

### DAFTAR PUSTAKA

- Arafat, M., Ahmed, Z., dan Arafat, O., 2017. Comparison Between Generic Drugs and Brand Name Drugs from Bioequivalence and Thermoequivalence Prospective. *International Journal of Pharmacy and Pharmaceutical Sciences*, **9**: 1–4.
- Ashnagar, A. dan Naseri, N.G., 2007. Analysis of Three Penicillin Antibiotics (Ampicillin, Amoxicillin and Cloxacillin) of Several Iranian Pharmaceutical Companies by HPLC. *E-Journal of Chemistry*, **4**: 536–545.
- Asyarie, S. dan Mudhakhir, D., 2011. Uji Disolusi Terbanding Zat Karbamazepin dalam Bentuk Sediaan Tablet. *Acta Pharmaceutica Indonesia*, **XXXVI**: 4.
- Badan Pengawas Obat dan Makanan, 2003. *Kriteria dan Tatalaksana Registrasi Obat*. Badan Pengawas Obat dan Makanan, Jakarta.
- Badan Pengawas Obat dan Makanan, 2005. *Pedoman Uji Bioekivalensi*. Badan Pengawas Obat dan Makanan, Jakarta.
- Baishya, H., 2017. Application of Mathematical Models in Drug Release Kinetics of Carbidopa and Levodopa ER Tablets. *Journal of Developing Drugs*, **6**: 8.
- Blix, H.S., Viktil, K.K., Moger, T.A., dan Reikvam, A., 2010. Drugs with narrow therapeutic index as indicators in the risk management of hospitalised patients. *Pharmacy Practice*, **8**: 50–55.
- Chavda, H., Patel, C., dan Anand, I., 2010. Biopharmaceutics Classification System. *Systematic Reviews in Pharmacy*, **1**: 62.
- Chow, S.-C., 2014. Bioavailability and Bioequivalence in Drug Development. *Wiley interdisciplinary reviews. Computational statistics*, **6**: 304–312.
- Costa, P., 2001. An alternative method to the evaluation of similarity factor in dissolution testing. *International Journal of Pharmaceutics*, **220**: 77–83.
- Costa, P. dan Lobo, J.M.S., 2001. Modeling and comparison of dissolution profiles. *European Journal of Pharmaceutical Sciences*, **13**: 123–133.
- Day, R.A. dan Underwood, A.L., 2001. *Analisis Kimia Kuantitatif Edisi Keenam*. Erlangga, Jakarta.
- Dressman, J., Butler, J., Hempenstall, J., dan Reppas, C., 2001. The BCS: Where Do We Go from Here? *Pharmaceutical Technology*, **5**.
- Dressman, J.J. dan Kramer, J., 2005. *Pharmaceutical Dissolution Testing*. Taylor & Francis.
- Dunne, S., Shannon, B., Dunne, C., dan Cullen, W., 2013. A review of the differences and similarities between generic drugs and their originator counterparts, including economic benefits associated with usage of generic medicines, using Ireland as a case study. *BMC Pharmacology and Toxicology*, **14**: 1–19.
- Fernandes, C., Junqueira, R.G., Campos, L.M.M., dan Pianetti, G.A., 2006. Dissolution test for lamivudine tablets: Optimization and statistical

- analysis. *Journal of Pharmaceutical and Biomedical Analysis*, **42**: 601–606.
- Food and Drug Administration, 2017. *Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System*. Food and Drug Administration, United States.
- Fudholi, A., 2013. *Disolusi Dan Pelepasan Obat In Vitro*. Pustaka Pelajar, Yogyakarta.
- Gaikwad, A., Gavali, S., Narendiran, Katale, D., Bonde, S., dan Bhadane, R.P., 2013. An LC–MS–MS method for the simultaneous quantification of amoxicillin and clavulanic acid in human plasma and its pharmacokinetic application. *Journal of Pharmacy Research*, **6**: 804–812.
- Gandjar, I.G. dan Rohman, A., 2007. *Kimia Farmasi Analisis*. Pustaka Pelajar, Yogyakarta.
- Gandjar, I.G. dan Rohman, A., 2012. *Analisis Obat Secara Spektrofotometri Dan Kromatografi*. Pustaka Pelajar, Yogyakarta.
- Gohel, M.C., Sarvaiya, K.G., Shah, A.R., dan Brahmabhatt, B.K., 2009. Mathematical approach for the assessment of similarity factor using a new scheme for calculating weight. *Indian Journal of Pharmaceutical Sciences*, **71**: 142.
- Hailu, G.S., Gutema, G.B., Hishe, H.Z., Ali, S., dan Asfaw, A.A., 2013. Comparative In vitro Bioequivalence Evaluation of Different Brands of Amoxicillin Capsules Marketed in Tigray, Ethiopia. *International Journal of Pharmaceutical Sciences and Nanotechnology*, **6**: 6.
- Hassali, 2012. Generic Substitution in Malaysia: Recommendations from a Systematic Review. *Journal of Applied Pharmaceutical Science*, .
- Kassaye, L. dan Genete, G., 2013. Evaluation and comparison of in-vitro dissolution profiles for different brands of amoxicillin capsules. *African Health Sciences*, **13**: 369–375.
- Kementerian Kesehatan Republik Indonesia, 2014. *Farmakope Indonesia*, V. ed. Kementerian Kesehatan Republik Indonesia, Jakarta.
- Kesselheim, A.S., 2008. Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease: A Systematic Review and Meta-analysis. *JAMA*, **300**: 2514–2526.
- Kesselheim, A.S., Stedman, M.R., Bubrick, E.J., Gagne, J.J., Misono, A.S., Lee, J.L., dkk., 2010. Seizure Outcomes Following the Use of Generic versus Brand-Name Antiepileptic Drugs: A Systematic Review and Meta-Analysis. *Drugs*, **70**: 605–621.
- Khopkar, S.M., 2003. *Konsep Dasar Kimia Analitik*. Universitas Indonesia Press, Jakarta.
- Kortajarvi, H., Urtti, A., dan Yliperttula, M., 2007. Pharmacokinetic simulation of biowaiver criteria: The effects of gastric emptying, dissolution, absorption and elimination rates. *European Journal of Pharmaceutical Sciences*, **30**: 155–166.
- Li, J., Chai, H., Li, Y., Chai, X., Zhao, Yan, Zhao, Yunfan, dkk., 2016. A Three-Pulse Release Tablet for Amoxicillin: Preparation, Pharmacokinetic Study

