiley, Chichester: Practical High Performance Liquid Chromatography (1994).
- [24] J.W. Dolan, L.R. Snyder, N.M. Djordjevic, D.W. Hill, T.J. Waeghe, Reversed-phase liquid chromatographic separation of complex samples by optimizing temperature and gradient time: I. Peak capacity limitations, *J. Chromatogr. A*, 857 (1999) 1–20.
- [25] J.W. Dolan, L.R. Snyder, N.M. Djordjevic, D.W. Hill, T.J. Waeghe, Reversed-phase liquid chromatographic separation of complex samples by optimizing temperature and gradient time: II. Two-run assay procedures, *J. Chromatogr. A*, 857 (1999) 21–39.
- [26] J.W. Dolan, L.R. Snyder, R.G. Wolcott, P. Haber, T. Baczer, R. aliszsan, L.C. Sander, Reversed-phase liquid chromatographic separation of complex samples by optimizing temperature and gradient time III. Improving the accuracy of computer simulation, *J. Chromatogr. A*, 857(1999) 41–68.
- [27] S. Chapman: Physical Review (1937) ; 10,184.
- [28] W. Paul & H. Steinwedel, Notizen: Ein neues Massenspektrometer ohne Magnetfeld, *Zeitschrift fur Naturforschung A*, 8 (1953) 448-450.
- [29] W. Paul, Electromagnetic Traps for Charged and Neutral Particles, *Agewandte Chemie - International Edition*, 29 (1990) 739-748.
- [30] W.C. Wiley & I.H. MacLaren, Time-of-Flight Mass Spectrometer with Improved Resolution, *The Review of Scientific Instruments*, 26 (1955) 1150-1157.
- [31] Wiza, Microchannel plate detectors, *Nucl. Instr. Meth.*, 162 (1979) 587- 601.
- [32] J.S. Becker, H.J. Dietze, Precise and accurate isotope ratio measurements by ICP-MS, *Fresenius J. Anal. Chem.*, 368 (2000) 23-30.
- [33] W.R. Leo, Techniques for Nuclear and Particle Physics Experiments Springer-Verlag (1987).
- [34] General Chapter 1225, Validation of compendial methods, United States Pharmacopeia 30, National Formulary 25, Rockville, Md., USA, The United States Pharmacopeial Convention, Inc: (2007).

- [35] U.S.FDA - Guidance for Industry (draft) Analytical Procedures and Methods Validation: Chemistry, Manufacturing and Controls and Documentation: (2000).
- [36] ISO/IEC 17025: General requirements for the competence of testing in calibration laboratories, (2005).
- [37] International Conference on Harmonization (ICH) of Technical Requirements for the Registration of Pharmaceuticals for Human Use, Validation of analytical procedures: Methodology, adopted in (1996), Geneva.
- [38] U.S. EPA, Guidance for methods development and methods validation for the Resource Conservation and Recovery Act (RCRA) Program, Washington, D.C. (1995)., <http://www.epa.gov/sw-846/pdfs/methdev.pdf>
- [39] General Chapter 1225, Validation of compendia methods, United States Pharmacopeia 30, National Formulary 25, Rockville, Md., USA, The United States Pharmacopeial Convention, Inc: (2007).
- [40] ICH “Draft guideline on validation of analytical procedures for pharmaceuticals; availability” Fed. Reg., 59 (40) (March, 1994) 9750.
- [41] Guidelines for Validation of Analytical Procedures, Q2 (R1), ICH, 1994.
- [42] S.R. Chitturi, Y.S. Somannavar, B.G. Peruri, S. Nallapati, H.K. Sharma, S.R. Budidet, V.K. Handa, H.B. Vurimindi, Gradient RP-HPLC method for the determination of potential impurities in atazanavir sulphate. *J Pharm Biomed Anal.*, 55 (2011) 31–47.
- [43] C.H. Bhirud, S.N. Hiremath, Stability indicating RP-HPLC method for the determination of Atazanavir sulphate in bulk and dosage form. *Drug Invent Today*, 5 (2013) 81–86.
- [44] S. Naazneen, A. Sridevi, Stability indicating RP- HPLC method for the simultaneous estimation of atazanavir and Cobicistat in bulk and tablet dosage form, *IOSR journal of pharmacy and Biological sciences*, 12 (2017) 61-68.
- [45] S. Dey, S.S. Patro, N.S. Babu, P.N. Murthy, S.K. Panda, Development and validation of a stability-indicating RP-HPLC method for estimation of atazanavir sulfate in bulk drug, *Journal of pharmaceutical Analysis*, 7 (2017) 134-140.

