3rd EDITION

2009

# Requirement for the Development of Pharmacy Facilities

in Hospitals, Health Clinics and Other Health Facilities, Ministry of Health, Malaysia


PHARMACEUTICAL SERVICES DIVISION
MINISTRY OF HEALTH, MALAYSIA

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# Preface

The Ministry of Health, Malaysia is continuously and proactively looking into areas that need improvement and expansion, in order to keep abreast with recent developments besides meeting the demands and expectations of the patients and stake holders. The policies, procedures and guidelines on development requirements are revised and improved dynamically, to ensure quality services to the public.

Appropriate infrastructure of healthcare facilities is a must to meet today's healthcare service requirements. Thus, it is timely for the Pharmaceutical Services Division, Ministry of Health, and Malaysia to publish the 3rd edition of *'The Requirements for Development of Pharmacy Facilities in Hospitals, Health Clinics and Other Health Facilities in Ministry of Health, Malaysia'.* I am certain that the content is up-to-date, applicable, and meets the relevant standards.

Proper planning is an essential process in both developing new facilities and upgrading existing ones. Development in accordance with the standard requirements will ensure that the department has a smooth workflow, besides adequate and appropriate infrastructures and equipments. Rectification of substandard facilities will incur additional cost to the government and hence, delay service delivery. Thus, this document should be used as a reference by those involved in the planning, development and upgrading of pharmacy departments in hospitals and health clinics.

Finally, I would like to convey my appreciation to the Pharmaceutical Services Division, Ministry of Health, Malaysia and the committee members for their tireless efforts and commitment to revise and publish the third edition of *'The Requirements for Development of Pharmacy Facilties in Hospitals Health Clinics and Other Health Facilities, Ministry of Health, Malaysia'.*

Thank you.

**Tan Sri Dato' Seri Dr. Hj Mohd. Ismail Merican**
Director General of Health
Ministry of Health, Malaysia

# Foreword

In tandem with the progressive development of new hospitals and health clinics by the Ministry of Health throughout the country, suitable guidelines on the development requirements are needed to assist those involved in planning. This has prompted the *'Requirement for Development of Pharmacy Facilities in Hospitals, Health Clinics and Other Health Facilities, Ministry of Health, Malaysia'* to be revised and published as the 3rd edition. This initiative is to ensure the standardised development of Good Hospital and Public Health Pharmacy Practice meets the current requirements imposed by the Ministry of Health.

This guideline focuses on the requirements and specifications for developing pharmacy facilities in new hospitals and health clinics. It also serves as a reference for upgrading existing facilities.

Compared to the earlier edition, the present requirements of space, layout, equipments and human resource for pharmacy services are more detailed and comprehensive. Requirements for new services such as Emergency Pharmacy and Ambulatory Care Pharmacy are also incorporated into this new edition. The requirements of Good Preparation Practice (GPP) especially for clean rooms have also been updated to keep abreast with current international standards as laid down by Pharmaceutical Inspection Co-operation Scheme (PIC/S), an international organization of which Malaysia is a member since January 2002.

I sincerely hope that this guideline will benefit all relevant parties. I would like to take this opportunity to congratulate and to express my appreciation to the Pharmacy Practice Working Committee (Hospitals and Health Clinics) for their efforts in producing this important guide.

Thank you.

**Eisah binti A. Rahman**
Senior Director of Pharmaceutical Services
Ministry of Health, Malaysia

# Prelude

First of all, I would like to convey my gratitude to the Pharmacy Practice Working Committee (Hospitals and Health Clinics) for their hard work to come up with the 3rd edition of *'Requirement for Development of Pharmacy Facilities in Hospitals, Health Clinics and Other Health Facilities, Ministry of Health Malaysia'*. It is very timely and appropriate for Pharmaceutical Services, Ministry of Health to publish this guideline, as there are vast changes in our healthcare services since the last edition in 2003.

The primary objective of this book is to assist those involved in planning, developing and upgrading pharmacy facilities. It also aims to be of benefit to pharmacist and others who are engaged in managing the facilities. The recommendations in this book are made by taking into account the pharmacy service policies, the fulfillments of customers' needs, pharmacy inventories and personnel safety, work flows and conducible working environment.

I believe that the content of this book will also serve as a standard reference for all pharmacists in the hospital and health clinics on the design, space and layout requirements, equipment and manpower needs. I therefore, strongly suggest to all pharmacists to look into the possibilities of upgrading their respective facilities based on the recommendations made in this book.

Finally, I would like to congratulate and thank all parties that has contributed to the success of the publication of this book.

Thank you.

**Hasnah binti Ismail**
Director
Pharmacy Practice and Development Division
Ministry of Health Malaysia

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# Introduction

## PHARMACY SERVICES IN HOSPITALS AND HEALTH CLINICS

Apart from the long-established activities of production and supply of medicines, the current Pharmacy Department of hospitals and health clinics shall provide comprehensive pharmaceutical care to patients with emphasis on clinical pharmacy. The quality system of the department shall consist of the following components; an organisational structure with clearly defined tasks, responsibilities and qualifications, a well-structured and sufficiently detailed documentation system, personnel having sufficient knowledge of quality management and a motivation for quality service, audit, and availability of necessary facilities and resources. Pharmacy personnel shall work with various disciplines and departments within the hospitals or health clinics in monitoring the quality use of medicines.

Services provided by the Pharmacy Department are categorised into three main functions with various activities:

### A. Patient Care

i) **Outpatient**
Dispensing, patient medication counseling and compounding extemporaneous preparations.

ii) **Inpatient**
Supplying medicines to wards, units and satellite pharmacies, patient medication counseling, ward rounds (inclusive of patients on TPN and cytotoxic drugs, and compounding extemporaneous preparations.

iii) **Clinical Pharmacokinetics**
Monitoring individual patient's medicine(s) level through laboratory analysis.

iv) **Drug and Poison Information Services**
Collecting and disseminating medicine and poison information to patients and health personnel.

### B. Pharmaceutical Preparation

i) **Sterile preparation**
Preparing intravenous admixtures, parenteral nutrition, sterile eye-drops and reconstituting cytotoxic drugs.

ii) **Galenical preparation**
Preparing creams, lotions and oral solutions that are not available commercially.

iii) **Repacking of medicines**
Packing of commonly used tablets/capsules and galenicals into individual units to facilitate dispensing.

## C. Procurement and supply

i) **Purchasing**
Ordering/buying medicines to be used by the hospital and health clinic.

ii) **Storage**
Safe keeping the medicines purchased in the store.

iii) **Distribution**
Supplying the medicines to various disciplines and units within the hospital community polyclinics.

Generally, all hospitals and health clinics within the Ministry of Health run all these three main functions but the type and extent of activities depends on the size, type and specialties of the facilities.



# 1 AMBULATORY CARE PHARMACY

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**LIST OF APPENDIX**

# 1. AMBULATORY CARE PHARMACY

## 1.1 INTRODUCTION

Ambulatory Care Pharmacy (ACP) Services shall provide optimal pharmaceutical care through the provision of medicines to patients in an accurate and timely manner for all Ministry of Health, Malaysia (MOH) prescriptions. ACP shall be sited in the vicinity of clinics, emergency & trauma and day care centres.

## 1.2 OBJECTIVES

1.2.1 To ensure the facility design and space area are adequate to provide medication dispensing, including extemporaneous product/s where appropriate.

1.2.2 To ensure facility design and space area are adequate to provide medication counselling service to patients or caretakers (inclusive of medication therapy adherence at the appropriate clinics), thus improving treatment outcome.

1.2.3 To acquire and implement technological advances wherever possible to allow ACP to strengthen patient-focused care.

1.2.4 To ensure proper dissemination of medicines information through acquired and implemented technological advances to the public and other healthcare providers thus promoting quality use of medicines.

## 1.3 POLICIES

### 1.3.1 General Operational Policies

a) Outpatient Pharmacy shall be located near the consultation / treatment rooms.

b) Dispensing of medicines shall be based on an authentic written or on-line prescriptions issued from the clinics / units / departments of hospitals and health institutions within the Ministry of Health, Malaysia (MOH).

c) "Island Dispensing System" shall be adopted, whereby all prescriptions received shall be screened by pharmacist, medications filled, labelled, counter checked and dispensed to prevent medication error at point of dispensing.

d) All prescriptions/ order received shall be screened and verified by authorised staff at the specified counter /station.

e) Any intervention if necessary shall be communicated to the prescriber and rectified.

f) Screened prescriptions shall be sent to filling station for labeling and filling process.

g) All filled prescriptions shall be counter-checked and verified by another authorised staff.

h) Medicines shall be made available in sufficient quantity, stored in appropriate storage condition and handled by trained and qualified personnel. The unit store shall store not less than 4 weeks stock while counter stock not less than 2 weeks stock.

i) The expiry date of the medicines kept shall be regularly monitored by the Pharmacy staff to avoid expiration in storage. There shall be sufficient space to implement FEFO (First Expiry First Out).

j) Integrated Drug Dispensing System (IDDS) shall be implemented (refer "Garispanduan Sistem Pendispensan Ubat Bersepadu, KKM"). All necessary communication and networking equipments shall be installed.

k) All supply and use of Dangerous Drugs / Psychotropic Substances shall be recorded in accordance to the requirements of relevant Acts and Regulations.

l) Pharmacist shall be in-charge of supplying Dangerous Drugs and Psychotropic Substances.

m) Every health clinic Outpatient Pharmacy shall establish Drug and Poison Information Service (DPIS), medication counseling service, Medication Therapy Adherence Clinic (MTAC), and pharmacy education services.

n) Safety and security of the staff, equipment and medicines shall not be compromised. Fire fighting equipment, smoke detector and automatic trigger alarm system shall be appropriately in place.

o) The sub-store shall be locked when the outpatient pharmacy is non-operational.

p) Access to pharmacy working area shall be restricted. Access card and electronic safety controlled doors shall be in place and closed circuit televisions (CCTVs) shall be installed. Emergency exit / escape door shall be available with clear signage.

### 1.3.2 General Development & Maintenance Policies

a) An appropriate conducive space shall be provided for pharmacy waiting area.

b) All counters shall be of open design and comply with guidelines provided by Pharmacy Services Division, Ministry of Health.

c) Every counter shall be provided with computer terminal or online dispensing system.

d) Outpatient Pharmacy counter shall be of open counter design with no barrier between patient and pharmacy staff and between one staff to another.

e) The Special Pharmacy Care (SPC) counter shall be provided to serve wheel

chair bound patients, geriatrics, handicap and mother and children. The counter shall be of sitting position for both patient and staff.

f) A designated area shall be provided for the storage and dispensing of all filled medicines waiting for collection, which are prepared for patients through appointment systems (e.g. SMS & Take).

g) Complete and appropriate Queue Management System shall be made available with sufficient quantity of digital calling system display panels located at strategic areas.

h) Sufficient space shall be provided for storage of all dispensed prescriptions and other documents.

i) The filling station design shall take into consideration the work flow, the handling material, the equipment, the manpower and the workload of the pharmacy. Adequate storage space with modular storage rack, cabinet or cupboard shall be considered.

j) Compounding of extemporaneous preparations which are prepared to be dispensed immediately to the patients, shall be done in specified preparation room near to the dispensing facilities.

k) Repacking of medicines shall be carried out in a designated room properly equipped with necessary equipments.

l) Outpatient facilities shall be complete and fully furnished with furniture, equipment, telecommunications and networking to meet the service requirements.

m) Proper signage shall be provided and be fixed at appropriate and strategic locations.

n) Storage of Dangerous Drugs / Psychotropic Substances shall be in a locked cabinet preferably with intruder alert system and in accordance to the relevant Act and Regulation.

o) Designated room(s) for patient medication counseling shall be provided to improve patient compliance towards medications.

p) There shall be a room for Pharmacist in-charge and modular workstations for other pharmacists and supporting staffs.

q) Appropriate and adequate space shall be allocated for Unit Store. This Unit Store shall be equipped with all necessary equipment and furniture to meet GSP requirement.

r) DPIS shall be completely furnished with necessary equipment, networking, references, telecommunications, storage systems and a discussion area. There shall be at least a pharmacist to run the services.

s) Computerized Medicine Information shall be made available e.g. Micromedex®, Lexicom® etc.

### 1.3.3 **Outpatient pharmacy**

a) Outpatient Pharmacy shall be established near the appropriate clinics to ease the congestion of the main pharmacy.

b) For hospitals providing Drive-thru Pharmacy services, the Drive-thru Pharmacy shall be located adjacent to the Outpatient Pharmacy.

### 1.3.4 **Emergency Pharmacy**

a) Emergency Pharmacy shall be established within the Emergency Department.

b) Emergency Pharmacy shall operate for twenty four hours per day with Pharmacist/s and adequate support staff.

### 1.3.5 **Day Care Pharmacy**

a) Day Care Pharmacy shall be established within the Day Care Centre for new hospitals.

b) Day Care Pharmacy shall operate during office hour with Pharmacist/s and adequate support staff working.

### 1.3.6 **Medication Therapy Adherence Clinic (MTAC)**

a) MTAC is a clinical pharmacy service, thus it shall emphasizes on medicines management to improve on quality, safety and cost-effectiveness of patient care.

b) MTAC shall be operated by pharmacists who provide counselling and education to patients with the purpose of helping to improve patient's ability to successfully manage their conditions and prevent debilitating symptoms.

c) MTAC shall also cover clinical pharmacokinetic consultation, laboratory monitoring and the initiation and dosage adjustment of relevant medicines.

## 1.4 MECHANICAL & ELECTRICAL REQUIREMENTS

### 1.4.1 **Power supply**

a) The heating, ventilation and air-conditioning (HVAC) system is very crucial and shall be designed to sustain the specific environment requirements under GSP. It shall also take into consideration the indoor air quality.

b) Standby or emergency power supply shall be connected to storage rooms, pharmaceutical refrigerators and freezer, the back door buzzer and dangerous drugs / psycho.

c) Standby or emergency power supply shall be connected to storage rooms, pharmaceutical refrigerators and freezer, the back door buzzer and dangerous drugs / psychotropic substances storage alarm.

1.4.2 **Air conditioning system**

a) All areas shall be centrally air-conditioned.

b) The storage areas for pharmaceutical items shall be air-conditioned for 24 hours. Two sets of alternating air conditioned system shall be provided for day and night use.

c) The patient waiting area shall be air-conditioned during operational hours.

1.4.3 **Lighting system**

a) Electrical outlet points shall be adequate for the optimum operation of outpatient services.

b) Uniform lighting over the entire area is required, preferably combining artificial and natural lighting. Localised lighting shall be provided for certain task area such as extemporaneous compounding area. Overall good lighting with appropriate intensity at different task level shall be considered to provide a safe, healthy and effective work place.

c) A special lighting such as sensor spotlight, automatic emergency lighting shall be fixed at appropriate locations such as the counters and the main entrance of area, with lighting ranging from 300-800 lux to minimize medication error during dispensing.

d) Ceiling lighting shall be flush mounted. Daylight white tube is preferable and shall be of optimum average illumination.

1.4.4 **Alarm system**

a) Automatic triggered alarm shall be fixed at dangerous drugs / psychotropic substances storage cabinet/area to detect any break-in.

## 1.5 DESIGN, LAYOUT AND SPECIFICATION

Refer ***Appendix B1.1 Design and Layout Plan for Outpatient Pharmacy***
Refer ***Appendix B1.2: Design and Layout Plan for Emergency/Day Care Pharmacy***

1.5.1 **Structural Design**

a) **Wall**

i) The walls shall be constructed of non-porous material and plastered both interior and exterior.

ii) Wall finishing shall be of washable antifungal paint (indoor) and weather proof paint (outdoor).

iii) Skirting shall be provided for office and staff areas.

iv) Walls for medicines and pharmaceutical storage (24-hrs-airconditioning) shall be of special building material and design as to prevent condensation.

b) **Floor**

i) The floor shall be non-porous, damp-proof and resistant to detergent.

ii) The floor shall be constructed from concrete and plastered smoothly, finished with non-slippery heavy duty materials to withstand the heavy loads, equipments and traffic.

c) **Ceiling**

i) The ceiling shall be made of fire-retardant, asbestos-free and non-shedding materials or mineral fibres.

ii) The ceiling shall offer acoustic balance and control for the room or space, preferably enhanced with sound absorption and attenuation.

d) **Door**

i) All doors shall be of fire-retardant material.

ii) The doors shall be two leaves, broad enough to allow free and easy movement of supplies and handling equipment such as medication trolleys.

iii) Doors shall be strong and reinforced to provide adequate security and fitted with double heavy duty locks.

iv) All doors shall be protected with trolley guard.

v) Main entrance and doors to all storage areas shall be equipped with electronic access control system.

vi) Grille/roller shutters shall be considered to be installed at issuing counters.

vii) All exit doors shall be strategically located and fitted with luminous emergency exit light.

e. **Window**

i) Windows shall be available at office and staff areas.

ii) Windows shall be either sliding or swing type.

iii) All windows shall be protected with metal grille.

