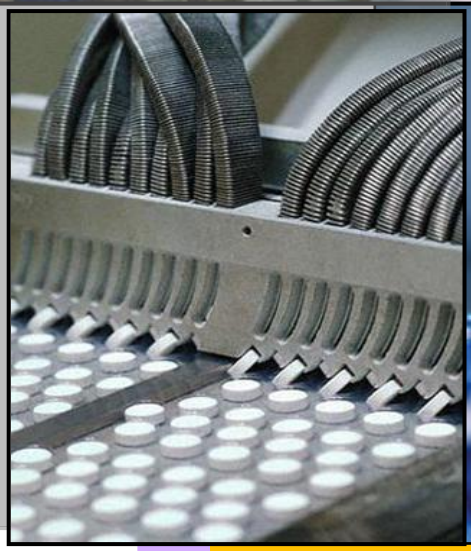
PHARMACEUTICAL INDUSTRY

RECORD OF TRAINING AND EXPERIENCE OF PROVISIONALLY REGISTERED PHARMACIST (PRP)





PHARMACY BOARD MALAYSIA
MINISTRY OF HEALTH MALAYSIA

PERSONAL PARTICULARS

[To Be Completed By the Provisionally Registered Pharmacist (PRP)]

1. **Name (in capital letters) :**
2. **New I/C Number :**
3. **Provisional Registration Number:**
4. **Telephone Numbers :**
5. **Home Address :**
6. **E-mail Address :**
7. **Qualification (Degree/ University/ Year):**
8. **Scholarship/Sponsor (Federal/MARA/Others):**
9. **Principal Training Place:**
10. **Duration of Training: From (date): …….. to ……**
11. **Name & Contact Number of person in case of emergency:**

I confirm that the above information provided above is true.

Signature: Date:

1. INTRODUCTION

1.1 The Registration of Pharmacists Act (Amendment) 2003 stipulates that a person who is provisionally registered shall be required to obtain experience immediately upon being provisionally registered, engage in employment as a Provisionally Registered Pharmacist (PRP) to the satisfaction of the Pharmacy Board for a period of not less than one year.

1.2 The engagement as a PRP must be in any premises listed in the *Second Schedule* in order to be entitled to apply for full registration.

1.3 The Pharmacy Board may extend the one year period of employment of a PRP if the Board is not satisfied with the performance of that person as a PRP.

1.4 The provisional registration of a person shall be revoked if that person fails to engage in employment as a PRP to the satisfaction of the Pharmacy Board for a period of not less than one year in any premises listed in the *Second Schedule*.

1.5 All PRPs **are required to pass** the Pharmacy Jurisprudence Examination conducted by the Pharmacy Board prior to full registration.

2. TRAINING MODULES AND RECORD OF TRAINING AND EXPERIENCE OF THE PROVISIONALLY REGISTERED PHARMACIST [PRP] IN PHARMACEUTICAL INDUSTRY

2.1 Preamble:

2.1.1 The pharmaceutical manufacturing industry is an emerging industry that requires specific sets of people competencies to align with the nature and challenges faced, internally and externally, by the industry.

2.1.2 By the end of the training, the PRP will be able to achieve key and functional competencies in the aspect of manufacturing sector. This shall then present diversity in the role, experience and contribution of the pharmacists in Malaysia.

2.2 Objective:

The training of pharmacists in the manufacturing sector aims to provide the pharmacists with sufficiently in-depth clarity in the understanding of the manufacturing of pharmaceutical products and to equip the pharmacists with relevant knowledge and skills required in the industry.

2.3 This record book is designed primarily to guide the provisionally pharmacists and their preceptors of various pharmacy disciplines in the training institution in coordinating activities and programs during the one-year provisional training.

2.4 This record book will be used for the purpose of **appraisals** by the Principal Preceptors and Master Preceptor, and will be submitted to the Pharmacy Board for the registration of the PRP as a fully registered pharmacist.

2.5 There are 6 main modules of training for the provisionally registered pharmacist [PRP] in the pharmaceutical industry;

2.5.1 Production Process: Manufacturing and Packaging of Pharmaceutical Products

2.5.2 Logistics, Warehousing and Distribution of Pharmaceutical Products

2.5.3 Regulatory Affairs

2.5.4 Research & Development/ Technical Services Of Pharmaceutical Products

2.5.5 Quality Assurance / Quality Control / Stability / Validation of Pharmaceutical Products

2.5.6 Sales & Marketing of Pharmaceutical Products

2.6 The PRP is required to provide the following information;

2.6.1 Name, I/C Number, Name of Institution and period of training and all other requested information in this book.

2.6.2 Date of task completed and evidence of proof for each section/unit of attachment.

(If the columns indicated are insufficient, please use an additional attachment.)

2.6.3 Each evidence given is to be endorsed by the immediate preceptor of the section/ unit.

2.7 The preceptor is required to complete the record by filling the following;

2.7.1 Endorse the completion of each task with signature, name and date in the column provided.

2.7.2 Level of performance is based on the following scale;

1- unsatisfactory
2- satisfactory
3- good
4- excellent or
N/A Not applicable

The passing mark is 60 % for every section and the sum total of all the units.