- [46] S.K. Konidala, K. Sujana, A.P. Rani, New validated RP-HPLC method for the determination of atazanavir sulphate in bulk and dosage form, *Der pharma chemica*, 4 (2012) 1305-1310.
- [47] K. Srinivasu, J.V. Rao, N.A. Raju, K. Mukkanti, A validated RP-HPLC method for the determination of atazanavir in pharmaceutical dosage form, *E-Journal of chemistry*, 8 (2011) 453-456.
- [48] D.S. Pawar, M. Dole, S. Sawant, J. Salunke, Development and validation of RP-HPLC method for the simultaneous estimation of atazanavir sulphate and ritonavir in bulk and formulations, *Int J Pharm Pharm sci.*, 5 (2013) 905-909.
- [49] U.P. Panigrahy, A.S. Kumar Reddy, A novel validated RP-HPLC method for the simultaneous estimation of atazanavir sulphate and Cobicistat in bulk and pharmaceutical dosage form, *Int. J. Pharm. Sci. Rev. Res.*, 36 (2016) 82-89.
- [50] S. Kuppusamy, K. Karunakaran, A Thambichetty, D Manasa, K Bhargavi, V Kagitala, Sridhankiran, Development and validation of HPTLC method for the estimation of atazanavir sulphate in bulk drugs, combined dosage form, *Int. J. Pharm. Sci. Rev. Res.*, 25 (2014) 217-220.
- [51] P. Anupama, A. Viswanath, P.S. Babu, R. Sasidhar, Development of novel and simple analytical method for the estimation of atazanavir sulphate in pharmaceutical formulation by RP-HPLC, *International journal of research in pharmacy and chemistry*, 3 (2013) 645-649.
- [52] D.A. Patel, B.N. Patel, C.N. Patel, Spectrophotometric method for simultaneous estimation of atazanavir sulphate and ritonavir in tablet dosage form, *Drug Dev Ther.*, 6 (2015) 1-4.
- [53] C. Divya, A. Ajitha, T.R. Mohana Reddy, V.U. Rao, Method development and validation of atazanavir sulphate by various analytical techniques- a review, *Int J Pharm.*, 5 (2014) 1293-1296.
- [54] R. ter Heine, M Davids, H. Rosing, E.C.M. van Gorp, J.W. Mulder, Y.T.van der Heide, J.H. Beijnen, A.D.R. Huitema, Quantification of HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors in peripheral blood mononuclear cell lysate using liquid chromatography coupled with tandem mass spectrometry, *J. Chromatogr. B*, 877 (2009) 575–580.

- [55] R. ter Heine, H. Rosing, E.C.M. van Gorp, J.W. Mulder, W.A. van der Steeg, J.H. Beijnen, A.D.R. Huitema, Quantification of protease inhibitors and nonnucleoside reverse transcriptase inhibitors in dried blood spots by liquid chromatography–triple quadrupole mass spectrometry, *J. Chromatogr. B* 867 (2008) 205–212.
- [56] A. D'Avolio, M. Siccardi, M. Sciandra, B. Lorena, S. Bonora, L. Trentini, G. Di Perri, HPLC–MS method for the simultaneous quantification of the new HIV protease inhibitor darunavir, and 11 other antiretroviral agents in plasma of HIV-infected patients, *J. Chromatogr. B*, 859 (2007) 234–240.
- [57] L. Dickinson, L. Robinson, J. Tjia, S. Khoo, D. Back, Simultaneous determination of HIV protease inhibitors amprenavir, atazanavir, indinavir, lopinavir, nelfinavir, ritonavir, and saquinavir in human plasma by high-performance liquid chromatography–tandem mass spectrometry, *J. Chromatogr. B*, 829 (2005) 82–90.
- [58] T. Koal, H. Burhenne, R. Roemling, M. Svoboda, K. Resch, V. Kaever, Quantification of antiretroviral drugs in dried blood spot samples by means of liquid chromatography/tandem mass spectrometry, *Rapid Commun. Mass Spectrom.*, 19 (2005) 2995–3001.
- [59] S. Colombo, A. Beguin, A. Telenti, J. Biollaz, T. Buclin, B. Rochat, L.A. Decosterd, Intracellular measurements of anti-HIV drugs indinavir, amprenavir, saquinavir, ritonavir, nelfinavir, lopinavir, atazanavir, efavirenz and nevirapine in peripheral blood mononuclear cells by liquid chromatography coupled to tandem mass spectrometry, *J. Chromatogr. B*, 819 (2005) 259–276.
- [60] U. Seshachalam, D.V.L. Narasimha Rao, B. Haribabu, K.B. Chandrasekhar, Determination of atazanavir in the presence of its degradation products by a stability-indicating LC method, *Chromatographia*, 65 (2007) 355–358.
- [61] K.G. Bhavani, K.B.M. Krishna, N. Srinivasu, D. Ramachandran, N.V.V.S.S. Raman, B.H. Babu, Determination of genotoxic impurity in atazanavir sulphate drug substance by LC-MS. *J Pharm Biomed Anal.*, 132 (2017) 156–158.

