

## DAFTAR PUSTAKA

- Almeida, A.M., Castel-Branco, M.M., and Falcão, A.C., 2002, Linear Regression for Calibration Lines Revisited: Weighting Schemes for Bioanalytical Methods, *J. Chromatogr. B*, **774**, 215–222.
- Badwaik, R.T., Dashputra, A.V., and Gupta, M., 2012, Determination of Levofloxacin in Some Commercial Oral Formulations by Using Spectrophotometer and HPLC, *Int. J. Med. Pharm. Sci.*, **3**, 14–19.
- BPOM, 2004, *Peraturan Kepala Badan Pengawas Obat dan Makanan Republik Indonesia, Nomor: HK.00.05.3.1818, Tentang Pedoman Uji Bioekivalensi*, Badan Pengawas Obat dan Makanan Republik Indonesia, Jakarta.
- Caufield, W.V., and Stewart, J.T., 2002, Determination of Zidovudine and Levofloxacin in Human Plasma by Reversed Phase HPLC and Solid Phase Extraction, *J. Liq. Chromatogr. Relat. Technol.*, **25**, 1791–1805.
- Cazedey, E.C.L., and Salgado, H.R.N., 2012, Spectrophotometric Determination of Ciprofloxacin Hydrochloride in Ophthalmic Solution, *Adv. Anal. Chem.*, **2**, 74–79.
- Chamseddin, C., and Jira, T.H., 2011, Comparison of The Chromatographic Behavior of levofloxacin, Ciprofloxacin, and Moxifloxacin on Various HPLC Phases, *Pharm.*, **66**, 244–248.
- Conte, J.E.J., Golden, J.A., McIver, M., and Zurlinden, E., 2006, Intrapulmonary Pharmacokinetics and Pharmacodynamics of High-Dose Levofloxacin in Healthy Volunteer Subjects, *Int. J. Antimicrob. Agents*, **28**, 114–121.
- Djabarouti, S., Boselli, E., Allaouchiche, B., Ba, B., Nguyen, A.T., Gordien, J.B., Bernadou, J.M., Saux, M.C., and Breilh, D., 2004, Determination of Levofloxacin in Plasma, Bronchoalveolar Lavage, and Bone Tissues by High-Performance Liquid Chromatography with Ultraviolet Detection Using a Fully Automated Extraction Method, *J. Chromatogr. B*, **799**, 165–172.
- EMA, 2011, *Guideline on Bioanalytical Method Validation*, European Medicine Agency, UK.
- Fang, P.-F., Cai, H.-L., Li, H.-D., Zhu, R.-H., Tan, Q.-Y., Gao, W., Xu, P., Liu, Y.-P., Zhang, W.-Y., Chen, Y.-C., and Zhang, F., 2010, High Performance Liquid Chromatography-Tandem Mass Spectrometry, *J. Chromatogr. B Analyt. Technol. Biomed. Life. Sci.*, **878**, 2286–2291.

- FDA, 1994, *Validation of Chromatographic Method*, Center for Drug Evaluation and Research, Rockville.
- FDA, 2014, *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, Accessed 19<sup>th</sup> February 2014, [www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm](http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm).
- FDA, 2001, *Guidance for Industry: Bioanalytical Method Validation*, US Department of Health and Human Services. Food and Drug Administration, USA.
- Fu, K.P., Lafredo, S.C., Foleno, B., Isaacson, D.M., Barrett, J.F., Tobia, A.J., and Rosenthale, M.E., 1992, In Vitro and in Vivo Antibacterial Activities of Levofloxacin (L-Ofloxacin), an Optically Active Ofloxacin, *Antimicrob. Agents Chemother.*, **36**, 860–866.
- Furlanut, M., Brollo, L., Lugatti, E., Di Qual, E., Dolcet, F., Talmassons, G., and Pea, F., 2003, Pharmacokinetic Aspects of Levofloxacin 500 mg Once Daily During Sequential Intravenous/Oral Therapy in Patients with Lower Respiratory Tract Infections, *J. Antimicrob. Chemother.*, **51**, 101–106.
- Hadi, U., Duerink, D.O., Lestari, E.S., Nagelkerke, N.J., Werter, S., Keuter, M., Suwandojo, E., Rahardjo, E., van den Broek, P., and Gyssens, I.C., 2008, Survey of Antibiotic Use of Individuals Visiting Public Healthcare Facilities in Indonesia, *Int. J. Infect. Dis.*, **12**, 622–629.
- ICH, 2005, *Validation of Analytical Procedures : Text and Methodology Q2 (R1)*, International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.
- Ji, H.Y., Jeong, D.W., Kim, Y.H., Kim, H.-H., Sohn, D.-R., and Lee, H.S., 2006, Hydrophilic Interaction Liquid Chromatography–Tandem Mass Spectrometry for The Determination of Levofloxacin in Human Plasma, *J. Pharm. Biomed. Anal.*, **41**, 622–627.
- Kingston, J., O'Connor, D., Sparey, T., and Thomas, S., 2004, 'Hyphenated Techniques in Drug Discovery: Purity Assessment, Purification, Quantitative Analysis and Metabolite Identification', in: Rosenfeld, J.M., *Sample Preparation for Hyphenated Analytical Techniques*, Blackwell Publishing Ltd., USA, pp. 114–149.
- Kontou, P., Manika, K., Chatzika, K., Papaioannou, M., Sionidou, M., Pitsiou, G., and Kioumis, I., 2013, Pharmacokinetics of Moxifloxacin and High-Dose Levofloxacin in Severe Lower Respiratory Tract Infections, *Int. J. Antimicrob. Agents*, **42**, 262–267.

