

**A HANDBOOK OF PHARMACIST
PROFESSION FIELDWORK PRACTICE
INDUSTRY**



PHARMACIST PROFESSION EDUCATION PROGRAM

FACULTY OF PHARMACY

UNIVERSITAS AIRLANGGA

2022

CHAPTER I

INTRODUCTION

Pharmacist Profession Program (PKP) in Industry is one of the professional-level educational activities intended for students of pharmacist professional education programs to gain a comprehensive understanding of the production of pharmaceutical preparations, especially drugs.

This book is a guideline for implementing PKP for preceptors in industry, advisors, and students of the Pharmacist Profession, Faculty of Pharmacy, Universitas Airlangga. This book is designed based on the established Competency Standards for pharmacist graduates enacted in the 2014 Curriculum, as follows:

1. Able to uphold professionalism, morals, ethics, and legal aspects in conducting pharmaceutical practices.
2. Able to provide pharmaceutical care to patients by considering legal, ethical, professional, socio-cultural, and economic aspects to ensure therapy's quality, safety, and efficacy.
3. Able to accurately and safely serve the demand for pharmaceutical preparations and medical equipment, both prescription and non-prescription.
4. Able to manage the required standardized pharmaceutical preparations and medical equipment
5. Able to formulate, manufacture, and guarantee the quality of pharmaceutical preparations based on pharmaceutical science and technology.
6. Able to communicate and cooperate with patients and fellow health professionals related to rational drug therapy to achieve improved health and quality of life.
7. Able to participate in preventive and promotive efforts to improve the quality of public health.
8. Able to be introspective and self-develop by the development of pharmaceutical science and technology.

PKP activities require participants to have cognitive and psychomotor skills and attitudes or affective when facing practical problems in the Pharmaceutical Industry. Hence, students will have basic skills that can be practically implemented in the workplace, especially in the Pharmaceutical Industry.

The Purpose of PKP in Industry

After participating in Industrial PKP, participants will be able to:

Explain effective and efficient management in the pharmaceutical industry (manufacturing) to provide quality, safe, and productive/useful pharmaceutical supplies for clients/communities in need. In addition, participants are expected to be able to explain the application of CPOB aspects and obtain a real picture of pharmaceutical work in the pharmaceutical industry.

Description of PKP in Industry

It is a form of profession fieldwork practice in the pharmaceutical industry or similar field, especially to provide a clearer picture of the industry, the application of CPOB and related laws and regulations, the process of making pharmaceutical preparations, facilities and infrastructure, and pharmaceutical functions.

Learning Methods

The learning process will be centralized to students through fieldwork practices, individual assignments and case studies in the pharmaceutical industry.

CHAPTER 2

GENERAL PROVISION

II.1. Rules for Participants of PKP in Industry:

1. Participants of PKP must be healthy supported with the evidence of a doctor's notes.
2. Clothing:
 - a. Neat and polite.
 - b. Follow the rules on the PKP site (for example, specific work clothes required to wear in certain places).
 - c. Wearing sandals and T-shirts is forbidden.
3. Attendance:
 - a. Must be punctual at the specified hour.
 - b. Participants who cannot attend must be able to provide a doctor's notes or other valid information.
4. Stationery must be brought individually.
5. Able to work with discipline, work collaboratively, and follow all procedures and rules at the PKP site.

II.2. Activities of PKP in Industry

The activities carried out in the implementation of Industrial PKPA include:

1. PKP Briefing Lecture
It is given before students are placed in the industry. The briefing material is summarized in two courses, namely Quality Management and Production Management conducted by pharmaceutical industry practitioners and teaching staffs of the Faculty of Pharmacy, Universitas Airlangga.
2. Guest Lecture
Guest lectures are held one time per period and used as an enrichment insight from industry practitioners.
3. PKP in Industry
Student activities in industrial PKPAZ are conducted for 6-8 weeks, lasting 40-48 hours per week.

4. Learning share session

Learning share sessions are in the form of presentations in their workplaces, followed by discussions/ questions and answers sessions. It serves as a medium to share experiences and knowledge from various industries to enrich students' knowledge and insights. This activity is guided by advisors from the faculty and assessments are made on the ability to convey results and to respond to questions.

