

**DAFTAR PUSTAKA**

- AA Pharma Inc. 2010. *Product Monograph Flunarizine Hydrochloride Capsules*. Vaughan Ontario.
- Ahuja, S., and Dong, M. W. 2005. *Handbook of Pharmaceutical Analysis by HPLC*. Volume 6. Elsevier Inc. ISBN: 0-12-088547-6.
- Amidon, G. L., Lennernäs, H., Shah, V. P., & Crison, J. R. 1995. A Theoretical Basis For A Biopharmaceutic Drug Classification: The Correlation Of In Vitro Drug Product Dissolution And In Vivo Bioavailability. *Pharmaceutical Research*, 12(3), 413–420. doi:10.1023/a:1016212804288.
- Anand, O., Yu, L. X., Conner, D. P., and Davit, B. M. 2011. Dissolution Testing for Generic Drugs: An FDA Perspective. *The AAPS Journal*, Vol. 13, No. 3.
- ASEAN Guideline on Stability Study of Drug Product (R1)*. Revision 25<sup>th</sup> ACCSQ-PPWG.
- Badan Pengawas Obat dan Makanan RI*. 2012. *Pedoman Cara Pembuatan Obat yang Baik*. Jakarta. ISBN 978-979-3707-65-5.
- Balakrishnan, A., Rege, B. D., Amidon, G. L., & Polli, J. E. 2004. Surfactant-mediated dissolution: Contributions of solubility enhancement and relatively low micelle diffusivity. *Journal of Pharmaceutical Sciences*, 93(8), 2064–2075. doi:10.1002/jps.20118.
- Bell, D. S., Muraco, C. E., and Flannery, C. 2018. Highlights from HPLC 2018 Symposium. *Research Gate*.
- Benet, L. Z. 2013. The Role of BCS (Biopharmaceutics Classification System) and BDDCS (Biopharmaceutics Drug Disposition Classification System) in Drug Development. *Journal of Pharmaceutical Sciences*, 102(1), 34–42. doi:10.1002/jps.23359.
- Brown, C. K. 2005. Dissolution Method Development: An Industry Perspective. In Dressman, J., and Krämer, J., Editor. *Pharmaceutical Dissolution Testing*. Taylor & Francis Group, LLC. ISBN-13: 978-0-8247-5467-9. Page. 357.
- Busaranon, K., Suntornsuk, W., and Suntornsuk, L. 2005. Comparison of UV spectrophotometric method and high performance liquid chromatography for the analysis of flunarizine and its application for the dissolution test. *Journal of Pharmaceutical and Biomedical Analysis* 41 158–164.
- Chan, C. C., Lam, H., Lee, Y. C., Zhang, X. M. 2004. *Analytical Method Validation and Instrument Performance Verification*. John Wiley & Sons, Inc. ISBN 0-471-25953-5.

- Chen, L. R., Wesley, J. A., Bhattachar, S., Ruiz, B., Bahash, K., and Babu, S. R. 2003. Dissolution Behaviour of a Poorly Water Soluble Compound in the Presence of Tween 80. *Pharmaceutical Research*, Vol. 20. No. 5.
- Chinese Pharmacopoeia Commission. 2011. *Pharmacopoeia of the People's Republic of China 2010*. Set of 3, English Edition, China Medical Science and Technology Press, Beijing.
- Deepthi G, Balakrishnan M, Dr., Yadav K, Y. R., Mallika K, and Shekhar G, Muni. 2016. RP-Method Development for The Estimation of Flunarizine dihydrochloride in Tablet Dosage Form. *Indo American Journal of Pharmaceutical Research*, Vol 6(Issue 03), 32.
- Deputi Bidang Pengawasan Produk Terapeutik dan Napza Badan Pengawas Obat Dan Makanan. 2018. *Pedoman Sampling Produk Terapeutik dan NAPZA Tahun 2018*. Badan POM RI.
- Diebold, S. M. 2005. Physiological Parameters Relevant to Dissolution Testing: Hydrodynamic Considerations. In Dressman, J., and Krämer, J., Editor. *Pharmaceutical Dissolution Testing*. Taylor & Francis Group, LLC. ISBN-13: 978-0-8247-5467-9. Page. 127-183.
- Dressman, J. B., Amidon, G. L., Reppas, C., & Shah, V. P. 1998. Dissolution Testing as a Prognostic Tool for Oral Drug Absorption: Immediate Release Dosage Forms. *Pharmaceutical Research*, 15(1), 11-22.
- Dong, M. W. 2019. *HPLC AND UHPLC FOR PRACTICING SCIENTISTS*. Second Edition. John Wiley & Sons, Inc. USA. Page. 294.
- Ermer, J., Miller, J. H. McB. 2005. *Method Validation in Pharmaceutical Analysis*. Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim. ISBN: 3-527-31255-2.
- Farmakope Indonesia Edisi V*. 2014. Kementerian Kesehatan Republik Indonesia.
- Fattah M, A., El Walily., El Gindy, A.A., and Wahbi, A. A. M. 1995. Spectrophotometric determination of Flunarizine duhydrochloride through the formation of charge-transfer complex with iodine. *Journal of Pharmaceutical & Biomedical Analysis*. Vol. 13 No. 1pp. 53-58. Elsevier Science Ltd.
- Fotaki, N., Brown, W., Kochling, J., Chokshi, H., Miao, H., Tang, K., and Gray, V. 2013. Rationale for Selection of Dissolution Media: Three Case Studies. *Dissolution Technologies*. dx.doi.org/10.14227/DT200313P6.
- Gray, V. A. 2005. Compendial Testing Equipment: Calibration, Qualification, and Sources of Error. In Dressman, J., and Krämer, J., Editor. *Pharmaceutical Dissolution Testing*. Taylor & Francis Group, LLC. ISBN-13: 978-0-8247-5467-9. Page. 39-65.

