

BAB V

SARAN

1. Calon Apoteker tidak dapat melihat langsung bagaimana keadaan Industri Farmasi secara langsung, dikarenakan pandemi Covid-19 yang menyebabkan PKPA ini dilaksanakan secara daring.
2. Secara keseluruhan pelaksanaan PKPA ini sudah sangat baik dan begitu banyak ilmu pengetahuan yang didapatkan oleh calon Apoteker.

DAFTAR PUSTAKA

- Asrina, R. 2020. Formulasi dan Uji mutu fisik sirup dari ekstrak etanol daun pare, *Jurnal Farmasi Sandi Karsa*, Makassar, Indonesia.
- BPOM RI., 2017. Peraturan Kepala Badan Pengawas Obat dan Makanan Republik Indonesia Nomor 24. Tentang Kriteria dan Tatalaksana kRegistrasi Obat. Jakarta: BPOM.
- Badan POM RI. 2018, Peraturan Badan Pengawas Obat dan Makanan Nomor 34 Tahun 2018 Tentang Pedoman Cara Pembuatan Obat yang Baik.
- Chandira, M., Venkateswarlu, B.S., Shankarrao, J.A., Bhowmik, D., Jyakar, B. and Narayana, T.V. 2010. Formulation and Evaluation of Extended Release Tablets containing Metformin HCl. *International Journal of ChemTech Research*, **2(2)**: 1320-1329.
- Booth, C. 2019. Endotoxin OOS and the Quest for the Root Cause, *ACTA Scientific Microbiology*, 2: 15-19
- Departemen Kesehatan Republik Indonesia, Undang-Undang Republik Indonesia Nomor 36 Tahun 2009 tentang Kesehatan, Departemen Kesehatan Republik Indonesia, Jakarta.
- Departemen Kesehatan Republik Indonesia. 1979. Farmakope Indonesia, Edisi III. Departemen KesehatanRI : Jakarta
- Departemen Kesehatan Republik Indonesia. 1995. Farmakope Indonesia, Edisi IV. Departemen KesehatanRI : Jakarta

- Departemen Kesehatan Republik Indonesia. 2014. Farmakope Indonesia, Edisi V. Departemen KesehatanRI : Jakarta
- Departemen Kesehatan Republik Indonesia. 2020. Farmakope Indonesia, Edisi VI. Departemen KesehatanRI : Jakarta
- Food and Drug Administration. 2011, Guidance for Industry “Process Validation: General Principles and Practices”, U.S. Department of Health and Human Services Food and Drug Administration, USA.
- Food and Drug Administration. 2006. Investigating Out of Specification (OOS) Test Result for Pharmaceutical Production, *Guidance for Industry*: U.S. Departement of Health and Human Services.
- Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container, EMA 2019.
- Gowtham, T., Punitha S., Thrishala, B., Soujaya, P. and Rajesekar S. 2013. Formulation and Evaluation of Atrovastatin Calcium
- Savale S., 2018, In Process Quality Control Tests (IPQC) For Parenteral or Sterile Dosage Forms
- Sustained Release Matrix Tablets. *International Journal of Research Pharmaceutical Sciences*. **4(1)**: 82-87.
- Hadisoewignyo, L dan Fudholi A., 2016, Sediaan Solida Edisi Revisi, Pustaka Pelajar, Yogyakarta.
- Hasan, M.R., Hossen, M.A., Roy, A., Islam, T. and Pathan, S.I. 2014. Preparation of Metformin Hydrochloride Extended Release Matrix Tablets by Direct Compression Method and Its In Vitro Evaluation. *British Journal of Pharmaceutical Research*, **4(24)** : 2679-2693.
- <https://pubchem.ncbi.nlm.nih.gov/compound/Metforminhydrochlorid>
e. Metformin HCl, diakses pada tanggal 18 Mei 2021.

- Kementerian Kesehatan Republik Indonesia. 2010, Peraturan Menteri Kesehatan Republik Indonesia No 1799/MENKES/PER/XII/2010 tentang Industri Farmasi, Jakarta Kementrian Kesehatan RI, 2014, Farmakope Indonesia Edisi V. Jakarta
- Lachman, C.L., Lieberman, H.A., dan Kanig, J.L., 1994. Teori dan Praktek Farmasi Industri. Edisi II. Diterjemahkan oleh Siti Suyatmi. Jakarta: Universitas Indonesia Press.
- Mahar, P. and Verma, A. 2014. Pharmaceutical Process Validaton : An Overview, *International Journal of Pharmaceutical Research and Bio-Science*, **3(4)**: 243-262
- Murtini, G. dan Elisa, Y. 2018. Teknologi Sediaan Solid, *Kementerian Kesehatan Republik Indonesia*, Jakarta.
- Medscape. Valproic acid (Rx). <https://reference.medscape.com/drug/depakene-stavzor-valproic-acid-343024>.
- Perka BPOM no 14 tahun 2019 tentang penarikan dan pemusnahan obat yang tidak memenuhi standart dan/atau persyaratan keamanan, khasiat, mutu dan label. Pharmaceutical Products Recall Guidelines, 2021
- Ram, P. R., Saroj, S., Shreekrishna, L. and Priyanka, P. 2015. A Review on Pharmaceutical Process Validation of Solid Dosage Form (Tablets). *Journal of Drug Delivery and Therapeutics*, **5(6)** : 1-7.
- The United States Pharmacopeial Convention edisi 35. 2012.
- The International Pharmacopoeia edisi 9, 2019.

- Vaigankar, P. and Amin, P. 2017. Continuous Melt Granulation to develop high drug loaded sustained release tablet of metformin HCl. *ScienceDirect*, **12**:37-50.
- Vitthalrao, S.K., and Chandrashekhar, M. 2016. Formulation Development and Evaluation of Astorvastatin Calcium Tablets using Co-Processed Excipients. *International Journal of Pharmaceutical Sciences Review and Research*, **39** : 217-222.
- World Health Organization, 2011. Anex 5 : Supplementary guidelines on good manufacturing practices for heating, ventilation and airconditioning systems for non-sterile pharmaceutical dosage forms, *WHO Technical Report Series*.