The PKPA materials in Industry include:

| No. | Materials | Delivered by Preceptor in Industry during PKP | |
|-----|---|---|----|
| | | Yes | No |
| 1 | Administrative and Law Legality Aspects related to Pharmaceutical Industry (Drug Industry). | | |
| 2 | Organization: The overview of effective and efficient Pharmaceutical Industry organization. | | |
| 3 | CPOB aspects that must be fulfilled by the Pharmaceutical Industry include: | | |
| | a. General Provision of CPOB concerning all aspects of production and quality assurance aimed at ensuring that drug products are made accurately and always meet the requirements of quality, safety, and usefulness as specified | | |
| | b. Personnel: officers involved in drug manufacture must meet certain requirements such as: having knowledge, skills, and abilities as assigned Idworkally and awareness to realize CPOB. | | |
| | c. Buildings and facilities The location is protected from environmental pollution, and building construction must meet applicable standards and regulations; additionally, the design and space layout is adjusted to accommodate activities, classrooms, and an AHU (Air Handling Unit). | | |
| | d. Equipment. | | |

| | | | |
|---|---|--|--|
| | e. Sanitation and hygiene. | | |
| | f. Production: The unit process, packaging, and in-process control. | | |
| | g. Quality Control. | | |
| | h. Self-inspection. | | |
| | i. Handling of drug complaints, recalls, and drugs return. | | |
| 4 | Registration: Collection of data, both research and development, results in the form of formulation, pharmacology and toxicology, process of production, and other technical data required for registration of new products. | | |
| 5 | Validation: is an act of proving in an appropriate manner that each material, process, procedure, activity, system, equipment, and mechanism used in production and supervision always achieves the desired results. | | |
| 6 | Water for the Pharmaceutical Industry: Water used in the Industry must be of high quality both for the production process and for other purposes. Preliminary checks are carried out through chemical, physical, and bacteriological examinations, followed by tiered treatment based on the purpose. | | |
| 7 | Material management (Flow of material) is related to purchase requests for raw materials, containers, supporting production materials, order journals, inspections, and the payment process. | | |
| 8 | Production management: production is performed by following standardized procedures to ensure the standard requirement for product specifications. Production activities are adjusted to the production plan, both monthly and yearly. | | |
| 9 | Quality assurance: is a critical stage of CPOB/ CPOTB / CPKB, GMP, GLP (Good laboratory method), and GCP (Good clinical test method). The system should be properly designed to ensure that every drug contains the | | |

| | | | |
|----|--|--|--|
| | accurate ingredients and quality. It consists of quality control, quality assurance, and post-production quality control. | | |
| 10 | <p>Wards</p> <p>They have 4 functions: receiving, storing, distributing, and counting goods.</p> <ol style="list-style-type: none"> a. Receiving goods: external and internal. External revenue includes goods for production (raw materials and packaging materials), non-production goods, goods for promotion, and returned drugs. b. Storing goods: Attention must be paid to storage conditions. In this case, drug and its materials require special treatment, especially storage temperature. c. Distributing goods: When distributing goods, especially finished products, it is necessary to aim for certain requirements stated in the released card, from the quality control department. There are two kinds of distribution: external and internal. Internal distribution involves distributing goods to be used internally, while external distribution involves the outside of the company, including the delivery of finished products to distributors. d. Counting goods: The ward also controls the inventory of goods and finished products. | | |
| 11 | <p>Production Planning and Inventory Control (PPPP) = PPIC (Production Planning and Inventory Control)</p> <p>This section serves as order management, material control, planning, and evaluation of products.</p> | | |
| 12 | <p>Research and development functions to conduct research and development, especially new products in the form of formula development (standardized formulas, alternative formulas, and experiments on a small scale), analysis development (validated examination and testing stability), and packaging development (composition and packaging design).</p> | | |

| | | | |
|----|--|--|--|
| 13 | Waste handling: waste handling in the pharmaceutical industry is a responsibility and necessity for the surrounding community and environment. Waste handling is also as implementation of quality and environmental policies. | | |
| 14 | Occupational Health and Safety (OHS). | | |

PKP Schedule and Material

PKP in the Pharmaceutical Industry is held for approximately two months (6 – 8 weeks) with the following schedule * :