- [62] V. K. Chakravarthy, D. G. Sankar, Development and validation of RP-HPLC method for estimation of erlotinib in bulk and its pharmaceuticals formulations, *Rasayan Journal of Chemistry*. 4 (2011) 393-399.
- [63] K. Ravi Kumar, K. Sankara Babu, C.H. Nagabhushanam, A validated LC method for the estimation of erlotinib hydrochloride in bulk and tablet dosage form, *International Journal of Pharmacy and Biomedical Research*. 4 (2013) 01–04.
- [64] S. T. Latha, S. Ananda Thangadurai, M. Jambulingam, K. Sereya, D. Kamalakkannan, M. Anilkumar, Development and validation of RP-HPLC method for the estimation of erlotinib in pharmaceutical formulation, *Arabian Journal of Chemistry*, 4 (2013) 55-66.
- [65] S.S. Pujeri, A.M.A. Khader, J.Seetharamappa, Validated stability-indicating chromatographic method for the assay of erlotinib active pharmaceutical ingredient, *Anal. Lett.*, 42 (2011) 1855–1867.
- [66] C. Karunakara, U. Aparna, V. Chandregowda, C.G. Reddy, Separation and determination of process-related impurities of erlotinib using reverse-phase HPLC with a photo-diode array detector, *Anal. Sci.*, 28 (2012) 305–308.
- [67] G.S.S. Geetha, J. Raveendra Reddy, P. Ramalingam, P. Malleshwari, Validated RP-HPLC method for determination of erlotinib HCl in tablet dosage forms and its application to stress degradation studies, *Am. J. Pharm. Tech. Res.*, 2 (2012) 842–852.
- [68] L. Faivre, C. Gomo, O. Mir, F. Taieb, A. Schoemann-Thomas, S. Ropert, A simple HPLC-UV method for the simultaneous quantification of gefitinib and erlotinib in human plasma, *J. Chromatogr. B.*, 879 (2011) 2345–2350.
- [69] Y.A. Hou, L.M. Wei, D.T. Zhang, J. Zhang, D.W. Yang, Determination of erlotinib in rat plasma by HPLC and application to a pharmacokinetic study, *Lat. Am. J. Pharm.*, 34 (2015) 980-984.
- [70] B. Soheila, D. Adeleh, V. Hadi, K. Arash, Z. M. Parvin, Development and application of an HPLC method for erlotinib protein binding studies, *Adv. Pharm. Bull.*, 3 (2013) 289–293.

- [71] B. Mohammed Ishaq, V.S. Thiruvengada Rajan, S. Angala Parameswari, N. Amruth, M. Madhu, C. Madhusudana Chetty, Analytical method development and validation of erlotinib by high performance liquid chromatography, Research J. Pharm. and Tech, 4 (2011)1787-1790.
- [72] Y. Zheng, A. Thomas-Schumann, L. Sakji, P. Boudou-Rouquette, N. Dupin, L. Mortier, M. Vidal, F. Goldwasser, B. Blanchet, An HPLC-UV method for the simultaneous quantification of vemurafenib and erlotinib in plasma from cancer patients, J. Chromatogr. B Analyt. Technol. Biomed. Life Sci., 928 (2013) 93-37.
- [73] G. Naveen Kumar Reddy, V.V.S. Rajendra Prasad, P.K. Maharana, Development and validation of a stability indicating uplc method for determination of erlotinib in pharmaceutical formulations, Der Pharma Chemica, 4 (2012) 2288-2297.
- [74] M. Padmalatha, S. Kulsum, C. Rahul, D. Thimma Reddy, G. Vidyasagar, Spectrophotometric methods for the determination of erlotinib in pure and pharmaceutical dosage forms, International Journal Pharmaceutical Research and Development, 3 (2011) 53-59.
- [75] V. Rajesh, V. Jagathi, K. Sinduri, G. Devala Rao, Spectrofluorimetric method for the estimation of erlotinib hydrochloride in pure and pharmaceutical formulations, Electronic Journal of Chemistry., 8(S1) (2011) S304-S308.
- [76] B. Mandal, P. Balabathula, N. Mittal, G.C. Wood, H. Bhattacharjee, Development and validation of a spectrofluorimetric method for the determination of erlotinib in spiked human plasma, J Fluoresc., 22 (2012) 1425-1429.
- [77] A.V. Raju, N. Appalaraju, Development and validation of a LC-MS/MS method for the determination of erlotinib in Sprague dawley rat serum and its application to pharmacokinetic study, Am. J. Phytomed. Clin. Ther., 1 (2013) 83–97.

