BERITA UBAT-UBATAN

NEWSLETTER OF THE DRUG CONTROL AUTHORITY, MALAYSIA

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National Pharmaceutical Control Bureau Welcomes the New Director, Mr Selvaraja S.Seerangam

The Editorial Board extends its heartiest congratulations to Mr Selvaraja S.Seerangam, on his appointment as the new Director of the National Pharmaceutical Control Bureau (NPCB), Ministry of Health Malaysia on 21st December 2007.

Mr Selvaraja S.Seerangam, better known as Mr Selva graduated from Universiti Sains Malaysia, Pulau Pinang with a Pharmacy degree in 1978. He then went on to earn his M. Phil in Pharmaceutical Technology from University of Wales, College of Cardiff, United Kingdom.

Mr Selva embarked on his career as a pharmacist in Hospital Besar Seremban, Negeri Sembilan in 1978. Being a hospital pharmacist, Mr Selva has served in many government hospitals such as Hospital Besar Seremban ,Hospital Sungai Buloh, Selangor , Hospital Daerah Tanjung Karang, Selangor and Hospital Tengku Ampuan Rahimah Klang, Selangor. In June 1985, there was a shift in his career as he was appointed as an auditor in the Centre for Good Manufacturing Practice, National Pharmaceutical Control Bureau (NPCB). After serving there for five years, he was promoted to a Senior Pharmacist position where he again served as a hospital pharmacist in Hospital Keningau, Sabah for 3

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DCA EDITORIAL TEAM

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years, after which he was transferred back to NPCB as the Head of Pharmaceutical Chemistry Laboratory and thereafter Head of Pharmacology/Toxicology Laboratory.

In August 2002, Mr Selva was promoted to Senior Principal Assistant Director attached to the Pharmaceutical Services Division (PSD) for 3 years and in November 2005, he was again promoted to Deputy Director of NPCB. Mr Selva then climbed the rank to be the Director of NPCB today.

Having been with the hospital, the NPCB and the PSD, Mr Selva is very knowledgeable on matters pertaining to clinical, laboratory and regulatory affairs. He also participated and served as an expert in several seminars, meetings and forums related to pharmacy and regulatory matters. He has also presented many major papers both locally and internationally.

His warm and pleasant personality, together with his vast experience and knowledge in the pharmacy field affirms NPCB that Mr Selva will shine as the new Director of NPCB. For your dedication and effort, Mr Selva, we wish you all the best in your now position! Once again,

CONGRATUALTIONS!

Appointment of the New Secretary of the Drug Control Authority (DCA)

Puan Abida Syed M. Haq graduated with a B. Pharm (Hons) from Universiti Sains Malaysia and holds a Post Grad. Diploma in Medical Microbiology from the Institute of Medical Research, Malaysia. She is also a holder of a Master's Degree in Clinical Pharmacy from Universiti Sains Malaysia. She has vast experience serving the government in many areas including hospital pharmacy (1982-1995), state pharmacy enforcement (1995-1996) and regulatory affairs (1997-present). She has previously held a number of positions in the NPCB including Head of Centre for Post Registration, Head of Centre for Organisational Development, and Head of Centre for Compliance & Licensing. She is currently serving as the Deputy Director of NPCB, Centre for Product Registration as well as the Secretary to the Drug Control Authority, Malaysia.

14th Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG)

20-22 February 2008, Vientiane, Lao PDR

The Fourteenth Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG) was held from 20-22 February 2008 in Vientiane, Lao PDR.

The Meeting was chaired by Mdm. Eisah Abd. Rahman, Director of Pharmacy Enforcement, Ministry of Health, Malaysia and co-chaired by Dr. Yuppadee Javroongrit, Assistant Director, Drug Control Division, Food and Drug Administration, Ministry of Public Health, Thailand.

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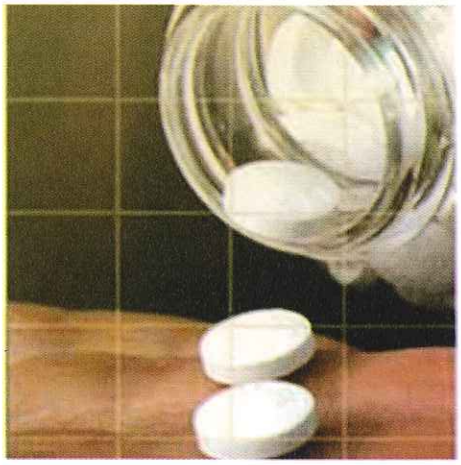
The Meeting was attended by representatives from the Drug Regulatory Authorities from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, Viet Nam and representatives from the ASEAN Secretariat. Representatives from the pharmaceutical associations and industries in ASEAN also attended the Meeting as observers.