- Medscape, 2011, *FDA Approves First Generic Versions of Levofloxacin*, Accessed 12<sup>th</sup> March 2014, [www.medscape.com/viewarticle/745007](http://www.medscape.com/viewarticle/745007)
- Meyer, V.R., 2004, *Practical High-Performance Liquid Chromatography*, 4<sup>th</sup> edition, Wiley & Sons, Chichester, UK, pp. 82–99
- Miller, J.M., 2005, *Chromatography: Concepts and Contrasts*, 2<sup>nd</sup> edition, John Wiley & Sons, Hoboken, New Jersey, pp. 194–259.
- Miller, J.N., and Miller, J.C., 2005, *Statistics and Chemometrics for Analytical Chemistry*, 5<sup>th</sup> edition, Pearson Education, Harlow, England, pp. 18–69.
- Mor, N., Vanderkolk, J., and Heifets, L., 1994, Inhibitory and Bactericidal Activities of Levofloxacin Against Mycobacterium Tuberculosis in Vitro and in Human Macrophages, *Antimicrob. Agents Chemother.*, **38**, 1161–1164.
- Naber, K.G., Roscher, K., Botto, H., and Schaefer, V., 2008, Oral Levofloxacin 500 mg Once Daily in The Treatment of Chronic Bacterial Prostatitis, *Int. J. Antimicrob. Agents*, **32**, 145–153.
- Nemutlu, E., Kır, S., Özyüncü, Ö., and Beksaç, M.S., 2007, Simultaneous Separation and Determination of Seven Quinolones Using HPLC: Analysis of Levofloxacin and Moxifloxacin in Plasma and Amniotic Fluid, *Chroma*, **66**, 15–24.
- Nguyen, H.A., Grellet, J., Ba, B.B., Quentin, C., and Saux, M.-C., 2004, Simultaneous Determination of Levofloxacin, Gatifloxacin and Moxifloxacin in Serum by Liquid Chromatography with Column Switching, *J. Chromatogr. B*, **810**, 77–83.
- Ornaf, R.M., and Dong, M.W., 2005, 'Key Concepts of HPLC in Pharmaceutical Analysis', in: Ahuja, S., and Dong, M.W., *Handbook of Pharmaceutical Analysis by HPLC*, Oxford, UK, Academic Press, pp. 19–45.
- Peedikayil, M.C., Alsohaibani, F.I., and Alkhenizan, A.H., 2014, Levofloxacin-Based First-Line Therapy versus Standard First-Line Therapy for Helicobacter pylori Eradication: Meta-Analysis of Randomized Controlled Trials, *Plos One*, **9**, 1–8.
- Qin, G.-D., Xiao, M.-Z., Zhou, Y.-D., Yang, J., He, H.-X., He, Y., and Zeng, Y., 2013, Tamsulosin Alters Levofloxacin Pharmacokinetics in Prostates Derived from Rats with Acute Bacterial Prostatitis, *Asian J. Androl.*, **15**, 254–260.
- Shapiro, S., and Wilk, M.B., 1965, An Analysis of Variance Test for Normality (Complete Samples), *Biometrika*, **52**, 591–611.