### 1.5.2 Outpatient Pharmacy

The design and layout of the outpatient pharmacy shall take into consideration the operational work-flow as well as personnel and material flow.

a) **Patient Waiting Area**

i) The area shall be spacious, with adequate lighting and properly ventilated.

ii) Adequate space shall be provided in front of the receiving/screening counter for patients to queue up to submit their prescriptions.

iii) Pharmacy information corner consisting of a suggestion box with writing facilities, notice board and reading materials shall be made available.

iv) Client's Charter, work flow and instructions to patients shall be displayed at appropriate places.

v) The area shall be air-conditioned, equipped with chairs and television. An electronic information display panel shall be installed.

vi) A water dispenser is an optional requirement.

b) **Counters**

i) General Design of Prescription Receiving, Screening, Filling, Labelling and Dispensing Counters

- The design and layout shall take into consideration the operational work-flow as well as personnel and material flow.
- The area shall be spacious with no barrier between pharmacy counter staff and patient, to ensure good communication on medicines instructions provided during the supply process.
- The area shall be air-conditioned, properly ventilated and with adequate lighting.
- The distance from the counter to the patient's seats (first row) shall be at least 96" (2.4 m) to ensure comfortable sitting and facilitate medicines collection.
- The front view portion of the counter shall be made of building materials suitable to reflect the corporate image and professional service of the pharmacy.
- The number of counters shall be sufficient to cater for the supply of medicines to patients of the hospital/clinic. In a general setting where there is a dispensing load of 100 prescriptions and lower, a minimum of 3 counters shall be built (receiving/screening, dispensing and special pharmacy care counter (SPC).

- An additional counter shall be required for every additional 100 prescriptions dispensed.

- A counter for SPC shall be made available and built of sitting down position.

- The counter shall be 2 tiered, the higher tier is of patient's standing height and the lower is for prescriptions receiving/screening and SPC.

- The height of the countertop shall be of patient standing height. The height is about 42" (~1m) from the countertop floor to ensure smoothness and ease in medicines collection.

- The width of the working counter bench shall be 24"- 26" (~0.6-0.65m). Counter top shall be 20" (0.5m) with 10"-12" (0.25m-0.3m) protrusion towards patient to ensure comfortable distance between staff and patient.

- The width of the counter shall depend on size of hospital/clinic and prescription load with minimum width of 4 feet per dispensing counter.

- THIS or facilities adopting online prescribing shall be equipped with a complete workstation (adequate quantity of computer, LCD monitor, labelling printer, heavy duty printer) to receive and process order. The counter design shall accommodate such hardware, without affecting the width and depth of the dispensing counter.

- Computerised QMS with Voice Calling System complete with LED display and Public Address (PA) System shall be provided. The QMS shall be integrated with the existing computerised dispensing system (e.g. THIS).

- Conveyor belt system shall be considered for outpatient pharmacies with more than 4 dispensing counters. The conveyor belt system shall be designed to meet local requirements, to ease the transfer of filled prescription and to expedite dispensing activities.

- The counter shall be equipped with motorised roller shutter.

- Air curtain shall be provided where applicable.

ii) Receiving & Screening Counter

- The QMS ticketing and PA system equipment shall be provided at this counter.

- The area shall cater for possible electronic transaction as well as for general enquiries and information.

- A telephone shall be provided for prescription enquiries / interventions

iii) Dispensing Counter

- The distance between dispensing counter staff shall be about 48" (1.2m) to maintain comfortable working distance.
- The distance between dispensing staff sitting at the counter to medicine filled trolley parking shall be 36 inches (0.91m) to allow easy movement.

c) **Filling Workstation**

i) The area for filling prescriptions shall be located near dispensing counters and equipped with pharmaceutical refrigerators, benches, racks and other appropriate furniture.

ii) Adequate space shall be provided for computer hardware (including LCD monitor, UPS, barcode reader and printers).

iii) Conveyor system shall be provided where appropriate to facilitate transfer of filled prescriptions to the dispensing counters.

iv) The filling workstation shall be designed appropriately to house adequate storage space for drugs and labelled in an appropriate manner to facilitate filling process and minimize movement of the staff.

v) A workstation with glass panel and sufficient opening space shall be provided to allow transfer of medicines to the dispensing area.

vi) The working area to conduct all operations related to medicines filling shall be concealed from the public/patient view.

vii) The surrounding working area and workstation shall have adequate space to ease staff, material, medicine and equipment movement to the filling area.

d) **Extemporaneous Area**

i) A designated area properly equipped with necessary equipments shall be made available for extemporaneous preparation.

ii) The area shall have a built-in concrete working bench with smooth and acid resistant surface suitable for pharmaceutical preparation.

iii) The area shall have a stainless steel sink with an appropriate depth (at least 16 inches deep) to avoid splashing, and 5 µm filter apparatus for hot and cold water outlets, complete with elbow tap.

iv) The area shall have stainless steel shelves.

v) Reverse osmosis water supply system shall be made available.

e) **Storage Area**

i) Storage Area for Medicines (Sub-store)

- An appropriate storage room with appropriate security measures shall be available for storing medicine.
- Suitable storage cabinets and shelves shall be made available.
- Pharmaceutical refrigerator to keep thermo labile medicines, trolleys and suitable open racks shall be made available.
- The area shall have air-conditioning facilities working 24 hours maintained between 18-25°C.
- Temperature of the storage area shall be monitored and documented.
- Back-up / essential power supply with trigger alarm system connected to the main control room shall be made available for pharmaceutical refrigerators and air conditioning facilities.
- The pharmaceutical fridge shall have temperature record system with alarm.
- The door shall accommodate trolleys and sufficient space shall be provided for trolley parking inside the store.

ii) Storage Of Dangerous Drugs And Psychotropic Substances

- Dangerous Drugs and Psychotropic Substances shall be stored in lockable metal cabinets equipped with audio / visual alarm system, in a dedicated room/pharmacist room.

iii) Storage Area for Ready-to-use Packs

- The area shall be equipped with sufficient heavy duty racks to cater for storing internal and external preparation.
- Additional area for unloading of ready-to-use packs shall be made available inside the store.
- The width of the door shall accommodate trolleys.

f) **Patient Counselling Room**

i) Dedicated room / rooms shall be located in area accessible to patients from the waiting area and the pharmacist from inside the outpatient pharmacy.

ii) A minimum of two counselling rooms shall be made available. The rooms shall be half-glass panelled with blinds.

iii) Conducive counselling environment shall be made available e.g. sofa sets, coffee table etc.

iv) The room shall be equipped with suitable racks and cupboard to store educational materials.

g) **Office Area**

i) Pharmacist office shall be half-glass panelled to allow supervision.

ii) Open concept shall be applied for general office complete with necessary equipments e.g. computers, photocopy machine, fax, and internet access.

iii) Meeting/ discussion/ seminar room shall be equipped with appropriate equipments e.g. LCD projectors, laptops and wireless access to the internet.

h) **Ancillary Area**

i) Document room

- Sufficient space with racks shall be made available to store the entire document as required by the laws and regulation/s

ii) Stationery Room

- Sufficient space with racks shall be made available to store the stationery

iii) Areas for Personnel

- Personnel rest room with sufficient personnel lockers shall be provided.
- Toilets with air locks for personnel shall be made available and shall be located away from the activity areas and counselling room.
- Muslim male and female prayer rooms shall be provided. The qiblat of the Muslim prayers room shall not be facing the toilet.

iv) Utility Room

- Utility room shall be provided to store cleaning materials and equipments

v) Disposal Room

- The room shall be accessible from outside the pharmacy.
- It also functions as a temporary storage area for items meant to be disposed e.g. boxes, plastic containers.

### 1.5.3 **Emergency Pharmacy**

a) **Patient Waiting Area**

i) The area shall be spacious, with adequate lighting and properly ventilated.

ii) Adequate space shall be provided in front of the receiving/screening counter for patients to queue up to submit their prescriptions.

iii) Pharmacy information corner consisting of a suggestion box with writing facilities, notice board and reading materials shall be made available.

iv) Client's Charter, work flow and instructions to patients shall be displayed at appropriate places.

v) The area shall be air-conditioned, equipped with chairs and television. An electronic information display panel shall be installed.

vi) A water dispenser is an optional requirement.

b) **Counters**

i) General Design of Prescription Receiving, Screening, Filling, Labelling and Dispensing Counters

- The design and layout shall take into consideration the operational work-flow as well as personnel and material flow.
- The area shall be spacious with no barrier between pharmacy counter staff and patient, to ensure good communication on medicines instructions provided during the supply process.
- The area shall be air-conditioned, properly ventilated and with adequate lighting.
- The distance from the counter to the patient's seats (first row) shall be at least 80" (2m) to ensure comfortable sitting and facilitate medicines collection.
- The front view portion of the counter shall be made of building materials suitable to reflect the corporate image and professional service of the pharmacy.
- The number of counters shall be sufficient to cater for the supply of medicines to patients of the hospital/clinic. In a general setting where there is a dispensing load of 100 prescriptions and lower, a minimum of 3 counters shall be built (receiving/screening, dispensing and special pharmacy care counter (SPC).
- An additional counter shall be required for every additional 100 prescriptions dispensed.

- A counter for SPC shall be made available and built of sitting down position.

- The counter shall be 2 tiered, the higher tier is of patient's standing height and the lower is for prescriptions receiving/screening and SPC.

- The height of the countertop shall be of patient standing height. The height shall be 42" (~1m) from the floor to ensure smoothness and ease in medicines collection.

- The width of the working counter bench shall be 24"- 26" (~0.6-0.65m). Counter top shall be 20" (0.5m) with 10"-12" (0.25m-0.3m) protrusion towards patient to ensure comfortable distance between staff and patient.

- The width of the counter shall depend on size of hospital/clinic and prescription load with minimum width of 4 feet per dispensing counter.

- THIS or facilities adopting online prescribing shall be equipped with a complete workstation (adequate quantity of computer, LCD monitor, labelling printer, heavy duty printer) to receive and process order. The counter design shall accommodate such hardware, without affecting the width and depth of the dispensing counter.

- Computerised QMS with Voice Calling System complete with LED display and Public Address (PA) System shall be provided. The QMS shall be integrated with the existing computerised dispensing system (e.g. THIS).

- Conveyor belt system shall be considered for emergency pharmacies with more than 4 dispensing counters. The conveyor belt system shall be designed to meet local requirements, to ease the transfer of filled prescription and to expedite dispensing activities.

- The counter shall be equipped with motorised roller shutter.

- Air curtain shall be provided where applicable.

ii) **Receiving & Screening Counter**

- The QMS ticketing and PA system equipment shall be provided at this counter.

- The area shall cater for possible electronic transaction as well as for general enquiries and information.

- A telephone shall be provided for prescription enquiries / interventions.

iii) **Dispensing Counter**

- The distance between dispensing counter staff shall be about 48" (1.2m) to maintain comfortable working distance.

- The distance between dispensing staff sitting at the counter to medicine filled trolley parking shall be 36" (0.91m) to allow easy movement.

c) **Filling Workstation**

i) The area for filling prescriptions shall be located near dispensing counters and equipped with pharmaceutical refrigerators, benches, racks and other appropriate furniture.

ii) Adequate space shall be provided for computer hardware (including LCD monitor, UPS, barcode reader and printers).

iii) The filling workstation shall be designed appropriately to house adequate storage space for drugs and labelled in an appropriate manner to facilitate filling process and minimize movement of the staff.

iv) A workstation with glass panel and sufficient opening space shall be provided to allow transfer of medicines to the dispensing area.

v) The working area to conduct all operations related to medicines filling shall be concealed from the public/patient view.

vi) The surrounding working area and workstation shall have adequate space to ease staff, material, medicine and equipment movement to the filling area.

d) **Extemporaneous Area**

i) A designated area properly equipped with necessary equipments shall be made available for extemporaneous preparation.

ii) The area shall have a built-in concrete working bench with smooth and acid resistant surface suitable for pharmaceutical preparation.

iii) The area shall have a stainless steel sink with an appropriate depth (at least 16 inches deep) to avoid splashing, and 5µm filter apparatus for hot and cold water outlets, complete with elbow tap.

iv) The area shall have stainless steel shelves.

v) Reverse osmosis water supply system shall be made available.

e) **Storage Area**

i) Storage Area for Medicines (Sub-store)

- An appropriate storage room with appropriate security measures shall be available for storing medicine.
- Suitable storage cabinets and shelves shall be made available.
- Pharmaceutical refrigerator to keep thermo labile medicines, trolleys and suitable open racks shall be made available.
- The area shall have air-conditioning facilities working 24 hours maintained between 18-25°C.
- Temperature of the storage area shall be monitored and documented.
- Back-up / essential power supply with trigger alarm system connected to the main control room shall be made available for pharmaceutical refrigerators and air conditioning facilities.
- The pharmaceutical fridge shall have temperature record system with alarm.
- The door shall accommodate trolleys and sufficient space shall be provided for trolley parking inside the store.

ii) Storage of Dangerous Drugs and Psychotropic Substances

- Dangerous Drugs and Psychotropic Substances shall be stored in lockable metal cabinets equipped with audio / visual alarm system, in a dedicated room/pharmacist room.

f) **Patient Counselling Room**

i) Dedicated room / rooms shall be located in area accessible to patients from the waiting area and the pharmacist from inside the outpatient pharmacy.

ii) A counselling room shall be made available. The room shall be half-glass panelled with blinds.

iii) Conducive counselling environment shall be made available e.g. sofa sets, coffee table etc.

iv) The room shall be equipped with suitable racks and cupboard to store educational materials.

g) **Ancillary Area**

i) Areas for Personnel

- Personnel rest room with sufficient personnel lockers shall be provided.
- Toilets with air locks for personnel shall be made available and shall be located away from the activity areas and counselling room.
- Muslim male and female prayer rooms shall be provided. The qiblat of the Muslim prayers room shall not be facing the toilet.

1.5.4 **Day Care Pharmacy**

Refer ***Appendix B1.2: Design and Layout Plan for Emergency/Day Care Pharmacy***

a) **Patient Waiting Area**

i) The area shall be spacious, with adequate lighting and properly ventilated.

ii) Adequate space shall be provided in front of the receiving/screening counter for patients to queue up to submit their prescriptions.

iii) Pharmacy information corner consisting of a suggestion box with writing facilities, notice board and reading materials shall be made available.

iv) Client's Charter, work flow and instructions to patients shall be displayed at appropriate places.

v) The area shall be air-conditioned, equipped with chairs and television. An electronic information display panel shall be installed.

vi) A water dispenser is an optional requirement.

b) **Counters**

i) General Design of Prescription Receiving, Screening, Filling, Labelling and Dispensing Counters

- The design and layout shall take into consideration the operational work-flow as well as personnel and material flow.
- The area shall be spacious with no barrier between pharmacy counter staff and patient, to ensure good communication on medicines instructions provided during the supply process.
- The area shall be air-conditioned, properly ventilated and with adequate lighting.

- The distance from the counter to the patient's seats (first row) shall be at least 80" (2m) to ensure comfortable sitting and facilitate medicines collection.

- The front view portion of the counter shall be made of building materials suitable to reflect the corporate image and professional service of the pharmacy.

- The number of counters shall be sufficient to cater for the supply of medicines to patients of the hospital/clinic. In a general setting where there is a dispensing load of 100 prescriptions and lower, a minimum of 3 counters shall be built (receiving/screening, dispensing and special pharmacy care counter (SPC).

- An additional counter shall be required for every additional 100 prescriptions dispensed.

- A counter for SPC shall be made available and built of sitting down position.

- The counter shall be 2 tiered, the higher tier is of patient's standing height and the lower is for prescriptions receiving/screening and SPC.

- The height of the countertop shall be of patient standing height. The height shall be 42" (~1m) from the floor to ensure smoothness and ease in medicines collection.

- The width of the working counter bench shall be 24"- 26" (~0.6-0.65m). Counter top shall be 20" (0.5m) with 10"-12" (0.25m-0.3m) protrusion towards patient to ensure comfortable distance between staff and patient.

- The width of the counter shall depend on size of hospital/clinic and prescription load with minimum width of 4 feet per dispensing counter.

- THIS or facilities adopting online prescribing shall be equipped with a complete workstation (adequate quantity of computer, LCD monitor, labelling printer, heavy duty printer) to receive and process order. The counter design shall accommodate such hardware, without affecting the width and depth of the dispensing counter.

- Computerised QMS with Voice Calling System complete with LED display and Public Address (PA) System shall be provided. The QMS shall be integrated with the existing computerised dispensing system (e.g. THIS).

- The counter shall be equipped with motorised roller shutter.

- Air curtain shall be provided where applicable.

ii) Receiving & Screening Counter

- The QMS ticketing and PA system equipment shall be provided at this counter.
- The area shall cater for possible electronic transaction as well as for general enquiries and information.
- A telephone shall be provided for prescription enquiries / interventions.

iii) Dispensing Counter

- The distance between dispensing counter staff shall be about 48" (1.2m) to maintain comfortable working distance.
- The distance between dispensing staff sitting at the counter to medicine filled tray parking shall be 36 " inches (0.91m) to allow easy movement.

c) **Filling Workstation**

i) The area for filling prescriptions shall be located near dispensing counters and equipped with pharmaceutical refrigerators, benches, racks and other appropriate furniture.

ii) Adequate space shall be provided for computer hardware (including LCD monitor, UPS, barcode reader and printers).

iii) The filling workstation shall be designed appropriately to house adequate storage space for drugs and labelled in an appropriate manner to facilitate filling process and minimize movement of the staff.

iv) A workstation with glass panel and sufficient opening space shall be provided to allow transfer of medicines to the dispensing area.

v) The working area to conduct all operations related to medicines filling shall be concealed from the public/patient view.

vi) The surrounding working area and workstation shall have adequate space to ease staff, material, medicine and equipment movement to the filling area.

d) **Extemporaneous Area**

i) A designated area properly equipped with necessary equipments shall be made available for extemporaneous preparation.

ii) The area shall have a built-in concrete working bench with smooth and acid resistant surface suitable for pharmaceutical preparation.

iii) The area shall have a stainless steel sink with an appropriate depth (at

least 16 inches deep) to avoid splashing, and 5 µm filter apparatus for hot and cold water outlets, complete with elbow tap.

iv) The area shall have stainless steel shelves.

v) Reverse osmosis water supply system shall be made available.

e) **Storage Area**

i) Storage Area for Medicines (Sub-store)

- An appropriate storage room with appropriate security measures shall be available for storing medicine.
- Suitable storage cabinets and shelves shall be made available.
- Pharmaceutical refrigerator to keep thermo labile medicines, trolleys and suitable open racks shall be made available.
- The area shall have air-conditioning facilities working 24 hours maintained between 18-25°C.
- Temperature of the storage area shall be monitored and documented.
- Back-up / essential power supply with trigger alarm system connected to the main control room shall be made available for pharmaceutical refrigerators and air conditioning facilities.
- The pharmaceutical fridge shall have temperature record system with alarm.
- The door shall accommodate trolleys and sufficient space shall be provided for trolley parking inside the store.

ii) Storage Of Dangerous Drugs And Psychotropic Substances

Dangerous Drugs and Psychotropic Substances shall be stored in lockable metal cabinets equipped with audio / visual alarm system, in a dedicated room/pharmacist room.

f) **Patient Counselling Room**

i) Dedicated room / rooms shall be located in area accessible to patients from the waiting area and the pharmacist from inside the outpatient pharmacy.

ii) A counselling room shall be made available. The room shall be half-glass panelled with blinds.

iii) Conducive counselling environment shall be made available e.g. sofa sets, coffee table etc.

iv) The room shall be equipped with suitable racks and cupboard to store educational materials.

g) **Ancillary Area**

i) Personnel rest room with sufficient personnel lockers shall be provided.