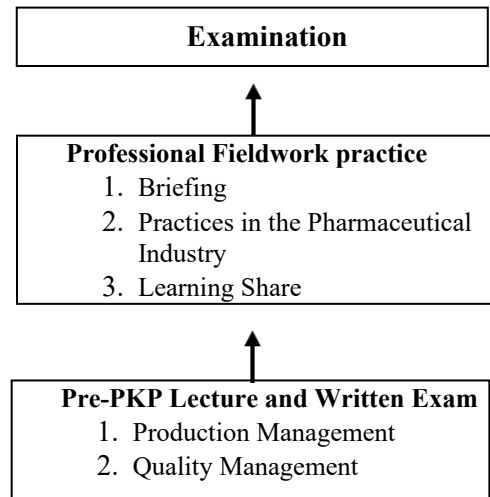
| No. | Day, Date | Activities | PIC |
|-----|-------------|--|-----|
| 1 | Week I | <ul style="list-style-type: none"> ● General explanation of the Pharmaceutical Industry where PKP is held. ● All Departments Plant Tour | |
| 2 | Week II-III | <ul style="list-style-type: none"> ● Learning one production cycle of one product, Including an understanding of Raw Materials, Production and QC Aspects, Supporting Units, packaging, retention samples, registration, and documentation. | |
| 3 | Week IV-V | <ul style="list-style-type: none"> ● Involved or explored one of the industry's activities, for example, Validation, PPIC, R&D, AHU, Water System, Ward, Sanitation/ Hygiene, Waste, Registration, etc. | |
| 4 | Week VI-VII | <ul style="list-style-type: none"> ● Specific Tasks: Assign PKP participants with a task to be reported and analyzed afterwards. | |
| 5 | Week VIII | <ul style="list-style-type: none"> ● Seminar in the Pharmaceutical Industry, PKP participants make reports in PowerPoint presentations about their PKP results (such as what activities were done) in front of Preceptors and advisors from the Faculty of Pharmacy, Universitas Airlangga. | |

* The realization order will be adjusted to the activities at the PKP site.

Consultation

During the practical learning process in the Pharmaceutical Industry, participants will be guided by an advisor at the PKP workplace and 2 advisors from the Faculty of Pharmacy.

Learning Map of PKP in Industry:



Final Learning Outcomes

Students must make:

- a. PKP Report Manuscript
- b. Logbook of PKP implementation in the Industry
- c. Product development Manuscript

Evaluation

Aspects being assessed by Preceptors on PKP participants are:

- a. Cognitive Aspects
- b. Affective Aspects
- c. Psychomotor Aspects

ASSESSMENT OF PKP ACTIVITIES
PHARMACIST PROFESSION EDUCATION PROGRAM PERIOD ...
FACULTY OF PHARMACY, UNIVERSITAS AIRLANGGA

| Name : Student numbers : PKP workplace : Address of the Industry : | | | | |
|---|--|-----------|---------------|---------|
| NO | PKP ASSESSMENT OBJECTIVES | PKP SCORE | MAXIMUM SCORE | REMARKS |
| 1 | <u>Cognitive:</u> -Attendance -Material Mastery -Work Report | | 30 | |
| 2 | <u>Affective:</u> - Discipline -Initiative -Responsibility -Collaboration | | 30 | |
| 3 | <u>Psychomotor:</u> -Fieldwork practice | | 40 | |
| | Total Score | | 100 | |

.....,

Validated by:
Head

Advisor in PKP workplace

(.....)

(.....)

Note:

| Score Conversion | | |
|------------------|-----------------|-----------------|
| Scoring Letter | Scoring Quality | Scoring Numbers |
| A | 4 | 86 – 100 |
| AB | 3,5 | 78 – < 86 |
| B | 3 | 70 – < 78 |
| BC | 2,5 | 62 – < 70 |
| C | 2 | 54 – < 62 |
| D | 1 | 40 – < 54 |
| E | 0 | < 40 |

CHAPTER 3

PKP in INDUSTRY OUTPUT

III.1. PKP in Industry Report

Writing Report formats include:

THE REPORT STRUCTURE

Preface

Table of Contents

List of Tables

List of Figures

Appendix

Chapter I: Introduction:

- Background
- PKP Objectives
- PKP benefits (maximum 2 pages)

Chapter II: Overview of the Pharmaceutical Industry

- Organizational Structure
- Roles and positions of Pharmacists in the Pharmaceutical Industry
- Product Type

Chapter III: PKP Activities

- Plant Tour
- The manufacturing process of one product, from raw materials to finished products
- Understanding Focus in one of the Departments
- Seminar

Chapter IV: Discussion

The PKP results are discussed by connecting them to the knowledge foundation, CPOB, laws, and regulations, such as Govt Reg. 51, and so on.