- Sigma Aldrich, 2014, *Solvent Center*, Accessed 31<sup>st</sup> 2014, [www.sigmaaldrich.com/chemistry/solvents/water-center.html](http://www.sigmaaldrich.com/chemistry/solvents/water-center.html).
- Snyder, L.R., Kirkland, J.J., and Dolan, J.W., 2010, *Introduction to Modern Liquid Chromatography*, 3<sup>rd</sup> edition, Wiley & Sons, Hoboken, New Jersey, pp. 253–331, 531–553.
- Snyder, L.R., Kirkland, J.J., and Glajch, J.L., 1997, *Practical HPLC Method Development*, 2<sup>nd</sup> edition, John Wiley & Sons, Hoboken, New Jersey, pp. 60–70.
- Sousa, J., Alves, G., Campos, G., Fortuna, A., and Falcão, A., 2013, First Liquid Chromatography Method for The Simultaneous Determination of Levofloxacin, Pazufloxacin, Gatifloxacin, Moxifloxacin, and Trovafloxacin in Human Plasma, *J. Chromatogr. B*, **930**, 104–111.
- Tasso, L., de Andrade, C., and Costa, T.D., 2011, Pharmacokinetic /Pharmacodynamic Modelling of The Bactericidal Activity of Free Lung Concentrations of Levofloxacin and Gatifloxacin Against *Streptococcus pneumoniae*, *Int. J. Antimicrob. Agents*, **38**, 307–313.
- Tjaniadi, P., Lesmana, M., Subekti, D., Machpud, N., Komalarini, S., Santoso, W., Simanjuntak, C.H., Punjabi, N., Campbell, J.R., Alexander, W.K., Beecham, H.J., Corwin, A.L., and Oyofu, B.A., 2003, Antimicrobial Resistance of Bacterial Pathogens Associated With Diarrhea Patients in Indonesia, *Am. J. Trop. Med. Hyg.*, **68**, 666–670.
- UNODC, 2009, *Guidance for the Validation of Analytical Methodology and Calibration of Equipment used for Testing of Illicit Drugs in Seized Materials and Biological Specimens*, United Nations Office on Drugs and Crime, New York.
- Usman, M., Ashraf, M., Khokhar, M.I., Ashiq, B., Masood, M.I., Afzal, S., Omer, O., Ali, M., and Qadir, M.I., 2013, Comparative Pharmacokinetics of Levofloxacin in Healthy Volunteers and in Patients Suffering from Typhoid Fever, *Iran J. Pharm. Res.*, **12**, 147–154.
- USP, 2006, *United States Pharmacopoeia No. 30-NF 25*, USP Convention, USA.
- Völgyi, G., Ruiz, R., Box, K., Comer, J., Bosch, E., and Takács-Novák, K., 2007, Potentiometric and Spectrophotometric pKa Determination of Water-Insoluble Compounds: Validation Study in a New Cosolvent System, *Anal. Chim. Acta*, **583**, 418–428.
- Völgyi, G., Vizseralek, G., Takacs-Novak, K., Avdeef, A., and Tam, K.Y., 2012, Predicting The Exposure and Antibacterial Activity of Fluoroquinolones Based on Physicochemical Properties, *Eur. J. Pharm. Sci.*, **47**, 21–27.

- Watabe, S., Yokoyama, Y., Nakazawa, K., Shinozaki, K., Hiraoka, R., Takeshita, K., and Suzuki, Y., 2010, Simultaneous Measurement of Pazufloxacin, Ciprofloxacin, and Levofloxacin in Human Serum by High-Performance Liquid Chromatography with Fluorescence Detection, *J. Chromatogr. B*, **878**, 1555–1561.
- Zhang, Y., Huang, H., Ren, Z., Zheng, H., Yu, Y., Lü, X., Xiao, Z., Yang, Hui-fen, Xiu, Q., Chen, B., Yue, H., Hao, Q., Huang, J., Ma, H., Xiao, W., Guo, D., Si, B., Sun, S., Zhang, W., Li, Q., Shen, H., Duan, J., Li, H., Yao, W., Gu, J., Xia, Q., Ying, K., Liu, A., Yang, He-ping, Shi, M., Sun, T., Ding, G., and Wu, G., 2009, Clinical Evaluation of Oral Levofloxacin 500 mg Once-Daily Dosage for Treatment of Lower Respiratory Tract Infections and Urinary Tract Infections: a Prospective Multicenter Study in China, *J. Infect. Chemother.*, **15**, 301–311.