



GUIDE TO GOOD DISPENSING PRACTICE



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This guide has been developed based on the Poisons Act 1952 (Revised 1989), Poisons Regulations 1952, Poisons (Psychotropic Substances) Regulations 1989 and other related acts, guidelines and standards which are currently being used in Malaysia.

The purpose of this guide is to ensure that medicines are dispensed in accordance with the laws and guidelines mentioned above in both government and private healthcare facilities and that patients receive the medicines correctly through which adherence can be improved, occurrence of adverse reactions minimised and medication errors avoided.

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1. Introduction

Dispensing refers to the process of preparing and supplying medicines to a named person together with clear instructions, advice and counselling where necessary on the use of those medicines. It involves the correct interpretation of the order for prescribed medicines and accurate preparation and labelling of medicines for use by the patient. The dispensing process includes all activities that occur between the time the prescription or request for medicine is presented up to the time the medicines or other prescribed items are issued to the patient.

Good Dispensing Practice ensures that the right medicines of desired quality are delivered correctly to the right patient with the right dose, strength, frequency, dosage form and quantity, together with clear instructions, both written and verbal and with appropriate packaging suitable for maintaining the quality and efficacy of the medicine.

A safe, clean and organised working environment provides the basis for good dispensing practice. The dispensing environment includes¹:

- Qualified / trained staff
- Appropriate physical surroundings
- Adequate shelving and storage areas
- Proper work surfaces
- Suitable equipment
- Necessary packaging materials

Responsibility for the accuracy and quality of the medicines supplied lies on the persons overseeing the dispensing process. It is important that the staff dispensing medicines are trained and equipped with the technical knowledge and the skills necessary to dispense the range of medicines prescribed and to communicate effectively with patients/ caregivers.

2. SCOPE

1. Applicable to Group B and C of Poisons Lists
2. Medicines for human use only
3. Applicable to public healthcare facilities
4. Applicable to the licensed private healthcare facilities (clinics, hospitals, community pharmacies, dental clinics)*

**not applicable to veterinary clinics*

3. Dispensing Process

Adherence to good dispensing procedures is vital in ensuring that medicines are dispensed correctly and any potential/ real errors which may occur during the dispensing process are detected and rectified before medicines reach the patient.

Who should be involved in the process of dispensing:

- a) **Screening of Prescription:** Healthcare professional (Registered medical practitioner/ registered dentist/ pharmacist)
- b) **Preparation of Medicines²:** Pharmacist, registered medical practitioner or a person under immediate supervision of a pharmacist/ medical practitioner
- c) **Supplying the Medicines²:** Registered medical practitioner, registered dentist or pharmacist
- d) **Counselling :** By healthcare professional

Dispensing of Psychotropic Substance

Regulation 11 of Poisons (Psychotropic Substances) Regulations 1989 stated that no psychotropic substance shall be sold or supplied for the purposes of medical or dental treatment of a particular patient except by a registered medical practitioner or registered dentist or pharmacist (upon a prescription by doctor or dentist).

Under the Regulation 16 of the same Regulations, it is stated that only a registered medical practitioner or registered dentist or a person acting in accordance with the direction of a registered medical practitioner/ registered dentist **shall administer any psychotropic substance**. The psychotropic substance is administered for the purpose of medical or dental treatment of a particular patient⁴.



Processing the Prescription

A-i. Screening

- On receiving a prescription, it should be screened and validated to ensure that it is for the correct patient and it complies with the requirements in the Poisons Act.
- The prescription should be written legibly or printed.
- The prescription should have the following information²:

<u>Patient Details</u>	<u>Prescription Details</u>
<ol style="list-style-type: none">1. Name2. Address3. Identification number (IC/Passport No)	<ol style="list-style-type: none">1. Drug regimen (name of medicine, dose, frequency, administration and duration)2. Doctor's signature, stamp and registration number3. Doctor's name and address4. Date of prescribing

- Names of medicines prescribed should be written in generic name and abbreviations should not be used. **Brand (trade) names** should be avoided as far as possible. If a patient must be given a particular brand, it should be indicated on the prescription.
- Age of the patient and body weight should be stated on prescriptions for children under 12 years of age.