2.7.3 The final appraisal is to be completed by the Master Preceptor at the 11th month of the training period and to be sent to;

Lembaga Farmasi Malaysia
Bahagian Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia
Beg Berkunci No.924,
Pejabat Pos Jalan Sultan
46790 PETALING JAYA

2.8 Criteria of Manufacturing Facility for Training of PRP

2.8.1 All Pharmaceutical Manufacturing Facilities, excluding those pharmaceutical manufacturers of Traditional Medicines and Health Supplements.

2.8.2 Pharmaceutical manufacturing facilities must meet current Good Manufacturing Practice (cGMP) requirements and have a valid Manufacturing License issued by the Drug Control Authority (DCA) for the current year.

2.8.3 Manufacturing Facilities shall have Principal Preceptors and a Master Preceptor qualified and appointed by the manufacturing facility; and approved by the Pharmacy Board.

3. DUTIES AND RESPONSIBILITIES OF A PRECEPTOR

3.1 Type of preceptors

Principal Preceptor : Head of Department, not necessarily a registered pharmacist

Master Preceptor : Plant / Manufacturing Head/ Quality Assurance Manager must be a registered pharmacist.

[Criteria of a preceptor: A Master Preceptor must have at least 4 years of practical experience in the pharmaceutical industry and a Principal Preceptor must have at least 3 years' experience in the respective department.]

3.2 Responsibilities Of A Preceptor

3.2.1 To serve as a learning resource for the PRP. Ensuring the PRP receives necessary training to develop skills and behaviors expected as a competence pharmacist in the pharmaceutical manufacturing industry.

3.2.2 To answer PRP queries or direct the PRP to the appropriate references and/or show them areas of learning still to be covered.

3.2.3 To serve as a role model instilling professional values and attitudes and to explain to the PRP reasons for your actions when called upon to make professional judgments.

3.2.4 To attempt in providing a full range of professional advice and guidance; and to provide positive and corrective feedbacks during the training/ learning process.

3.2.5 To assess PRP performances or delegate some of the assessment to another suitable person and to discuss the PRP strengths and weaknesses.

4. DUTIES AND RESPONSIBILITIES OF A PROVISIONALLY REGISTERED PHARMACIST [PRP]

Being a Provisionally Registered Pharmacist [PRP], you should;

4.1 At all-times comply with the directives and orders given to you by the department head.

4.2 Aim to become a competent registered pharmacist by the end of the training period.

4.3 Undertake the training modules/ program with a positive attitude and a commitment to learn from the preceptor and other staff in the training environment.

4.4 Remember that obtaining adequate working experience is your responsibility. Others will help, but it requires a conscientious effort on your own part, not just passive acceptance.

4.5 Recognise that not all of the preceptor's time can be devoted to teaching, and you should therefore actively acquire knowledge and skills by observation, reading and questioning others.

4.6 Be aware that, in addition to the daily activities, your time should be set aside to consider activities outside working/office hours.

4.7 Always actively participate in professional development as it is essential to build on your undergraduate studies and keep abreast of current knowledge.

4.8 Be aware that; the Certificate of Satisfactory Experience, required under Section 6A(2) Registration of Pharmacists Act (Amendment) 2003 will only be issued to you if;

(i) You have passed the Pharmacy Jurisprudence Exam which will be conducted by the Pharmacy Board in **March/June/November.**
[Please inform your immediate preceptor if you wish to sit for the test at least a month earlier]

(ii) The average passing mark of your training performance must be **at least 60% for each section and the sum total of all the units.**

4.9 Overview Of Competencies Training Schedule:

During the entire training duration, the PRP will be placed in the core Divisions/Departments in the Company under the guidance and supervision of the Department/Division Head and supervised overall by a Master Preceptor. The duration of training in each module is as indicated in **Table 1.1.**

Mini project where indicated under the different modules are optional but it will be in the interest of the PRP to be given at least ONE (1) mini project throughout the period of training.

Table 1.1: Training Time-table

COMPETENCY TRAINING MODULES	**Duration (Weeks)**
PRODUCTION PROCESSES : THE MANUFACTURING AND PACKAGING OF PHARMACEUTICAL PRODUCTS	**22**
LOGISTICS, WAREHOUSING AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS	**4**
REGULATORY AFFAIR : REGISTRATION PROCEDURES, POST REGISTRATION ACTIVITIES AND RELATED LICENCES OF PHARMACEUTICAL PRODUCTS	**4**
RESEARCH & DEVELOPMENT OF PHARMACEUTICAL PRODUCTS	**8**
QUALITY ASSURANCE / QUALITY CONTROL / STABILITY / VALIDATION OF PHARMACEUTICAL PRODUCTS	**12**
SALES & MARKETING OF PHARMACEUTICAL PRODUCTS	**2**
TOTAL	**52**

5. RECORD OF TRAINING AND EXPERIENCES

PRODUCTION PROCESSES: THE MANUFACTURING AND PACKAGING OF PHARMACEUTICAL PRODUCTS

(Duration of Attachment: 22 weeks)

1. Knowledge and the understanding of the principle of production process planning and structure of the organization.

2. Familiarity with terminology, guidelines and specification related to manufacturing according to PIC/S cGMP, ISO Certification and ICH documents.

3. Knowledge of Standard Operating Procedures (SOPs) and ability to adhere to the SOP during operation.

4. Knowledge of master formula, production record and their contents, manufacturing techniques, use and selection of appropriate equipment, shelf sample, and product release procedures etc.