The Meeting noted the key issues discussed at the PIC/S-ASEAN forum as well as possible areas of cooperation as follows:

a) GMP Training including participation in Annual PIC/S Seminars, Expert Circles and Joint Inspection Programmes

b) Exchange of Information/Rapid Alert (contact points, information to be exchanged, format, etc)

c) Harmonization of GMP Standards (including Herbal Medicinal Products)



With regard to technical issues on BA/BE, the Meeting agreed that Malaysia, as Lead Country for BA/BE will continue to lead discussions on the technical guidelines on BA/BE. The Meeting also agreed to establish a Technical Working Group (TWG) on BA/BE Guidelines reporting to the Implementation Working Group to address the technical issues.

The Meeting recommended Member States to take note of the recommendations from the survey and take the appropriate follow-up actions on the implementation of ACTD and ACTR:

a) Member States should focus on the interpretation of Part II of the ACTD on Quality Document as the industries are facing difficulties in filling it.

b) Member States need to continue to strengthen their capacity building for the industries as well as the regulators to enhance the evaluation of the technical documents.

c) Member States should also conduct their own survey 12 months after the implementation of the ACTD from 1 January 2009.

Singapore, as the Lead Country for Post Marketing Alert System (PMAS), updated the Meeting on the progress of the implementation of the Post Marketing Alert System. The Meeting noted that the PMAS was an important communication tool for sharing of information on defective and unsafe health products in the market and urged all Member States to participate actively in the PMAS. The Meeting requested the ASEAN Secretariat to coordinate circulation of the report to the ASEAN Cosmetic Committee (ACC) and the Traditional Medicine and Health Supplement PWG (TMHSPWG) as well for their information and onward action.

The Meeting further noted on the progress of vaccine chapter, combatting counterfeit drugs, cooperation with ICH Global Cooperation Group and ASEAN-US Cooperation on Pharmaceuticals.

Lastly, the Meeting accepted the gracious offer from Brunei Darussalam to host the 15th PPWG Meeting tentatively in August 2008.

Report of the Third Meeting of The ASEAN Cosmetic Committee (ACC) Heads of Delegations Meeting

4-5 March 2008, Jakarta, Indonesia

The 3rd ASEAN Cosmetic Committee (ACC) Heads of Delegations Meeting was held from 4-5 March 2008, in Jakarta, Indonesia.

The Meeting was attended by representatives from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, and Thailand. Representatives from the ASEAN Secretariat, the ASEAN Cosmetic Association (ACA) and an expert from APRIS II were also in attendance.

The ACA highlighted that the implementation of ACD by all Member States is very important as the role model for other sectors as well as towards the realisation of ASEAN Economic Community by 2015.

To date, all Member States have implemented the ACD at national level, except for Brunei Darussalam, Cambodia, Indonesia, Lao PDR, and Thailand which are in the progress of implementation.

In Malaysia, the notification system has been put in place with effect from 1 January 2008. In complying with the ACD requirements, the National Pharmaceutical Control Bureau must be notified of new cosmetic products before placing the products in the market complying with ACD requirements. Existing cosmetic products, i.e. products which are already registered and having MAL No. will require notification upon the expiry of the existing registration validity period. As part of the post market surveillance requirement, the Certificate of Analysis (CoA) is to be submitted to the NPCB within one month after the notification has been made for skin whitening products. At present, "douche" (vaginal cleanser) is temporarily classified as cosmetics due to insufficient data to classify it as a pharmaceutical product.

On the subject of effective implementation of ACD, the Meeting agreed on the importance of an effective Post Market Surveillance and Alert System to complement the implementation of the ACD. All Member States are reminded to as far as possible adhere to Article 12.2 of the ACD which stipulates that Member States may, for a period of 36 months from the implementation of the ACD, authorise the marketing of the existing products within their territory.

Finally, the Meeting noted that the 10th ACC Meeting will be hosted by Indonesia at a date and venue which will be confirmed in due course.

An Approach To Product Information File (PIF) & Safety Assessment Management For ASEAN Cosmetics Directive (ACD) Compliance

A one-day workshop on the approach to PIF and Safety Assessment Management based on the ASEAN Cosmetics Directives (ACD) was held on 24th March 2008 at Sunway Resort Hotel & Spa, Subang Jaya.

Below is a summary of the lectures conducted:

ACD requirements for cosmetic products include the following:

- Notification
- Good Manufacturing Practice
- Safety Assessment
- Product Information File (PIF)
- Labeling

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Notification

Notification is a simple procedure whereby every new cosmetic product launched after 1st January 2008 must be notified to the Drug Control Authority (DCA) in Malaysia prior to their sales in Malaysia.