1.5.5 **Medication Therapy Adherence Clinic (MTAC) Room**

a) An MTAC room shall have the same set up and requirement as Patient Counselling Room.

b) Dedicated room / rooms shall be located in area accessible to patients from the waiting area at the appropriate clinics.

c) Conducive counselling environment shall be made available.

d) The room shall be equipped with suitable racks and cupboard to store educational materials.

e) Computerized Medicine Information shall be made available e.g. Micromedex®, Lexicom® etc.

f) Certain medicines shall be kept in filing cabinet to be dispensed to patients after consultation.

g) Adequate monitoring equipment / material shall be made available to the patient.

## 1.6 SPACE REQUIREMENT

Refer ***Appendix A1.1 Space Requirement for Outpatient Pharmacy***
Refer ***Appendix A1.2 Space Requirement for Emergency / Day Care Pharmacy***
Refer ***Appendix A1.3 Space Requirement for MTAC***

## 1.7 EQUIPMENT REQUIREMENT

Refer ***Appendix C1: Equipment Requirement for Outpatient / Emergency / Day Care Pharmacy***

## 1.8 MANPOWER REQUIREMENT

Refer ***Appendix D1: Manpower Requirement for Ambulatory Care Pharmacy***

APPENDIX A1.1 : **SPACE REQUIREMENT FOR OUTPATIENT PHARMACY**

| Hospital Size (No. of Prescrip-tions) | Outpatient Pharmacy Area (square meter) | | | | | | | | | | | | | Waiting Area for Patients |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Counter and Pharmacy Work Area | Drug Store | Controlled Item/ DD Room | Tabs/Caps/ Repacking Room and Internal/Ex-ternal Liquid Extempora-neous/Repac-king Room | Individual Counseling Room | Pharmacist Room (Head of Unit) | Office Space (Cubicles) | Record Room | Staff Rest Room | Toilet | Disposal Room | Utility Room | Prayer Room | |
| <250 | 46 (4 counters) | 38 | 16 | 3 x 14 | 1 X 14 | 12 (1 U44) | 38 (2 U41 & 1 U32) | 10 | 20 | 2 X 10 | 10 | 10 | 2 X 14 | 46 (50 chairs) |
| 251- 500 | 92 (6 counters) | 56 | 20 | 3 x 14 | 2 X 14 | 12 (1 U44) | 56 (4 U41, 1 U36) | 10 | 24 | 2 X 10 | 10 | 10 | 2 X 14 | 92 (80 chairs) |
| 501-700 | 138 (8 counters) | 75 | 25 | 3 x 14 | 2 X 14 | 14 (1 U48) | 74 (6 U41, 1 U36) | 14 | 28 | 2 X 10 | 10 | 10 | 2 X 14 | 138 (120 chairs) |
| 701-1000 | 186 (10 counters) | 92 | 32 | 3 x 14 | 2 X 45 | 14 (1 U48) | 100 (8 U41, 1 U36 & 1 U32) | 20 | 30 | 4 X 10 | 10 | 10 | 2 X 14 | 185 (160 chairs) |
| >1000 | 232 (12 counters) | 138 | 36 | 3 x 14 | 3 X 45 | 14 (1 U48) | 120 (10 U41, 1 U36 & 1 U32) | 24 | 32 | 4 X 10 | 10 | 10 | 2 X 16 | 232 (200 chairs) |

The above space requirement does not include passage way

APPENDIX A1.2 : **SPACE REQUIREMENT FOR EMERGENCY / DAY CARE PHARMACY**

| No. of Prescriptions /day received from Emergency Dept/ Day Care Unit | Pharmacy Area (square meter) | | | |
|---|---|---|---|---|
| | Counter and Pharmacy Work Area | Drug Storage Area | Waiting Area for Patients | Counseling Room |
| <50 | 16 | - | 16 | 14 |
| 51- 100 | 25 | 16 | 25 | 14 |
| 101-200 | 36 | 22 | 30 | 14 |
| >200 | 40 | 42 | 42 | 14 |

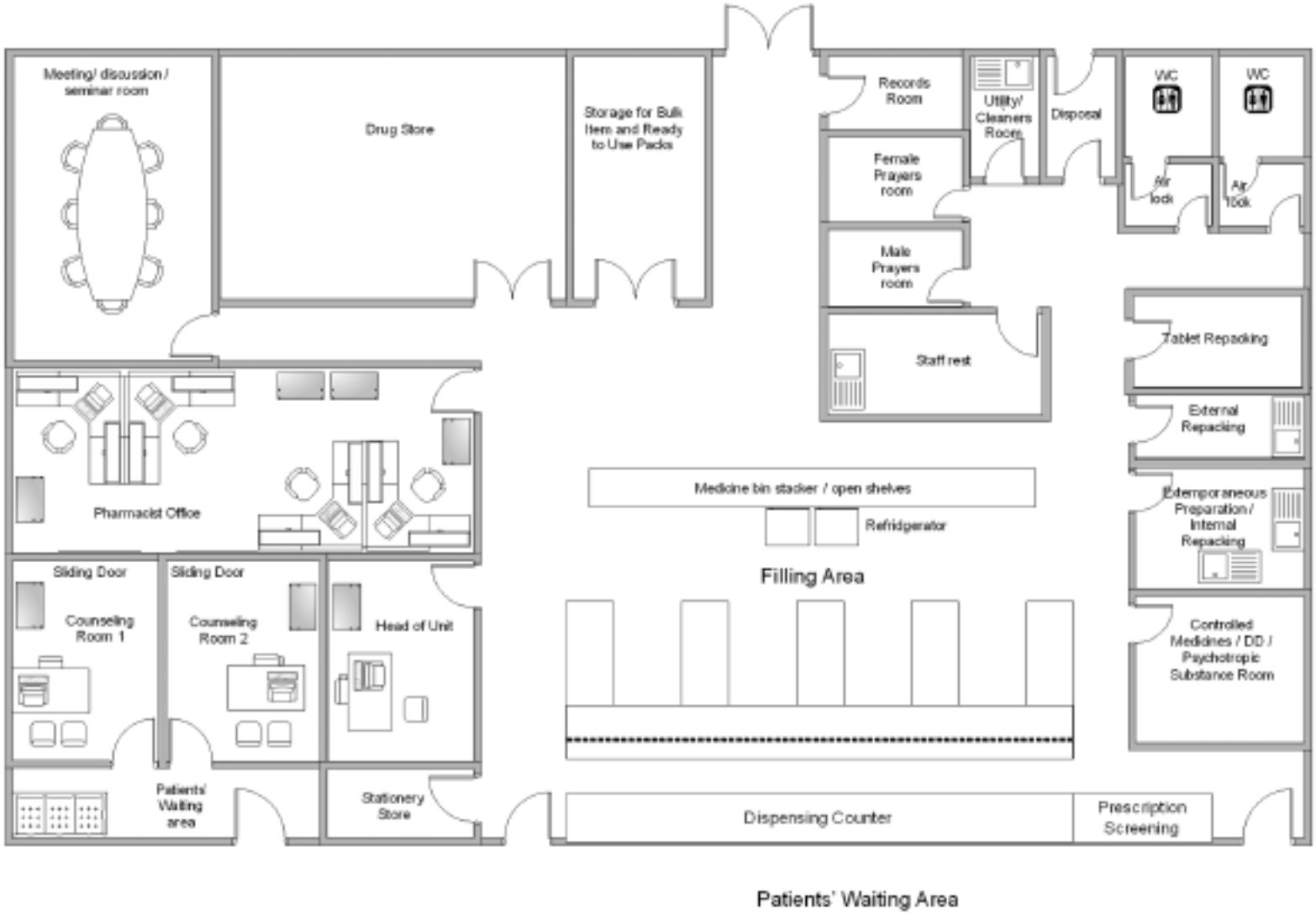
The above space requirement does not include passage way

APPENDIX A1.3 : **SPACE REQUIREMENT FOR MEDICATION THERAPY ADHERENCE CLINIC (MTAC)**

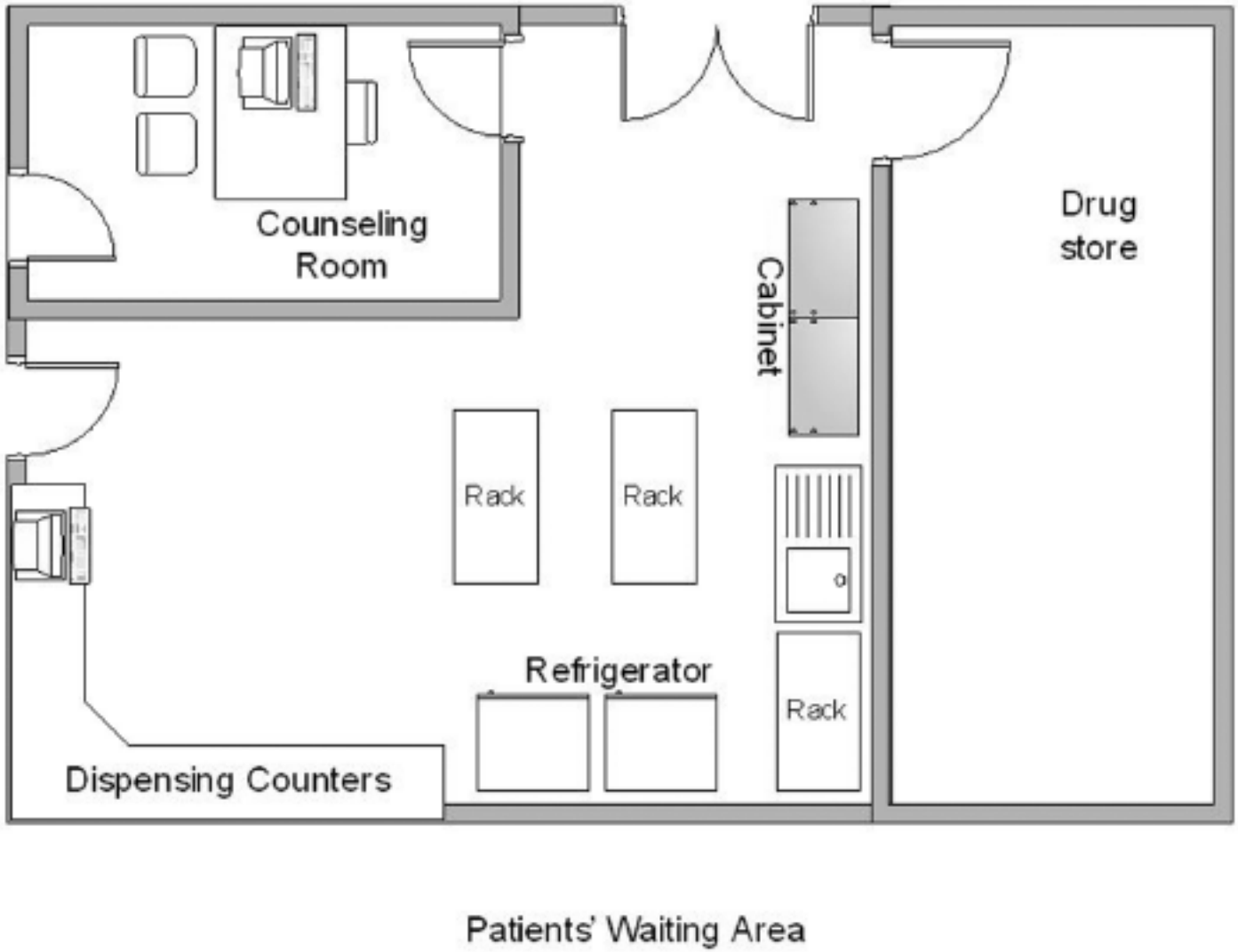
| No of MTAC according to appropriate clinics** | MTAC Room (square meter) |
|---|---|
| 1 | 1 X 14 |
| 3 | 2 X 14 |
| 6 | 3 X 14 |
| >10 | 4 X 14 |

**Example : Diabetes,Cardiovascular, Warfarin, Osteoporosis, HAART, Asthma, Neurology and etc.

APPENDIX B1.1 : **DESIGN AND LAYOUT PLAN FOR OUTPATIENT PHARMACY**



APPENDIX B1.2 : **DESIGN AND LAYOUT PLAN FOR EMERGENCY/DAY CARE PHARMACY**



APPENDIX C1 : **EQUIPMENT REQUIREMENT FOR AMBULATORY CARE PHARMACY**

| No. | Equipment | Location | | |
|---|---|---|---|---|
| | | OP | EP/DCP | MTAC |
| 1 | Air-Condition | 3 | 3 | 3 |
| 2 | Audio video set/ DVD/ Television set (For seminar room) | 3 | 3 | |
| 3 | Bar Code Labeler | 3 | 3 | |
| 4 | Bar Code Reader | 3 | 3 | |
| 5 | Benches | 3 | 3 | |
| 6 | Bins (Stackable, various sizes) | 3 | 3 | 3 |
| 7 | Book Shelf | 3 | | 3 |
| 8 | Cabinet, Filing | 3 | 3 | 3 |
| 9 | Cabinet, Stainless Steel | 3 | 3 | |
| 10 | Cabinet, Dangerous Drugs | 3 | 3 | |
| 11 | Calculator | 3 | 3 | 3 |
| 12 | Chair - counter with back rest (Adjustable for Dispensing) | 3 | 3 | |
| 13 | Chair (Office) | 3 | 3 | 3 |
| 14 | Chair (Visitor) | 3 | 3 | 3 |
| 15 | Chair (Waiting area) | 3 | 3 | 3 |
| 16 | Clock | 3 | 3 | 3 |
| 17 | Close Circuit TV | 3 | | |
| 18 | Coffee table | 3 | | |
| 19 | Compactors | 3 | | |
| 20 | Computer sets (LCD Screen, UPS, Printer) | 3 | 3 | 3 |
| 21 | Computer, notebook | 3 | | |
| 22 | Computerized Queue Management system with Electronic Calling System | 3 | 3 | |
| 23 | Digital Calling System | | | 3 |
| 24 | Dining Set for 6 | 3 | | |
| 25 | Electronic door with card access | 3 | 3 | |
| 26 | Electronic Information Display | 3 | | |

| No. | Equipment | Location | | |
|---|---|---|---|---|
| | | OP | EP/DCP | MTAC |
| 27 | Facsimile machine | 3 | | |
| 28 | Fire Safety equipments (fire extinguishers, fire blanket e.t.c.) | 3 | 3 | 3 |
| 29 | Freezer | 3 | | |
| 30 | Water Filter with Hot and Cold Water Dispenser (staff rest) | 3 | 3 | |
| 31 | Labeler (Hand) | 3 | 3 | |
| 32 | Labeler Machine | 3 | | |
| 33 | Ladder Aluminum | 3 | | |
| 34 | Measuring cylinder | 3 | 3 | |
| 35 | Measuring jar | 3 | 3 | |
| 36 | Microphone (PA system) | 3 | | |
| 37 | Microwave (staff rest room) | 3 | | |
| 38 | Mill care Storage Cabinet | 3 | 3 | |
| 39 | Mirror | 3 | 3 | |
| 40 | Mortar & Pestle | 3 | 3 | |
| 41 | Notice Board | 3 | 3 | 3 |
| 42 | Personal protective equipment (gloves, ear protectors and masks) | 3 | | |
| 43 | Photostat machine | 3 | | |
| 44 | Pocket PC | 3 | 3 | 3 |
| 45 | Portable dust extractor unit | 3 | | |
| 46 | Printer LaserJet A4 | 3 | 3 | 3 |
| 47 | Rack - heavy duty | 3 | | |
| 48 | Refrigerator Pharmaceutical, Single door | | 3 | |
| 49 | Refrigerator Pharmaceutical, Single door (separate fridge for cytotoxic medicines) | 3 | | |
| 50 | Refrigerator, Domestic 225 L (staff rest) | 3 | | |
| 51 | Refrigerator, Pharmaceutical 2 door (Glass) | 3 | | |
| 52 | Scale , weighing (300g) - Electronic | 3 | | |
| 53 | Sealer machine | 3 | | |

| No. | Equipment | Location | | |
|---|---|---|---|---|
| | | OP | EP/DCP | MTAC |
| 54 | Shoe rack ( For personnel room) | 3 | | |
| 55 | Sofa sets (For Personnel/ counseling rooms) | 3 | | |
| 56 | Spatula | 3 | 3 | |
| 57 | Staff locker | 3 | 3 | |
| 58 | Suggestion box with writing facilities | 3 | | |
| 59 | Table for conference room | 3 | | |
| 60 | Table/Office Chair | 3 | 3 | 3 |
| 61 | Tables for 6 (personnel rest room) | 3 | | |
| 62 | Television set (for waiting area) | 3 | | |
| 63 | Toaster | 3 | | |
| 64 | Trolley (Hand) | 3 | 3 | |
| 65 | Trolley, 2-tier stainless steel | 3 | | |
| 66 | Trolley, Instruments with guard rail | 3 | 3 | |
| 67 | Trolley, Medicines (Emergency) | | 3 | |
| 68 | Trolley, Multipurpose platform (heavy duty) | 3 | | |
| 69 | Truck, Pallet (heavy-duty), Store | 3 | 3 | |
| 70 | Vacuum Cleaner | 3 | | |
| 71 | Water Dispenser | 3 | 3 | |
| 72 | White Board (Magnetic) | 3 | 3 | 3 |
| 73 | Magazine rack | 3 | | |
| 74 | Blood Pressure Set | | | 3 |
| 75 | Weighing Scale With Height | | | 3 |
| 76 | INR Machine | | | 3 |
| 77 | Spirometry Machine | | | 3 |
| 78 | Glucometer Machine | | | 3 |
| 79 | Palm Top | 3 | 3 | 3 |
| 80 | Mobile Phone with Prepaid Card | 3 | | |

