



# UBAT-UBATAN

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## NEWS UPDATE ON ASEAN PHARMACEUTICAL HARMONIZATION

*Ninth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ)  
Pharmaceutical Product Working Group (PPWG)*



The Ninth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) was held on 22-24 February 2005 in Makati City, Philippines.

The Meeting was chaired by Y. Bhg. Dato' Che Mohd Zin Che Awang, Director of Pharmaceutical Services, Ministry of Health, Malaysia and co-chaired by Dr. Yuppadee Javroongrit, Senior Pharmacist, Drug Control Division, Food and Drug Administration, Ministry of Public Health, Thailand.

The Meeting was attended by regulatory representatives from Brunei Darussalam,

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Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, Vietnam, and staffs of the ASEAN Secretariat. Representatives from pharmaceutical associations and industries in ASEAN were also in attendance as observers. The objective of the PPWG is to harmonize the technical requirements for pharmaceuticals to complement and facilitate the ASEAN Free Trade Area (AFTA).

The Meeting was informed on the outcome of the 24th ACCSQ Meeting held on 3-4 August 2004 in Kuala Lumpur, Malaysia on consideration and endorsement of Guideline on Stability Studies, Guideline on Bioavailability (BA)/Bioequivalence (BE) Study and ASEAN Common Technical Dossier (ACTD) on Quality. The meeting was also informed on the inputs of the PPWG to the roadmap for the healthcare integration and the agreement of forming two new product working groups, namely PWG on Medical Device and PWG on Traditional Medicines and Health Supplement to discuss appropriate measures to facilitate the integration of these sectors.

The Meeting noted that the 21st Meeting of the ASEAN Working Group for Technical Cooperation in Pharmaceuticals (AWGTCP) held on 22-24 September 2004 in Vientiane, Lao PDR on the activities which have been taken such as Training on GMP Inspection, Training on Quality Assurance and Non-Pharmacopoeia Analytical Methods, Training for Production and Utilisation of Regional Standards and Reference Substance (ASEAN Reference Substances) and Building and Strengthening ASEAN's Capacity on Good Clinical Practice (GCP) and Clinical trials.

The Meeting discussed and agreed that the harmonization of BA/ BE is important as it would enable Member Countries to work towards the mutual acceptance of the BA/ BE report in ASEAN. The Meeting also noted two approaches to further accelerate the harmonization of BA/BE for further consideration: (i) the listing of products requiring BA/BE studies and their comparators; and (ii) the accreditation of laboratories by the national accreditation bodies. The Meeting noted the revised targeted ACTD implementation dates of Member Countries as follows:

- (i) Singapore and Malaysia by 31 December 2005
- (ii) Thailand by 31 December 2006
- (iii) Indonesia and Viet Nam by 31 December 2007
- (iv) Brunei Darussalam, Cambodia, Lao PDR and Philippines by 31 December 2008

The Meeting discussed and agreed that amongst 16 labelling requirements, 15 of them are considered common requirements for ASEAN Member Countries, except "Special Labelling" as this requirement is country specific. The ASEAN Secretariat presented to the Meeting on the proposed outlines for the possible Mutual Recognition Arrangement (MRA) for Pharmaceuticals in ASEAN such as GMP Inspection in ASEAN without waiting for full implementation of the ACTD by Member Countries. In doing so, there is a need to standardize the format of GMP Inspection Report in ASEAN in accordance to the Pharmaceutical Inspection Cooperation Scheme (PIC/S) format. The Meeting discussed and agreed that the PPWG should keep monitoring its progress in implementing the roadmap for healthcare integration in the area of pharmaceuticals to make sure that the timeframe given in the roadmap will be met by member countries.

A progress update of the WHO-ASEAN Harmonization Project on Summary of Product Characteristics (SPC) was also presented and the Meeting agreed to the proposal of Indonesia to look into the terminology for the product information for generic product in the region. The Meeting also agreed to the proposal of Indonesia that this product information should not be part of the ACTD and ACTR. As for training assistance to new members, additional training will be provided for Cambodia and Viet Nam. The Meeting noted that two training courses have been conducted in Lao PDR and Myanmar in 2004 and 2005 respectively.