5. Knowledge and understanding cleaning, sanitization, safety and security in production process.

6. Knowledge of the manufacturing of various dosage forms of products either sterile or non-sterile (e.g. tablets, capsules, soft-gels, creams, liquids, injectables, whichever is/ are manufactured in the plant) including:

    - the properties of ingredients used in the manufacturing process;
    - manufacturing processes and machinery employed in various dosage forms;
    - knowledge of essential & critical utilities used in manufacturing plant;
    - the properties of various dosage forms;
    - the packaging of finished products, including stability characteristics and storage requirements;
    - understanding of the principles of Good Manufacturing Practices (GMP)

7. Knowledge on master planned preventive maintenance, risk management in controlling cross contamination and the implications.

8. Knowledge on validation in production process.

SECTION 1 : PRODUCTION PROCESS PLANNING

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Attending the briefing session.							
2	Able to understand structure/ layout and identify own role in the Organization.							
3	Knowledge on the role of Production Planning.							
4	Knowledge on production planning terminologies (MPS, MRP, MOQ, JIT etc)							
5	Able to translate MPS to weekly production planning. Quantity: _____							
6	Able to understand the basic component of ERP systems, how it works and the benefits							
7	Ability to deliver good presentation (optional)							

SECTION 2 : SYSTEM AND PROCEDURE MANAGEMENT

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Attending the briefing session.							
2	Knowledge on preparation of standard operating procedures (SOP's) and adhering to standard operating procedures during operations							
3	Knowledge on monitoring, storage, distribution and controlling SOP's							
4	Understanding of guidelines and specifications related to manufacturing according to PIC/S cGMP, ISO certifications & ICH documents.							
5	Knowledge on cleaning, sanitization and the differences between them							
6	Knowledge on different type of cleaning agents used: detergent, solvent cleaners, acid cleaners and abrasive cleaners.							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
	• Able to prepare cleaning agents Quantity : _____							
7	Knowledge on different sanitizing terms: antiseptic, disinfectant, bactericide, etc and different sanitization method: chemical, heat and radiation. • Perform sanitization and microbial sampling Quantity : _____							
8	Knowledge on facility and equipment management • Perform replacement for consumable parts							
9	Knowledge on equipment master list and its foot print.							
10	Knowledge on master planned preventive maintenance							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
11	Knowledge on risk management in controlling cross contamination							
12	Knowledge on implication of cross contamination: patient safety, cost, reputation							
13	Knowledge of role of production in Validation (Process, Cleaning, Machine Qualification - understanding of URS, DQ, IQ, OQ and PQ) • Assist in validation/qualification process and report preparation							
14	Knowledge and skill on preparing User Requirement Specification (URS)							
15	Knowledge on "V" model and its application in validation							
16	Knowledge on the difference and application of prospective, retrospective and con-current validation.							

SECTION 3 : CORE MANUFACTURING PROCESS

Knowledge of the function and purpose of production

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Attending the briefing session.							
2	Able to explain the objectives of manufacturing function and processes.							
3	Knowledge on the differences of sterile and non-sterile products.							
4	Describe the meaning of the main terms used in production.							
5	Knowledge on main production operations, critical pathways for each process and control functions.							
6	Knowledge on process flow for different dosage form • Formula calculation in BMR • pH adjustment • Perform IPQC checking							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
7	Knowledge on the technology and functionality of each machine/equipment used in each process, such as : Mixer, Granulator/ Oscillator, FBD, Oven, IBC, One-Pot Process, Compression machine, etc.							
8	Knowledge on essential & critical utilities used in manufacturing plant: Plant steam, Pure steam, HVAC system, Compressed air, Vacuum system, Waste Water treatment Plant, Dust extractor and Water System.							
9	Knowledge on the role of each critical utility in the operation system.							
10	Knowledge on critical measurements/ specifications of the different utilities in different types of manufacturing facility.							
11	To comprehend the technical knowledge on core production processes: Granulation, Sieving, Milling, Tablet Compression, Coating, Capsulation, Blistering, etc.							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
12	Knowledge of and perform yield calculation and re-conciliation.							

Sterile Production

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Knowledge on defining sterile product							
2	Knowledge on the differences between terminally sterilized product and aseptic product							
3	Knowledge on Sterility Assurance program							
4	Knowledge on application of aseptic technique							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
5	Knowledge on different grade of clean room, its specification and qualification of clean room							
6	Knowledge on personnel qualification							
7	Knowledge on the critical parameters to monitor in clean room: Temperature, humidity, differential pressure, air flow velocity, air flow rate, air borne particulate count, air change rate, air flow direction, HEPA filter leakage test, containment test, recovery test.							
8	Knowledge on gowning procedure and able to demonstrate adherence to procedure							
9	Able to demonstrate understanding on aseptic technique during broth evaluation study							
10	Knowledge on production process flow in sterile production area: Washing, Dispensing, Compounding, Filtration, Filling, Leak testing, Inspection, Labeling and Cartoning.							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
11	Knowledge on the technology used in each process step.							
12	Knowledge on different sterilization method, advantages and disadvantages of each sterilization method and validating the process.							
13	Knowledge on de-pyrogenation and validation of the process							
14	Knowledge on specific requirement for utilities used in clean room: Pure steam, WFI, Compressed air, Pharmaceutical Gasses, HVAC system							
15	Knowledge on sterility testing							
16	Knowledge on microbiological environmental monitoring • Perform sampling							
17	Knowledge on media fill							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
18	Knowledge on Blow fill and seal technology (container moulding, container filling and container sealing)							
19	Knowledge on the application and advantages of using BFS technology.							

