

## **BAB 5**

### **KESIMPULAN DAN SARAN**

#### **5.1. Kesimpulan**

Praktek Kerja Profesi Apoteker (PKPA) di industri yang dilaksanakan pada tanggal 02 Agustus 2021 hingga 25 September 2021 dapat diperoleh kesimpulan sebagai berikut:

1. PKPA di industri farmasi dapat meningkatkan pemahaman calon apoteker tentang peran, fungsi, posisi dan tanggung jawab apoteker di industri farmasi.
2. PKPA di industri farmasi dapat membekali calon apoteker agar memiliki wawasan, pengetahuan, keterampilan, dan pengalaman praktis untuk melakukan pekerjaan kefarmasian di industri farmasi.
3. PKPA di industri farmasi dapat memberi pemahaman bagi calon apoteker mengenai prinsip Cara Pembuatan Obat yang Baik (CPOB) serta penerapannya dalam industri farmasi.
4. PKPA di industri farmasi dapat memberi gambaran nyata tentang permasalahan pekerjaan kefarmasian di industri farmasi.

#### **5.2. Saran**

Saran yang dapat diberikan selama melakukan PKPA di industri farmasi adalah:

1. Calon apoteker hendaknya mempersiapkan diri dengan mencari informasi terlebih dahulu terkait peraturan industri farmasi.

2. Calon apoteker perlu meningkatkan kemampuan dalam berkomunikasi, kepercayaan diri, dan lebih aktif dalam mencari pustaka saat mengerjakan tugas yang diberikan.
3. Calon apoteker harus berperan aktif dalam melaksanakan diskusi, agar dapat memperoleh informasi yang optimal sehingga dapat menambah wawasan, pengetahuan, dan keterampilan dalam mengelola dan melakukan pekerjaan kefarmasian dalam industri farmasi.

## DAFTAR PUSTAKA

- Afikoh, N. dkk. "Pengaruh Konsentrasi PEG 400 dan PEG 4000 Terhadap Formulasi dan Uji Sifat Fisik Suppositoria Ekstrak Sosor Bebek (*Kalanchoe pinnata* [L.] pers)". *Jurnal Para Pemikir*, vol. 6, no. 2, 2017, pp. 156-160.  
[ejournal.poltektegal.ac.id/index.php/parapemikir/article/view/588/509](http://ejournal.poltektegal.ac.id/index.php/parapemikir/article/view/588/509).
- Allen, L.V. *Suppositories*. 1st Ed., Pharmaceutical Press, 2013.
- Allen, L.V. "Chapter 15: Suppositories and Inserts". *The Art, Science, and Technology of Pharmaceutical Compounding*, 6th Ed., American Pharmacists Association, 2020.
- ASEAN *Guideline for The Conduct of Bioequivalence Studies*. Revision 1, 2015.
- ASEAN *Guideline on Stability Study of Drug Product*. Revision 2, 2018.
- BPOM RI. 'Peraturan Badan Pengawas Obat dan Makanan Nomor 13 Tahun 2018 tentang Perubahan Atas Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor HK.03.1.33.12.12.8195 Tahun 2012 Tentang Penerapan Pedoman Cara Pembuatan Obat Yang Baik'. 2018.
- BPOM RI. 'Peraturan Badan Pengawas Obat dan Makanan Nomor 14 Tahun 2019 tentang Penarikan dan Pemusnahan Obat yang Tidak Memenuhi Standar dan/atau Persyaratan Keamanan, Khasiat, Mutu, dan Label'. 2019.
- BPOM RI. 'Peraturan Badan Pengawas Obat dan Makanan Nomor 34 Tahun 2018 tentang Pedoman Cara Pembuatan Obat yang Baik'. 2018.
- BPOM RI. 'Peraturan Kepala Badan Pengawas Obat dan Makanan RI No. HK.00.05.3.1818 tentang Pedoman Uji Bioekivalensi'. 2005.
- BPOM RI. *Petunjuk Operasional Penerapan Pedoman Cara Pembuatan Obat yang Baik*, Jilid 1. BPOM RI, 2013.
- BPOM RI. *Petunjuk Operasional Penerapan Pedoman Cara Pembuatan Obat yang Baik*, Jilid 2. BPOM RI, 2014.