The Meeting was of the view that since there is increasing number of new vaccines which are either manufactured or requested for approval in Member Countries, ASEAN should be more proactive in establishing and strengthening its regulatory system for vaccines. The Tenth Meeting of the ACCSQ Pharmaceutical Product Working Group will be held in Singapore in August 2005.

# NEWS UPDATE ON ASEAN TRADITIONAL MEDICINES AND HEALTH SUPPLEMENT HARMONIZATION

*Second Meeting of the ASEAN Consultative Committee for Standard and Quality (ACCSQ)  
Traditional Medicines and Health Supplements Product Working Group (TMHS-PWG)*



The 2nd Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Product Working Group on Traditional Medicines and Health Supplements (TMHSPWG) was held on 27-28 January 2005 in Kuala Lumpur, Malaysia. Prior to the Meeting, a Seminar on the Current Trend on Control of Quality and Safety of Traditional Medicines and Health Supplement was held on 26 January 2005 at the same venue.

The Meeting was chaired by Ms. Mawarwati Djamaluddin, Permanent Secretary, the National Agency of Drug and Food Control of the Republic of Indonesia and co-chaired by Ms. Eisah A. Rahman, Deputy Director, Centre for Product Registration, National Pharmaceutical Control Bureau, Ministry of Health, Malaysia. The Meeting was attended by delegates from Brunei Darussalam, Cambodia, Indonesia, Malaysia, Singapore, Thailand, Viet Nam and representatives of the ASEAN Secretariat. Representatives from industry associations for traditional medicines and health supplements of ASEAN Member Countries were also attended the Meeting as observers.

The Meeting noted the following areas to be taken into account for the harmonization exercise:

- i. Product placement requirements;
- ii. Testing method;
- iii. Advertisement requirements;
- iv. Post Marketing Alert System
- v. GMP and GAP; and
- vi. Labelling.

The Meeting also discussed the lead countries for specific strategies and agreed on the following:

- i. Exchange of information and analysis of the existing standards, definition, terminologies, regulations and procedures amongst ASEAN Member Countries. Brunei Darussalam and Viet Nam will provide support for activity on definition and terminologies.
- ii. Comparative study on international and other regional technical requirements for TMHS.
- iii. Specified areas for harmonization in ASEAN.
- iv. Review and analyze technical requirements for each specific areas amongst ASEAN Member Countries. The following specific areas and lead countries were agreed:

- ◆ GMP and testing method.
- ◆ Product placement.
- ◆ Labelling and advertisement.
- ◆ Post Marketing Alert System Guideline.

v. Cooperation with international organization.

The Meeting further discussed the timeframe for completion of activities and agreed that the Work Programme be finalized. The final work programme will be submitted for consideration and endorsement by ACCSQ at its next meeting. The 3rd Meeting of the TMHSPWG will be held tentatively in 3rd or 4th week of July 2005 in Indonesia.

## FAREWELL AND ACKNOWLEDGEMENTS

The Editorial Board would like to express its gratitude and heartfelt appreciation to the former members of the DCA for their commitments, dedication and commendable contributions. The distinguished members who have previously served the DCA between 2002-2004 are as follows:

### PAST MEMBERS OF DRUG CONTROL AUTHORITY (2002 – 2004)

#### Name of Members

Tan Sri Datu Dr. Mohamad Taha bin Arif  
Director General of Health  
(until April 2005)

Datin Hasiah Hj. Abdullah  
Director  
National Pharmaceutical Control Bureau  
(until December 2004)

Dato' Dr. Hj. Abdul Aziz Abdullah  
Senior Consultant Psychiatrist and Head  
Department of Psychiatry  
Hospital Kuala Lumpur

Dato' Dr. Tharmizi Thayaparan  
Senior Consultant Physician and Head  
Department of Medicine  
Hospital Seremban

Ass. Prof. Dr. Aminuddin Ahmad  
Consultant Physician (Gastroenterology) and Lecturer  
Hospital Universiti Kebangsaan Malaysia

Prof. Dr. Saringat bin Bai @ Baie  
Dean, School of Pharmaceutical Sciences  
Universiti Sains Malaysia

Hajjah Hazimah bt. Othman  
State Health Deputy Director (Pharmacy)  
State Health Department  
Negeri Sembilan