SECTION 4 : PROCESS DOCUMENTATION IN MANUFACTURING

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Knowledge on preparing documentation - BMR / BPR, SOP, Status Labels • Drafting new document • Reviewing SOP and BMR							
2	Knowledge of the content and importance of BMR/BPR: traceability etc.							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
3	Knowledge on status labels and why it's used. • Ascertain correct label for correct product							
4	Knowledge on the importance of documentation and management of Controlled Drugs & Import / Export Permit. (Referring to Poison Act etc) • Recording of Controlled Drugs transactions							
5	Knowledge on the process flow in handling of Controlled Drugs & Import / Export Permit							
6	Knowledge on the role of pharmacist on handling of controlled drugs							
7	Ability to deliver good presentation (optional)							

GENERAL COMMENT ON ATTITUDE

Mark = _____ x 100%
244

= _____ %

Preceptor's Name & Signature :

Date :

NOTE:

1. If the service is not available in the industry, the Principal Preceptor/ Head of Pharmacists in the organisation therefore has right to transfer the PRP to other units/ sections.

2. % mark should not less than 60% for every units/ sections.

LOGISTICS, WAREHOUSING AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

(Duration of Attachment: 4 weeks)

1. Knowledge and understanding of the principles of store management, inventory, stock movement and control, cleanliness and sanitation and security in accordance to Procedures in Store Management.

2. Knowledge of storage and distribution of biological, handling of cytotoxic drugs, refrigerated items, inflammables and corrosive items, safety measures, maintenance of cold chain on transit and storage in accordance to Good Storage Practice (GSP) and Good Distribution Practice (GDP).

3. Knowledge of disposal procedures and its documentation.

4. Knowledge of recall management according to procedures and regulatory requirements.

5. Knowledge on handling of returned, damaged, spilled products and expired stocks according to procedures and regulatory requirements.

6. Knowledge of the statutory aspect related to storage and distribution of materials, drugs and finished products in accordance to the respective legislations:

    - Dangerous Drugs Act 1952 & its Regulations
    - Poisons Act 1952 & its Regulations
    - Poisons (Psychotropic Substance) Regulations 1989

7. Knowledge and understanding the management of goods transportation.

SECTION 1 : OVERVIEW OF LOGISTIC, WAREHOUSING AND DISTRIBUTION

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	**Organization Structure/Layout/ Chart** Able to understand structure/layout and identify your role in the organization							
2	**Inventory** Awareness of Store Catalogue and type of products managed.							
3	**Stock Movement And Control** Able to explain stock movement and control of drugs and non-drugs							
4	**Cleanliness** Able to identify requirements							
5	**Security/ Safety** Able to list security/safety aspects of store							
6	**Pest Control** Monitor pest control activities with contractor							

SECTION 2 : SUPPLY CHAIN AND INVENTORY MANAGEMENT

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Able to understand what is meant by inventory and the importance of it.							
2	Able to understand demand and supply in supply chain and procurement management for manufacturing needs							
3	Knowledge on supply chain business process integration							
4	Able to manage inventory in the supply chain							
5	Able to identify the major challenges to effective supply chain strategy							
6	Able to understand the basic principles behind the quantitative approach on deciding how much inventory to keep							

SECTION 3 : STORAGE AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	**Good Storage Practice (GSP) and Good Distribution Practice (GDP)** Able to understand GSP and GDP requirements and key principles to storage conditions, stock discrepancies and stock disposal management							
2	Able to understand the management of effective stock levels in prevention of backorders or over stocking							
3	Able to conduct the following during receiving of stocks • Weighing and counting of received stocks • Visual inspection • Verifying documents (COA, DO vs PO)							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
4	**Stock Movement Management** • Able to allocate stocks based on FIFO • Preparation of stocks for production need – weighing/counting/packing/etc • Cleaning down of stock containers prior to entrance into production buffer area							
5	Knowledge on the requirement of storage and documentation relating to specially controlled items.							
6	Knowledge and understanding the need of a cycle-count and stock take • Conduct an actual exercise from involvement in preparatory work to involvement in generation of final report							
7	Able to understand the implementation of proper segregation, markings at designated areas within the warehouse. • Product storage in appropriate areas based on status							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
8	Knowledge on requirements of certain items with temperature and humidity control needs. • Temperature and humidity monitoring							

SECTION 4 : STOCK MANAGEMENT ACCORDING TO STATUTORY REQUIREMENTS AND STANDARD PROCEDURES

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Knowledge on the relevant legislation in the effective management of scheduled drugs and controlled medicines.							
2	Knowledge on documentation requirements and compliance to various legislation such as Poison Act, Dangerous Drugs Act, and Sale of Drugs Act and Control of Drugs and Cosmetic Regulations							
3	Knowledge of recall management including storage & disposal according to procedures and regulatory requirements							
4	Handling of returned, damaged, spilled products and expired stocks and their appropriate storage & disposal according to procedures and related regulatory requirements							

SECTION 5 : MANAGEMENT OF TRANSPORTATION

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Able to understand the selection of vendor for transportation of finished goods							
2	Continuous education on GDP with transport vendors							
3	Understand the significance of stacking orientation during uploading of goods onto transport							

GENERAL COMMENT ON ATTITUDE

Mark = _____ x 100%
108

= _____ %

Preceptor's Name & Signature:

NOTE:

1. If the service is not available in the industry, the Principal Preceptor/ Head of Pharmacists in the organisation therefore has right to transfer the PRP to other units/ sections.

