

## DAFTAR PUSTAKA

- Anonim (2020) *Farmakope Indonesia edisi VI, Departemen Kesehatan Republik Indonesia*.
- Anonim (2021) 'The Japanese Pharmacopoeia', (c), pp. 45–47. doi: 10.1021/bk-1997-0680.
- Anonim (2022) 'British Pharmacopoeia 2022 Volume I', I(January), pp. 397–400.
- BPOM RI (2014) 'Petunjuk Operasional Penerapan Pedoman Cara Pembuatan Obat Yang Baik 2012', *PPOP*, 1999(December), pp. 1–6.
- BPOM RI (2018) 'Pedoman Cara Pembuatan Obat yang Baik', *Bpom RI*.
- BPOM RI (2019) 'Peraturan Badan Pengawas Obat dan Makanan Nomor 15 Tahun 2019 Tentang Kriteria dan Tata Laksana Registrasi Obat', (778).
- Europe, C. of (2019) *European Pharmacopeia, Journal of the American Pharmaceutical Association (1961)*. doi: 10.1016/s0003-0465(16)31141-7.
- International Conference on Harmonisation (2017) 'ICH Topic Q 8 (R2) Pharmaceutical Development', *Regulatory ICH*, 8(June). Available at: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500002872.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002872.pdf).
- International Conference on Harmonization (2003) 'Q1A(R2) Stability Testing of New Drug Substances and Products', *Ich Harmonised Tripartite Guideline*, 4(February), p. 24.
- RI, M. K. (2010) 'Peraturan Menteri Kesehatan Republik Indonesia Nomor 1799/MENKES/PER/XII/2010 Tentang Industri Farmasi'.
- Rowe, R. C., Sheskey, P. J. and Quinn, M. E. (2009) 'Handbook of Pharmaceutical excipients 8th', *Remington: The Science and Practice of Pharmacy*, pp. 633–643. doi: 10.1016/B978-0-12-820007-0.00032-5.
- Saudagar, R. and Doltade, M. (2019) 'Role of Quality Assurance Department in Pharmaceutical Industries: A Review', *Journal of Drug Delivery and Therapeutics*, 9(3), pp. 678–683. Available at: <http://jddtonline.info/index.php/jddt/article/view/2904/2133>.
- WHO (2012) 'Quality assurance for pharmaceuticals', *Managemente sciences for health*.
- USP.Oral Drug Products-Product Quality Test <2>. In : USP-NF. Rockville, MD: USP; Aug 16,2022.
- DOI : [https://doi.org/10.31003/USPNF\\_M3211\\_05\\_01](https://doi.org/10.31003/USPNF_M3211_05_01)
- USP.Microbial Examination of Nonsterile Products : Acceptance Pharmaceutical

Preparation and Substances for Pharmaceutical Use <1111>. In : USP-NF.  
Rockville, MD: USP; Aug 16,2022.

DOI : [https://doi.org/10.31003/USPNF\\_M99830\\_01\\_01](https://doi.org/10.31003/USPNF_M99830_01_01)