A-ii. Interpreting the Prescription Order

- The person receiving the prescription should check for:
 - Dose, frequency and duration
 - Drug interactions, medicine duplication, polypharmacy, inappropriate drug therapy, contra-indications.
 - Allergies
 - Unusual usage and suspected drug misuse or abuse.
- For partial medicine supply, ensure that the second or subsequent supply does not exceed the quantity for the duration prescribed.

A-iii. Handling Prescriptions which Require Clarification

- If an incomplete prescription or one which requires further clarification is received, attempts must always be made to contact the prescriber:
 - i. If the prescriber can be contacted and is available on site, arrange for the incomplete/missing details to be inserted on the prescription by the prescriber. Remedial action for such prescriptions should be discussed with the prescriber prior to sending the prescription back to him/her.
 - ii. If the prescriber is not available to amend the prescription himself/herself, authorisation to make the change may be obtained verbally through the phone.
 - iii. The amendments to the prescription should be repeated back to the prescriber to ensure accuracy. The amendments should be documented on the prescription and endorsed with "PRESCRIBER CONTACTED" (PC), dated and initialled by the pharmacist/person dispensing.
 - iv. If the prescriber cannot be contacted, patient should be informed and the prescription must be sent back to the prescriber with information on the clarification/action needed.
 - v. Prescriber should document any changes made to the patient's medical record.

A-iv. Handling Prescriptions In A Stock-Out Situation

- Stock-out is defined as a situation where the prescribed medicine is not available at the pharmacy when a prescription is being processed. This may be due to the medicine being temporarily out-of stock at that time or the pharmacy does not keep stock of that particular medicine.
- If such situation occurs:
 - i. Inform the prescriber. If the medicine cannot be substituted with another medicine that is available, inform the patient.
 - ii. If the patient agrees for it to be supplied at a later time, arrange to get stocks so

- as to enable prompt supply the medicine to the patient;
- iii. If the patient requires the medicine urgently, the pharmacist/person dispensing must communicate with the prescriber to discuss if the prescribed medicine can be substituted with another medicine which is readily available.
 - iv. Any substitution of medicine must be approved by the prescriber and documented on the prescription.
 - v. Prescriber should document these changes in the patient's medical record.

B

Preparing the Medicines

B-i. Filling

a) Selecting the Medicines

- When selecting the medicine to be dispensed, prevent any medication errors by establishing an appropriate system to ensure that the correct medicine is selected, especially if there are medicines with similar names and packaging. Pick the medicine by reading the label at least twice and cross-checking the medicine name and strength against the prescription.
- If a barcode system is available, it should be used to enable correct and accurate selection of the medicine.
- Check the expiry date of dispensed medicines to ensure that they remain unexpired for the duration of the supply course.
- Medicines should be dispensed in original packaging as far as possible.
- Tablets/capsules should not be removed from the strip/blister when dispensing.
- Bulk loose packs for supply are not encouraged. Avoid direct contact with the hand if loose packs are to be used.
- Medicines which need to be packed such as loose capsules/tablets should be packed into a clean, dry container, such as a bottle or plastic envelope which will not compromise the quality of the product after dispensing.

b) Extemporaneous Preparation/ Compounding

Extemporaneous preparations should only be prepared if there is no equivalent product available commercially and the product has to be compounded based on the patient's needs.

For compounding of psychotropic substance, no person shall dispense, compound or mix any psychotropic substance with any other substance, whether a psychotropic substance or not, for the purpose of it being used for medical, dental or animal treatment unless he is a licensed pharmacist; or a pharmacist in the public service. However, a pharmacy assistant or medical assistant employed in any government facility may also compound or mix any psychotropic substance for the purpose of medical treatment upon prescription prescribed by a registered medical practitioner or registered dentist⁴.

- Compounding of extemporaneous preparation should only be done on a patient-specific basis.
- Ingredients used for compounding are sourced from recognised pharmaceutical

suppliers.