**Legends:**
OP : Outpatient Pharmacy
EP : Emergency Pharmacy
DCP : Day Care Pharmacy
MTAC : Medication Therapy Adherence Clinic

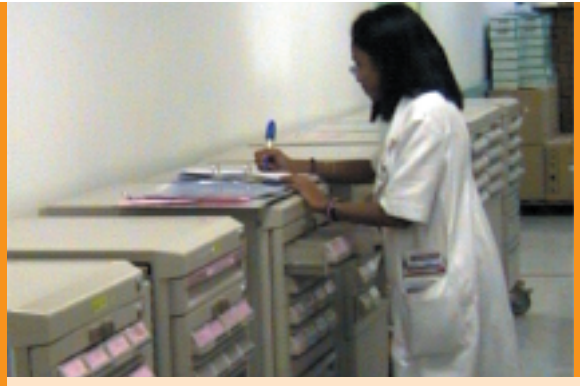
## APPENDIX D1 : **MANPOWER REQUIREMENT FOR AMBULATORY CARE PHARMACY**

| Category of Manpower | No. of prescriptions per day | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | <250 | | | | | 250 - 500 | | | | | 501-1000 | | | | | >1000 | | | | |
| | Number of Staff Required | | | | | | | | | | | | | | | | | | | |
| | OP | | | EP/ DCP | MTAC | OP | | | EP/ DCP | MTAC | OP | | | EP/ DCP | MTAC | OP | | | EP/ DCP | MTAC |
| | Scr | Ctr | Co | | | Scr | Ctr | Co | | | Scr | Ctr | Co | | | Scr | Ctr | Co | | |
| Pharmacist (U48) | - | - | - | - | - | - | - | - | - | - | - | 1 | - | - | 1 | - | 1 | - | - | 2 |
| Pharmacist (U44) | - | 1 | - | - | - | - | 2 | - | - | 1 | - | 2 | - | 1 | 1 | - | 3 | - | 1 | 2 |
| Pharmacist (U41) | 1 | 3 | 1 | 1 | 1 | 2 | 7 | 2 | 2 | 2 | 3 | 13 | 2 | 3 | 3 | 3 | 15 | 3 | 5 | 5 |
| Pharmacy Assistant (U36) | - | - | - | - | - | - | 1 | - | - | - | - | 1 | - | - | - | - | 1 | - | - | - |
| Pharmacy Assistant (U32) | - | 1 | - | 1 | - | - | 1 | - | 1 | - | - | 3 | - | 1 | - | - | 4 | - | 1 | - |
| Pharmacy Assistant (U29) | - | 4 | - | 3 | - | - | 7 | - | 3 | - | - | 13 | - | 3 | - | - | 15 | - | 3 | - |
| General Workers | - | 1 | - | 0 | - | - | 2 | - | 1 | - | - | 3 | - | 1 | - | - | 4 | - | 1 | - |

U41 norm 1:100

**Legends**

**OP** : Outpatient Pharmacy
**Ctr** : Dispensing Counter
**EP/DCP** : Emergency Pharmacy/Day Care Pharmacy
**Scr** : Screening of Prescriptions
**Co** : Medication Counseling Services
**MTAC** : Medication Therapy Adherence Clinic



# 2 INPATIENT PHARMACY





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**LIST OF APPENDIX**

# 2. INPATIENT PHARMACY

## 2.1 INTRODUCTION

The Inpatient Pharmacy provides comprehensive pharmaceutical services to all categories of patients from newborn to geriatric admitted to the wards of the hospital.

These include stocking and dispensing of medication, medication history investigation, evaluation of medication and dosing on an individual patients basis, collaborating with the doctors and nurses on the appropriate plan of care regarding drug use, discharge planning, implementing and evaluating cost containment, drug therapy evaluation for the Drug and Therapeutic Committee, educating and disseminating drug information to patients, family members and other healthcare professionals.

The medication supply service is provided through Unit Dose Drug Distribution system, which can be developed to an automated dispensing system for provision of routine medication in unit dose packaging. This includes those which need sterile preparation in the Production Pharmacy namely intravenous admixtures, parenteral nutrition preparations and cytotoxic drug reconstitution. Scheduled checks shall be carried out on medication storage and expiration, as well as in ensuring right administration of right medications to the right patients.

## 2.2 OBJECTIVES

2.2.1 To ensure the Ward Supply / Satellite Pharmacy Unit design, build and maintenance accommodate the workflows and operational requirement towards effective and efficient medication supply to inpatients.

2.2.2 To ensure the facilities are sufficiently equipped with appropriate and adequate resources in order to enhance the delivery of total pharmaceutical care that meets the patients needs.

2.2.3 To acquire and implement technological advances wherever possible to allow the inpatient pharmacy to improve patient medication supply and strengthen patient-focused pharmaceutical care.

## 2.3 POLICIES

### 2.3.1 General Operational Policies

a) Ward Supply Pharmacy stores and provides central medication supply to all wards/ units in the hospital including the Satellite Pharmacies.

b) The Inpatient Satellite Pharmacy shall be established to provide;
   i) improved control over individual patient medication supply
   ii) improved accessibility to medications and drug information,
   iii) improved communication between pharmacist and other health care team.

c) Ward Supply Pharmacy and Satellite Pharmacy shall be opened during office hours on weekdays. Operational hours on other days and after office hours shall be determined by departmental policies.

d) Pharmacists shall be on duty throughout the operational hours of the inpatient pharmacy facilities.

e) All areas of drug storage shall be locked after normal working hours. Keys shall be put under the control of pharmacist in charge.

f) Dangerous Drugs and Psychotropic Substances shall be stored under lock and key in accordance with the requirement of relevant Acts and Regulations.

g) All written orders shall be screened and verified by pharmacists prior to filling and dispensing.

h) Unit Dose System shall be implemented in all wards whereby patients' medications are prepared on daily dose basis and put in individual cassettes of medication trolleys. All medication trolleys shall be locked and kept within the satellite pharmacy area prior to collection by authorised ward/unit staff.

i) Sufficient After Office Hours (AOH) stock of frequently used medication, other than Dangerous Drugs / Psychotropic Substances, shall be made available in the wards. These medications can only be used when the inpatient pharmacy supply is non-operational.

j) Topping up of AOH and emergency trolley medication shall be done by the pharmacy staff.

k) Discharge medications shall be prepared and dispensed at the bedside, and counseling shall be provided to enhance patients' understanding and compliance.

l) Clinical Pharmacokinetic Service shall be made available and results shall be interpreted by the Pharmacist. In toxic cases, results shall be communicated to the requesting doctors for immediate management.

m) Drug and Poison Information Service shall be made available and managed by the pharmacist.

### 2.3.2 General Development & Maintenance Policies

a) The Ward Supply Pharmacy shall be centrally located in areas which are easily accessible to facilitate medication supplies from the main Pharmacy Store and to the requesting satellite pharmacies, wards and other units.

b) The Satellite Pharmacy shall be located in an area which is easily accessible to facilitate medication supplies from the Ward Supply Pharmacy and to the requesting wards and other units.

c) The Ward Supply Pharmacy and Satellite Pharmacy shall be located away from public areas.

d) The Ward Supply Pharmacy and Satellite Pharmacy shall be accessible only to the authorised pharmacy staff via ID access card.

e) Security alarm and CCTV shall be installed and operational in all access points and drug storage areas and connected to hospital security control room.

f) The hospital shall take measures to provide adequate security both to inpatient pharmacy staff as well as the medication stock, during and after office hours.

g) Panic alarm shall be provided with full instruction on how to operate them made known to the inpatient pharmacy staff.

h) Fire safety equipment shall be installed and meet the requirement of the Fire and Rescue Department, Malaysia.

i) The storage area shall be sufficient for keeping all inventories at appropriate stock holding levels and shall be stored in accordance to Good Storage Practice Guidelines (GSP) and other government/ authority regulations.

j) There shall be sufficient physically separated areas with appropriate storage conditions for orderly segregation of products namely biological, refrigerated, inflammable and corrosive liquid and solids, cytotoxic drugs, Dangerous Drugs and Psychotropic Substances.

k) Where controlled storage environment is required, its conditions shall be continuously monitored using appropriate equipment at predetermined intervals. Maximum and minimum temperature of the day shall be monitored and recorded.

l) Expensive and attractive items shall be stored in a dedicated storage area with limited access. All storage areas shall be properly labeled.

m) Storage of Dangerous Drugs / Psychotropic Substances in the wards / units shall be kept under lock and key and put under the control of authorised personnel.

n) Compounding of extemporaneous preparations which are prepared to be dispensed immediately to the patients, shall be done in specified preparation areas in the Ward Supply Pharmacy / Satellite Pharmacy.

o) Computerisation and online drug management system shall be made available. Computerised identification system such as bar coding shall be considered to be used for inventory and asset management.

p) The following requirement shall be considered to provide functional environment for Inpatient Pharmacies:
   i) Practical and suitable workstations to the work function and condition.
   ii) Space for IT networking & hardware.
   iii) Adequate space for housing all equipment, furniture and office automations.
   iv) Adequate issuing area.
   v) Adequate storage for records and filing
   vi) Pantry, rest and prayer rooms for staff
   vii) An appropriate space for condemn inventory
   viii) An appropriate space for disposal
   ix) Storage for utilities

## 2.4 MECHANICAL & ELECTRICAL REQUIREMENT

2.4.1 The heating, ventilation and air-conditioning (HVAC) system shall be designed to sustain the specific environment requirement under GSP. It shall also take into consideration the indoor air quality.

2.4.2 All areas of Inpatient Pharmacy shall be centrally air-conditioned. Areas which provide storage for pharmaceutical items shall have 24 hours air-conditioning facilities.

2.4.3 Electrical outlet points shall be adequate for the optimum operation of inpatient services.

2.4.4 Standby or emergency power supply shall be connected to storage rooms, pharmaceutical refrigerators and freezer, the back door buzzer and Dangerous Drugs / Psychotropic Substances storage alarm.

2.4.5 Automatic triggered alarm shall be fixed at Dangerous Drugs / Psychotropic Substances storage cabinet/area to detect any break-in.

2.4.6 Uniform lighting over the entire Inpatient Pharmacy area is required, preferably combining artificial and natural lighting. Localised lighting shall be provided for certain task area such as extemporaneous compounding area. Overall good lighting with appropriate intensity at different task level shall be considered to provide a safe, healthy and effective work place.

2.4.7 A special lighting such as sensor spotlight, automatic emergency lighting shall be fixed at appropriate locations such as the medication trolley parking bay and the main entrance of the ward supply area, with lighting ranging from 300-800 lux to minimize medication error during dispensing.

2.4.8 Ceiling lighting shall be flush mounted. Daylight white tube is preferable and shall be of optimum average illumination.



## 2.5 DESIGN, LAYOUT AND SPECIFICATION

The general design and construction shall take into consideration the functionality of inpatient pharmacy services. The location and size shall accommodate anticipated personnel and inventory movement, work processes and activities.

Refer ***Appendix B2.1 Example Of Design And Layout Plan For Ward Supply Pharmacy*** and ***Appendix B2.2 Example Of Design And Layout Plan For Satellite Pharmacy.***

### 2.5.1 Structural Design

a) **Wall**

i) The walls shall be constructed of non-porous material and plastered both interior and exterior.

ii) Wall finishing shall be of washable antifungal paint (indoor) and weather proof paint (outdoor).

iii) Skirting shall be provided for office and staff areas.

iv) Walls for medicines and pharmaceutical storage (24-hrs-airconditioning) require special building material and design as to prevent condensation.

b) **Floor**

i) The floor shall be non-porous, damp-proof and resistant to detergent.

ii) The floor shall be constructed from concrete and plastered smoothly, finished with non-slippery heavy duty materials to withstand the heavy loads and traffic.

c) **Ceiling**

i) The ceiling shall be made of fire-retardant, asbestos-free and non-shedding materials or mineral fibres.

ii) The ceiling shall offer acoustic balance and control for the room or space, preferably enhanced with sound absorption and attenuation.

d) **Door**

i) All doors shall be of fire-retardant material.

ii) The doors shall be two leaves, broad enough to allow free and easy movement of supplies and handling equipment such as medication trolleys.

iii) Doors shall be strong and reinforced to provide adequate security and fitted with double heavy duty locks.

iv) All doors shall be protected with trolley guard.

v) Main entrance and doors to all storage areas shall be equipped with electronic access control system.

vi) Grille/roller shutters shall be considered to be installed at issuing counters.

vii) All exit doors shall be strategically located and fitted with luminous emergency exit light.

e) **Window**

i) The windows shall be available in the office and staff areas.

ii) Window shall be either sliding or swing type.

iii) All windows shall be protected with metal grille.

2.5.2 **Ward Supply Pharmacy**

a) **Trolley Parking Bay and Waiting Area**

i) Trolley parking bay shall be located in front or adjacent to the ward supply counter. The space shall be adequate for trolley parking and movement and shall be based on the number of wards and units served.

ii) Sufficient space and chairs for waiting area shall be provided.

b) **Issuing Area**

i) The area shall be easily accessible to wards and units.

ii) An open counter for supply and receiving shall be provided. The counter shall accommodate at least two persons at the same time.

iii) Adequate storage cabinets or shelves or pigeon holes shall be made available for holding issued items prior to ward/unit collection.

iv) Adequate space shall be provided for computer hardware (including LCD monitor, UPS, barcode reader and printers).

c.) **Filling area**

i) Filling area shall be located behind the ward supply receiving counters and shall be equipped with benches, racks, stackable bins and other furniture.

ii) Working space shall be provided according to the workload, number of personnel and medication trolleys involved at any one time. A minimum of 25 square feet (7 sqm) space shall be provided for each medication trolley attended by one personnel.

iii) The location and design of workbench and filling station shall accommodate personnel, material and equipment flow and facilitate movement.

iv) Adequate space shall be provided for computer hardware (including LCD monitor, UPS, barcode reader and printers).

v) Adequate lighting of 500 - 800 lux shall be made available to prevent errors in filling.

d) **Extemporaneous Room**

i) A designated area properly equipped with necessary equipments shall be made available for extemporaneous preparation.

ii) The area shall have a built-in concrete working bench with smooth and acid resistant surface suitable for pharmaceutical preparation.

iii) The area shall have a stainless steel sink with an appropriate depth (at least 16 inches deep) to avoid splashing, and 5 µm filter apparatus for hot and cold water outlets, complete with elbow tap.

iv) The area shall have stainless steel shelves.

v) Reverse osmosis water supply system shall be made available.

e) **Storage Area for Medicines**

i) Appropriate storage rooms / areas with appropriate security measures shall be available for storing medicine.

ii) The door and space between racks shall accommodate trolleys and sufficient space shall be provided for trolley parking inside the store.

iii) There shall be enough space to accommodate portable or built-in storage cabinets / shelves, suitable open racks and pharmaceutical refrigerators to keep thermo labile medicines.

iv) Designated areas for internal and external items, injections, thermo-labile products, cytotoxic drugs, galenical preparations, inflammable and corrosive liquid and solid pharmaceutical items and biological items shall be provided.

v) The areas shall have air-conditioning facilities working 24 hours maintained between 18-25°C.

vi) Temperature of the storage area and pharmaceutical refrigerators shall be monitored and documented daily.

vii) Temperature control probe shall be installed with digital display monitor fixed outside the room. The pharmaceutical refrigerator shall have temperature record system with alarm.

viii) Back-up / essential power supply with trigger alarm system shall be made available for pharmaceutical refrigerators and air conditioning facilities.

ix) Cytotoxic spill kit shall be made available within the Ward Supply Pharmacy area.

x) The corrosive item storage area shall be equipped with water supply for emergency wash.

xi) The storage of all inflammable items shall be in a dedicated room / area built from /equipped with fire retardant materials.

f. **Storage Area for Bulk Items (intravenous solution)**

i) Adequate storage space for intravenous solutions shall be made available. Heavy duty open racks and heavy duty plastic pallets shall be made available.

ii) Appropriate space for material handling equipment shall be provided.

g) **Dangerous Drugs / Psychotropic Substances Room**

i) Dangerous Drugs and Psychotropic Substances shall be stored under lock and key in accordance with the requirement of relevant Acts and Regulations and equipped with trigger alarm system.

ii) There shall be a dedicated space for issuing and transit prior to collection.