- Cunningham, Andrew. "Just in Time. An Approach for A cGMP Fill-Finish Facility". *Pharmaceutical Engineering*, vol. 30, no. 2, 2010. pp. 8-20. [flad.com/content/epubs/just-in-time.pdf](http://flad.com/content/epubs/just-in-time.pdf).
- Davis, Bruce S. and Line Lundsberg-Nielsen. "Practical Implementation of The Lifecycle Approach to Process Validation". *The International Society for Pharmaceutical Engineering*. [ispe.org/sites/default/files/Webinar/practical-implementation-of-the-lifecycle-approach-to-pv-april-2020-final-watermarked-reduced.pdf](https://ispe.org/sites/default/files/Webinar/practical-implementation-of-the-lifecycle-approach-to-pv-april-2020-final-watermarked-reduced.pdf). Diakses pada tanggal 4 September 2021.
- El-Majri, M. A. and Mokhtar M. El-Baseir. "Formulation and Evaluation of Ibuprofen Suppositories". *International Research Journal of Pharmacy*, vol. 7, no. 6, 2016, pp. 87-90. doi : 10.7897/2230-8407.07670.
- European Medicines Agency and U.S. Food and Drug Administration. *Questions and Answers on Design Space Verification*. 2013.
- Food and Drug Administration (FDA), U.S. Department of Health and Human Services. "Guidance for Industry - Process Validation: General Principles and Practices". *Guidance for Industry Process Validation: General Principles and Practices Revision 1*, 2011.
- Food and Drug Administration (FDA), U.S. Department of Health and Human Services. "Guidance for Industry - Q8, Q9, & Q10 Questions and Answers: Appendix Q&As from Training Sessions". 2012.
- Goloveshkin, A.S. et al. "Novel Polymorph of Favipiravir—An Antiviral Medication". *Pharmaceutics*, vol. 13, no. 139, 2021, pp. 1-14. doi:10.3390/pharmaceutics13020139.
- Hadisoewignyo, L. dan Fudholi, A. *Sediaan Solida*. Pustaka Pelajar, 2016.
- Ham, Anthony S. and Robert W. Buckheit. "Designing and Developing Suppository Formulations for Anti-HIV Drug Delivery". *Therapeutic Delivery*, vol. 8, no. 9, 2017, pp. 805-817. Doi: 10.4155/tde-2017-0056.
- Haley, S. "Methylparaben". *Handbook of Pharmaceutical Excipients*. 6th ed, edited by Raymond C. Rowe, Paul J. Sheskey, and Marian E. Quinn. Pharmaceutical Press, 2009.
- International Conference on Harmonisation. "Guideline Validation of Analytical Procedures: Text and Methodology Q2 (R1)". *International Conference on Harmonisation of Technical*

*Requirements For Registration of Pharmaceuticals For Human Use*, 2005.

*International Conference on Harmonisation*. “Guidance for Industry: Q10 Pharmaceutical Quality System”. U.S. Department of Health and Human Services Food and Drug Administration, 2009.

Jadhav, V.M. *et al.* “Validation Of Pharmaceutical Water System – A Review”. *Journal of Pharmacy Research*, vol. 2, no. 5, 2009, pp. 1-5. [Pharmacyresearchjournal.org](http://Pharmacyresearchjournal.org).

Kementerian Kesehatan RI. *Farmakope Indonesia VI*. Departemen Kesehatan Republik Indonesia, 2020.

Khairuddin, N. Laila. *et al.* “Design of Fill and Finish Facility for Active Pharmaceutical Ingredients (API)”. *Journal of Engineering Science and Technology*, vol. 11, no. 8, 2016, pp. 1135-1154. [jestec.taylors.edu.my/Vol%2011%20issue%208%20August%202016/11\\_8\\_6.pdf](http://jestec.taylors.edu.my/Vol%2011%20issue%208%20August%202016/11_8_6.pdf).

Kockler, J. *et al.* “Stability of Paracetamol Tablets Repackaged in Dose Administration Aids for Use: Implications for Practice”. *Journal of Pharmacy Practice and Research*, vol. 43, no. 3, 2013, pp. 218-220. [research-repository.griffith.edu.au](http://research-repository.griffith.edu.au).

Kotra, Seetha R. *et al.* “Deviation Management System – A Boon in Industrial Quality Sciences for Compliance”, *International Journal of u- and e- Service, Science, and Technology*, vol. 11, no. 3, 2018, pp. 15-26. doi: 10.14257/ijunesst.2018.11.3.02.

Lewis, R.J.Sr. *Hawley's Condensed Chemical Dictionary*. 15th ed., John Wiley & Sons, Inc., 2007.

Mangilal, Teelavath. *et al.* “Pharmaceutical Waste and Public Health”. *International Journal of Pharmacy Education and Research*, vol. 1, no. 2, 2014, pp. 22-27. doi:10.17812/IJPER/2014;1(2):22-27.