- Ensure that the preparation is prepared according to formulation from a reputable reference. Suggested references are stated in Appendix 1.
- There should be worksheets for the compounding which should be checked by a staff member knowledgeable in compounding and counter-checked by a pharmacist/ another qualified staff member / doctor.
- Staff involved in compounding should be competent to perform this task under the supervision of pharmacist or registered medical practitioner.
- Availability of requisite facilities and equipment (Appendix 2) which are maintained in good order.
- In a situation where hazardous substance, such as cytotoxic medicines (as listed under NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings¹⁴) is to be handled, staff should use appropriate Personal Protective Equipment (PPE) and follow the stipulated procedures.
- Once the preparation is ready, label the product with necessary particulars including expiry date/ special requirements for safe handling and storage.
- Keep worksheets or record books for a minimum of two years. The document should contain information as below:
 - Formula
 - Ingredients and quantity used
 - Manufacturer, batch number and expiry date of ingredients used
 - Patient & prescription details
 - Names of persons involved in preparing and counterchecking the product
 - Date of compounding

Note: The MOH Extemporaneous Formulation¹⁰ and *Garis Panduan Pembancuhan (Compounding) Sediaan Ekstemporanus*¹¹ can be used as references.

B-ii. Labelling

- Every medicine containing any scheduled poison sold or supplied must be prepared and labelled by or under the immediate personal supervision of the medical practitioner or dentist³.
- All dispensed medicines should be labelled according to the requirement stated by law. It is advisable for labels to be printed. If handwritten, it should be neat and legible with clear instructions on use.
- Label should contain:
 - Name, address, and contact number of hospital / clinic / pharmacy
 - Patient's name
 - Name of medicines (generic and/or trade names)
 - Dosage form with the strength and quantity per unit dosage form: mg/ml of liquid, mg/g for semi-solid preparations
 - Directions for use: dose, frequency and duration (if necessary)
 - Date of supply
 - Expiry date (especially if dispensed medicine is not in its original

- packaging)
- “Controlled Medicine” or “*Ubat Terkawal*” should be labelled for all controlled medicines
 - Medicines for external use should be dispensed in suitable containers and should be labelled conspicuously with the words “Not to be Taken” or “For External Use Only” in *Bahasa Malaysia* and/or English printed in red OR on a red background
 - Special precautionary labels should be used where necessary (e.g., “Complete the course” for antibiotics, “May cause drowsiness” for sedating drugs, etc)
- Whenever possible, **always dispense the medicine in its original packaging** so that patients will have access to the product information.

If a medicine is not dispensed in its original packaging and it is not possible to include all the necessary information on the label, it should be written/printed separately and dispensed together with the medicine. **Patient information leaflet (PIL) should be provided, where available.** Approved PILs can be downloaded from the National Pharmaceutical Regulatory Agency (NPRA) website at <http://npra.moh.gov.my/> under Public - *Risalah Maklumat Ubat Pengguna (RiMUP)*.

B-iii. Checking

Check the prescription and the filled medicines to ensure that the filled medicines correlate with the prescription



Counter-Checking

- Counter-checking should be done by a second person, other than the staff who did the previous filling and labelling tasks.
- Check all the medicines prepared for dispensing against the prescription.
- Once the counter-checking is done, the person performing this task should initial on the prescription.

Proper record keeping is an essential part of dispensing as it facilitates good management and monitoring of services provided. Such records can be used to verify the stocks used in dispensing, and will be required if a need arises to trace patients dispensed with a particular medicine.

- **All sale or supply of poisons in private facilities must be recorded in a “Prescription Book” on the day of the sale or supply².**

The following particulars need to be recorded:

1. Date of sale or supply and the serial number of the entry of the prescription (if any);
2. Name of the active ingredients of the medicine or in the case of a proprietary medicine, the name of the medicine and the quantity supplied
3. Name and address of the patient

- **All sale or supply of Psychotropic Substances must be recorded in a “Prescription Register for Psychotropic Substances” on the day of the sale or supply⁴.**

The following particulars need to be recorded:

1. Date and serial number of sale or supply
2. Name and strength of the psychotropic substance and the quantity sold/ supplied/ administered
3. Name, identity card/passport number and address of the patient
4. The balance stock should be updated for each supply of the psychotropic substance in possession
5. The required entry must be in chronological order with respect to the previous entries in the register
6. Any correction to the entry must be made by way of a marginal note or a footnote which must specify the date on which the correction is made. Correction should not be made by cancellation / deletion /using liquid paper.
7. Each strength or type of psychotropic substance must be recorded in a separate register or a separate part of the register

- **All record books must be in the form of a bound book⁴.** Records kept as soft copy must be printed daily (if there is a transaction) and form a bound book.