h) **Drug and Poison Information Services Area**

i) There shall be a dedicated room, furnished with appropriate furniture and equipped with telecommunication and networking system in handling, managing, delivering and disseminating information to patients and care givers.

ii) Adequate number of personal computers, personal digital assistants (PDA), printers, and telephone shall be provided.

iii) Source of references such as Micromedex®, Lexicom® of updated version and other references shall be made available.

iv) A dedicated space for small group discussion shall be made available.

v) Storage space or cabinet for hard copy information and documents shall be made available.

i) **Clinical Pharmacokinetic Services (TDM) Area**

i) The service shall be managed by a pharmacist.

ii) A fully furnished workstation including storage facilities for documents shall be made available.

iii) Adequate references to ensure accurate and good service quality. shall be made available.

j) **Management and Administrative Area**

i) A room shall be provided for the Pharmacist in charged.

ii) A dedicated open office area with furnished workstation and appropriate equipment shall be provided.

iii) A fully equipped and furnished meeting and discussion room shall be provided for Inpatient / Ward Pharmacy activities.

k) **Ancillary Area**

i) Staff rest room shall be complete with pantry and furniture shall be made available.

ii) Toilet and changing rooms complete with staff lockers adjacent to staff rest room shall be provided.

iii) Separate prayer room for male and female complete with ablution facilities shall be provided.

iv) Extractor fan shall be made available.

l) **Cleaner's / Utility Room**

Cleaners / Utility room shall be provided.

m) **Disposal Room**

This room shall be accessible from outside of the inpatient pharmacy

2.5.3 **Satellite Pharmacy**

a) Satellite pharmacy shall be made available for hospitals with more than 250 beds. For every 120 beds or 4 wards, one satellite pharmacy shall be provided. A maximum of 10 satellites shall be considered for hospital with more than 1000 beds.

b) Satellite pharmacy shall also serves as one stop center for discharge medication.

c) Adequate workspace for dispensing counter, filling and labeling, workstation, extemporaneous compounding, refrigerator, drug storage, personnel and all the necessary equipment shall be provided.

d) Adequate space shall be provided for computer hardware (including LCD monitor, UPS, barcode reader and printers) at the counter and filling station.

e) There shall be adequate parking space for 4 trolleys at one time in the satellite pharmacy trolley parking bay, in front of the counter. An area of at least 25 square feet (7 square meters) is needed for each trolley.

f) A minimum of 2 open counters for receiving indents and medication orders shall be provided.

g) Area for prescriptions filling shall be equipped with benches, racks, stackable bins and other furniture.

h) Sufficient space is needed to accommodate two medication trolleys at one time for each filling workbench.

i) Built-in concrete working bench with smooth and acid resistant surface suitable for pharmaceuticals complete with a stainless steel sink (at least 16 inches deep) shall be provided for extemporaneous preparation.

j) Adequate storage area with air-conditioning facilities running 24 hours daily shall be made available for drug storage areas. Sufficient built-in open racks/cabinets shall be provided.

k.) Back-up / essential power supply shall be made available for pharmaceutical refrigerators and air conditioning facilities.

l) A dedicated open office area with furnished workstation and appropriate equipment shall be provided.

m) Utility room shall be provided to store cleaning material and equipment.

## 2.6 SPACE REQUIREMENT

Refer ***Appendix A2 Space Requirement For Ward Supply Pharmacy and Satellite Pharmacy.***

## 2.7 EQUIPMENT REQUIREMENT

Refer ***Appendix C2: Equipment Requirement for Inpatient and Satellite Pharmacy.*** The equipment required in each facility is governed by the activities, services, function and workload.

## 2.8 MANPOWER REQUIREMENT

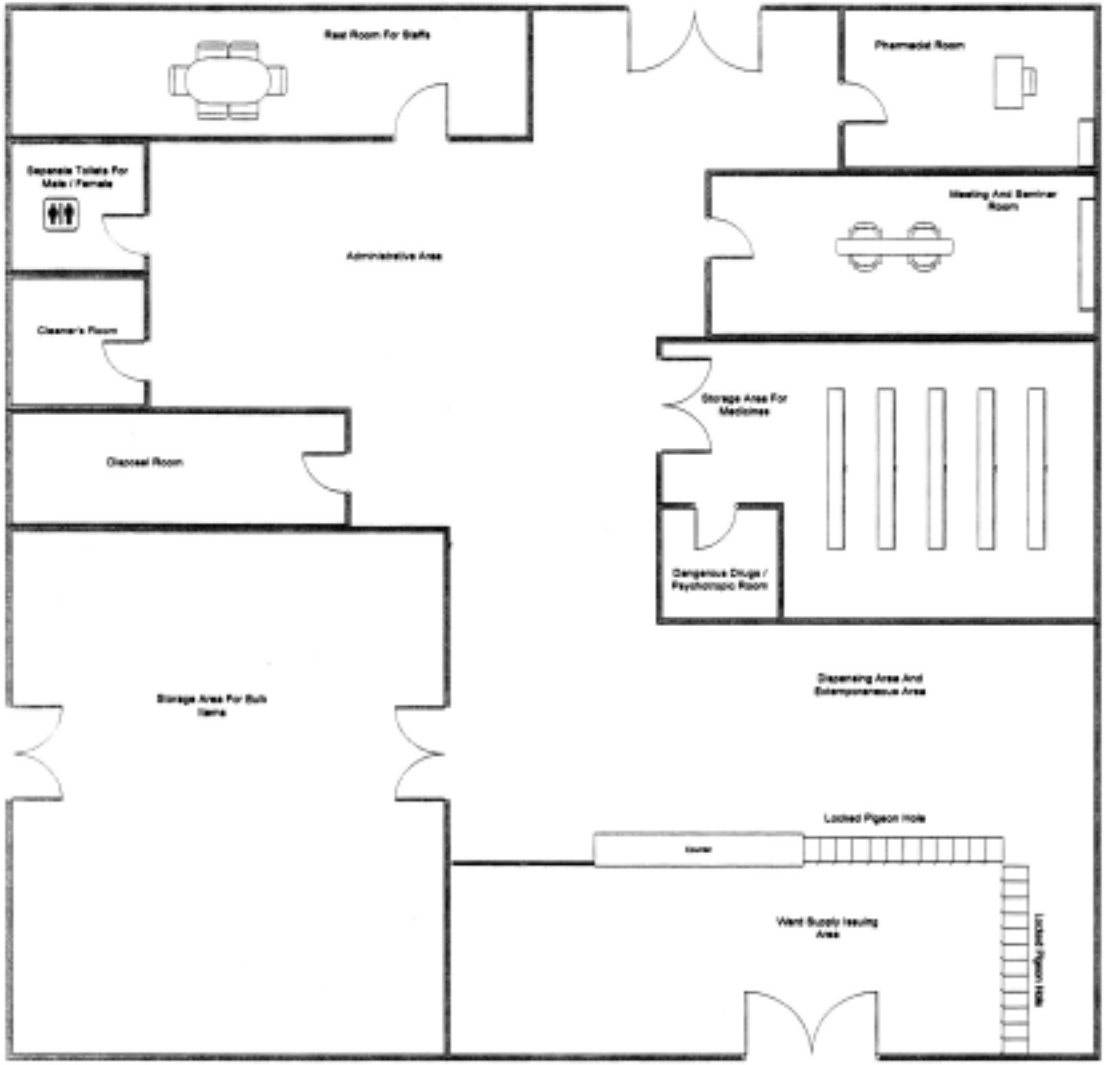
Refer ***Appendix D2: Manpower Requirement for Inpatient and Satellite Pharmacy.*** Manpower requirement is base on man-hours or full time equivalent. Therefore the design and planning of Inpatient Pharmacy shall consider the period and time of activities performed by Inpatient Pharmacy.

APPENDIX A2 : **SPACE REQUIREMENT FOR WARD SUPPLY PHARMACY AND SATELLITE PHARMACY**

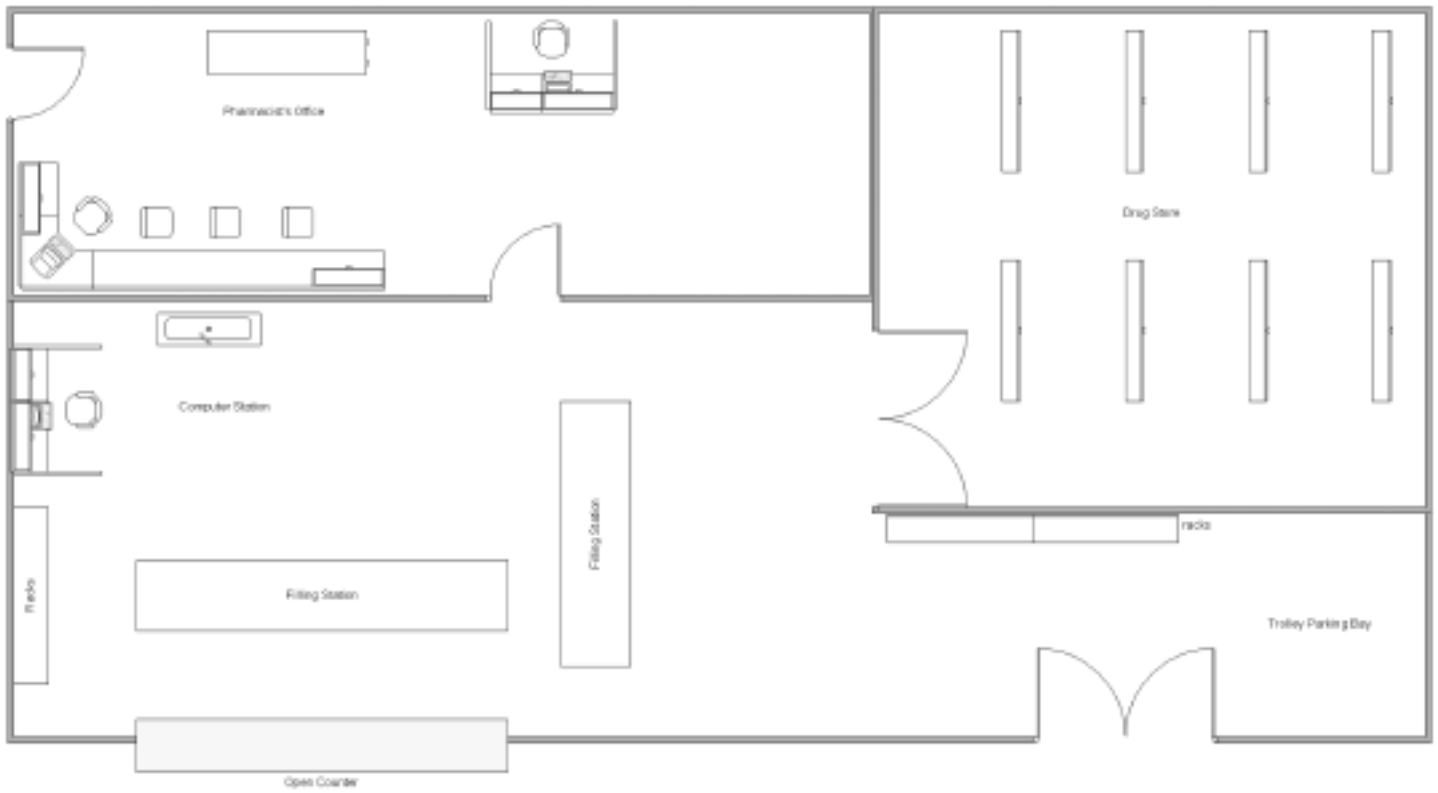
| Hospital Size (No. of Beds) | Inpatient Pharmacy Area (square meter) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Ward Supply/ Issuing Area | Extempora-neous Preparation Area | Storage Area | | Office Areas | | Drug and Poison Information Room | Areas for Personnel | | | Satellite Pharmacy |
| | | | Drugs | Bulks | Pharmacist Office | Office Space | | Prayer Room | Toilet | Rest Room & Pantry | |
| < 250 | 28 | 10 | 28 | 28 | 12 (1 U44) | 38 (3 U41 & 1 U32) | 14 | - | 2 x 8 | 38 | 80 x 2 |
| 250-500 | 38 | 10 | 48 | 48 | 12 (1 U44) | 65 (5 U41 & 1 U32) | 14 | - | 2 x 8 | 42 | 80 x 4 |
| 500-700 | 48 | 10 | 56 | 65 | 14 (1 U48) | 150 (2 U44, 7 U41, 1 U36 & 1 U32) | 14 | 2 x 14 | 4 x 8 | 48 | 80 x 6 |
| 700-1000 | 56 | 10 | 65 | 75 | 14 (1 U48) | 186 (2 U44, 11 U41, 1 U36 & 1 U32) | 18 | 2 x 14 | 4 x 8 | 65 | 80 x 8 |
| >1000 | 65 | 10 | 75 | 94 | 14(1 U48) | 200 (2 U44, > 11 U41, 1 U36 & 2U32) | 20 | 2 x 20 | 4 x 8 | 70 | 80 x 10 |

INPATIENT PHARMACY

## APPENDIX B2.1 : **EXAMPLE OF DESIGN AND LAYOUT PLAN FOR WARD SUPPLY PHARMACY**



APPENDIX B2.2 : **EXAMPLE OF DESIGN AND LAYOUTPLAN FOR SATELLITE PHARMACY**




**INPATIENT PHARMACY**

APPENDIX C2 : **EQUIPMENT REQUIREMENT FOR INPATIENT PHARMACY**

| NO. | ITEMS | WARD SUPPLY | SATELLITE |
|---|---|---|---|
| 1 | Bar Code Reader | 3 | 3 |
| 2 | Bar Code Labeler | 3 | 3 |
| 3 | Bins(Stackable, various sizes) | 3 | 3 |
| 4 | Book Shelf | 3 | 3 |
| 5 | Cabinet Filling | 3 | 3 |
| 6 | Cabinet Stainless Steel (Unit Dose) | 3 | 3 |
| 7 | Cabinet, Dangerous Drugs with audio / alarm system | 3 | |
| 8 | Calculator, scientific | 3 | 3 |
| 9 | Central Air-Condition, Split Unit | 3 | 3 |
| 10 | Chair (Office) | 3 | 3 |
| 11 | Chair (Adjustable for Dispensing) | 3 | 3 |
| 12 | Chair (Visitor) | 3 | 3 |
| 13 | Clock | 3 | 3 |
| 14 | Close Circuit TV | 3 | 3 |
| 15 | Computer, notebook | 3 | 3 |
| 16 | Computer | 3 | 3 |
| 17 | Counter, with internet access plug points | 3 | 3 |
| 18 | Compactors | 3 | |
| 19 | Dixon Angle | 3 | 3 |
| 20 | Distiller, water purifier | 3 | |
| 21 | Dining Set For 6 | 3 | 3 |
| 22 | Electric Kettle | 3 | 3 |
| 23 | Facsimile machine | 3 | |
| 24 | Fire extinguisher | 3 | 3 |
| 25 | Freezer capacity 125L | 3 | |
| 26 | Hand-held PDA | 3 | 3 |
| 27 | Labeler Machine | 3 | |
| 28 | Labeler (Hand) | 3 | 3 |
| 29 | Ladder Aluminum | 3 | 3 |
| 30 | Measuring cylinder | 3 | 3 |
| 31 | Machine, Photostat | 3 | 3 |
| 32 | Microwave | 3 | |
| 33 | Mill care Storage Cabinet | 3 | 3 |
| 34 | Mirror | 3 | 3 |
| 35 | Mortar & Pestle | 3 | 3 |

| NO. | ITEMS | WARD SUPPLY | SATELLITE |
|---|---|---|---|
| 36 | Notice board | 3 | 3 |
| 37 | Pneumatic tube | 3 | 3 |
| 38 | Printer, Inkjet | 3 | 3 |
| 39 | Printer LaserJet A4 | 3 | 3 |
| 40 | Printer LaserJet Color | 3 | |
| 41 | Projector Screen | 3 | |
| 42 | Projector/LCD, (preferably fixed to ceiling) | 3 | |
| 43 | Refrigerator, Pharmaceutical 2 / 3 door (Glass) with anti-frost, alarm | 3 | 3 |
| 44 | Refrigerator, Domestic 225 L | 3 | 3 |
| 45 | Scale electronic, weighing (0.5kg) | 3 | 3 |
| 46 | Scanner, computer | 3 | 3 |
| 47 | Sealer machine | 3 | 3 |
| 48 | Spatula | 3 | 3 |
| 49 | Staff locker | 3 | 3 |
| 50 | Steps, mobile | 3 | 3 |
| 51 | Sofa Set For Personnel Rest Room | 3 | |
| 52 | Shoe Rack | 3 | |
| 53 | Shredder (Heavy Duty) | 3 | |
| 54 | Table, Dining For 6 | 3 | |
| 55 | Table for Meeting Room | 3 | |
| 56 | Table/Office Chair | 3 | 3 |
| 57 | Toaster | 3 | |
| 58 | Trolley, 2-tier stainless steel | 3 | 3 |
| 59 | Trolley, Instruments with guard rail (Unit Dose) | 3 | 3 |
| 60 | Trolley, Issue satellite pharmacy | 3 | 3 |
| 61 | Trolley, Medication (Unit Dose) | 3 | 3 |
| 62 | Trolley, Medication (Emergency) | 3 | |
| 63 | Trolley (Hand) | 3 | 3 |
| 64 | Trolley, Multipurpose platform (heavy duty) | 3 | |
| 65 | Truck, Pallet (heavy duty ), Store | 3 | |
| 66 | Television And DVD Player For Meeting / Discussion / Seminar room | 3 | |
| 67 | Vacuum Cleaner | 3 | |
| 68 | Water Dispenser | 3 | 3 |
| 69 | White Board (Magnetic) | 3 | 3 |

APPENDIX D2 : **MANPOWER REQUIREMENT FOR INPATIENT PHARMACY**

| Human Resource | Number of Staff | | | | |
|---|---|---|---|---|---|
| | Hospital (< 250 beds) | Hospital (250-500 beds) | Hospital (501-700 beds) | Hospital (701-1,000 beds) | Hospital (>1,000 beds) |
| Pharmacist JUSA C | - | - | - | - | 1 |
| Pharmacist U54 | - | - | 2 | 4 | 4 |
| Pharmacist U52 | - | 1 | 4 | 4 | 4 |
| Pharmacist U48 | 1 | 2 | 4 | 4 | 4 |
| Pharmacist U44 | 4 | 4 | 8 | 10 | 14 |
| Pharmacist U41 | 4 | 8 | 12 | 14 | 18 |
| Pharmacist Assistant U38 | - | - | 1 | 2 | 3 |
| Pharmacist Assistant U36 | 1 | 2 | 3 | 4 | 5 |
| Pharmacist Assistant U32 | 2 | 4 | 4 | 4 | 4 |
| Pharmacist Assistant U29 | 2 | 4 | 4 | 5 | 6 |
| Pekerja Rendah Awam R4 | 1 | 2 | 4 | 6 | 8 |
| Pekerja Rendah Awam R1 | 3 | 5 | 8 | 10 | 12 |

Norms: 1 pharmacist to every 4 wards (28 bedded / ward) for medication supply

# 3 PRODUCTION PHARMACY



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**LIST OF APPENDIX**

# 3. PRODUCTION PHARMACY

## 3.1 INTRODUCTION

Preparation of pharmaceutical products in hospitals involves the activities such as preparation of sterile and non-sterile products in relatively small quantity and normally for in-house use only. The activities are carried out in a Production Pharmacy Unit under the management of the Hospital Pharmacy Department.