McEvoy, Gerald K. *et al.* *AHFS Drug Information*, American Society of Health-System Pharmacist, American Hospital Formulary Service, 2011.

Millati, Ria, *et al.* “Agricultural, Industrial, Municipal, and Forest Wastes: An Overview”. *Sustainable Resource Recovery and Zero Waste Approaches*, edited by Mohammad J. Taherzadeh, Kim Bolton, Jonathan Wong, and Ashok Pandey. Elsevier, 2019, pp. 1-22.

- Mohrle, R. "Effervescent Tablet". *Pharmaceutical Dosage Forms: Tablet*. 2nd ed., edited by Lieberman H. A. and Lachman L. and J.B. Marcel Dekker, 1980.
- Mosher, Gretchen A. *et al.* "Using Mock Recall Data to Measure Continuous Quality Improvement". *Agricultural and Biosystems Engineering Conference Proceedings and Presentations*, 2009. lib.dr.iastate.edu/abe\_eng\_conf/349.
- O'Neil, M.J. *The Merck Index-An Encyclopedia of Chemicals, Drugs, and Biologicals*. Royal Society of Chemistry, 2013.
- Owusu, A.W.F. *et al.* "Formulation and *In Vitro* Evaluation of Nifedipine Suppositories for Geriatric and Severely Ill Patients with Hypertension". *Journal of Pharmacy and Drug Development*, vol. 2, no. 2, 2020, pp. 3. [escientificpublishers.com/formulation-and-in-vitro-evaluation-of-nifedipine-suppositories-for-geriatric-and-severely-ill-patients-with-hypertension-JPDD-02-0020](http://escientificpublishers.com/formulation-and-in-vitro-evaluation-of-nifedipine-suppositories-for-geriatric-and-severely-ill-patients-with-hypertension-JPDD-02-0020).
- Pai, Deeksha R. *et al.* "Personnel Training for Pharmaceutical Industry". *International Journal of Pharmaceutical Quality Assurance*, vol. 7, no. 3, 2016, pp. 55-61. [impactfactor.org/PDF/IJPQA/7/IJPQA,Vol7,Issue3,Article5.pdf](http://impactfactor.org/PDF/IJPQA/7/IJPQA,Vol7,Issue3,Article5.pdf)
- Patel, K.T. and Chotai, N.P. "Documentation and Records: Harmonized GMP Requirements". *Journal of Young Pharmacists*, vol. 3, no. 2, 2011. pp. 138-150. doi: 10.4103/0975-1483.80303.
- Peraturan Gubernur Jawa Timur No 52 tahun 2014 tentang Perubahan Atas Peraturan Gubernur Jawa Timur Nomor 72 Tahun 2013 tentang Baku Mutu Air Limbah Bagi Industri dan/atau Kegiatan Usaha Lainnya, 2014.
- Peraturan Pemerintah Republik Indonesia Nomor 51 Tahun 2009 tentang Pekerjaan Kefarmasian, 2009.
- Pharmaceutical and Food Safety Bureau. "Guideline for Bioequivalence Studies for Different Strengths of Oral Solid Dosage Forms", Attachment 2 of Division-Notification 0229 No. 10, 2012.
- Piehler, Maiké. *et al.* "Comparison of LAL and rFC Assays-Participation in a Proficiency Test Program between 2014 and 2019". *Microorganisms*, vol. 8, no. 418, 2020, pp. 1-11. doi: 10.3390/microorganisms8030418.