- Harmita, Departemen Farmasi FMIPA UI. 2004. Petunjuk Pelaksanaan Validasi Metode dan Cara Perhitungannya. *Majalah Ilmu Kefarmasian*. Vol. I. No.3. hal. 117-135.
- Hassan, B. A. R. 2012. HPLC Uses and Importance in the Pharmaceutical Analysis and Industrial Field. *Pharmaceutica Analytica Acta*.
- Holmes, B., Brogden, R.N., Heel, R.C., Speight, T.M., and Avery, G.S. 1984. Flunarizine. A review of its pharmacodynamic and pharmacokinetic properties and therapeutic use. *Drugs* 27:6–44. ©ADIS Press Limited.
- Huber, L. 2003. Validation of Analytical Methods and Processes. In Nash, R. A., and Wachter, A. H., Editor. *Pharmaceutical Process Validation*. An International Third Edition. Marcel Dekker, Inc.
- ICH Harmonised Tripartite Guideline*. 2005. Validation of Analytical Procedures: Text and Methodology Q2(R1). Current Step 4 version. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.
- ICH Topic Q 2 B*. 1997. Validation of Analytical Procedures: Methodology. Step 4, Consensus Guideline. The European Agency for the Evaluation of Medicinal Products: Human Medicines Evaluation Units.
- ICH Harmonised Guideline*. 2018. Biopharmaceutics Classification System-Based Biowaivers. M9. ICH Consensus Guideline.
- Kartinasari, W. F., Chufianty, H. and Indrayanto, G. 2003. HPLC Determination of Flunarizine Dihydrochloride in Tablets and Its Validation. *Journal of Liquid Chromatography & Related Technologies*, 26:7, 1059 – 1067. <https://doi.org/10.1081/JLC-120020093>
- Khan, K. A. 1975. The Concept of Dissolution Efficiency. *Journal of Pharmacy and Pharmacology*, 27(1), 48–49. doi:10.1111/j.2042-7158.1975.tb09378.x.
- Komite Akreditasi Nasional*. 2004. SR 03: Jaminan Mutu Peralatan yang Digunakan oleh Laboratorium Pengujian Kimia dan Pengujian Biologi. DPLP 07 Rev. 0. Jakarta.
- Krämer, J., Grady, L. T., and Gajendran, J. 2005. Historical Development of Dissolution Testing. In Dressman, J., and Krämer, J., Editor. *Pharmaceutical Dissolution Testing*. Taylor & Francis Group, LLC. ISBN-13: 978-0-8247-5467-9. Page. 14.
- Li, M., Gao, Z., Wang, Z., Li, Z., & Wang, B. 2019. Measurement and correlation of solubility of flunarizine hydrochloride in ten pure and ethanol + n-propanol mixed solvents at temperatures within 293.15–333.15 K. *Journal of Molecular Liquids*, 112214. doi:10.1016/j.molliq.2019.112214.