Chapter V: Conclusions and Recommendations

The conclusion answers the objectives and recommendations, at least for the Faculty of Pharmacy, Universitas Airlangga.

References

Appendix

Specific Assignment

Guidelines for Specific Assignment

- Title
- Introduction
- Objectives
- Activities
- Results
- Discussions
- Conclusions

The format of the Cover of the Report:

PHARMACIST PROFESSION FIELDWORK PRACTICE

PT.

Address.

From..... to

(Day, Month, Year)



By

Name/ Students Number :

PHARMACIST PROFESSION EDUCATION PROGRAM

PERIOD.....

FACULTY OF PHARMACY UNIVERSITAS AIRLANGGA

20..

Format of Approval Sheet

REPORT

PHARMACIST PROFESSION FIELDWORK PRACTICE IN INDUSTRY

PT.

ADDRESS.

Period

PKP starting and ending date

WRITTEN TO FULFILL ONE OF THE REQUIREMENTS

TO ACHIEVE A PHARMACIST DEGREE

Written by :

Name:

Student Number:

Approved by:

Company advisor.....

Name

Position

Advisor I

Advisor II

Name

Name

Employee number

Employee number

CONSULTATION FORM*

PHARMACIST PROFESSION EDUCATION PROGRAM

PERIOD Year

Name: Student number:

| No. | TIME (Day/Date) | ACTIVITIES | Advisor Signature |
|--------------------------------------|----------------------------|-------------------|------------------------------|
| 1. | | | |
| 2. | | | |
| 3. | | | |
| 4. | | | |
| 5. | | | |
| 6. | | | |
| 7. | | | |
| 8. | | | |
| Advisor remarks : | | | |

Note:

*Consultation by an advisor from the Faculty of Pharmacy, Universitas Airlangga, and also Meetings/discussions with the advisor from the Faculty are conducted before, during, and at the end of PKP.

..... ,

Advisor

(.....)

III.2. Log Book of PKP Industri
The format of PKP Log Book

LOGBOOK
PHARMACIST PROFESSION FIELDWORK PRACTICE
IN INDUSTRY
COMPANY.



Agus Harianto, S.Farm

Student Number

PHARMACIST PROFESSION EDUCATION PROGRAM PERIOD 108

FACULTY OF PHARMACY

UNIVERSITAS AIRLANGGA

SURABAYA

20...

The Format of PKP Daily Log Book

ACTIVITY REPORT DAY-.....

| | |
|------------|--|
| Day/ Date | |
| Activities | |
| Objectives | |
| Outcomes | |
| Remarks | |

by

Validated

Advisor/ Preceptor

.....

III.3. Product Development Paper

THE STRUCTURE of Product Development Paper

| | |
|---------------|---|
| CHAPTER I. | Introduction |
| CHAPTER II. | Literature review/pre-formulation study |
| CHAPTER III. | Formulation, product specifications, formula, etc. |
| CHAPTER IV. | Procedure in product manufacture, Flowchart, IPC, QC, etc. |
| CHAPTER V. | Analysis Methods / Development of analytical methods, Verification, validation, etc. |
| CHAPTER VI. | Stability test |
| CHAPTER VII. | BA-BE test (if applicable) |
| CHAPTER VIII. | Packaging |
| CHAPTER IX. | Registration |
| CHAPTER X. | Discussion |
| CHAPTER XI. | Conclusion |
| | References |

Format for Cover for Product Development Paper

PRODUCT DEVELOPMENT PAPER

TITLE



Written by :

NAME

STUDENT NUMBER

PHARMACIST PROFESSION EDUCATION PROGRAM....