- [78] R.S.T. Satheeshmanikandan, K. Varanasi, S. Veeraraghavan, A. Rambabu, S. Chennupati, M. Rajamanickam, V. Swaroop, K. Mukkanti, Simultaneous determination of celecoxib, erlotinib, and its metabolite desmethyl-erlotinib (OSI-420) in rat plasma by liquid chromatography/tandem mass spectrometry with positive/negative ion-switching electro spray ionisation, *Sci Pharm.*, 80 (2012) 633–646.
- [79] A. Chahbouni, J.C. Den Burger, R.M. Vos, A. Sinjewel, A.J. Wilhelm, Simultaneous quantification of erlotinib, gefitinib, and imatinib in human plasma by liquid chromatography tandem mass spectrometry, *Ther. Drug Monit.*, 31 (2009) 683–687.
- [80] R.M. Andrea, J.S. Christopher, R.J. David, The quantification of erlotinib (OSI-774) and OSI-420 in human plasma by liquid chromatography - Tandem mass spectrometry, *J. Chromatogr. B*, 848 (2207) 379–383.
- [81] A.A. Mahajan, P.B. Miniyar, A.S. Patil, R.U. Waghmare, J.J. Patil, K. Mohanraj, R.N. Tiwari, Separation, identification, and characterization of degradation products of erlotinib hydrochloride under ICH-recommended stress conditions by LC, LC-MS/TOF, *Journal of Liquid Chromatography and Related Technologies*, 38 (2015) 629-639.
- [82] H. Zhang, L.M. Shi, W.Q. Chen, F.M. Shang, C.H. Mo, X.M. Wang, Validated LC-MS/MS method for the determination of Erlotinib in rat plasma, *Lat. Am. J. Pharm.*, 34 (2015) 1293-1297.
- [83] L. Narasimharao, K.N. Devanna, K.V.N. Suresh Reddy, Method development and validation study for quantitative determination of 3-ethynylaniline content in erlotinib by liquid chromatography-tandem mass spectrometry, *Indian journal of advances in chemical sciences*, 4 (2016) 208-213.
- [84] J. Kumar Raja, V. D. Sundar, A. R Magesh, S. Nandha Kumar and M. D. Dhanaraju, Validated spectrometric estimation of Imatinib mesylate in pure and tablet dosage form, *International journal of pharmacy and technology*, 2 (2010) 490-495.

- [85] K. Ramakrishna, N.V.V.S.S. Raman, K.M.V. Narayana Rao, A.V.S.S. Prasad, K. Subhaschandar Reddy, Development and validation of GC-MS method for the determination of methyl methanesulfonate and ethyl methanesulfonate in imatinib mesylate, *Journal of pharmaceutical and biomedical analysis*, 46 (2008) 780-783.
- [86] Vaibhav Bhatt, G. Prasad, H. Bhatt, A. Sharma, Quantification of potential genotoxic impurity in imatinib mesylate by LC-MS/MS, *Acta Chim. Pharm. Indica.*, 3 (2013) 182-191.
- [87] Veera Reddy Arava, M.R. Bethi, K.R. Cherukuri, G. Thota, S.R. Cherukupalli, LC-MS/MS method for determination of potential genotoxic impurities in imatinib mesylate, *Der Pharma chemica*, 5 (2013) 47-52.
- [88] M.S. Wajurkar, M.N. Dole, S.D. Saawant, Development and validation of analytical methods for estimation of imatinib mesylate in bulk and solid dosage forms by UV spectroscopy, *Der Pharmacia Lettre*, 7 (2015) 214-220.
- [89] S. Naga Sindhu, Y. Srinivasa Rao, T. Hemanth kumar, K. Vara Prasad Rao, Method development and validation of RP-HPLC method for estimation of imatinib mesylate in pure and pharmaceutical dosage form, *Der Pharmacia Lettre*, 7 (2015) 33-38.
- [90] P. Ravisankar, A. Niharica, K. Anusha Rani, S.M. Neeha, G. Pavan, Development and validation of RP-HPLC method for quantitative determination of imatinib mesylate in bulk drug and pharmaceutical dosage form, *Der Pharmacia Lettre*, 7 (2015) 102-112.
- [91] Arun Kumar Kuna, Ganapaty Seru, Gadela Venkata Radha, Analytical method development and validation for the estimation of imatinib mesylate and its dimer impurity in pharmaceutical formulation by RP-HPLC, *Asian journal of pharmaceutical and clinical research*, 11 (2018) 136-139.
- [92] U. Elżbieta, Stolarczyk, Kamil Eksanow & Katarzyna Filip, Determination of three potential genotoxic impurities in imatinib mesylate by Gas chromatography—mass spectrometry, *Analytical Letters*, 49 (2016) 2337-2346.

- [93] Esen Bellur Atici, Bekir Karlı̇ga, Quantitative determination of two polymorphic forms of imatinib mesylate in a drug substance and tablet formulation by X-ray powder diffraction, differential scanning calorimetry and attenuated total reflectance Fourier transform infrared spectroscopy, Journal of pharmaceutical and Biomedical analysis, 114 (2015) 330-340.
- [94] Mao-Wei Ni¹, Jie Zhou, Hui, Li¹, Wei Chen¹, Han-Zhou Mou¹, Zhi-Guo Zheng, Simultaneous determination of six tyrosine kinase inhibitors in human plasma usingHPLC-Q-Orbitrap mass spectrometry, Bioanalysis, 9 (2017) 925-935.
- [95] Pratik Shah, Nisha Shah, Rutesh Shah, Method development and validation of a stability indicating RP-HPLC method for assay determination of imatinib in imatinib mesylate tablets dosage form, International journal of pharmaceutical sciences and research, 6 (2015) 4453-4468.
- [96] P. Sandhya, P. Vishnu Priya, Shyamala, N. Anjali Devi, JVC. Sharma, Method development and validation of imatinib mesylate in pharmaceutical dosage form by RP-HPLC, World Journal of Pharmacy and Pharmaceutical Sciences, 3 (2013) 682-688.
- [97] D.N. Suresha, T. Pramila, C. Jose Gnana Babu, Method development and validation of imatinib mesylate in bulk and tablet dosage forms by using UV-spectrophotometric method, Imperial Journal of Interdisciplinary Research, 3 (2017) 1283-1287.
- [98] Ka Liong Tana, Ravindran Ankathilb, Siew Hua Ganb, Method development and validation for the simultaneous determination of imatinib mesylate and N-desmethyl imatinib using rapid resolution high performance liquid chromatography coupled with UV-detection, Journal of chromatography B, 879 (2011) 3583-3591.
- [99] Arun Kumar Kuna, Kuna Jagadeesh kumar, RP-HPLC method development and validation of imatinib mesylate in tablet dosage form, International journal of pharmacy and pharmaceutical sciences, 3 (2011) 162-165.
- [100] Shaik Munwar Pasha, R. Vani, RP-HPLC method development and validation for the estimation of imatinib mesylate and application to its dosage forms, Indo American Journal of Pharmaceutical Research, 5 (2015) 3140-3149.