#### Name of Alternate members:

Dr. Chuah Siew Kee  
Senior Consultant Physician and Head  
Department of Medicine  
Hospital Tuanku Ampuan Rahimah

Ass. Prof Dr. Roslan Harun  
Consultant Physician and Lecturer  
Hospital Universiti Sains Malaysia

Ass. Prof. Dr. Shafiq Abdullah  
Lecturer, Department of Pharmacy  
Faculty of Medicine  
Universiti Malaya

Tan Sri Datuk Dr. R.P. Lingham  
MMA Representative

Ruhaiyem Yahaya  
State Health Deputy Director (Pharmacy)  
State Health Department  
Perlis

## NEW MEMBERS OF DRUG CONTROL AUTHORITY

The Editorial Board is very pleased to congratulate all newly appointed as well as reappointed members of Drug Control Authority (DCA) effective from 1st March, 2005 for a three year term and the appointment of Y. Bhg. Datuk Dr . Haji Mohd. Ismail Merican as the new Director General of Health and Chairman of DCA.

The DCA members for the new term are as follows:

### **Ex-officio members:**

Datuk Dr . Haji Mohd. Ismail Merican – *Chairman*  
Director General of Health Malaysia

Dato' Che Mohd Zin bin Che Awang – *Alternate Chairman*  
Director of Pharmaceutical Services  
Ministry of Health Malaysia

### **Appointed Members:**

Datin Dr. Aziah Ahmad Mahayiddin  
Senior Consultant Chest Physician  
Hospital Serdang

Dr. Mohamed Mansor Manan  
Chief Pharmacist  
Hospital Sultan Ismail

Prof. Madya Dr. Abas Hussin  
Dean, School of Pharmaceutical Sciences  
Universiti Sains Malaysia

Prof. Madya Dr. Samsinah Hussain  
Lecturer, Department of Pharmacy  
Universiti Malaya

Dr. Ahmad Asmadi Yusof  
Lecturer and Head  
Department of Pharmacology  
Universiti Kebangsaan Malaysia

Dr. Suarn Singh a/l Jasmit Singh  
Senior Consultant Psychiatrist & Director  
of Hospital Bahagia Ulu Kinta

Dr. A. Rajamohan Annamalai  
Registered Medical Practitioner

Mdm. Eisah Abd Rahman  
Deputy Director  
Centre for Product Registration  
National Pharmaceutical Control Bureau  
Ministry of Health Malaysia

### **Appointed Alternate members:**

Dato' Dr. Chandran Krishnan @ Aris Abdullah  
Consultant Physician & Head Department of Medicine  
Hospital Ipoh

Abdol Malek Abd Aziz  
Clinical Pharmacist U48  
Hospital Melaka

Ass. Prof. Dr. Rahmat Awang  
Director of National Poison Centre  
Universiti Sains Malaysia

Ass. Prof. Dr. Chung Lip Yong  
Lecturer and Head  
Department of Pharmacy  
Universiti Malaya

Prof. Dr. Ima Nirwana Soelaiman  
Lecturer, Department of Pharmacology  
Universiti Kebangsaan Malaysia

Dr. Toh Chin Lee  
Senior Consultant Child and Adolescent Psychiatrist  
Hospital Kuala Lumpur

Dr. M. Ponnusamy a/l Muthaya  
Registered Medical Practitioner

– *Secretary*

# ANNUAL REPORT 2004

*WHO Collaborating Centre for Regulatory Control of Pharmaceuticals*

## ACTIVITIES OF THE COLLABORATING CENTRE

### **i. Training for WHO Fellows**

As a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals, the National Pharmaceutical Control Bureau (NPCB), Ministry of Health Malaysia continues to provide training in pharmaceutical quality assurance and regulatory affairs to fellows from other countries.

The centre recorded a total of 28 international visitors and WHO fellows from various countries namely Brunei Darussalam, China, Cuba, Fiji, Hong Kong, Mongolia, Singapore, South Africa and Vietnam.