- Loftsson, T. 2015. Physicochemical Properties and Pharmacokinetics. *Essential Pharmacokinetics*, 85–104. doi:10.1016/b978-0-12-801411-0.00003-2.
- Misiuk W. 2010. The role of assay methods in characterizing the quality of bulk pharmaceuticals. *J Pharm Bioall Sci*;2:88-92.
- Moore, J.W. and Flanner, H.H. 1996. Mathematical Comparison of Curves with an Emphasis on in Vitro Dissolution Profiles. *Pharmaceutical Technology*, 20, 64-74.
- Nagarajan, R. Polymer–Surfactant Interactions. 2001. In Detergents for the New Millennium, Proceeding of New Horizons Conference. *American Oil Chemists Society and Consumer Specialty Products Association*, Fort Myers, FL, Oct 14–17.
- National Center for Biotechnology Information. 2020. *PubChem Database*. Flunarizine hydrochloride, CID=5282407, <https://pubchem.ncbi.nlm.nih.gov/compound/Flunarizine-hydrochloride> (accessed on May 29, 2020).
- Niu, J., and Hu, R. 2017. Role of flunarizine hydrochloride in secondary brain injury following intracerebral hemorrhage in rats. *International Journal of Immunopathology and Pharmacology*.
- Paithankar, H. V. 2013. HPLC METHOD VALIDATION FOR PHARMACEUTICALS: A REVIEW. *International Journal of Universal Pharmacy and Bio Sciences* 2(4): July-August.
- Prashanth, K. N., Basavaiah, K., Raghu, M. S., Xavier, C. M., & Vinay, K. B. 2013. Determination of Flunarazine Dihydrochloride in Bulk Drug and Tablets by RP-UPLC: A Stability-Indicating Assay. *Proceedings of the National Academy of Sciences, India Section A: Physical Sciences*, 83(2), 79–88. doi:10.1007/s40010-013-0068-6.
- Prashanth, K. N., Swamy, N., and Basavaiah, K. 2016. Investigation and Optimization of Titrimetric and Spectrophotometric Methods for the Assay of Flunarizine dihydrochloride Using *in situ* Bromine. *Acta Poloniae Pharmaceutica-Drug Research*, Vol. 73 No. 1 pp 35-45.
- Shah, V. P. 2005. The Role of Dissolution Testing in the Regulation of Pharmaceuticals: The FDA Perspective. In Dressman, J., and Krämer, J., Editor. *Pharmaceutical Dissolution Testing*. Taylor & Francis Group, LLC. ISBN-13: 978-0-8247-5467-9. Page. 82.
- Shah, V. P., & Amidon, G. L. 2014. A Theoretical Basis for a Biopharmaceutic Drug Classification: The Correlation of In Vitro Drug Product Dissolution and In Vivo Bioavailability, *Pharm Res* 12, 413–420, 1995—Backstory of BCS. *The AAPS Journal*, 16(5), 894–898. doi:10.1208/s12248-014-9620-9.

- Showa Denko America. Inc., 25 Nopember 2018. *Lesson 1 : Introduction to HPLC*. <https://shodexhplc.com/lessons/lesson-1-introduction-to-hplc/>.
- Skoog, D.A., Holler, F.J., and Crouch, S.R. 2006. *Principles of Instrumental Analysis*, 6e. Pacific Groves, CA: Brook Cole.
- Stout, T. H., Dorsey, J. G. 2002. High-Performance Liquid Chromatography. In Ohannesian, Lena., and Streeter, Antony J., Editor. *Handbook of Pharmaceutical Analysis*. Marcel Dekker, Inc. New York. Page 103.
- The Japanese Pharmacopoeia*. Seventeenth Edition. 2016. English Version. Ministry of Health, Labour and Welfare. Japan.
- The United States Pharmacopoeia 39–National Formulary 34*. The United States Pharmacopoeial Convention, Inc.: Rockville, MD, 2016.
- Upadhyay, S. K., and Ali, S. M. 2018. Molecular recognition of flunarizine dihydrochloride and  $\beta$ -cyclodextrin inclusion complex by NMR and computational approaches. *Chemistry Central Journal*.
- U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER). December 2017. Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System Guidance for Industry.
- Van Nueten, J. M., and Vanhoutte, P. M. 1981. Calcium entry blockers and vascular smooth muscle heterogeneity. *Fed. Proc.*, 40:2862-2865.
- Van Nueten, J. M., and Janssen, P. A. J. 1973. Comparative study of the effects of flunarizine and cinnarizine on smooth muscle and cardiac tissues. *Arch. Int. Pharmacodyn. Ther.*, 204:37-55.
- Van Nueten, J. M., and Vanhoutte, P. M. 1984. Flunarizine. *New Drugs Annual: Cardiovascular Drugs*. Vol. 2, edited by Alexander Scriabine. Raven Press New York.
- Wang, Q., Ma, D., Higgins, J. P. 2006. Analytical Method Selection for Drug Product Dissolution Testing. *Dissolution Technologies*. [dx.doi.org/10.14227/DT130306P6](https://doi.org/10.14227/DT130306P6).