- [101] Masatomo Miura, Naoto Takahashi, Ken-ichi Sawada, Quantitative determination of imatinib in human plasma with High-Performance Liquid Chromatography and Ultraviolet detection, *Journal of Chromatographic Science*, 49 (2011) 412-415.
- [102] Yunjing Zhang, Shuping Qiang, Zhi Yu, Weiwei Zhang, Zhongnan Xu, Lin Yang, Aidong Wen, Taijun Hang, LC-MS-MS Determination of Imatinib and N-Desmethyl Imatinib in Human Plasma, *Journal of Chromatographic Science*, 52 (2014) 344-350.
- [103] Senthamil Selvan Perumal, Sanmuga Priya Ekambaram, Samundeswari Raja, Analytical method development and validation of simultaneous estimation of rabeprazole, pantoprazole, and itopride by reverse-phase high-performance liquid chromatography, *Journal of food and drug analysis*, 22 (2014) 520-526.
- [104] Shinde Vaishali, Sarode Varsha, Kshirsagar Sandip, Jadhav Ashwini, Development and validation of UV spectrophotometric method for estimation of pantoprazole sodium in bulk and tablet dosage form, *CIBTech Journal of Pharmaceutical Sciences*, 5 (2016) 22-26.
- [105] Byendla Mahendar Amarnath, Medidi Srinivas, Method development and validation of RP-HPLC method for the simultaneous estimation of pantoprazole and ondansetron hydrochloride in bulk and in a synthetic mixture, *International Journal of PharmTech Research*, 6 (2014) 1794-1802.
- [106] Keyur B. Ahir, Dharti N. Solanki, Charmee B. Gandhi, Harsh S. Naik, Akshay S. Patel, Analytical method development and validation for simultaneous estimation of cinitapride and pantoprazole in pharmaceutical dosage form, *Der Pharma Chemica*, 6 (2014) 252-257.
- [107] N.V. Pimpodkar, R.S. Nalawade, B.S. Kuchekar, N.S. Mahajan, R.L. Jadhav, New spectrophotometric method for the estimation of pantoprazole in bulk and pharmaceutical formulation, *Int. J. Chem. Sci.*, 6(2008) 993-999.
- [108] G. Madhusudhan Reddy, B. Vijaya Bhaskar, P. Pratap Reddy, S. Ashok, P. Sudhakar, J. Moses Babu, K. Vyas, K. Mukkanti, Structural identification and characterization of potential impurities of pantoprazole sodium, *Journal of Pharmaceutical and Biomedical Analysis*, 45 (2007) 201–210.

- [109] R.B. Kakde, S.N. Gedam, N.K. Chadhary, A.G. Barsade, D.L. Kale, A.V. Kasture, Three-wavelength spectrophotometric method for simultaneous estimation of pantoprazole and domperidone in pharmaceutical preparations, International Journal of PharmTech Research, 1 (2009) 386-389.
- [110] V.V.S.S. Nanduri, K. Ratnakar Reddy, A.V.S.S. Prasad, K. Ramakrishna, Validated chromatographic methods for the determination of process related toxic impurities in pantoprazole sodium, J. Chromatogr., 68 (2008) 481-484.
- [111] N. Venugopal, A. Vijaya Bhaskar Reddy, K. Gangadhar Reddy, V. Madhavi, G. Madhavi, Method development and validation study for quantitative determination of 2-chloromethyl-3, 4-dimethoxy pyridine hydrochloride a genotoxic impurity in pantoprazole active pharmaceutical ingredient by LC-MS/MS, Journal of pharmaceutical and biomedical analysis, 70 (2012) 592-597.
- [112] Sravanthi Macharla, Ravindar Bairam, Mahesh Nasare, Analytical method development and validation of UV-spectrometric for estimation of cinitapride hydrogen tartrate & pantoprazole sodium in combined dosage form, J Pharm Res., 6 (2017) 47-51.
- [113] Balasekhara R. Challaa, Sai H.S. Boddu, Bahlul Z. Awen, Babu R. Chandu, Chandrasekhar K. Bannoth, Mukkanti Khagga, Kanchanamala Kanalae, Rihana P. Shaik, Development and validation of a sensitive bioanalytical method for the quantitative estimation of Pantoprazole in human plasma samples by LC-MS/MS: Application to bioequivalence study, Journal of Chromatography B, 878 (2010) 1499–1505.
- [114] Prasanna Reddy Battu, N. Kiran Kumar Reddy, Development and Validation of RP-HPLC for the Pantoprazole Sodium Sesquihydrate in pharmaceutical dosage forms and Human Plasma, International Journal of ChemTech Research, 1 (2009) 195-198.
- [115] Xiangjun QIU, Ren-ai XU, Yuancai ZHENG, Haichao ZHAN, Zhe WANG, Lufeng HU, Determination of Pantoprazole in Rat Plasma by LC-MS/MS and its Application to Pharmacokinetics, Lat. Am. J. Pharm., 31 (2012) 653-658.