FACULTY OF PHARMACY UNIVERSITAS AIRLANGGA

Format of Writer Signature Sheet:

PRODUCT DEVELOPMENT PAPER.

.....TITLE.....

**WRITTEN FOR ONE OF THE REQUIREMENTS TO ACHIEVE
PHARMACIST DEGREE**

Written by:

Signature

Name

Student Number

CHAPTER IV

GUIDELINES FOR PKP in INDUSTRY ASSESSMENT

Reference to the Indonesian Pharmacist Competency Standard 2016.

COMPETENCY STANDARD 5: FORMULATION AND PRODUCTION OF PHARMACEUTICAL PREPARATIONS

UNIT COMPETENCY 5.1

Principles and Procedures for Making Pharmaceutical Preparations.

Core Competencies:

Able to explain the principles and procedures for making pharmaceutical preparations.

Pharmacist graduates can:

- 5.1.1. Search for information related to physical, chemical, physicochemical, pharmacological, microbiological, and regulatory characteristics as a basis for pre-formulation studies.
- 5.1.2. Describe the basic principles, techniques, and equipment used in the manufacture of pharmaceutical preparations.
- 5.1.3. Explain the role of additives in the formulation of pharmaceutical preparations, such as buffers, preservatives, antioxidants, and/or other auxiliary materials.
- 5.1.4. Describe the stability principle of pharmaceutical preparations, their influencing factors, and testing techniques.

COMPETENCY UNIT 5.2

Pharmaceutical Preparation Formulations

Core Competencies:

Able to set the accurate formula by standards and regulations.

Pharmacist graduates can:

- 5.2.1. Conduct pre-formulation studies and determine the formulation of pharmaceutical preparations by considering aspects of quality, effectiveness, safety, and stability of

preparations.

- 5.2.2. Determine the specifications of raw materials, packaging materials, and preparations/products referring to the Indonesian Pharmacopoeia or other appropriate compendiums.
- 5.2.3. Design procedures for making sterile and non-sterile pharmaceutical preparations, complying with Good Pharmaceutical Preparation Manufacturing Practices (GMP) provisions.
- 5.2.4. Design pharmaceutical preparations' packaging, labels, and brochures/leaflets and ensure the availability of required information, e.g., ED (Expiration Date), BUD (Beyond Use Date), solvents, compatibility, and storage conditions.
- 5.2.5. Establish the conformity of raw materials to standardized specifications.

UNIT COMPETENCY 5.3

Manufacture of Pharmaceutical Preparations

Core Competencies:

Able to make and ensure the quality of pharmaceutical preparations by standards and regulations.

Pharmacist graduates can:

- 5.3.1. Prepare worksheets, calculate material and equipment requirements, and ensure the availability of materials and equipment in the workplace.
- 5.3.2. Prepare materials, equipment and space for the manufacture of pharmaceutical preparations as required.
- 5.3.3. Make sterile and/or non-sterile pharmaceutical preparations using appropriate techniques according to established procedures.
- 5.3.4. Conduct quality testing during the production process, intermediate and final products.
- 5.3.5. Ensure product quality conformity with established specifications and establish product feasibility.
- 5.3.6. Document data/information related to the manufacturing process and product quality testing responsibly..

COMPETENCY UNIT 5.4

Quality Assurance of Pharmaceutical Preparations

Core Competencies:

Able to ensure the quality of pharmaceutical preparations by standards & regulations.

Pharmacist graduates are able to:

- 5.4.1. Explain the principles of quality management: quality assurance (QA) & quality control (QC).
- 5.4.2. Explain the principles of quality risk management.
- 5.4.3. Explain the classification division of production rooms along with their parameters and measurements.
- 5.4.4. Explain the qualification principles of production rooms and machines, validation of process, cleaning, and analysis methods.
- 5.4.5. Describe the principle of calibration of production machines.
- 5.4.6. Explain the principles of self-inspection, audit, and making corrective action & preventive action (CAPA).
- 5.4.7. Explain the principles of handling complaints and returned drugs.
- 5.4.8. Describe the employees' hygienic and training requirements.

LEVEL OF ABILITY / SKILL

OBJECTIVES

The skills to practice the pharmacist profession need to be trained on an ongoing basis from the beginning to the end of pharmacist education. This list of skills is prepared to be a reference for educational institutions in designing curricula and learning activities, resulting in graduated pharmacists having the minimum skills that must be mastered by pharmacist professional education graduates.