- and Physiologically Based Pharmacokinetic Modeling. *PLOS ONE*, **11**: e0160260.
- Löbenberg, R., Chacra, N.B., Stippler, E.S., Shah, V.P., DeStefano, A.J., Hauck, W.W., dkk., 2012. Toward Global Standards for Comparator Pharmaceutical Products: Case Studies of Amoxicillin, Metronidazole, and Zidovudine in the Americas. *The AAPS Journal*, **14**: 462–472.
- Logoyda, L., Horlachuk, N., Zarivna, N., Polyauk, O., Soroka, Y., dan Herasymiuk, M., 2019. In Vitro Dissolution Kinetics of Bisoprolol Tablets Under Biowaiver Conditions. *Asian Journal of Pharmaceutics*, **13**: 54–58.
- Lopes, G. D. L., 2013. Cost comparison and economic implications of commonly used originator and generic chemotherapy drugs in India. *Annals of Oncology*, **24**: v13–v16.
- Manzoli, L., Flacco, M.E., Boccia, S., D’Andrea, E., Panic, N., Marzuillo, C., dkk., 2016. Generic versus brand-name drugs used in cardiovascular diseases. *European Journal of Epidemiology*, **31**: 351–368.
- Mhamunkar, S.M., Srinivasan, G., Khan, T., dan Bhoir, S.I., 2013. Comparative dissolution studies of an extended release formulation of Tolterodine tartrate and Tamsulosin Hcl. *BioMedRx*, **1**: 333–338.
- Moffat, A.C., Osselton, M.D., Widdop, B., dan Watts, J., 2011. *Clarke’s Analysis of Drugs and Poisons*, 4th ed. Pharmaceutical Press, London.
- Reddy, N.H.S., Patnala, S., Löbenberg, R., dan Kanfer, I., 2014. In Vitro Dissolution of Generic Immediate-Release Solid Oral Dosage Forms Containing BCS Class I Drugs: Comparative Assessment of Metronidazole, Zidovudine, and Amoxicillin Versus Relevant Comparator Pharmaceutical Products in South Africa and India. *AAPS PharmSciTech*, **15**: 1076–1086.
- Rohilla, S., Rohilla, A., dan Nanda, A., 2010. Biowaivers: Criteria and Requirements. *International Journal of Pharmaceutical & Biological Archives*, **3**: 5.
- Saptarini, N.M., 2012. Evaluation of Content and Dissolution Profile of Generic Amoxicillin Tablets Marketed in Indonesia. *International Research Journal of Pharmacy*, **3**: 3.
- Sari, D.P., Sulaiman, T.N.S., dan Mafruhah, O.R., 2013. Uji Disolusi Terbanding Tablet Metformin Hidroklorida Generik Berlogo dan Bermerek. *Majalah Farmasuetik*, **9**: 5.
- Sedyaningsih, E.R., 2010. *Kewajiban Menggunakan Obat Generik Di Fasilitas Pelayanan Kesehatan Pemerintah*. Menteri Kesehatan Republik Indonesia, Jakarta.
- Shaikh, H.K., Kshirsagar, R.V., dan Patil, S.G., 2015. Mathematical Models for Drug Release Characterization: A Review. *World Journal of Pharmaceutical Research*, **4**: 15.
- Smit, E. van der M. dan Bredenkamp, J., 2013. Originator and generic medicine: pricing and market share. *International Journal of Pharmaceutical and Healthcare Marketing*, **7**: 104–119.
- Stuart, A.V., Zuo, J., dan Löbenberg, R., 2014. Investigating the Dissolution Profiles of Amoxicillin, Metronidazole, and Zidovudine Formulations

- used in Trinidad and Tobago, West Indies. *AAPS PharmSciTech*, **15**: 1060–1069.
- Thambavita, D., Fernando, S., Galappatthy, P., dan Jayakody, R., 2018. Application of Biowaiver Methodology for a Post-Marketing Study of Generic and Brand Name Metronidazole Tablets. *Dissolution Technologies*, **25**: 34–38.
- Thambavita, D., Galappatthy, P., Mannapperuma, U., Jayakody, L., Cristofolletti, R., Abrahamsson, B., dkk., 2017. Biowaiver Monograph for Immediate-Release Solid Oral Dosage Forms: Amoxicillin Trihydrate. *Journal of Pharmaceutical Sciences*, **106**: 2930–2945.
- US Pharmacopeia National Formulary, 2015. *USP 38/ NF 33*. United States Pharmacopeia Inc., Rockville.
- World Health Organization, 2006. *WHO Expert Committee on Specifications for Pharmaceutical Preparations*, 40th ed. World Health Organization, Geneva.
- World Health Organization, 2015. *WHO Expert Committee on Specifications for Pharmaceutical Preparations*, 49th ed. World Health Organization, Geneva.
- Yu, L.X., Amidon, G.L., Polli, J.E., Zhao, H., Mehta, M.U., Conner, D.P., dkk., 2002. Biopharmaceutics Classification System: The Scientific Basis for Biowaiver Extensions **19**: 5.