- [116] Honggang Lou, Hong Yuan, Zourong Ruan&, Donghang Xu, Quan Zhou, LC Determination and Bioequivalence Study of Pantoprazole in Human Plasma, *Chromatographia*, 67 (2008) 795-799.
- [117] Osmair Peres, Celso H. Oliveira, Rafael E. Barrientos-Astigarraga, Vinícius M. Rezende, Gustavo D. Mendes, Gilberto de Nucci, Determination of Pantoprazole in Human Plasma by LC-MS-MS Using Lansoprazole as Internal Standard, *Arzneimittelforschung*, 54 (2004) 314-319.
- [118] B. Kocyigit-Kaymakcoglu, S. Unsalan, S. Rollas, Determination and validation of ketoprofen, pantoprazole and valsartan together in human plasma by high performance liquid chromatography, *Pharmazie*, 61 (2006) 586–589.
- [119] Ali S. Abdelhameed, Samar A. Afifi, A Validated HPLC-DAD Method for Simultaneous Determination of Etodolac and Pantoprazole in Rat Plasma, *Journal of chemistry*, 2014 (2014) 1-8.
- [120] Azza A.M. Moustafa, Spectrophotometric methods for the determination of lansoprazole and pantoprazole sodium sesquihydrate, *Journal of Pharmaceutical and Biomedical Analysis* 22 (2000) 45–58.
- [121] Y.S.R. Krishnaiah, K. Latha, R.S. Karthikeyan, V. Satyanarayana, HPLC method for the estimation of albendazole in pharmaceutical dosage forms, *Asian journal of chemistry*, 14 (2002) 67-71.
- [122] M. Mariene, Fregonezi-Nery, M. Marcela, R.M. Baracat Erika, Kedor-Hackman, Rafael Mota Pinheiro, Determination of albendazole in oral suspension, *Analytical letters*, 34 (2001) 1255-1263.
- [123] R. Shreya, S. Shah, S. Deyb, Prasanna Pradhana, H.K. Jaina, Umesh M. Upadhyay, Method development and validation for simultaneous estimation of albendazole and praziquantel in bulk and in a synthetic mixture, *Journal of Taibah University for Science*, 8 (2014) 54–63.
- [124] Sajid Mahmood,Zaheer Ahmad, Muhammad Aslam, Sonia Hussain, Abrar Hussain, Naresh Kumar, Method Development and Validation for the Estimation of Anthelmintic Drug (Albendazole) in Tablet Preparations, *Int. J. Pharm. Sci.*, 32 (2015) 284-287.

- [125] M. SPhatak, V.V. Vaidya, H. MPhatak, Development and validation of a high performance liquid chromatography method for the simultaneous quantification of albendazole and closeted from veterinary formulation, International Journal of Research in Pharmacy and Chemistry, 4 (2014) 972-976.
- [126] A. Sai Datri, A Lakshmana Rao, Development and Validation of Albendazole and Praziquental, Indian Journal of Pharmacy and Pharmacology, 3 (2016) 201-205.
- [127] K. Patel Asmita, V. Joshi Hirak, J.K. Patel, Development and validation of stability indicating RP-HPLC method for estimation of ivermectin and albendazole in pharmaceutical dosage form, Indian Journal of drugs, 3 (2015) 57-70.
- [128] KumaraswamyGandla, R. Lalitha, SadhanaBommakanti, R. Suthakaran, K. Pallavi, Development and Validation of RP-HPLC Method for Simultaneous Estimation of Albendazole and Praziqantel in Tablet Dosage Form, Asian J. Pharm. Ana., 5 (2015) 115-118.
- [129] Ram S Wadje, Nisharani S Ranpise. UV-Spectrophotometric Method Development and Validation of Albendazole in Bulk and Tablet Dosage Form, Inventi Rapid: Pharm Analysis & Quality Assurance, 3 (2016) 1-5.
- [130] Z. Khalil, M. El Karbane, M. Azougagh, J. Taoufik, HPLC method for simultaneous determination of Albendazole metabolites in plasma, Journal of Chemical and Pharmaceutical Research, 6 (2014) 860-865.
- [131] Noor Shabana, K. Dayananda Reddy,Method Validation and Quantitative Determination of 2-Mercapto Benzimidazole in Lansoprazole by LC/MS/MS, International Journal of Scientific Research,4 (2015) 45-48.
- [132] A. Vijay Bhaskar Reddy, N. Venugopal N, G. Madhavi, K. Gangadhar Reddy, V. Madhavi, A selective and sensitive UPLC–MS/MS approach for trace level quantification of four potential genotoxic impurities in zolmitriptan drug substance, J Pharm Biomed Anal, 84 (2013) 84-89.
- [133] M. Srinivasa Rao, S. Vinay Rao, K.P. Ramesh Babu, P. Satish Kumar, Hemant Kumar Sharma, Quantification of genotoxic impurities in amlodipine drug substance by LC-MS, Der Pharm Lettre, 6 (2014) 47-55.