2. % mark should not less than 60% for every units/ sections.

REGULATORY AFFAIRS: REGISTRATION PROCEDURES, POST REGISTRATION ACTIVITIES AND RELATED LICENCES OF PHARMACEUTICAL PRODUCTS

(Duration of Attachment: 4 weeks)

1. Knowledge and understanding the essential functions and core activities of the Regulatory Affairs Department.

2. Knowledge of the statutory aspect relating to registration, clinical testing, post registration and document controls.

3. Knowledge on the importance of being updated on ever-changing legislation in all the regions in which the organization wishes to distribute its products.

4. Knowledge and understanding on the legal and scientific restraint and requirement.

SECTION 1 : REGISTRATION PROCEDURES

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Knowledge on regulatory guidelines of Malaysia and ASEAN for Ethical Drugs, OTCs, Health Supplements, Traditional Medicines and Cosmetics							
2	Knowledge on International Regulatory Guidelines for Pharmaceuticals such as ICH, WHO, EMA & FDA							
3	**Labeling, Package Insert, Patient Information Leaflet (PIL) requirements** Able to investigate product history of similar products to assess approval implications Quantity : _____							
	Able to conduct research on submission requirements and options Quantity : _____							
	Knowledge on requirement of Hologram							

SECTION 2 : POST REGISTRATION ACTIVITIES

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Able to comprehend the variations in Malaysia							
2	Knowledge in renewal procedure of product licences in Malaysia							
3	Able to assist in the preparation of routine reports and regulatory agency communications • Communication Log							
4	Able to assist in the review of advertising and promotional items							
5	Able to coordinate internal audits and inspection							
6	Able to assist in the preparation of post-market reports and submission							
7	Knowledge on tracking product events, complaints and recalls • Awareness on counterfeit issues							

SECTION 3 : INFORMATION MANAGEMENT AND CONTROL IN REGULATORY AFFAIRS

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Knowledge on transfer information of registered product to the manufacturing facility							
2	Knowledge on database management of submitted dossiers to the authority							
	Participate in product and/or regulatory teams to coordinate documentation							
	Maintain records to comply with regulatory requirements							
	Compose routine correspondence to regulatory agencies							
3	Respond to RA information requests							
4	Able to interact with outside experts, partners and regulatory agencies, as requested							
5	Able to assist in preparation for technical meetings with regulatory agencies							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
6	Able to maintain records on legislation, regulation and guidelines							

SECTION 4 : RELATED LICENSING ACTIVITY

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Able to demonstrate understanding of the functions and activities of the RA department in application for Manufacturer's Licence, Import Licence and other required licences							
	Able to prepare licence application							

GENERAL COMMENT ON ATTITUDE

Mark = _____ x 100%
92

= _____ %

Preceptor's Name & Signature:

NOTE:

1. If the service is not available in the industry, the Principal Preceptor/ Head of Pharmacists in the organisation therefore has right to transfer the PRP to other units/ sections.

2. % mark should not less than 60% for every units/ sections.

RESEARCH & DEVELOPMENT/TECHNICAL SERVICES OF PHARMACEUTICAL PRODUCT

(Duration of Attachment: 8 weeks)

1. Understanding of Research & Development functions in the company.

2. Understanding on Patent/Intellectual Properties/Data Exclusivity in Pharmaceutical Industry.

3. Understanding of pre-formulation, formulation, development and product improvement of various pharmaceutical dosage forms.

4. Ability to conduct Experimental Formulation Development.

5. Understanding on Bioequivalence Study design and overall conduct of study.

6. Understanding on method development and validation for new formulation.

7. Ability to design and conduct stability study in drug development process.

8. Ability to write a Pharmaceutical Development Report.

9. Activities' involves in this department are:

    - Mini project on new product/product improvement formulation
    - Conduct literature search
    - Excipient incompatibility study in formulation
    - Conduct laboratory batch experiments
    - Conduct pilot batch experiments(optional)
    - Conduct Physical/Chemical/Microbiology analysis
    - Data analysis reporting

ASSESSMENT

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Understanding of R&D function in Pharmaceutical Industry							
2	Ability to conduct search on Patent/Intellectual Properties/Data Exclusivity in Pharmaceutical Industry							
3	Ability to conduct pre-formulation study by evaluate data of API and FP formulation							
4	Ability to operate laboratory instruments for basic physical and chemical tests							
5	Ability to conduct laboratory scale study							
6	Ability to conduct pilot scale batch study							
7	Ability to conduct data analysis and reporting on Physical/Chemical/Microbiological Tests							
8	Understanding of design and conduct a BE study							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
9	Understanding of method development and method validation							
10	Ability of establish parameters to monitor for stability study in new formulation							
11	Ability to deliver quality development report on the assigned mini project							
12	Ability to deliver good presentation							

GENERAL COMMENT ON ATTITUDE

Mark = _____ x 100%

48

= _____ %

Preceptor's Name & Signature:

NOTE:

1. If the service is not available in the industry, the Principal Preceptor/ Head of Pharmacists in the organisation therefore has right to transfer the PRP to other units/ sections.

2. % mark should not less than 60% for every units/ sections.