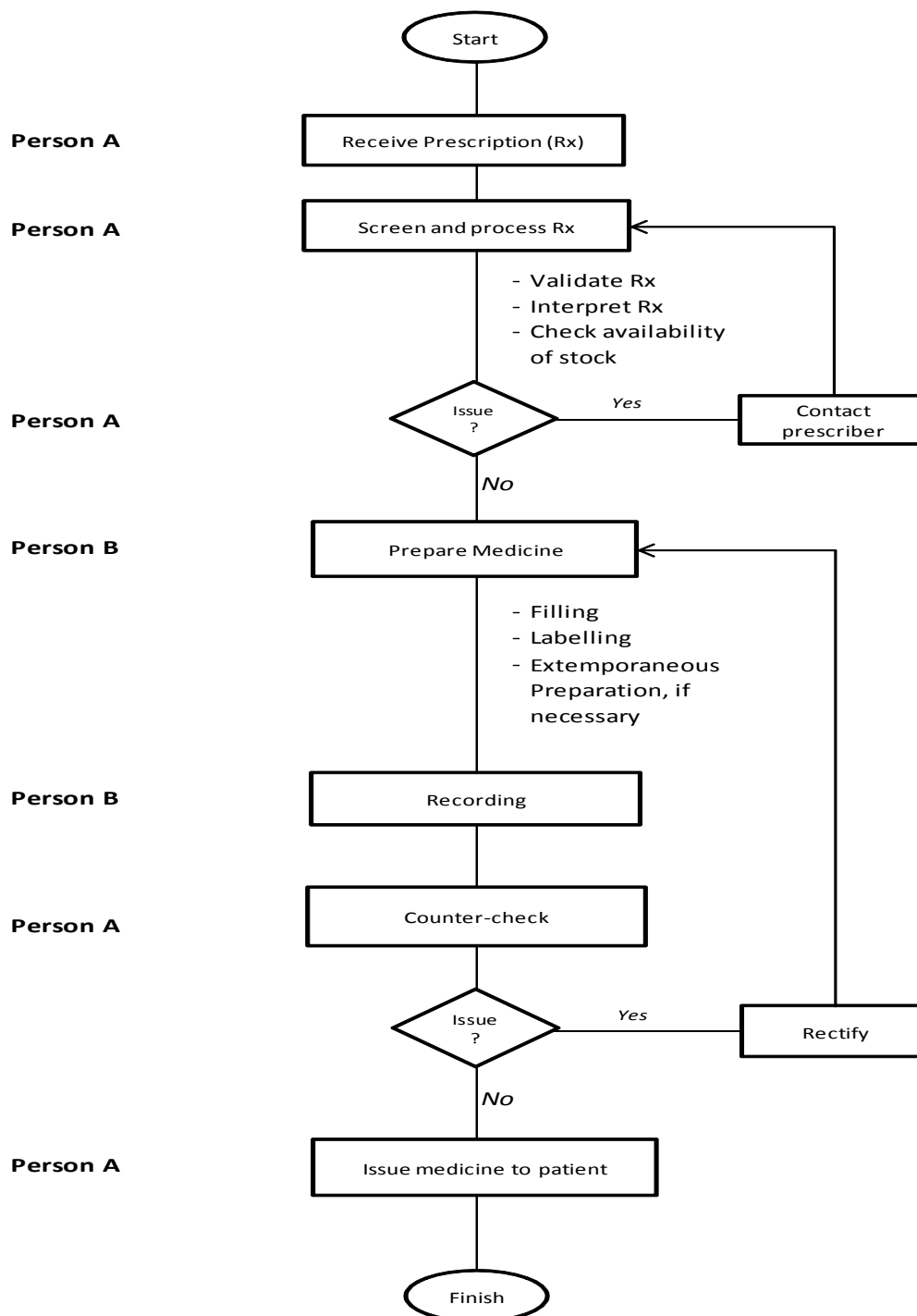


Issuing Medicines to the Patient

Issuing or supply of medicine should only be done by registered medical practitioner or a pharmacist². When dispensing the medicines, ensure the **5Rs**:

- **Right Patient**
 - **Right Medicine**
 - **Right Dose**
 - **Right Route**
 - **Right Time**
-
- Check the name and ID to verify the right patient.
 - Medicines supplied for a person under 18 years of age is for the purpose of his medical treatment only².
 - Ask about allergies or known adverse drug reactions (ADR).
 - Give **clear instructions** and **proper advice** on how to take/ use the medicines dispensed.
 - Ensure the patient is made aware if there are special requirements during transportation, proper storage conditions and usage requirements for the medicines.
 - Compliance aids (e.g. measuring spoon or syringe) for the appropriate dose should be provided, if required.
 - Every effort must be made to ensure that the recipient understands the information/instructions and advice provided.
 - Advise patients to inform the clinic/pharmacy should they encounter any adverse drug reactions (ADRs) when taking the dispensed medicines.
 - Supply of medicines based on prescription, the name of the person who dispensed the medicines, address and the date of supply should be written on the prescription above the doctor's signature as a form of endorsement.

4. Dispensing Process Flow Chart



Persons A or B refers to different personnel doing the task to minimise any possible error.

- Preparation of medicine for dispensing can be done by medical practitioner/ registered dentist/ pharmacist or a person under their immediate supervision for the purpose of it being used for medical treatment.
- Only a medical practitioner/ registered dentist/ pharmacist can dispense medicines with proper instructions.
- Any procedure involving psychotropic substance should follow the regulations stated under Poisons (Psychotropic Substances) Regulations 1989.

5. Medication Counselling

- Where necessary, provide medication counselling to patients to ensure proper use of medicines dispensed.
- It is encouraged to counsel patients with chronic diseases on multiple medications.
- Maintain records of the counselling done.

6. Maintaining Pharmaceutical Stocks

- Store all medicines in the original containers as supplied by the manufacturer. If the contents need to be transferred to other containers (pre-packing), care must be taken to avoid contamination and mix up. The new containers of the pre-packed / repacked medicines should be labelled appropriately with:
 - Name, address, and contact number of clinic/pharmacy
 - Name of medicines (generic and/or trade names)
 - Dosage form with the medicine strength (mg of tablet, mg/ml of liquid, mg/g for semi-solid preparations)
 - Manufacturer batch number
 - Manufacturer expiry date
- Store medicines under suitable conditions, taking into consideration the general usage of the medicine (internal/ external item should be segregated/ store separately), stability of the drug and manufacturer recommendations.
- Protect medications from contamination, sunlight, moisture and adverse temperatures.
- All psychotropic substances must be stored in a locked cabinet, safe or receptacle and can only be locked or unlocked by the registered medical practitioner or pharmacist⁴.
- Application of Tallman Lettering, Handling of Look Alike, Sound Alike Guideline and High Alert Medications Guideline in arranging medication stocks is encouraged in order to prevent medication error.

7. Disposal of Pharmaceutical Stocks

- Segregate deteriorated/ recalled/ expired/ returned medicines for proper disposal and store in an appropriate bin/ container to prevent unauthorised access.
- Management of disposal of expired/ returned medicines should follow as below:
 1. Poisons (Psychotropic Substances) Regulations 1989⁴ for disposal of psychotropic substance – needs to be witnessed by a Pharmacy Enforcement Officer, Ministry of Health.
 2. The Guidelines on the Management and Handling of Clinical Waste in Malaysia¹⁷ by the Department of Environment, Ministry of Natural Resources & Environment for disposal of medicines.

8. Supply of Medicines on Long-term Prescription

- Partial supply of medicines is based on the validity of the prescription and duration for its supply.
- Ensure that a copy of the original prescription is kept for recording purposes. Also, ensure that the quantity supplied by the pharmacy is recorded on the original prescription as reference for the next supply.
- The original prescription should be returned to the patient as it will be required for the next supply.