- [134] A. Vijay Bhaskar Reddy, Venugopal N, Madhavi G, A selective and sensitive LC-MS/MS method for the simultaneous determination of two potential genotoxic impurities in celecoxib, *J Anal SciTech*, 5 (2014)18-25.
- [135] A.M.V. Wijk, B. Beerman, H.A.G. Niederlander, A.H.G. Siebum, G.J.D. Jong, A new approach for generic screening and quantitation of potential genotoxic alkylation compounds by pre-column derivatization and LC-MS/MS analysis, *Anal Bioanal Chem*, 400 (2011)1375-1385.
- [136] G. Szekely, B. Henriques, M. Gil, C. Alvarez, Experimental design for the optimization and robustness testing of a liquid chromatography tandem mass spectrometry method for the trace analysis of the potentially genotoxic 1,3-diisopropylurea, *Drug Test Anal*, 6 (2014) 898-908.
- [137] J. Nagadeep, P. Kamaraj, M. Arthnareeswari, J. Rajamanohar, Trace level quantification of (-)-2-(2-amino-5-chlorophenyl)-4cyclopropyl-1,1,1-trifluoro-3-butyn-2-ol genotoxic impurity in efavirenz drug substance and drug product using LC-MS/MS, *Sci. Pharm.*, 84 (2016) 456-466.
- [138] S. Natarajan, B.K. Kempegowda, M. Bharathiar, Determination of traceable genotoxic impurity chloroacetyl chloride a carcinogen by LC/MS/MS in drug substances, *Asian J Pharm Clin Res*, 9 (2016) 97-100.
- [139] D.P. Elder, A.M. Lipczynski, A. Teasdale, Control and analysis of alkyl and benzyl halides and other related reactive organohalides as potential genotoxic impurities in active pharmaceutical ingredients (APIs). *J Pharm Biomed Anal*, 48 (2008) 497–507.
- [140] G. Szekely, B. Henriques, M. Gil, A. Ramos, C. Alvarez, Design of experiments as a tool for LC-MS/MS method development for the trace analysis of the potentially genotoxic 4-dimethylaminopyridine impurity in glucocorticoids, *J Pharm Biomed Anal*, 70 (2012) 251-258.
- [141] Justin Pennington, Ryan D. Cohen, Ye Tian, Fabien Boulineau, Development of an LC-MS method for ultra-trace-level determination of 2,2,6,6-tetramethylpiperidine-1-oxl (TEMPO), a potential genotoxic impurity within active pharmaceutical ingredients, *Journal of Pharmaceutical and Biomedical Analysis*, 114 (2015) 488-492.

- [142] Jianguo An, Mingjiang Sun, Lin Bai, Ted Chen, David Q. Liu, Alireza Kord, A practical derivatization LC/MS approach for determination of trace level alkyl sulfonates and dialkyl sulfates genotoxic impurities in drug substances, *Journal of Pharmaceutical and Biomedical Analysis*, 48 (2008) 1006–1010.
- [143] G. Suneetha, P. Venkateswarlu¹, P.S.S. Prasad, Method development and validation for determination of 2-chloro-n-(2-chloro-4-methyl-3-pyridinyl)-3-pyridine carboxamide in nevirapine drug substance by using LC-MS/MS, *International Journal of Pharmaceutical Chemistry Research*, 24 (2014) 24-33.
- [144] N. Venugopal, A. Vijaya Bhaskar Reddy, G. Madhavi, Development and validation of a systematic UPLC–MS/MS method for simultaneous determination of three phenol impurities in ritonavir, *Journal of Pharmaceutical and Biomedical Analysis*, 90 (2014) 127–133.
- [145] Metta Srinivasa Rao, Sumathi Vinay Rao, Kollisetti Prasanna Ramesh Babu, Pallerla, Satish Kumar and Hemant Kumar Sharma, Quantification of genotoxic impurities in amlodipine drug substance by LC-MS, *Der Pharmacia Lettre*, 6 (2014) 47-55.
- [146] P.R. Kakadiya, B. Pratapa Reddy, V. Singha, S. Ganguly, T.G. Chandrashekhar, D.K. Singh, Low level determinations of methyl methanesulfonate and ethyl methanesulfonate impurities in Lopinavir and Ritonavir Active pharmaceutical ingredients by LC/MS/MS using electrospray ionization, *Journal of Pharmaceutical and Biomedical Analysis* 55 (2011) 379–384.
- [147] Uwe Wollein, Nicholas Schramek, Simultaneous determination of alkyl mesilates and alkyl besilates in finished drug products by direct injection GC/MS, *European Journal of Pharmaceutical Sciences*, 45 (2012) 201–204.
- [148] Vijaya Bhaskar Reddy, Zulkifli Yusopa, Jafariah Jaafarb, Azmi B. Arisa, Zaiton A. Majid, Khalid Umara, Juhaizah Taliba, Development and validation of a selective, sensitive and stability indicating UPLC–MS/MS method for rapid, simultaneous determination of six process related impurities in darunavir drug substance, *Journal of Pharmaceutical and Biomedical Analysis* 128 (2016) 141–148.