## 3.2 OBJECTIVE AND SCOPE

The objective of the production pharmacy service is to produce pharmaceutical products that are safe, efficacious and of quality. The production facilities only produce pharmaceutical products that are either not readily available commercially, not cost-effective to be purchased or not practical to be transported from outside the hospital.

## 3.3 POLICIES

### 3.3.1 General Operational Policies

a) Preparation activities shall be kept minimal strictly for pharmaceutical products mentioned in the objective and scope of this document. Wherever possible, ready made pharmaceutical products shall be purchased.

b) CDR facility shall be made available in each state hospital and hospitals with relevant disciplines.

c) Parenteral Nutrition preparation facility shall be made available in hospitals with ICU, NICU and surgical units.

d) IV Admixture preparation service shall be made available in all hospitals.

e) Preparation of pharmaceutical products shall be carried out in accordance to the appropriate Good Preparation Practice (GPP) requirements.

f) GPP requirements for products prepared in hospitals shall be in accordance to Pharmaceutical Inspection Cooperation Scheme (PIC/S) Guide to Good Practices for Preparation of Medicinal Products in Healthcare Establishments.

g) Products and materials shall be stored in accordance to Malaysian Good Storage Practice Guidelines (GSP).

h) Pharmacist shall be in charge of the Production Pharmacy Unit.

i) All pharmacy personnel shall be trained continuously and appropriately according to their job functions. There shall be sufficient personnel for efficient and effective operations of the preparation facilities.

j) Personnel working in controlled areas and clean rooms shall be selected with care, to ensure that they can be relied on to observe the appropriate codes of practice and not having any diseases or conditions that could compromise the integrity of the product. Personnel working in clean-room areas shall be qualified according to approved personnel qualification procedures.

k) Quality control tests of products prepared for multiple doses shall be done in the attached Quality Control Room, minimum of 100 sq ft. The products shall be released only by the pharmacist in-charge of the facility or any authorized person.

l) All preparation activities shall be done according to approved procedures and recorded in the appropriate batch preparation record. Upon completion of the preparation process, all finished products shall be labeled and checked accordingly prior to release. Preparation and quality control records shall be maintained for a period of two years from the date of preparation.

m) Quality control on all products shall be carried out in-house and/or outsourced.

n) Preparation areas including clean rooms shall be maintained regularly according to approved, planned preventive maintenance procedures

o) Dispensing bottles for internal and external galenical products shall be procured clean and ready to be used.

p) Preparation facility shall be inspected for pre-qualification by the Pharmacy Practice and Development Division, Ministry of Health prior to start operation. If the facility is found to be satisfactory, an approval letter for use shall be issued by the Pharmacy Practice and Development Division.

q) All preparation facilities shall be inspected routinely by the Pharmacy Practice and Development Division, at least every 2 years.

### 3.3.2 General Development & Maintenance Policies

Pharmacy Practice and Development Division has outlined policies for the development of preparation facilities for pharmaceutical preparations as follows:

a) All pharmaceutical preparations produced in hospitals shall be carried out in specifically designed and built facilities suitable for their intended use.

b) The Production Pharmacy Unit shall be located in In-Patient Pharmacy of the Hospital Pharmacy Department.

c.) Clean rooms shall be located within an air-conditioned area, to minimize condensation problem.

d) All Production Pharmacy Unit shall have dedicated rooms/areas for:
- personnel change
- material weighing
- product preparation
- product labeling
- quality control activities

- housekeeping
- water treatment system
- waste disposal
- storage and distribution
- documentation
- management and administration
- other ancillaries

e) If space permits, a one-way flow of production processes shall be adhered to.

f) Preparation of labels, dispensing of envelopes and labeling of containers shall be carried out in the same labeling room within the non-sterile preparation area.

g) The minimum recommended room size shall be double the space required for equipment, furniture and other facilities placed therein for performing the operations.

h) Quality control activities for sterile and non-sterile products shall be carried out within the same quality control room.

i) Appropriate numbers of electrical plug points shall be made available for each room whenever required.

j) Dedicated storage area/store for cytotoxic drugs shall be made available.

## 3.4 STERILE PREPARATION FACILITIES

Preparation of sterile pharmaceutical products in hospitals involves the activities such as preparation of eye drops, intravenous admixtures, parenteral nutritions and cytotoxic drug reconstitutions. For the purpose of these guidelines, the sterile preparation facilities are classified into Cytotoxic Drug Reconstitution (CDR) and Non-Cytotoxic Drug Reconstitution (Non-CDR).

### 3.4.1 **Policies**

a) All sterile pharmaceutical preparations shall be produced in a qualified clean room facilities designed and built in accordance to Good Preparation Practice (GPP) requirements.

b) Clean rooms shall be designed and built by experienced clean room contractors. The proposed layout plan, grades and control parameters shall be submitted to the Pharmacy Practice and Development Division, Ministry of Health for approval prior to the development of the facilities.

c.) The calibration of equipment including the monitoring devices used in clean rooms shall be conducted by an accredited agent.

d) Upon commissioning, clean rooms and their major equipment (laminar airflow cabinet and cytotoxic drug safety cabinet/isolator) shall be tested by an independent third party agent for confirmation of compliance to

standards. The testing agent shall be certified by appropriate certification bodies such as National Associations of Testing Authorities (NATA - Australia) or National Environmental and Balancing Bureau (NEBB - USA).

e) Prior to use, clean room facilities have to be inspected and qualified by the Pharmacy Practice and Development Division, Ministry of Health Malaysia. Approval letter for use will be issued by the Pharmacy Practice and Development Division.

f) Clean rooms, unidirectional airflow cabinet and cytotoxic drug safety cabinet/isolators shall be maintained regularly according to approved planned preventive maintenance procedures. The maintenance shall include thorough cleaning and testing by the certified testing contractor. Microbial monitoring shall be done regularly depending on the usage of the facilities and outcome of the test results.

g) Qualified clean room facilities shall be inspected routinely by the Pharmacy Practice and Development Division, Ministry of Health Malaysia at least every 2 years.

### 3.4.2 **Design, Layout and Specification**

a) This area is for sterile preparation activities that may consist of either Cytotoxic Drug Reconstitution (CDR) Facility, Non-CDR Facility or both.

b) Premises and utilities for CDR Facility shall be separated from Non-CDR Facility (for eye drops, IV admixtures and parenteral nutritions).

c) The building design shall take into account the flow of the materials, products and personnel. The layout of the facility shall be in such a way as to avoid cross-contamination and mix-ups. One way flow of materials, personnel and finished products is ideal.

d) A recommended total built-up area of 1,200 sq feet shall be made available for a complete CDR or Non-CDR facility.

e) Air handling systems for sterile preparation facilities shall be dedicated and shall be fitted with alarms so that the working personnel are warned of any failure of the systems. The systems shall be able to maintain 24 hours pressure differentials without cooling whenever the facilities are not in use.

f) Humidity, temperature, pressurization and air filtration or air cleanliness shall be controlled in order to protect the products, personnel and the environment. Appropriate devices for measuring and monitoring the parameters shall be installed or made available (e.g. pressure gauges, thermo-hygrometers, particle counter). Ideally, the monitoring and alarm systems for clean rooms shall be made online.

g) Labeling Room shall be designed and laid out so as to avoid mix-ups.

h) Adequate lighting shall be provided in all clean rooms. Normally, a range of 500 - 600 lux ensures personnel comfort and ability to perform work efficiently

and effectively. Lights fixtures shall be flush-mounted in the ceiling and sealed to prevent air leaks. It is preferable that they can be maintained and serviced from above. Electrical outlets shall be flushed-mounted, watertight, have no crevices and shall be cleanable.

i) The choice of construction materials is one of the most important considerations in the facility design. When choosing the materials for floors, ceilings and walls, the following specifications for the premises shall be considered:

   i) Ceilings, walls, floors, fixtures, shelves, counters and cabinets shall be resistant to sanitizing agents and crevices free to avoid dirt accumulation.

   ii) Construction materials shall resist chipping, shedding, flaking, oxidizing, or other deterioration.

   iii) Junctions of walls, floor and ceiling shall be curved (coved) to facilitate cleaning.

   iv) There shall not be horizontal fixed pipes or conduits over exposed components, in-process materials, drug products, and drug product contact surfaces.

   v) All service fittings shall be flushed with surrounding surfaces.

   vi) The size of all doors shall be sufficient for the equipment to be brought into.

   vii) Airtight ceilings and walls, close fitting doors and sealed light fittings shall be in place as these all have an impact on the HVAC system (heating, ventilation and air-conditioning).

j) CCTV system shall be installed.

### 3.4.3 **Cytotoxic Drug Reconstitution**

a) **Facility Requirements**

   i) A totally separate clean room area (premises and utilities) shall be provided for Cytotoxic Drug Reconstitution (CDR) activities that require containment for the protection of the environment. Entrance and exit of the CDR room shall be via a containment airlock or a sink airlock (or negative sink).

   ii) A CDR facility shall have personnel changing rooms (for change and gowning), a component room, a CDR room and a labeling room.

   iii) Design of the facility shall consider and fulfill the requirement of containment. This can be achieved by having a negative airlock adjacent to the CDR room. Depending on the layout design, this airlock can also be suitably located to contain the whole facility.

iv) Although one-way flow of processes is recommended, the requirement for containment shall not be compromised.

v) Air handling unit (AHU) and its room shall be dedicated. The air handling system for CDR room shall not be re-circulated and shall be fitted with an emergency push button for use during spillage.

vi) Flooring shall be a continuous, non-cracking material that is mechanically and chemically robust. Preferably, floors shall be overlaid with wide sheet vinyl flooring with heat-welded seams and coving to the sidewall. Alternatively, self leveling epoxy resin flooring could be used.

vii) Walls and ceilings shall be free from cracks, built with a smooth, non-shedding, cleanable finish that is impervious to water, cleaning and sanitizing solution. Wall paneling (e.g. Polyurethane panel) shall be used for CDR rooms.

viii) Bare wood, ledges and other unsealed surfaces shall be avoided in clean rooms. Glass window is required for CDR room and it shall be of flushed double glazed type.

ix) There shall be two parts of personnel change room. The second or final part of the personnel change room leading into the CDR room shall be of the same grade of the latter.

x) A sink for hand wash can be fitted in the first or earlier part of the change room. The CDR room shall not contain any sink or floor drains.

xi) Taps shall be elbow, foot or beam-operated. Surfaces materials, including bench tops, shall have a minimum of joints and seams and be non-shedding and easy to clean.

xii) All doors for clean rooms shall be fitted with inter-locking systems so that only one door can be opened at a time to ensure the pressure cascade is not compromised. All airlock doors shall be provided with self-closers.

xiii) Doors and windows shall have a hard, smooth, impervious finish and close tightly and also fit flush with surrounding walls.

xiv) A cytotoxic drug safety cabinet or isolator (CDR cabinet/isolator) shall be used to ensure maximum personnel protection. The cabinet and isolator used shall be of Grade A standard for the protection of product.

xv) A CDR Isolator shall be used by hospitals with less than 10 CDR preparations per day.

xvi) Appropriate measuring devices shall be installed for CDR cabinet or isolator such as :
- Pressure gauges for monitoring the pressure across the HEPA filters
- Down flow sensor for velocity
- A limit window sash sensor shall be available to ensure negativity within CDR cabinet

xvii) The CDR room shall be of Grade B if a cytotoxic drug safety cabinet is used. If an isolator (negative isolator) is used, the room shall be of at least Grade D.

xviii) Since the CDR room shall not have a workbench, equipment installed (either cabinet or isolator) shall come with its own stands. There shall be sufficient space underneath the cabinet for allowing cleaning process.

xix) A component room shall be of Grade C or D and shall be entered by personnel via a personnel change room of a similar grade.

xx) Stainless steel sink with an appropriate depth to avoid splashing, stainless steel shelves, and work bench shall be fitted in the component room.

xxi) A buffer/staging room or a hatch shall be used for transferring in materials (e.g. components, cleaning materials and equipment). If a one way flow facility is not possible, the buffer/staging room or hatch can be used for transferring materials and products out as well.

xxii) Adequate numbers of plug points shall be made available.

xxiii) Plug points connected to essential power supply shall be made available for pharmaceutical refrigerators. In case of power failure, Uninterrupted Power Supply (UPS) shall be provided for Cytotoxic Drugs Reconstitution (CDR) cabinet/ isolator and HVAC system.

xxiv) For existing facilities, a certified contractor shall be appointed to test the performance of the facilities on a regular basis.

xxv) Heating, Ventilation and Air-conditioning (HVAC) System

- Due consideration shall be given to the placement of ceiling mounted HEPA filters to avoid creating of air currents inside the cabinet underneath. Diffusers shall not be used.

- Pre-filters (primary and secondary) of AHU and HEPA filters shall be changeable from outside the clean room.

- Temperature not more than 22°C and humidity (55 ± 5%) need to be controlled primarily for the stability of products and the comfort of personnel.

- Equipment installed shall not jeopardise the set room conditions including temperature, humidity, air pressure, noise level, etc.

- The air pressure shall be made higher in the cleaner grade of clean rooms. The air return grilles shall be at a low-level to sweep or purge the rooms.

- Air extracted from areas where cytotoxic drugs are reconstituted shall not be re-circulated; air outlets shall be designed to avoid possible environmental contamination from particles and vapors.

xxvi) Environmental control is a critical factor in determining the successful operation of the manufacturing facility especially a clean room. Therefore, the design and construction which relates to a clean room shall include consideration of the following:

- Building finishes and structure
- Air filtration
- Air change rate or flushing rate
- Location of air terminals and directional airflow
- Room pressure
- Particulate loading (viable and non-viable)
- Temperature (not more than 22°C
- Relative humidity (55 ± 5%)
- Pressure differentials (10 - 15 Pascal's)
- Material flow
- Personnel flow

b) **List of Equipments Required**

Refer to ***Appendix 3.9.7***

### 3.4.4 TPN / IV Admixture / Eye Drop (Non-CDR)

a) **Facility Requirements**

i) Appropriate clean room facilities shall be provided for Non-Cytotoxic Drugs Reconstitution (Non-CDR) activities such as the preparation of parenteral nutrition solutions, intravenous admixtures and eye drops.

ii) The facility shall have personnel changing rooms (for change and gowning), a component room, a preparation room and a labeling room.

iii) Flooring shall be a continuous, non-cracking material that is mechanically and chemically robust. Preferably, floors shall be overlaid with wide sheet vinyl flooring with heat-welded seams and coving to the sidewall. Alternatively, self leveling epoxy resin flooring could be used.

iv) Walls and ceilings shall be free from cracks, built with a smooth, non-shedding, cleanable finish that is impervious to water, cleaning and sanitizing solution. Wall paneling (e.g. Polyurethane panel) shall be used for the preparation rooms.

v) Bare wood, ledges and other unsealed surfaces shall be avoided in clean rooms. Glass window is required for the preparation room and it shall be of flushed double glazed type.

vi) There shall be two parts of personnel change room. The second or final part of the personnel change room leading into the preparation room shall be of the same grade as the latter.

vii) A sink for hand wash can be fitted in the first or earlier part of the change room. The preparation room shall not contain any sink or floor drains.

viii) Taps shall be elbow, foot or beam-operated. Surfaces materials, including bench tops, shall have minimum joints and seams and be non-shedding and easy to clean.

ix) All doors for clean rooms shall be fitted with inter-locking system so that only one door can be opened at a time to ensure the pressure cascade is not compromised. All airlock doors shall be provided with self-closers.

x) Doors and windows shall have a hard, smooth, impervious finish and close tightly and also fit flush with surrounding walls.

xi) A positive pressure unidirectional airflow cabinet or isolator shall be used for Parenteral Nutrition and Eye Drop. For IV Admixture preparations, a negative pressure unidirectional cabinet or isolator is needed. There shall be sufficient space underneath the cabinet for allowing cleaning process

xii) The preparation room shall be of Grade B if a unidirectional airflow cabinet is used. If an isolator (positive isolator) is used, the room shall be of at least Grade D.

xiii) Since the preparation room shall not have a work bench, equipment installed (either cabinet or isolator) shall come with its own stands.

xiv) A component room shall be of Grade C or D and shall be entered by personnel via a personnel change room of a similar grade.

xv) A utility cabinet, stainless steel sink with an appropriate depth to avoid splashing and work bench shall be fitted in the component room.

xvi) A buffer/staging room or a hatch shall be used for transferring in materials (e.g. components, cleaning materials and equipment). If a one way flow of facility is not possible, the buffer/staging room or hatch can be used for transferring materials and products out as well.

xvii) Adequate numbers of plug points shall be made available.

xviii) Plug points connected to essential power supply shall be made available for pharmaceutical refrigerators. In case of power failure, Uninterrupted Power Supply (UPS) shall be provided for the unidirectional airflow cabinet/ isolator and HVAC system.

xix) For existing facilities, a certified agent shall be appointed to test the performance of the facilities on a regular basis.

xx) Heating, Ventilation and Air-conditioning (HVAC) System

- Due consideration shall be given to the placement of ceiling mounted HEPA filters to avoid creating of air currents inside the cabinet underneath. Diffusers shall not be used.