9. Delivery of Repeat Medicines by Post

- First time supply **must always** be dispensed at the pharmacy counter.
- Delivery service should **ONLY** be provided for **prescription that is partially-supplied**.
- The delivery service is only applicable when it has been established that the patient/caregiver understands the use of the medicines and direct face-to-face contact with the patient or caregiver is deemed not necessary for subsequent refills of the prescription.

Criteria for eligibility:

- Only stable and compliant patients should be eligible to receive medicines through the delivery service.
- Only partial supply medicines for chronic diseases should be considered for delivery services. Only medicines that do not require specific storage conditions can be delivered through post.
- Psychotropic drugs and medicines containing pseudoephedrine, ephedrine, codeine and tramadol **should not** be delivered by post.
- Agreement from the patient must be obtained prior to providing the delivery service and appropriate records of requests for the service must be kept.
- The delivery mechanism used **must be secure and medicines delivered promptly to the patient** so as not to compromise on the quality of the medicines and to ensure continuity of their medicines.

Note: The *Garis Panduan Perkhidmatan Ubat Melalui Pos 1Malaysia (UMP 1Malaysia)*¹⁸ should be referred for further information.

10. Non-Prescription Medicines

When non-prescription medicine is supplied, ensure that:

1. Sufficient information is gathered from the client to assess nature of problems, symptoms and past medical / medication history (if any)
2. Select an appropriate medicine (refer section 3.B.(i))
3. Label for the medicines prepared (refer section 3.B(ii))
4. Checking of the medicine before issuing it
5. Recording done (refer Section 3.D)
6. Medicine is supplied with proper instruction

Glossary

- a) **Pharmacist:** Refers to either a registered pharmacist or a licensed pharmacist, which ever term is appropriate to the context according to law
- b) **Licensed pharmacist:** A registered pharmacist who is the holder of a Type A Licence issued to him under section 26 of Poison Act 1952²
- c) **Non-prescription Medicine:** Refers to Group C Poison
- a) **Original brand (trade) name:** Brand name given to a medicine by the pharmaceutical company.
- d) **Poison:** any substance specified by name in the first column of the Poisons List and includes any preparation, solution, compound, mixture or natural substance containing such substance, other than an exempted preparation or an article or preparation included for the time being in the Second Schedule²
- b) **Prescription:** Any written or oral instruction to the seller or supplier to supply any poison, or medicine containing any poison, for the purpose of the medical or dental treatment of any person, given by any person²
- c) **Professional:** Registered medical practitioner, registered dentist, registered pharmacist
- d) **Private healthcare facility:** Any premise, other than a Government healthcare facility, used or intended to be used for the provision of healthcare services or health-related services, such as a private hospital, hospice, ambulatory care centre, nursing home, maternity home, psychiatric hospital, psychiatric nursing home, community mental health centre, haemodialysis centre, medical clinic, dental clinic and such other healthcare or health-related premises as the Minister may from time to time, by notification in the Gazette⁵
- e) **Registered medical practitioner:** A medical practitioner registered under the Medical Act 1971 [Act 50]⁵
- f) **Registered dentist:** A dental practitioner registered in Division I or Division II of the Register kept under subsection 11 (1) of the Dental Act 1971[Act 51]; and "registered dentist Division I" and "registered dentist Division II" means a dental practitioner whose name has been registered in the first or second division respectively of the said Register²
- a) **Registered pharmacist:** A pharmacist registered under any written law relating to the registration of pharmacists, and includes, in Sabah or Sarawak, a person holding a qualification recognised by the Director of Medical Services in Sabah or Sarawak, as the case may be, as a sufficient guarantee of the possession of the requisite

knowledge and skill for the efficient practice of the profession of a pharmacist².