SYSTEMATICS

This skill list is compiled based on the scope of pharmaceutical practice in health services. Pharmacists' competence to practice the profession is divided into 4 (four) ability levels of ability to achieve at the end of the term. The ability level in this skill list refers to Miller's Pyramid (knows; knows how, shows, does).

Ability Level 1 (Knows): Knowing and explaining

Pharmacist graduates master theoretical knowledge in the pharmaceutical field and its application in practice, including pharmacological, clinical, social, and administrative aspects. They can explain to patients, peers, and other professionals the principles/mechanisms and goals to achieve. This ability can be obtained through lectures, practicums, discussions, assignments, and independent study.

Skill assessment of ability level 1 can be done using written exams and/or practical exams.

Ability Level 2 (Knows How): Understand the how/procedure

Pharmacist graduates master the theoretical knowledge of these skills along with standard operational procedures in performing these skills, focusing on the ability to provide the scientific foundation (reasoning ability) and solve problems (problem-solving ability). This ability can be acquired through demonstration or observing its implementation directly in the patient/community.

Skill of ability level 2 can be assessed using multiple-choice written exams and/or written or oral/oral case solving.

Ability Level 3 (Shows): Able to perform under supervision

Pharmacist graduates master the theoretical knowledge of these skills and their application in practice, including the pharmaceutical, clinical, social, and administrative aspects. They can perform these skills in "case simulation" under supervision. Skill assessment level 3 is performed using the OSCE (Objective Structured Clinical Examination) or OSATS (Objective Structured Assessment of Technical Skill, Case Study) method.

Ability Level 4 (Does): Able to perform independently

Pharmacist graduates can demonstrate these skills independently by mastering all theories, principles, procedures, and steps to perform them.

This level 4 skill is assessed with work-based assessment by supervisors and/or using logbooks, portfolios, etc.

DESIGNING PHARMACEUTICAL PREPARATIONS

| No | Skills | Ability Level |
|----|---|---------------|
| 1 | Pre-formulation studies | 4A |
| 2 | Pharmaceutical preparation formulations design and/or arrangement | 4A |
| 3 | Specifications arrangement for raw materials, preparations, and packaging materials | 4A |
| 4 | Selection and arrangement of raw materials, additives, and packaging materials by standardized specifications | 4A |
| 5 | Selection of methods and arrangement of procedures for manufacturing pharmaceutical preparations with regard to management principles quality | 4A |
| 6 | Selection of methods and setting procedures for quality evaluation of pharmaceutical preparations | 4A |
| 7 | Design of 4A dosage packaging, labels, brochures, and/or leaflets | 4A |
| 8 | Design of stability testing for deciding ED | 4A |
| 9 | Documentation of data/information and formulation of selected pharmaceutical preparations to be made | 4A |

MANUFACTURE OF PHARMACEUTICAL PREPARATIONS

| No | Skills | Ability Level |
|----|--|---------------|
| 1 | Preparation of room for the manufacture of pharmaceutical preparations by considering the principles of quality management (QA & QC). | 4A |
| 2 | Preparation of worksheets and calculation of the need for ingredients in pharmaceutical preparation formulas. | 4A |
| 3 | Preparation of tools and facilities required for manufacturing, quality evaluation, and pharmaceutical preparation stability tests. | 4A |
| 4 | Making pharmaceutical preparations according to the design determined by considering management principles quality (QA&QC). | 4A |
| 5 | Quality testing of pharmaceutical preparations during the production process, intermediates, and final products. | 4A |
| 6 | Analysis of the conformity of the quality of pharmaceutical preparations to Quality Specifications. | 4A |
| 7 | Implementation of stability tests for setting the ED. | 4A |
| 8 | Packaging, marking, and labeling of pharmaceutical preparations. | 4A |
| 9 | Determination of pharmaceutical preparations feasibility to deliver to consumers. | 4A |
| 10 | Waste management. | 4A |
| 11 | Documentation of the manufacturing process, quality evaluation of stability testings, and determination of feasibility of pharmaceutical preparations. | 4A |