The courses provided under this program are designed specifically to cater for the needs of the individual fellows. For personnel with laboratory background the courses include training in pharmaceutical analysis which includes dosage performance testing, chemical, microbiological, pharmacological and toxicological test methods, testing of traditional medicines as well as preparation and handling of reference standards. Other areas of training include aspects pertaining to GMP requirements and licensing system, drug registration, pharmacovigilance and post-marketing surveillance activities.

### **ii. Collaborative Studies for the Production of ASEAN Reference Standards**

In 2004, Malaysia sent 3 proposed ASEAN reference standards namely prednisolone, nystatin and diphenhydramine to Singapore and Philippines. Malaysia also participated and had submitted collaborative study reports for other proposed ASEAN reference standards which include betamethasone dipropionate, rifampicin and cefradoxil.

### **iii. Network for Surveillance and Pharmacovigilance**

As a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S), the NPCB participated in the PIC/S Rapid Alert System which provided information pertaining to punitive actions taken by the Drug Control Authority (DCA) to other PIC/S member countries. Similar information was also disseminated to other regulatory authorities through the WHO network.

#### **a. WHO Collaboration in the Field of GMP Inspection**

The NPCB collaborated with the WHO and PIC/S in conducting GMP training and regional assessments under the EC-ASEAN Technical Cooperation Programme. Joint PIC/S GMP inspections were also conducted in Greece and Netherlands.

#### **b. Capacity Building of other Regional National Regulatory Authorities**

In accordance with the ASEAN harmonization initiatives, the NPCB had provided technical assistance to Vietnam in the implementation of ASEAN Common Technical Dossier/Requirement. Review of regulatory systems in Cambodia and Thailand were also conducted in collaboration with the WHO.

**c. WHO Collaboration in the Evaluation of Dossiers**

In collaboration with the WHO, the NPCB had also been involved in the evaluation of dossiers for HIV/AIDS, malaria and TB drugs for the purpose of pre-qualification.

**d. Staff Development**

In 2004, officers from the centre had undergone training courses in several areas to upgrade and improve their knowledge and skills.

## REGULATORY STATUS

- i. Up to December 2004, a cumulative total of 113,347 product applications for registration have been received, of which 77,939 have been approved.

The following are the breakdown for the type of applications received in 2004:

Scheduled poisons (prescription item)	- 529
Non-scheduled poisons (non – prescription item)	- 720
Cosmetics	- 30,630
Traditional medicines	- 2,220

- ii. Up until 2004, the cumulative total number of products registered is 77,939. Of these, 10,012 are prescription drugs, 7432 are over-the-counter medicines, 13,077 are traditional medicines and health supplements and 47,418 are cosmetics.
- iii. A total of 1886 Certificates of Pharmaceutical Product (CPP) and 1305 Certificates of Free Sale (CFS) were issued for the year 2004. The total number of Clinical Trial Import Licences (CTIL) issued was 277.
- iv. A total of 227 manufacturing premises were licensed in 2004, of which 74 are for pharmaceutical, 131 for traditional and 22 for cosmetic. For importers, a total of 456 were licensed, of which 180 are for pharmaceutical, 131 traditional and 145 cosmetic. For wholesalers, a total of 867 were licensed, of which 407 are for scheduled poisons while 460 are for non-scheduled poisons.
- v. Under the post-market surveillance program, a total of 3094 samples were taken from the market, 1792 labels and package inserts examined, 179 products were recalled, 81 warnings were issued and 297 product complaints were handled.
- vi. As for quality control testing, a total of 4847 samples were tested of which 2270 were registration samples, 2305 were surveillance samples, 139 were from complaints and 124 were enforcement samples. A total of 51,424 tests were conducted.
- vii. A total of 885 vials of ASEAN and NPCB reference standards were supplied to government departments (Chemistry Department, Government Medical Store Sarawak and State Enforcement Units) and a total of 507 vials were sold to the private sector.
- viii. Under the Adverse Drug Reactions Monitoring Program, a total of 1665 ADR reports were received in 2004, of which 1454 reports had been evaluated and sent to the Uppsala WHO Monitoring Centre for inclusion into the WHO database.

- ix. A total of 1489 queries pertaining to products and also general information from both the public and private sectors were dealt with.