QUALITY ASSURANCE / QUALITY CONTROL / STABILITY / VALIDATION OF PHARMACEUTICAL PRODUCTS

(Duration of Attachment: 12 weeks)

1. Knowledge and understanding of roles and activities of QA/QC/Stability/Validation in pharmaceutical manufacturing.

2. Knowledge on key QA system e.g. CAPA system, Quality Risk Management (QRM), deviation management, handling of non-conformity, OOS investigation, quality audits, change control and management, principle of validation and qualification, documentation control, product complaint handling, annual product review etc.

3. Knowledge and understanding of Quality control activities like testing, sampling, specifications, method validation, validation analysis, microbiological testing, environmental monitoring, standardization etc.

4. Knowledge in product stability studies.

5. Knowledge of the various qualification & validation requirements in pharmaceutical industry

SECTION 1 : INTRODUCTION AND OVERVIEW ON ROLES OF QA & QC

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Able to comprehend Quality Management System principles in pharmaceuticals • cGMP • Quality Management System							
2	Knowledge on roles & responsibilities of QA & QC							
3	Knowledge on management responsibility & review							

SECTION 2 : QUALITY ASSURANCE MANAGEMENT

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Comprehend the keys in QA system: • Quality System & Manual • Site Master File • Vendor qualification and performance monitoring • Annual product review • Principle of Good Documentation as an essential part of the QA System • Essential Documents and records in Quality Management System according to c-GMP e.g. Specifications, Manufacturing formula, processing and packaging instructions, records and procedure • Quality audits, Quality Risk Management (QRM) and CAPA system							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
	• Sterility Assurance Program (SAP) • Product releasing and rejection, & handling of non-conforming products • Out Of Specification (OOS) investigation • Handling of deviations & change control							
2	Able to handle product complaints, goods return and product recall							
3	Knowledge in Qualification & Validation principles & programs : • Validation Master Plan (VMP) • Qualification on Facilities, utilities & Equipment • Validation on analytical methods • Process Validation • Cleaning Validation • Revalidation & Requalification							

SECTION 3 : OVERVIEW OF QUALITY CONTROL FUNCTIONS

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Knowledge on various facilities in QC of the company : • Chemical Laboratory • Microbiological Laboratory • Retention Sample Storage • Reference Standard Storage • Waste Management • Sampling Facilities etc							
2	Knowledge on testing and releasing of raw & packaging materials, In-process QC, finished products QC							
3	Understand incoming raw material , in process, and finished product, QC and procedure							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
4	Understand specifications and various compendia standards such as BP, USP, EP etc							
5	Knowledge on environmental monitoring, water monitoring & waste water monitoring							
6	Comprehend Good Laboratory Practice (GLP) & Laboratory Quality Management System							
7	Documentation system like preparation of SOPs, protocol of analysis, worksheets, preparation of CoA etc.							

SECTION 4 : QC DOCUMENTATION

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Able to prepare specifications for raw materials, packaging & finished products							
2	Able to prepare protocol of analysis, worksheets, training manuals, MSDS, vendor rating etc.							
3	Able to prepare documents for cleaning validation & method validation							

SECTION 5 : CHEMICAL ANALYSIS LABORATORY

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Knowledge of theory and fundamental of analysis (chemical & physical) in pharmaceutical industry							
2	Knowledge on sampling plans, how to set sampling plans and sampling procedure							
3	Knowledge on analysis employed in the laboratory (Assays (UV, HPLC, GC, titrimetric etc.), dissolution, disintegration, pH, viscosity, identification, impurities, etc.)							
4	Able to handle of out-of-specifications (OOS), out-of-trend investigations and technical complaints							
5	Exposure to laboratory equipment qualification, calibration & maintenance, and the control of consumables in the laboratory							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
6	Knowledge on laboratory safety & chemical safety in chemical laboratory including chemical spillage							

SECTION 6 : CHEMICAL ANALYSIS LABORATORY

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Knowledge on theory and fundamental of microbiological analysis in Pharmaceutical Industry							
2	Exposure to all testing in Microbiological laboratory • Sterility Test, Endotoxin test, Microbial limit test, Preservative Efficacy Test, environmental monitoring and water system monitoring • Able to conduct testing							

SECTION 7 : CHEMICAL ANALYSIS LABORATORY

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Comprehend stability studies requirements and guidelines : Product Stability studies – accelerated, real time and simulation stability studies, various testing requirements. • Review stability report							

GENERAL COMMENT ON ATTITUDE

Mark = _____ x 100%
100

= _____ %

Preceptor's Name & Signature:

NOTE:

1. If the service is not available in the industry, the Principal Preceptor/ Head of Pharmacists in the organisation therefore has right to transfer the PRP to other units/ sections.

2. % mark should not less than 60% for every units/ sections.

SALES & MARKETING OF PHARMACEUTICAL PRODUCTS

(Duration of Attachment: 12 weeks)

1. Knowledge and understanding of the role and responsibilities of sales and marketing.

2. Knowledge and understanding of the principles of Good Governance of Medicines (GGM).

3. Knowledge on the selling process, meeting and getting customers feedback, understanding the concept of ethical marketing practices, and the concept of good marketing material design.