- Pre-filters (primary and secondary) of AHU and HEPA filters shall be changeable from outside the clean room.

- Temperature (not more than 22°C and humidity (55 ± 5%) need to be controlled primarily for the stability of products and the comfort of personnel.

- Equipment installed shall not jeopardise the set room conditions including temperature, humidity, air pressure, noise level, etc.

- The air pressure shall be made higher in the cleaner grade of clean rooms. The air return grilles shall be at the low-level to sweep or purge the rooms.

xxi) Environmental control is a critical factor in determining the successful operation of the manufacturing facility especially a clean room. Therefore, the design and construction, which related to a clean room shall include consideration for:

- Building finishes and structure
- Air filtration
- Air change rate or flushing rate
- Location of air terminals and directional airflow
- Room pressure
- Particulate loading (viable and non-viable)
- Temperature (not more than 22°C
- Relative humidity (55 ± 5%)
- Pressure differentials (10 - 15 Pascals)
- Material flow
- Personnel flow

b) **List of Equipment Required**

Refer to ***Appendix 3.9.7***

## 3.5 NON-STERILE PREPARATION FACILITIES

Preparation of non-sterile pharmaceutical products in hospitals involves the activities such as preparation of galenicals and repacking of supplied medicines.

### 3.5.1 Policies

a) Computer automation system shall be made available for accuracy of formulating, compounding and labelling.

b) Preparation of galenicals shall only be carried out if commercial products are not available.

c) Compounding of extemporaneous preparations which are prepared to be dispensed immediately to the patients, shall be done in specified preparation areas in the dispensing facilities.

d) Mixing, filling and labeling of a galenical preparation shall not be done simultaneously with another preparation within the same preparation area.

e) Purified water shall be used for the preparation of galenical preparations to minimize microbial contamination.

f) Medicines supplied or prepared in bulk shall be repacked centrally into ready-to-dispense units to facilitate dispensing for outpatient and inpatient (Unit Dose packs). Therefore, dedicated rooms shall be made available within the non-sterile preparation area for repacking and filling activities.

g) Pharmacy personnel shall be responsible for planning of repacking activities depending on the level of stock and usage from various units within the pharmacy department.

h) The labels of packed medicines shall contain product name (generic and trade), strength, weight/quantity, expiry date, date of packing, product batch number and manufacturer's name.

i) The repacked medicines shall be checked and verified prior to storage.

j) Storage of the repacked medicines shall be done according to specifications by the manufacturer. Sufficient storage area shall be provided and the medicines shall be arranged accordingly for easy access and traceability.

k) Utility room shall be provided for storing of housekeeping equipment and shall be well ventilated to facilitate drying processes of mops and towels.

l) A disposal room shall be situated in such a way that it can be accessible from both sides. This is to avoid the preparation personnel from going out to throw the garbage and to prevent garbage collector from entering the preparation area.

m) Equipments in direct contact with materials used for production of internal and external preparations shall not be shared. (e.g. tanks, stirrer, mortar and pestle, jugs)

### 3.5.2 **Design, Layout and Specification**

a) The building design shall take into account the flow of the materials, products and personnel. Personnel, equipment and work-in-process shall not be moved through areas in which other operations are running.

b) Adequate lighting shall be provided in all preparation areas. Normally, a range of 500 - 600 lux ensures personnel comfort and ability to perform work efficiently and effectively. Lights fixtures shall be flush-mounted in the ceiling and sealed to prevent air leaks. Electrical outlets shall be flushed-mounted, watertight, have no crevices and shall be cleanable.

c) The choice of construction materials is one of the most important considerations in the facility design. When choosing the materials for floors, ceilings and walls, the following specifications for the premises shall be considered:

   i) Ceilings, walls, floors, fixtures, shelves, counters and cabinets shall be resistant to sanitizing agents and crevices free to avoid dirt accumulation.

ii) Construction materials shall resist chipping, shedding, flaking, oxidizing, or other deterioration.

iii) Junctions of walls, floor and ceiling shall be curved (coved) to facilitate cleaning.

iv) There shall not be horizontal fixed pipes or conduits over exposed components, in-process materials, drug products, and drug product contact surfaces.

v) All service fittings shall be flushed with surrounding surfaces.

vi) The size of all doors shall be sufficient for the equipment to be brought into.

vii) Asbestos shall not be used for constructing the ceilings.

d) Dedicated HVAC system shall be provided for the whole area of non-sterile preparation facilities.

### 3.5.3 Galenical Preparations

a) **Facility Requirement**

i) Personnel entering into Galenical Preparation Area shall be through a personnel change room.

ii) Rooms for external and internal galenical preparations shall be separated and well ventilated. Equipments used for these preparations also shall be dedicated.

iii) Since the mixing and packing of galenical preparations are done in the same room (i.e. galenical preparation room), the activities shall be carried out product by product to avoid the risk of cross contamination and mix-up.

iv) Washing room shall be used for washing and drying of bottles and preparation equipment. This room shall be situated close to the internal and external preparation rooms to minimize movements of heavy loads.

v) The preparation and washing rooms shall have:

- A built-in concrete working bench with smooth and acid resistant work surface.

- A deep stainless steel sink with 5 µm filter apparatus for water outlets.

vi) The facilities shall also be used to carry out repacking of liquid / semi solid (external and internal) medicinal products which are supplied in bulk, according to the needs.

vii) A holding area for galenical preparations / bulk products to be packed / repacked shall be provided within the room.

viii) Water treatment plant for supplying treated/purified water (preferably reverse osmosis) shall be located close to the Galenical Preparation Area. Depending on the type of treated/purified water system installed, the accessibility to the plant shall be from outside.

ix) Weighing room shall be equipped with weighing balances suitable for weighing of large and small quantity of raw materials. These balances shall be calibrated at least once a year by an accredited agent.

x) Since drains can be a potential source of microbial hazard, an air break shall be included between drain and sewer to eliminate the possibility of back-flow. A trap-gully shall be installed to prevent pest intrusion.

b) **List of Equipment Required**

Refer to Appendix 3.9.8

3.5.4 **Repacking Area (Dry)**

a) **Facility Requirements**

i) Personnel entering into repacking area shall be through a personnel change room

ii) In order to avoid mix-up, repacking of different products shall not be done in the same room simultaneously

iii) Preparation of labels, dispensing envelopes and labeling of containers shall be done in the Labeling Room

iv) A holding area for products to be repacked shall be provided within the room.

b) **List of Equipment Required**

Refer to Appendix 3.9.8

## 3.6 MANAGEMENT AND QUALITY CONTROL AREA

This area consists of an administration office for preparation planning, documentation and quality control activities. Thus, appropriate facilities for an office shall be provided. An open office space for personnel with computer terminals shall be made available according to norms and working space for sufficient number of personnel. Within this office area there shall be rooms for:

3.6.1 **Pharmacist In-Charge's Room**

Room shall be provided for Pharmacist in-charge of the Production Pharmacy Unit, Pharmacist in-charge of non-sterile preparation facilities, Pharmacist in-charge of CDR facilities and Pharmacist in-charge of TPN facilities. Their rooms shall be strategically located to allow supervision and administrative works. Each room shall be equipped with:

a) Computer and printer including 'Uninterrupted Power Supply'
b) Table and chairs
c) Telephone
d) Filing cabinets
e) Pneumatic tube terminal (optional, except for Pharmacist in-charged of CDR facilities)

3.6.2 **Meeting / Discussion**

This room shall be equipped with chairs, tables, white board and LCD projectors.

3.6.3 **Documentation and Storage of Records**

Adequate space is required to hold 2 years documents such as batch records, preparation procedures and distribution records. This room shall be equipped with metal filing cabinets, telephone, fax, tables, chairs and computer.

3.6.4 **Quality Control**

a) Basic quality control procedures shall be carried out on finished products in the attached Quality Control Room. This room can be used for sterile and non-sterile products quality control activities. The room shall have:

   i) A built-in concrete working bench with smooth and acid resistant work surface.

   ii) A deep stainless steel sink with 5 µm filter apparatus for water outlet.

b) Quality control tests that cannot be performed in-house shall be outsourced. (E.g. microbial test)

## 3.7 STORAGE AND DISTRIBUTION AREA

3.7.1 This section shall have sufficient reception area (receiving and dispatch bays). The area shall be designed to protect materials and products from the weather and equipped to allow containers of incoming materials to be cleaned where necessary before storage.

3.7.2 Sufficient storage area including shelves (or racking system) shall be provided for storage of products and materials including disposables.

3.7.3 Storage areas shall be designed to ensure good storage conditions e.g. clean, dry and maintained. If special storage conditions are required (e.g. temperature and humidity) these shall be provided, checked and monitored regularly using appropriate devices.

3.7.4 Stores shall be equipped with:

a) Pharmaceutical refrigerator
b) Storage shelves
c) Table/chairs

d) Trolley (stainless steel)
e) Computer

## 3.8 ANCILLARY AREAS

a) Rest and refreshment rooms shall be separated from preparation and control areas. This room shall be equipped accordingly.

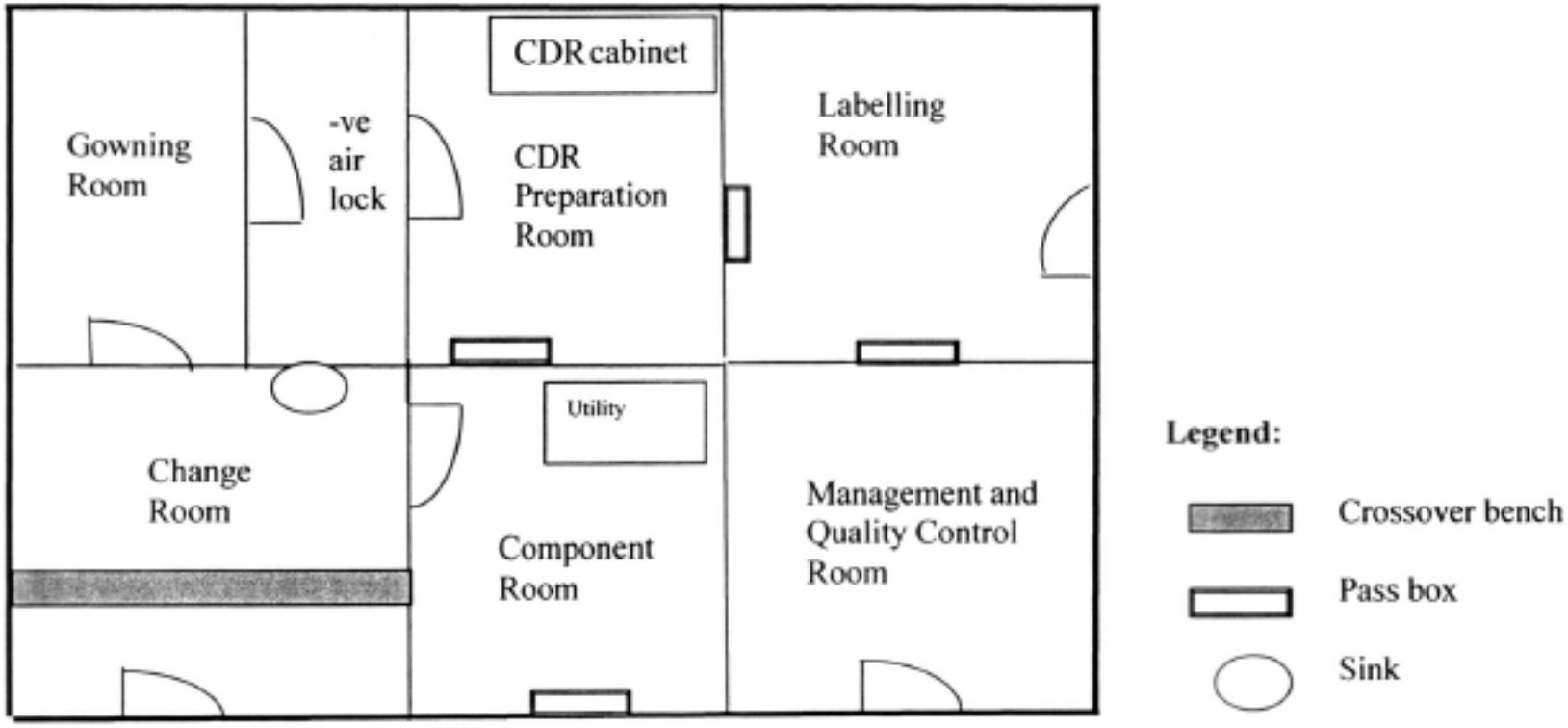
b) Facilities for changing and storing clothes and for washing and toilet purposes shall be easily accessible and appropriate for the number of users. Toilets shall not directly communicate with preparation or storage areas.

c) Adequate office space for staff shall be made available.

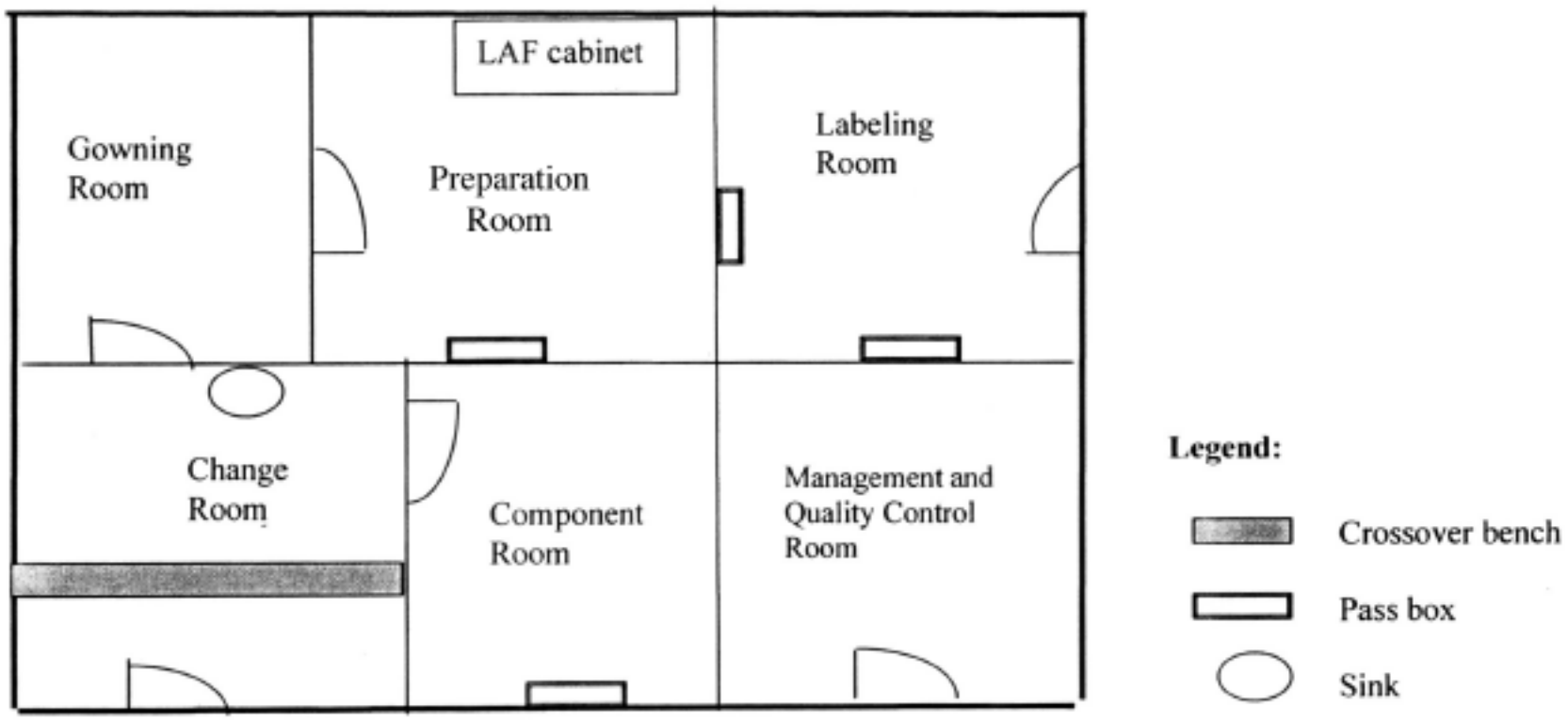
d) The qiblat direction of Muslim Male and Female prayer rooms with ablution facilities shall not be facing any nearby toilet.

e) Utility room shall be equipped for storing of housekeeping equipment and shall be well ventilated to facilitate drying processes of mops and towels.