- Pramadona and Akbar Adhiutama. "The Application of Lean Manufacturing for Operation Improvement: A Case Study of Black Cough Medicine Production in Indonesia". *The Asian Journal of Technology Management*, vol. 6, no. 1, 2013, pp. 56-64. doi: 10.12695/ajtm.2013.6.1.5.
- Process Flow of Pharma Companies*. Spine, 2016.
- Ranjita, Shegokar and Singh K. Kamalinder. "In-Vitro Release of Paracetamol from Suppocire Suppositories: Role of Additives". *Malaysian Journal of Pharmaceutical Sciences*, vol. 8, no. 1, 2010, pp. 57-71. [web.usm.my/mjps/mjps08012010/mjps08012010\\_6.pdf](http://web.usm.my/mjps/mjps08012010/mjps08012010_6.pdf).
- Ranjita, Shegokar and Singh K. Kamalinder. "In Vivo Evaluation of Suppocire Paracetamol Rectal Suppositories". *International Journal of Pharmacy and Pharmaceutical Sciences*, vol. 4, no. 4, 2012, pp. 205-209. [innovareacademics.in/journal/ijpps/Vol4Suppl4/4254.pdf](http://innovareacademics.in/journal/ijpps/Vol4Suppl4/4254.pdf)
- Rectal Drug Delivery with Lipid Excipients*. Gattefosse, 2014.
- Rohit, V.V.S.S. et al. "An Overview on Pharmaceutical Drug Recalls". *The Pharmaceutical and Chemical Journal*, vol. 7, no. 2, 2020, pp. 16-22. [researchgate.net/publication/342199902\\_An\\_Overview\\_on\\_Pharmaceutical\\_Drug\\_Recalls](https://www.researchgate.net/publication/342199902_An_Overview_on_Pharmaceutical_Drug_Recalls).
- Sheskey, P.J. et al. *Handbook of Pharmaceutical Excipients*. 8th ed., Pharmaceutical Press, 2017.
- Shukla, Tripti. et al. "Role of Pharmacist in Pharmaceutical Waste Management." *World Journal of Environmental Biosciences*, vol. 6, no. 2, 2014, pp. 1-13. [researchgate.net/publication/319136156\\_ROLE\\_OF\\_PHARMACIST\\_IN\\_PHARMACEUTICAL\\_WASTE\\_MANAGEMENT](https://www.researchgate.net/publication/319136156_ROLE_OF_PHARMACIST_IN_PHARMACEUTICAL_WASTE_MANAGEMENT).
- Stainless Steel Grade Datasheets*. Atlas Steels, 2013.
- Sweetman, S.C. *Martindale: The Complete Drug Reference*. 36th ed., Pharmaceutical Press, 2009.
- Taisho Toyama Pharmaceutical. "Avigan Tablets 200 mg", 2017.
- Undang-Undang Republik Indonesia Nomor 36 Tahun 2009 tentang Kesehatan, 2009.

- United States Pharmacopeia Convention. *USP42 NF37, 2019: U. S. Pharmacopoeia National Formulary*. United States Pharmacopeial, 2019.
- United States Pharmacopeia. “USP (71) Sterility Tests”. *USP Education*, 2021. [latam-edu.usp.org/wp-content/uploads/2021/01/Module-09-USP-71-Sterility-Tests.pdf](http://latam-edu.usp.org/wp-content/uploads/2021/01/Module-09-USP-71-Sterility-Tests.pdf).
- Vamsi, Borra. *et al.* “Vendor Qualification and Evaluation in Pharmaceutical Industry”. *International Journal Of Research in Pharmaceutical Sciences*, vol. 11, no. 2, 2020, pp. 1987-1994. doi: 10.26452/ijrps.v11i2.2129.
- Voigt, R. *Buku Pelajaran Teknologi Sediaan Farmasi Industri*. Gadjah Mada University Press, 1995.
- Wafa, Amru K. dan Bambang Purwanggono. “Perhitungan OEE (*Overall Equipment Effectiveness*) pada Mesin Komuri 2 Lithrone S40 dan Heidelberg 4WE dalam Rangka Penerapan *Total Productive Maintenance (TPM)*”. *Media Neliti*, 2015. [media.neliti.com/media/publications/184411-ID-none.pdf](http://media.neliti.com/media/publications/184411-ID-none.pdf).
- Wang, I.C. *et al.* “Polymorph Transformation in Paracetamol Monitored by In-line NIR Spectroscopy During a Cooling Crystallization Process”. *AAPS PharmSciTech*, vol. 12, no. 2, 2011, pp. 764-770. doi: 10.1208/s12249-011-9642-x.
- World Health Organization (WHO). *A WHO Guide to Good Manufacturing Practice (GMP) Requirements – Part 3: Training*, 2006.
- World Health Organization (WHO). *Annex 1: Manufacture of Sterile Medicinal Products*, 2017.
- World Health Organization (WHO). *Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies*, 1999.
- World Health Organization (WHO). *Proposal to Waive In Vivo Bioequivalence Requirements for The WHO Model List of Essential Medicines Immediate Release, Solid Dosage Forms*, 2005.
- World Health Organization (WHO), WHO Expert Committee on Specifications for Pharmaceutical Preparations. “Annex 3: Guidelines on Good Manufacturing Practices: Validation, Appendix 7: Non-Sterile Process Validation”. *WHO Technical Report Series No. 992*, 2015.



*World Health Organization (WHO). WHO Technical Report Series no. 1019, 2019.*

Zhang, Lan *and* Shirui Mao. “Application of Quality by Design in The Current Drug Development”. *Asian Journal of Pharmaceutical Sciences*, vol. 12, 2017. doi: 10.1016/j.ajps.2016.07.006.