ASSESSMENT

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
1	Understanding the concept of ethical marketing practices (Code of Ethics and related legislations)							
2	Understanding the principles of Good Governance of Medicines (GGM).							
3	Understanding The Role of Sales and Marketing							
	Knowledge on planning a marketing program							
	Knowledge on marketing strategy and implementation							
	Monitoring / review of the marketing strategy							
	Able to analyzes past and present market data to monitor current and possible trends							

No.	Knowledge/Task	Level of Performance					Comments	Name and Signature of Preceptor
		1	2	3	4	NA		
	Able to provide healthcare professionals with details on the most current brand and disease state information							
	Understanding the fundamental of good marketing material design							

GENERAL COMMENT ON ATTITUDE

Mark = _____ x 100%
36

= _____ %

Preceptor's Name & Signature:

NOTE:

1. If the service is not available in the industry, the Principal Preceptor/ Head of Pharmacists in the organisation therefore has right to transfer the PRP to other units/ sections.

2. % mark should not less than 60% for every units/ sections.

DAILY TRAINING LOG

Date	Task/Assignment	Job Performed	Remarks	Name & Signature Preceptor

DAILY TRAINING LOG

Date	Task/Assignment	Job Performed	Remarks	Name & Signature Preceptor

DAILY TRAINING LOG

Date	Task/Assignment	Job Performed	Remarks	Name & Signature Preceptor

DAILY TRAINING LOG

Date	Task/Assignment	Job Performed	Remarks	Name & Signature Preceptor

DAILY TRAINING LOG

Date	Task/Assignment	Job Performed	Remarks	Name & Signature Preceptor

DAILY TRAINING LOG

Date	Task/Assignment	Job Performed	Remarks	Name & Signature Preceptor

DAILY TRAINING LOG

Date	Task/Assignment	Job Performed	Remarks	Name & Signature Preceptor

6. APPRAISALS

APPRAISAL BY PRINCIPAL PRECEPTOR

Name of Provisionally Registered Pharmacist [PRP]:

……

I/C Number: …….

PRP Registration Number: ……..

Place of Training: ……..

Photo (to be affixed here)

I certify that the above PRP has completed his/ her training as required under subsection 6A (2) of the Registration of Pharmacists Act 1951.

1. Proposal:

1A. The above PRP has obtained average mark of: _____ % and

1B. He/ She has ***passed/ failed** the Pharmacy Jurisprudence Examination

☐ 1C. *Certificate of satisfactory experience in accordance to sub-regulation 7(1) Registration of Pharmacists Regulations 2004 is **recommended** to be given to him/ her*.

☐ 1D. *Certificate of satisfactory experience in accordance to sub-regulation 7(1) Registration of Pharmacists Regulations 2004 is **not recommended** to be given to *him/ her **and***

☐ 1E. **He/ she needs to extend the training for another _____month/s;*

☐ *in Unit/Section _____*

**or/and*

☐ **He/ She needs to pass the Pharmacy Jurisprudence Examination*

2. Principal Preceptor's detail:

2.1 Name:

2.2 Office address:

2.3 Principal Preceptor's signature: …….

2.4 Date:

APPRAISAL BY MASTER PRECEPTOR

Setiausaha
Lembaga Farmasi Malaysia
Bahagian Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia
Beg Berkunci No.924
Pejabat Pos Jalan Sultan
46790 PETALING JAYA

PROPOSAL OF FULL REGISTRATION

Name of Provisionally Registered Pharmacist [PRP]: …….

I/C Number: ……

PRP Registration Number: …….

Place of Training: ……

I certify that the above PRP has completed his/ her training as required under subsection 6A (2) of the Registration of Pharmacists Act 1951.

1. Proposal:

☐ *1A. Certificate of satisfactory experience in accordance to sub-regulation 7(1) Registration of Pharmacists Regulations 2004 is *recommended/ not recommended to be given to him/ her and he/ she is *qualified/ not qualified for Full Registration.*

☐ *1B. *He/ she needs to extend the training for another _____month/s from (date):_____to_____ (date).*

1C. The extension of the training is because;

☐ *i) His /her performance was below 60% or /and*

☐ *ii) He/ she needs to pass the Pharmacy Jurisprudence Examination*

2. Master Preceptor's detail:

2.1 Name:
2.2 Office address:
2.3 Master Preceptor's signature: …….
2.4 Date:

APPRAISAL BY PROVISIONALLY REGISTERED PHARMACIST [PRP] TO PRECEPTOR – (optional)

Setiausaha
Lembaga Farmasi Malaysia
Bahagian Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia
Beg Berkunci No.924
Pejabat Pos Jalan Sultan
46790 PETALING JAYA

APPRAISAL OF PRECEPTORS

Name of Provisionally Registered Pharmacist [PRP]: …….

I/C Number: ……

PRP Registration Number: …….

Place of Training: ……

I have undergone training at the above place from (date): _____to: _____(date)

Subject	**Grade**				
	1 = unsatisfactory	**2 = satisfactory**	**3 = good**	**4 = excellent**	**N/A = not applicable**
A. Facilities of Training Place					
Comment *(how things can be improved); Please make attachment where necessary)*					
B. Professional Exposure by Preceptors					
Comment *(how things can be improved); Please make attachment where necessary)*					

C. Professional Guidance by Preceptors					
Comment *(how things can be improved); Please make attachment where necessary)*					
D. Training Skills of The Preceptors					
Comment *(how things can be improved); Please make attachment where necessary)*					

PRP PERSONAL ASSESSMENT BY PRINCIPLE PRECEPTORS

1 = unsatisfactory; 2 = satisfactory; 3 = good; 4 = excellent; N/A = not applicable