- [149] Saji Thomas, Amber Bharti, Pawan Kumar Maddhesia, Sanjeev Shandilya, Ashutosh Agarwal, Dharamvir, Sujay Biswas, Vikas Bhansal, Ashish Kumar Gupta, Praveen Kumar Tewari, Chandra S. Mathela, highly efficient, selective, sensitive and stability indicating RP-HPLC–UV method for the quantitative determination of potential impurities and characterization of four novel impurities in eslicarbazepine acetate active pharmaceutical ingredient by LC/ESI-IT/MS/MS, *Journal of Pharmaceutical and Biomedical Analysis* 61 (2012) 165– 175.
- [150] P.R. Kakadiya, T.G. Chandrashekhar, S. Ganguly, D.K. Singh, V. Singh, Low Level Determinations of Methyl Methanesulfonate and Ethyl Methanesulfonate Impurities in Emtricitabine Active Pharmaceutical Ingredient by LC/MS/MS Using Electro spray Ionization, *Analytical Chemistry Insights*, 6 (2011) 21-28.
- [151] International conference on Harmonisation Q3A-Q3D Impurities-International Council for Harmonization guidelines.
- [152] H.M. Bolt, H. Foth, J.G. Hengstler, G.H. Degen, Carcinogenicity categorization of chemicals—new aspects to be considered in a European perspective. *Toxicol Lett.*, 151 (2004) 29–41.
- [153] D. Jacobson-Kram, T. McGovern, Toxicological overview of impurities in pharmaceutical products, *Adv Drug Deliv Rev.*, 59 (2007) 38–42.
- [154] Guideline on the limits of genotoxic impurities, EMA guidance MEA/CHMP/QWP/251344/2006.
- [155] Guideline for Assessment and Control of DNA Reactive (Mutagenic) Impurities in pharmaceuticals to Limit Potential Carcinogenic risk, M7 ICH, 2014.
- [156] A. Dipple, DNA adducts of chemical carcinogens. *Carcinogenesis* 16 (1995) 37–41.
- [157] M. Koskinen, K. Plná, Specific DNA adducts induced by some mono-substituted epoxides in vitro and in vivo, *Chem Biol Interact.*, 129(2000) 09–29.

- [158] Deductive Estimation of Risk from Existing Knowledge (DEREK) nexus, marketed by LHASA Ltd, Leeds, Yorkshire, U.K, DEREK nexus program Version Derek Nexus: 3.0.1, Nexus: 1.5.1.
- [159] S. Klick, Evaluation of different injection techniques in the gas chromatographic determination of thermolabile trace impurities in a drug substance. *J Chromatogr. A.*, 689 (1995) 69–76.
- [160] L. Valvo, R. Alimenti, S. Alimonti, S. Raimondi, F. Foglietta, F. Campana, Development and validation of a liquid chromatographic method for the determination of related substances in verapamil hydrochloride, *J Pharm Biomed Anal.*, 15 (1997) 89–96.
- [161] Y. Hsieh, A. W. KorfmacherW, Increasing Speed and Throughput When Using HPLC-MS/MS Systems for Drug Metabolism and Pharmacokinetic Screening, *Curr Drug Metab.*, 7 (2006) 79–89.
- [162] M.S. Lee, E.H. Kerns, LC/MS applications in drug development, *Mass Spectrom Rev.*, 18 (1999) 187–279.
- [163] M.H. Cohen, J.R. Johnson, Y.F. Chen, R. Sridhar, R. Pazdur, Oncologist, 10 (2005) 461-466.
- [164] Novartis Pharma AG. Gleevec® (Imatinib mesylate) tablets prescribing information. East Hanover, NJ; Anon. Drugs of choice for cancer. Treat Guidel Med Lett. Sep 2006.
- [165] Pantoprazole monograph USP 40-NF 45, The United States Pharmacopeial Convention, 12601 Twinbrook parkway, Rockville, MD, 20852, 5563.
- [166] Albendazole monograph USP40-NF 45, The United States Pharmacopeial Convention, 12601 Twinbrook parkway, Rockville, MD, 20852, 2604.