Appendix

Appendix 1: Suggested References for Extemporaneous Preparation/Compounding

- a) Allen L.V, Jr. Suppositories, 1st Edition. 2007
- b) Allen L.V, Jr. The Art, Science, and Technology of Pharmaceutical Compounding
- c) Alberta Health Services. Pharmacy Compounding Manual. 2011
- d) British Pharmacopoeia
- e) Extemporaneous Formulation, Pharmaceutical Services Division, Ministry of Health
- f) Jew RK, Soo-Hoo W, Erush SC. Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients, 2nd Edition.2010
- g) International Journal of Pharmaceutical Compounding and other established journals
- h) Martindale: The Complete Drug Reference
- i) Nahata MC, Pai VB. Pediatric Drug Formulations, 6th Edition.2011
- j) Calgary Health Region Pharmacy. Pharmacy Compounding Manual. 2008.
- k) Rowe, Raymond C, Sheskey, Paul J, Cook, Walter G, Fenton, Marian E. Handbook of Pharmaceutical Excipients, 7th Edition. 2012
- l) Sarfaraz K. Niazi. Handbook of Pharmaceutical Manufacturing Formulations (Vol. 1-6). 2004
- m) Trissel LA. Trissel's™ Stability of Compounded Formulations 5th Edition
- n) Rockville, MD: The United States Pharmacopeia Convention. USP Pharmacists' Pharmacopeia Second Edition. 2008-2009

Appendix 2: Requirements for Medicines Preparation Area¹⁹

- Washbasin with water supply should be available, other than in the toilet.

- a) “Wet Compounding Area” (for the purpose of extemporaneous preparations only)
 - A designated area with sink and water supply.
 - Should be away from food and drinks.
 - All working surfaces and shelves should have a smooth impervious surface and washable material finishing.
 - Wet compounding area must be equipped with the following, if applicable:
 - i. Weighing scale - Regular verification and calibration by relevant bodies are required to ensure reliability and efficiency
 - ii. Mortar and pestle - Must be maintained in good condition.
 - iii. Tile/glass slabs with spatula - Must be maintained in good condition.
 - iv. Measuring appliances - Must be maintained in good condition.

- b) “Dry Compounding Area”
 - A designated area for counting tablets/ capsules, filling and packing of medicines as well as labelling the prepared medicines.
 - Should be away from food and drinks.
 - Provide suitable and hygienic means of counting tablets/capsules (e.g. counting tray).

Acknowledgement

- Pharmaceutical Care Section, Pharmaceutical Services Division, Ministry of Health Malaysia
- Enforcement Division, Pharmaceutical Services Division, Ministry of Health Malaysia
- Private Medical Practice Control Section (CKAPS), Medical Practice Division, Ministry of Health Malaysia
- Oral Health Division, Ministry of Health Malaysia
- *Bahagian Perkhidmatan Kesihatan, Kementerian Pertahanan*
- Dermatological Society of Malaysia
- Malaysia Medical Association
- Malaysia Pharmaceutical Society
- Malaysia Community Pharmacy Guild
- Pharmacy Team, Sunway Medical Centre
- Pharmacy Department, *Universiti Kebangsaan Malaysia* Medical Centre

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2. Poisons Act 1952 (Revised 1989)
3. Poisons Regulations 1952
4. Poisons (Psychotropic Substances) Regulations 1989
5. Private Healthcare Facilities and Services Act 1998
6. *Private Healthcare Facilities and Services (Private Medical Clinics or Private Dental Clinics) Regulations*. 2006 [P.U.(A) 137/2006]
7. *Private Healthcare Facilities and Services (Private Hospitals and Other Private Healthcare Facilities) Regulations* [P.U.(A) 138/2006]
8. *Bahagian Perkhidmatan Farmasi & Bahagian Pembangunan Kesihatan Keluarga, Kementerian Kesihatan Malaysia. Prosedur Operasi Piawai Farmasi Kesihatan*. 2005
9. *Bahagian Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia. Polisi Operasi Farmasi Ambulatori (Hospital & Klinik Kesihatan) Edisi 1*. 2011
10. Pharmaceutical Services Division, Ministry of Health Malaysia. Extemporaneous Formulation. 2015
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12. The United States Pharmacopeial Convention. Chapter 795: Pharmaceutical Compounding— Nonsterile Preparations. http://www.usp.org/sites/default/files/usp_pdf/EN/gc795.pdf. Accessed on 22 December 2015
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14. National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC). NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. 2014
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 19. Pharmaceutical Services Division, Ministry of Health Malaysia. Community Pharmacy Benchmarking Guidelines, 2nd Edition. 2015