Demonstrate a Professional Approach

Assessment	Score
1. Action and attitudes are demonstrated which indicate a commitment to quality performance	
2. A polite and helpful manner is demonstrated	
3. Dress code and behavior meet the requirements of the organization	
4. Reliability is demonstrated	
5. Initiative is demonstrated when is the warranted	
6. Recognition of personal limitation is demonstrated	
7. Works is carried out in an organized manner and with attention to detail so that the desired result is achieved	
8. Works is prioritized effectively	
9. Tasks are pursued to completion and within agreed time limits (unless overriding circumstances make this impossible)	
10. Problems or potential problems are identified and the appropriate corrective action taken or solution found	
11. New situation are responded to with flexibility and willingness	
12. Stressful situations are handle without undue agitation	
13. Decision are made which demonstrated the ability to think clearly and logically and to use discretion	
14. Tasks and situation are approached with due regard to legal implications and organizational policy	
15. The safety of the working area is maintained to all times so that the health and safety of colleagues and the public is not compromised	
16. The security of the premises is upheld at all times	
Total Marks =	
Average Total =	
Average Performance in %= _____ x (100%) = % **64**	

Work Effectively as Part of a Team

Assessment	Score
1. A manner is demonstrated which indicates that due respect is given to the ideas and opinion of colleagues	
2. Advice and criticisms are offered to colleagues in a manner unlikely to cause offence	
3. Constructive criticism is receive in a positive manner	
Total Marks =	
Average Total =	
Average Performance in %= _____ x 100 = % **12**	

Undertake Personal and Professional Development

Assessment	Score
1. The ability to self-evaluate and reflect on experiences is demonstrated	
2. Feedback on performance is used effectively to improved competence	
3. The ability to accept responsibility for meeting own development needs and achieving targets is demonstrated	
Total Marks =	
Average Total =	
Average Performance in %= _____ x 100 = % **12**	

Communication Skills

Assessment	Score
1. A sufficient command of the Bahasa Malaysia and English Language is demonstrated	
2. Conversations (in person or over the telephone) are conducted in a manner which demonstrates due regard to confidentiality and the feelings of the other person	
3. Questioning is used effectively to elicit necessary information and increase understanding	
4. Responses in conversation are helpful and clear	
5. Body language is appropriate to the situation	
6. Clear, concise and well-structured written material is provided when required	
7. All responses (whether spoken or written) are tailored to the needs of the recipient	
8. A clear, polite and helpful telephone manner is demonstrated	
9. Complaints or demands are responded to in a polite manner	
10. An appropriately assertive manner is used when unreasonable demands or complaints are made	
Total Marks=	
Average Total=	
Average Performance in %= _____ x 100 = % **40**	

PRP Personal Assessment Average Performance

INDICATORS (%)	**1. Demonstrate a Professional Approach**	**2. Work Effectively as Part of a Team**	**3. Undertake Personal and Professional Development**	**4. Communication Skills**
PERFORMANCE				
AVERAGE				

Appendix A

SUMMARY OF PERFORMANCE (%) FOR EACH SECTION

MARK (%) FOR EACH SECTION		
No.	**Section**	**Mark (%)**
1.	*Production Processes : The Manufacturing and Packaging of Pharmaceutical Products*	
2.	*Logistics, Warehousing and Distribution of Pharmaceutical Products*	
3.	*Regulatory Affair : Registration Procedures, Post Registration Activities and Related Licences of Pharmaceutical Products*	
4.	*Research & Development of Pharmaceutical Products*	
5.	*Quality Assurance / Quality Control / Stability / Validation of Pharmaceutical Products*	
6.	*Sales & Marketing of Pharmaceutical Products*	
	AVERAGE MARK	
PRP PERSONAL ASSESSMENT AVERAGE PERFORMANCE		
7.	*Demonstrate a Professional Approach*	
8.	*Work Effectively as Part of a Team*	
9.	*Undertake Personal and Professional Development*	
10.	*Communication Skills*	
	AVERAGE MARK	

Appendix A1

(TO BE FILLED BY PRINCIPAL PRECEPTOR FOR THOSE EXTENDED)
SUMMARY OF PERFORMANCE (%) FOR EACH SECTION

MARK (%) FOR EACH SECTION				
No.	**Section**	**Mark % prior to extension period**	**Mark % after extension period**	**Actual extension period**
1.	*Production Processes : The Manufacturing and Packaging of Pharmaceutical Products*			
2.	*Logistics, Warehousing and Distribution of Pharmaceutical Products*			
3.	*Regulatory Affair : Registration Procedures, Post Registration Activities and Related Licences of Pharmaceutical Products*			
4.	*Research & Development of Pharmaceutical Products*			
5.	*Quality Assurance / Quality Control / Stability / Validation of Pharmaceutical Products*			
6.	*Sales & Marketing of Pharmaceutical Products*			
	AVERAGE MARK			
PRP PERSONAL ASSESSMENT AVERAGE PERFORMANCE				
7.	*Demonstrate a Professional Approach*			
8.	*Work Effectively as Part of a Team*			
9.	*Undertake Personal and Professional Development*			
10.	*Communication Skills*			
	AVERAGE MARK			

Advisor

Dr.Salmah binti Bahri
Pharmaceutical Services Division, Ministry of Health Malaysia

Committee Members/Participants during " Bengkel Penyediaan Buku Log PRP 2012, Kuala Terengganu, 26-29 March 2012"

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National Pharmaceutical Control Bureau

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Reviewer

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