## HIGHLIGHTS OF ACHIEVEMENTS IN 2004

- i. The organization of NPCB was restructured in June 2004 to streamline the registration, quality control, GMP, post registration and organizational developments functions. The physical infrastructure was also upgraded.
- ii. The on-line registration for traditional medicines and health supplements was implemented in January 2004. Additional funds were acquired for upgrading the QUEST 2 computer infrastructure and maintenance, both in terms of hardware and software. Additional new on-line modules were developed to increase work efficiency and productivity.
- iii. Several new guidelines pertaining to product registration were adopted and made available in the NPCB website ([www.bpfk.gov.my](http://www.bpfk.gov.my)).
- iv. Licensing for cosmetic manufacturers, importers and wholesalers was enforced in January 2004.
- v. The quality management system based on MS ISO 9001 version 2000 was maintained and certified by SIRIM. The scope of accreditation was expanded to include cosmetics registration and QUEST 2 on-line procedure.
- vi. The ASEAN Common Technical Dossier/Requirements for the purpose of harmonization was incorporated into the QUEST 2 on-line system and implemented as requirement for registration.
- vii. The NPCB was actively involved in the harmonization efforts through the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG), ASEAN Cosmetic Committee (ACC) and Traditional Medicines and Health Supplements Product Working Group (PWGTMHS). Other international involvements include facilitating the fast-track ASEAN healthcare integration and EC-ASEAN Economic Cooperation on Quality, Standards and Conformity Assessments.
- viii. Other international involvements include Technical Meetings and initiation of Bilateral Arrangements with ASEAN member countries.

## FUTURE PLANS

- i. **Expansion of Scope for Product Registration**  
To implement a system for registration and licensing of veterinary medicines and active pharmaceutical ingredients (API).
- ii. **Reinforcing PIC/S GMP**  
To further strengthen and upgrade the level of GMP compliance of local pharmaceutical and traditional medicines manufacturers to gain global recognition and facilitate global market penetration.



**iii. Intensification of post-market surveillance**

To intensify surveillance activities to combat problems associated with adulteration, counterfeits and product authentication and to promote public health protection through education and awareness.

**iv. Detection method for adulterants in traditional medicines**

To organize laboratory training on analytical techniques for the detection of adulterants particularly in traditional preparations and health supplements.

**v. Enhancement of Information and Communication Technology (ICT)**

To implement the on-line registration for New Chemical Entities (NCE) and biotechnology products.

To integrate the different on-line modules involving product registration, licensing of premises, analytical testing, surveillance, ADR monitoring and dissemination of information to enable better networking.

To further enhance the existing IT infrastructure.

**vi. ISO 17025 Certification**

To further upgrade the laboratory quality management system to achieve the ISO 17025 accreditation.

**vii. Inspection of Clinical Testing Facilities**

To strengthen capacity and capability in the inspection of clinical testing facilities.

To implement a system of inspection for clinical testing facilities in accordance to adopted GCP, GLP and BA/BE requirements.

## CONCLUSION

As a WHO Collaborating Centre for Regulatory Control of Pharmaceuticals since 1996, the NPCB will continue to play important roles to fulfill the commitments and expectations as laid down in the terms of reference. International collaborations in relevant technical areas provide an excellent platform for establishing mutual understanding amongst regulatory partners towards strengthening pharmaceutical quality assurance. Capacity and capability building will remain the topmost priority to ensure continuous improvements and to keep abreast with current global regulatory developments.

# DCA NEWS

## “Review of Cox-2 Inhibitors”

Rofecoxib (Vioxx) had been voluntarily withdrawn globally in September 2004 due to cardiovascular risks. Data interim studies from ‘Adenoma Prevention with Celecoxib (APC) in USA’ that was carried out in December 2004 also showed an increase in cardiovascular risks as compared to placebo. Following these findings, the safety issues of Cox-2 Inhibitor products were reviewed globally.

The Drug Control Authority at its 167th meeting held on 18th February, 2005 has agreed to:-

- (i) take action on the labeling requirement on warnings, contraindications, and indications as required by the international regulatory bodies including the EU, TGA Australia, Taiwan and USFDA.
- (ii) hold the evaluation on the product ‘Lumiracoxib’ until further information is available regarding the safety of Cox-2 Inhibitors.