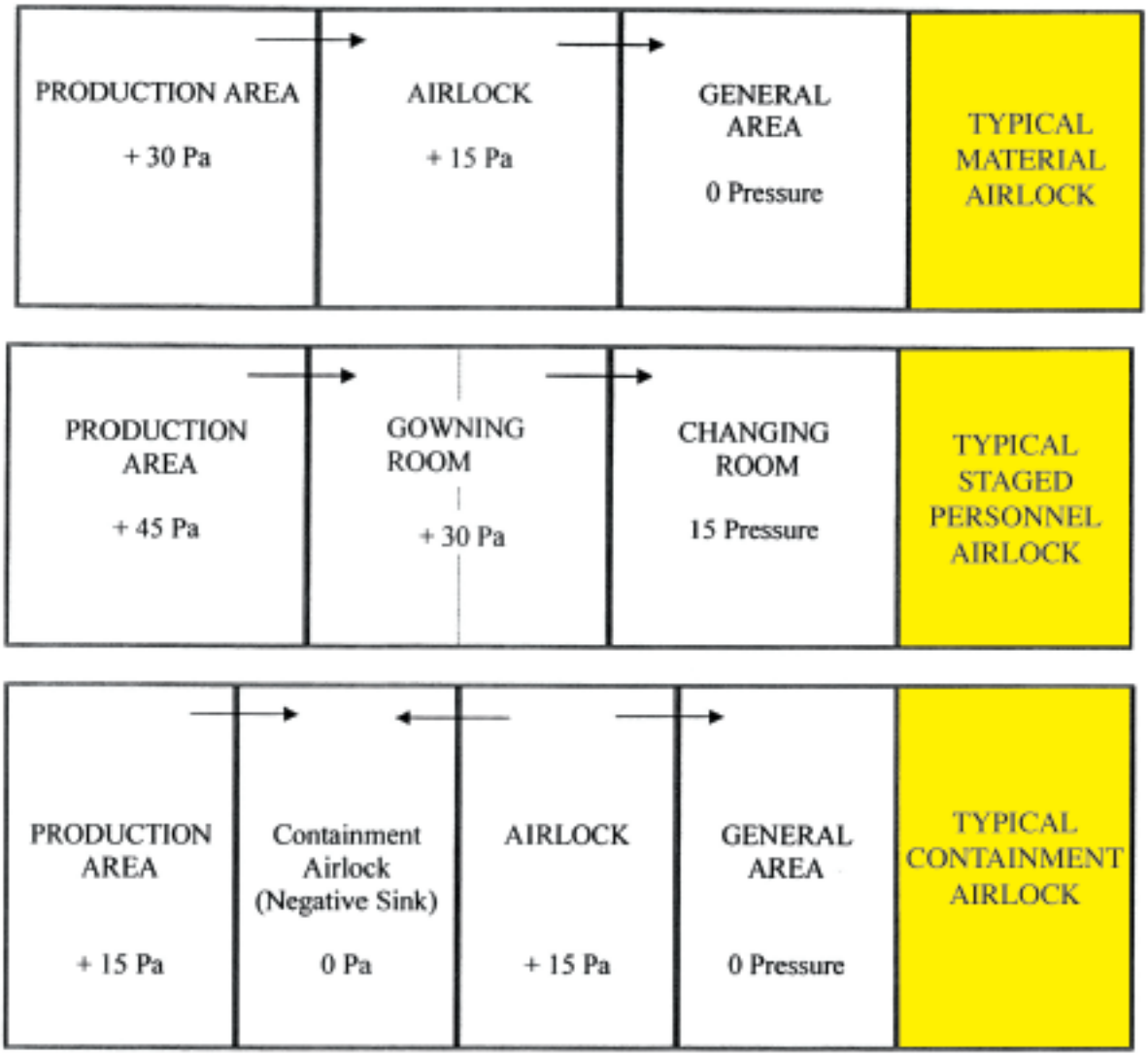
APPENDIX 3.9.1 : **EXAMPLE OF LAYOUT PLAN FOR CYTOTOXIC DRUG RECONSTITUTION (CDR) PREPARATION FACILITIES**



APPENDIX 3.9.2: **EXAMPLE OF LAYOUT PLAN FOR TPN / IV ADMIXTURE / EYE DROP (NON-CDR) PREPARATION FACILITIES**



APPENDIX 3.9.3 : **AIR LOCKS FOR PERSONEL AND MATERIALS IN CLEAN ROOMS**




**Legend:**

Air Flow

APPENDIX 3.9.4 : **EXAMPLES OF TYPES OF CONSTRUCTION MATERIAL**

| INTERIOR SURFACE | TYPES OF MATERIALS | COMMENTS | SUITABLE FOR |
|---|---|---|---|
| **FLOOR** | a) Solid concrete | - dust accumulating<br>- non resistant to chemical spills | Store areas only |
| | b) Solid concrete with the following alternative finishes: | | |
| | - Vinyl tiles | - limited chemical resistance<br>- requires welded joints in order to damp proof, abrasive<br>- for moderately light usage | Non-production areas - offices, corridors and laboratories |
| | - Epoxy, polyurethane or heavy duty vinyl sheets | - monolithic, non-porous topping with non-skid surface<br>- retards bacterial growth, abrasive | Production areas, including clean rooms |
| | - Cement tiles | - economical and easy to repair<br>- requires grouting<br>- joints are difficult to clean<br>- non-resistant to chemical spills<br>- abrasive | Offices and pantry |
| **WALL** | a) Bricks or block, structural wall of high density, smoothly plastered, made water-proof by painting with acrylic or high polymer enamel polyurethane or epoxy | - Easily crack of improperly processed<br>- generate dust during demolishing for repair or renovation | Non-sterile production area |
| | b) Polyurethane panels or other suitable equivalent material | - non shedding<br>- generally maintenance free<br>- moderately durable<br>- difficult to repair in case of damage by impact<br>- crevices at joints need to be sealed e.g. with flexible silicone rubber material | Clean rooms |

| INTERIOR SURFACE | TYPES OF MATERIALS | COMMENTS | SUITABLE FOR |
|---|---|---|---|
| **CEILING** | a) Solid concrete painted with acrylic or high polymer enamel or Polyurethane panel | - designed for heavy loads<br>- space above ceiling can be used for ducts and servicing activities | Clean rooms, processing and filling areas |
| | b) Suspended | - requires supporting steel work<br>- not suitable for heavy loadings<br>- shall be sealed to prevent contamination from the space above them e.g. with silicone rubber<br>- not suitable for sterile processing rooms which a monolithic surface is required. | Non-sterile production area |

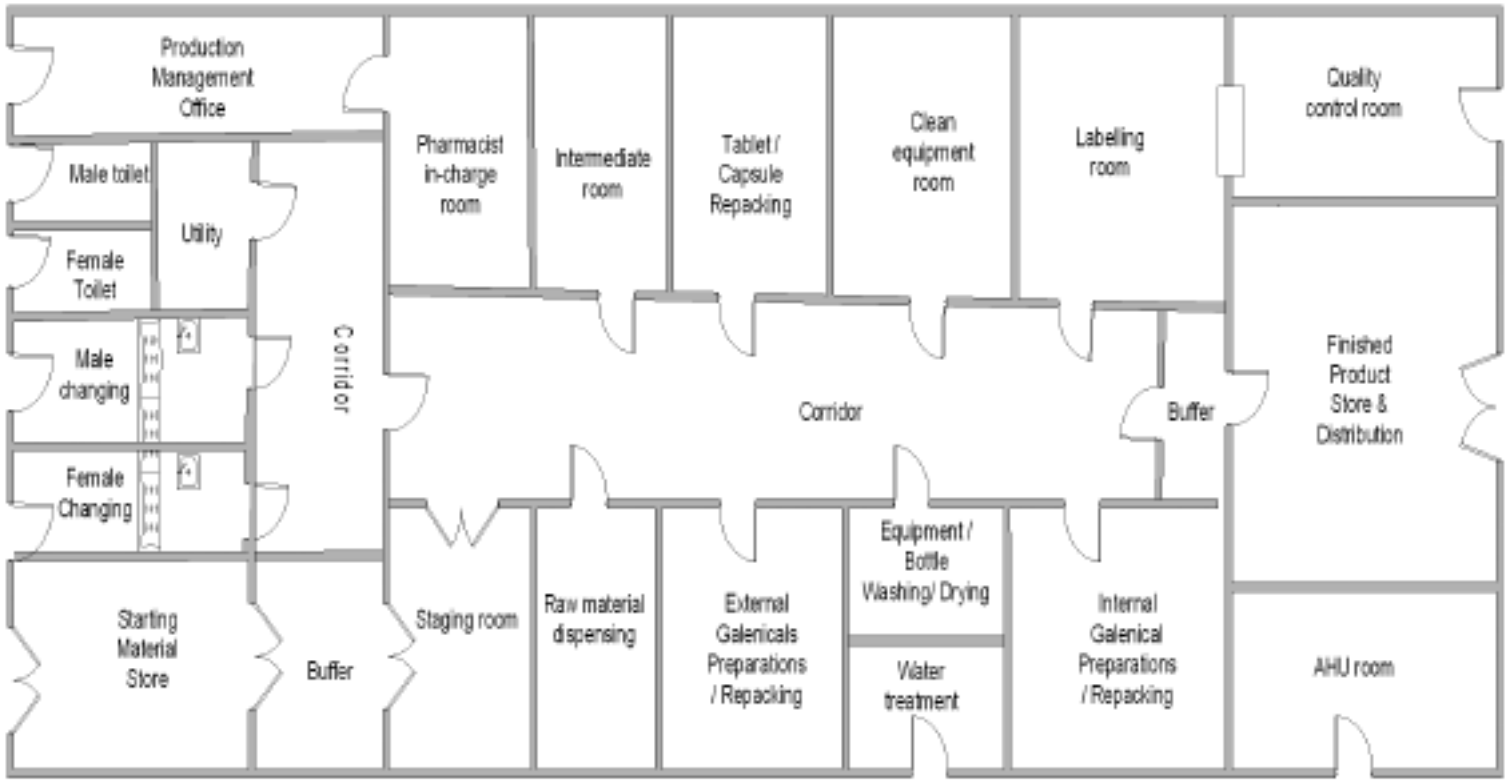
APPENDIX 3.9.5 : **CLEAN ROOM CLASSIFICATION**

| CLEAN ROOM GRADE & Type of filter | AIR CHANGE RATE (changes per hour) | Maximum Particle Count (> 0.5um) | | Activities/Purpose |
|---|---|---|---|---|
| | | State | Per meter$^3$ | |
| A (ISO 5) HEPA filter | >120 vertical air flow: 0.3 m/sec horizontal air flow: 0.45 m/sec | at rest | 3,520 | Laminar flow area for manufacturing of sterile products. Space where sterile product is exposed. |
| | | in operation | 3,520 | |
| B (ISO 6) HEPA filter | >40 | at rest | 3,520 | Clean room for sterile products. Background Environment for Grade A |
| | | in operation | 352,000 | |
| C (ISO 7) HEPA filter | >25 | at rest | 352,000 | Clean room for manufacturing of sterile products. (less critical steps) |
| | | in operation | 3,520,000 | |
| D (ISO 8) Secondary filter | >20 (WHO) | at rest | 3,520,000 | Clean room for manufacturing of sterile products - less critical steps. Also being used for non-sterile manufacturing |
| | | in operation | Not Defined | |

**Note:**

Air change rates are the key to cleaning a room effectively shall it get contaminated. Hence, the higher the air change rate, the better quality the room. High rates shall be selected where the air quality is continually challenged - e.g. by dusty environment.

APPENDIX 3.9.6 : **EXAMPLE OF LAYOUT PLAN FOR NON-STERILE PREPARATION FACILITIES**




LEGENDS:

Sink

Cross-over Bench

Pass-box

**PRODUCTION PHARMACY**

APPENDIX 3.9.7 : **LIST OF EQUIPMENTS FOR STERILE PREPARATION FACILITIES**

| EQUIPMENT | LOCATION | | |
|---|---|---|---|
| | CDR | NON-CDR | |
| | | TPN | IV ADMIXTURE |
| **PREPARATION ROOM** | | | |
| Cytotoxic Drug Reconstitution Cabinet (connected to essential power supply) | 3 | - | - |
| Unidirectional Airflow Cabinet (connected to essential power supply) | - | 3 | 3 |
| Stainless steel trolley | 3 | 3 | 3 |
| Stainless steel stools with wheels and adjustable height | 3 | 3 | 3 |
| Intercom System | 3 | 3 | 3 |
| Roller mixer | 3 | - | - |
| Power points √ | 3 | 3 | 3 |
| **COMPONENT ROOM** | | | |
| Stainless steel rack/shelves for keeping of sterile bags, syringes, needles, filters, etc. | 3 | 3 | 3 |
| Phenolic bench top with stainless steel drawers | 3 | 3 | 3 |
| Stainless steel trolley | 3 | 3 | 3 |
| Stainless steel sink | 3 | 3 | 3 |
| Utility cabinet | 3 | 3 | 3 |
| Intercom system | 3 | 3 | 3 |
| Power points | 3 | 3 | 3 |
| **PERSONNEL GOWNING ROOM** | | | |
| Garment cabinet | 3 | 3 | 3 |
| Wall mounted six foot long mirror | 3 | 3 | 3 |
| Cross over bench | 3 | 3 | 3 |
| Stainless steel sink (elbow / foot operated or automated) | 3 | 3 | 3 |
| Cabinet (to hang street clothes) | 3 | 3 | 3 |
| Electrical hand dryer | 3 | 3 | 3 |

| EQUIPMENT | LOCATION | | |
|---|---|---|---|
| | CDR | NON-CDR | |
| | | TPN | IV ADMIXTURE |
| **PERSONNEL GOWNING ROOM** | | | |
| Liquid soap dispenser / hand sanitizer (foot operated or automated) | 3 | 3 | 3 |
| Power points | 3 | 3 | 3 |
| Cross over bench | 3 | 3 | 3 |
| **LABELING ROOM** | | | |
| Pharmaceutical refrigerator (connected to essential power supply) | 3 | 3 | 3 |
| Stainless steel trolley | 3 | 3 | 3 |
| Online display for temperature, relative humidity, air pressure and particle for clean rooms | 3 | 3 | 3 |
| Computers and printers | 3 | 3 | 3 |
| Intercom system | 3 | 3 | 3 |
| Telephone | 3 | 3 | 3 |
| Filing cabinets | 3 | 3 | 3 |
| Power points | 3 | 3 | 3 |
| Pneumatic tube terminal | Optional | Optional | Optional |

APPENDIX 3.9.8 : **LIST OF EQUIPMENTS FOR NON-STERILE PREPARATION FACILITIES**

| EQUIPMENT | LOCATION | | |
|---|---|---|---|
| | INTERNAL | EXTERNAL | DRY REPACKING |
| **PREPARATION ROOM** | | | |
| Height adjustable laboratory stool | 3 | 3 | 3 |
| Trolley | 3 | 3 | 3 |
| Mortar & pestle | 3 | 3 | - |
| Stainless steel mixing tank with lid (minimum 20L) | 3 | 3 | - |
| Stainless steel graduated jugs | 3 | 3 | - |
| Stainless steel funnels | 3 | 3 | - |
| Workbench with shelves | 3 | 3 | - |
| Planetary stirring unit | 3 | 3 | - |
| Hotplate | 3 | 3 | - |
| Power points | 3 | 3 | 3 |
| Tablet counting machine | 3 | - | 3 |
| Unit Dose liquid packing machine | - | - | 3 |
| Unit Dose tablet/capsule packing machine | - | - | 3 |
| Sealer machine | - | - | 3 |
| **PERSONNEL CHANGING ROOM** | | | |
| Stainless steel sink (elbow / foot operated or automated) | 3 | 3 | 3 |
| Cabinet (to hang street clothes) | 3 | 3 | 3 |
| Electrical hand dryer | 3 | 3 | 3 |
| Liquid soap dispenser / hand sanitizer (foot operated or automated) | 3 | 3 | 3 |
| Power points | 3 | 3 | 3 |
| Cross over bench | 3 | 3 | 3 |

| EQUIPMENT | LOCATION | | |
|---|---|---|---|
| | INTERNAL | EXTERNAL | DRY REPACKING |
| **STAGING ROOM** | | | |
| Electronic balance | 3 | 3 | - |
| Plug points | 3 | 3 | - |
| Stainless steel table top √ | 3 | 3 | - |
| **LABELING ROOM / AREA** | | | |
| Stainless steel trolley | 3 | 3 | 3 |
| Computers and printers | 3 | 3 | 3 |
| Telephone | 3 | 3 | 3 |
| Filing cabinets | 3 | 3 | 3 |
| Power points | 3 | 3 | 3 |
| Pneumatic tube terminal | Optional | Optional | Optional |
| **UTILITY ROOM** (well ventilated) | | | |
| Stainless steel cabinet √ | 3 | 3 | 3 |
| **WASHING & DRYING AREA** | | | |
| Deep stainless steel sink | 3 | 3 | - |
| Drying shelves | 3 | 3 | - |

APPENDIX 3.9.9 : **MINIMUM MANPOWER REQUIREMENT FOR PRODUCTION**

| HUMAN RESOURCES | CDR | TPN | IV ADMIXTURE | NON-STERILE | TOTAL |
|---|---|---|---|---|---|
| U48 | 1 | | | | 1 |
| U44 | 1 | 1 | | 1 | 3 |
| U41 | 2 | 1 | 1 | 2 | 6 |
| U32 | 1 | 1 | | 1 | 3 |
| U29 | 2 | 2 | 2 | 2 | 8 |
| N17 | 1 | | | | 1 |
| PRA R4 | 1 | 1 | 1 | 3 | 6 |