QUALITY ASSURANCE

| No | Skills | Ability Level |
|----|-----------------------------------|---------------|
| 1 | SPO design in pharmaceutical work | 4A |
| 2 | SPO Validation | 4A |
| 3 | SPO Assignment | 4A |

| | | |
|---|--|----|
| 4 | Compliance with performing the by SPO | 4A |
| 5 | SPO Review | 4A |
| 6 | Documentation of activities properly and correctly | 4A |

ASSESSMENT FORM

PHARMACIST PROFESSION FIELDWORK PRACTICE : INDUSTRY

NAME :
STUDENT NUMBER :
Period/Rotation :
Advisor Name :

COMPETENCY AREA I: PROFESSIONAL AND ETHICAL PHARMACEUTICAL PRACTICE

Competency I: Mastering the Code of Ethics Applicable in Professional Practice
Understanding and leading the code of ethics in professional practice

| No. | Assessment of Ability | Ability Level | | | Reference |
|-----|---|-----------------------------------|----------------------------|----------------------------------|---|
| | | 1 Fairly Good (Score 65-77) | 2 Good (Score 78-85) | 3 Excellent (Score 86-100) | |
| 1 | Discipline | | | | • Consultation Form • Discussion |
| 2 | Initiative | | | | |
| 3 | Responsibility | | | | |
| 4 | Communication skills | | | | |
| | TOTAL SCORE (TS) | | | | |
| | AVERAGE COMPETENCE SCORE I: TS/4 | | | | |

**COMPETENCY AREA V: FORMULATION AND PRODUCTION OF
PHARMACEUTICAL PREPARATIONS**

Competency V.1: Principles and Procedures for Making Pharmaceutical Preparations

| No. | Expected Ability | Ability Level | | | Reference |
|-----|---|------------------------------------|-----------------------------|-----------------------------------|--|
| | | 1 Fairly Clear (Score 65-77) | 2 Clear (Score 78-85) | 3 Very Clear (Score 86-100) | |
| V.1 | Able to explain the principles and procedures for making pharmaceutical preparations | | | | • NPP |
| V.2 | Able to determine the accurate formula by standards and regulations | | | | • NPP • Discussion |
| V.3 | Able to make and ensure the quality of pharmaceutical preparations by standards and regulations | | | | • NPP • Discussion |
| V.4 | Able to ensure the quality of pharmaceutical preparations by standards and statutory provisions | | | | • Report • Log book • Discussion |
| | TOTAL SCORE (TS) | | | | |
| | AVERAGE COMPETENCE SCORE V : TN/4 | | | | |

FINAL SCORE : 0,5 x average competence score I + 0,5 x average competence score V

| Average competence score I | Average competence score V | FINAL SCORE |
|----------------------------|----------------------------|-------------|
| | | |

Surabaya,20...

Advisor,

()

The assessment is based on :

1. PKP Report
2. Logbook
3. Product Development Paper (NPP)
4. Discussion during consultation

Note:

| Score Conversion | | |
|------------------|-----------------|----------------|
| Scoring Letter | Scoring Quality | Scoring Number |
| A | 4 | 86 – 100 |
| AB | 3,5 | 78 – < 86 |
| B | 3 | 70 – < 78 |
| BC | 2,5 | 62 – < 70 |
| C | 2 | 54 – < 62 |
| D | 1 | 40 – < 54 |
| E | 0 | < 40 |

The minimum score of passing PKP is B

REFERENCE :

Standar Kompetensi Apoteker Indonesia, 2016, Ikatan Apoteker Indonesia.

REFERENCE

1. Anonim, 2011, Kode Etik Apoteker dan Pedoman Pelaksanaan, Ikatan Apoteker Indonesia – Majelis Pembina Etik Apoteker, Jakarta.
2. Aulton, ME, 2002. *Pharmaceutics: The Science of Dosage Form Design*, Second Edition, London, Churchill Livingstone.
3. Badan POM, 2012, Pedoman Cara Pembuatan Obat Yang Baik, Badan POM RI, Jakarta.
4. Dep Kes RI, 2014. *Farmakope Indonesia V*. Departemen Kesehatan RI, Jakarta.
5. Ikatan Apoteker Indonesia, 2016 *Standar Kompetensi Apoteker Indonesia*, Jakarta.