## Registration of Cosmetic Products Containing *Comfrey* Herb

At the same meeting, the DCA has decided not to register all products including cosmetic products containing *Comfrey* herb & *Senecio spp* due to safety issue. However, this policy does not comply with the **Asean Cosmetic Committee (ACC)**, which allows the use of *Comfrey* herb in cosmetic products.

Therefore, the DCA was asked to consider excluding cosmetic products from this decision.

After reviewing all aspects and for the safety of consumers, the meeting had decided to **not exclude cosmetic products** from the restriction. The risks of adverse effects in consumers may occur even though for external use in cosmetic preparations.

## Suggestion to Exclude the Use of Hologram (Meditag™) on “External Personal Care” (EPC) OTC Products

The DCA at its 167th meeting also agreed with the suggestion to:-

- (i) exclude ‘External Personal Care (EPC)’ OTC product from the requirement to use the label hologram (Meditag™).
- (ii) Categories of EPC OTC products involve include:-
  - a) EPC- Anti-acne
  - b) EPC- Anti-dandruff
  - c) EPC- Oral Care
  - d) EPC- Skin Protectant
  - e) EPC- Antibacterial

### **NEVIRAPINE: Suggestion to Amend the Indication Base on CD4 Cell Count**

At the same meeting, the DCA has been agreed with the suggestions to:-

- (i) amend the indication for products that contain Nevirapine, so that the use in patients with 'CD4 + cell counts' more than 250 cells/mm<sup>3</sup> could be avoided.
- (ii) add in the statement regarding the avoidance of use in the patients with 'CD4 + cell counts' more than 250 cells/mm<sup>3</sup>, to the approved indications for the products that contain Nevirapine.
- (iii) request the product holders to inform the prescribers regarding the amendment of the indication.

# NATIONAL PHARMACEUTICAL CONTROL BUREAU

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## OFFICERS TO CONTACT

ORGANISATION	SECTIONS / UNITS	NAME OF OFFICER	TEL-EXT
National Pharmaceutical Control Bureau	Director		300
Centre for Product Registration	Deputy Director	Eishah Abdul Rahman	270
Application for registration of :	-Prescription Unit	Noorizam Ibrahim	239
(i) Generic Medicines Section	-Non-Prescription Unit	Mazuwin Zainal Abidin	278
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(ii) Complementary Medicines & Cosmetic Section	-Natural Products Unit	Saleha Md. Ewan	238
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(iii) Investigational & New Drug Section	-New Drug Unit	Fudziah Ariffin	242
	-Clinical Trial Regulatory Unit	Dr. Kamaruzaman Saleh	371
	-Biotechnology Unit	Arpah Abas	241
(iv) Regulatory Coordination Unit	-Regulatory Coordination Unit	Rosilawati Ahmad	245
Centre for Post-Registration	-Pharmacovigilance Unit	Abida Syed Haq	258
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Centre for Good Manufacturing Practice	-Inspectorate I Unit	Dr. Tajuddin Akasah	898
	-Inspectorate II Unit	Sulaiman Ahmad	878
	-GMP Guidance Unit	Kadariah Mohd Ali	818
	-GMP Investigation Unit	Muhd. Lukmani Ibrahim	838
	-Licensing & Certification Unit	Wan Othman Wan Ismail	808
Centre for Quality Control	Deputy Director	Yogeswary Markandoo	204
(i) Reference Standard Unit	Reference Standard Unit	Abdul Aziz Mansor	510
(ii) Laboratory Services Unit	Laboratory Services Unit	Tan Ann Ling	515
(iii) Pharmaceutical Chemistry Testing Section	-Chromatography Unit	Dr. Sulaikah Moideen	521
	-Dosage Performance Unit		613
	-Spectroscopy/General Chemistry Unit	Tan Chuan Ai	614
	-Chemistry Research Unit		521
(ii) Pharmaceutical Biology Testing Section	-Pharmacology/Toxicology Unit	Faridah Ab. Malek	605
	-Microbiology Unit	Siti Madziah Mohamed	608
	-Tissue Culture & Biological Research Unit		605
(iii) Natural Product Testing Section	-Herbal Monograph Unit		250
	-Adulteration Screening Unit	Mazli Muhamad	249
	-Toxic Compound Detection Unit		250