Good Manufacturing Practice (GMP)

In essence, GMP is about good management practices and abiding by the principle of "write what you do and do what you write". Companies can start by doing an audit to ensure that the manufacturing processes are in line with the process objectives. At the beginning of the manufacturing process, a Management Action Plan (MAP) is a good way for a company to organise and review progress.

The following 5 GMP guidelines/requirements are equivalent to the ASEAN Cosmetics GMP Guidelines:

a) WHO GMP for Pharmaceuticals
b) PIC/S/Australia GMP for Pharmaceuticals
c) Draft ISO 22716
d) US CTFA Draft (April 28, 2005)
e) COLIPA, EU

Safety Assessment

The safety assessment of any cosmetic product clearly relates to the manner of use. This factor is most important since it determines the amount of substance which may be absorbed through the skin or mucous membranes, ingested or inhaled.

In general, the potential sensitisation, genotoxicity and all other types of systemic (toxic) effects of a cosmetic product will be evaluated on the basis of the properties of the ingredients. The question of possible interaction between different ingredients will usually be evaluated on the basis of experience (similarities, published data on related compounds/ mixtures, theoretical considerations, etc).

The company may obtain the following data on the raw materials from the suppliers:

- INCI name and function
- Material Safety Data Sheet (MSDS)
- Safety Data
- Specifications
- Certificate of Analysis (CoA)
- Efficacy, etc

A safety assessor must be appointed by the company to evaluate and assess the safety statement of the said product.

Product Information File (PIF)

The ACD Guidelines for PIF recommends the following format for the compilation of a PIF:
Part I - Administrative documents and product summary
Part II - Quality data of raw materials
Part III - Quality data of finished product
Part IV – Safety and efficacy data

A table of Contents should be provided for each of the 4 parts.

The PIF must be available in the local language or English. Article 8 of the ACD clearly states that the PIF must be kept at the address of the company responsible for placing the product in the market (as specified on the label), be it the manufacturer, importer or distributor of the said product. It is recommended that the PIF be kept for a minimum duration of 3 years after the product is last placed in the market. As audits will be conducted at a routine or ad-hoc basis, the PIF must be readily accessible and kept updated of all modifications.

Labeling

Labeling requirements include the following:

- Ingredient listing
- Claims, in line with Claims Guidelines
- Full address of the company
- Manufacturing or expiry date
- Mandatory warning (if any)
- Country of manufacturing

DCA NEWS

IMPLEMENTATION OF PATIENT PACK SIZE FOR PHARMACEUTICAL PRODUCTS IN MALAYSIA

The Drug Control Authority (DCA) at its 201st meeting on 31st January 2008 agreed on the following:

a) To implement a **maximum pack size** requirement for **pharmaceutical products including tablet, capsule, oral liquid preparation and external use preparation categories.**
b) The implementation is based on guidelines found in **appendix 1, 2, and 3.**
c) Voluntary implementation will commence on **1st March 2008** and mandatory implementation will take its full effect on **1st September 2008.**
d) The manufacturing of local and import pharmaceutical products beyond the pack size allowed must be stopped with the effect of mandatory implementation.
e) Manufacturing of products beyond the pack size limit is allowed for export-only products.

All product registration holders are compelled to follow this order.

PROHIBITION FOR USE OF COLOURING SUBSTANCE IN PRODUCTS CONTAINING PREDNISOLONE AS AN ACTIVE INGREDIENT IN SOLID ORAL DOSE PRODUCTS

The Drug Control Authority (DCA) at its 201st meeting held on 31st January 2008 has agreed that the formulation of all solid oral prednisolone products CANNOT contain any colouring substance due to an alarming number of adverse drug reaction reports received. As such, all product registration holders involved must review the existing product formulation so that the new formulation does not contain any colouring substance(s). Hence, all product registration holders are required to make submission for variation application within 3 MONTHS from the date of notice (27th February 2008).

NOTIFICATION PROCEDURE FOR COSMETICS

Notification procedure for cosmetics has been implemented since 1st January 2008. The Drug Control Authority (DCA) at its 201st meeting held on 31st January 2008 decided that companies should carry out test for *hydroquinone* and *tretinoin* in 'high risk' cosmetic products which include skin whitening products. The companies are to submit the certificate of analysis to the National Pharmaceutical Control Bureau (NPCB) within one month from the date of notification. Companies failing to abide by the rule may face cancellation of the Notification Note of their products.

THE USE OF THE NAME FARMASEUTIKAL/ PHARMACEUTICAL/ PHARMA FOR COMPANIES INVOLVED IN MANUFACTURING/ IMPORTATION/ DISTRIBUTION OF TRADITIONAL PRODUCTS.

In the 201st meeting of the Drug Control Authority (DCA) held on 31st January 2008, the members were informed that the use of name/ pharmacy title including the words 'pharmaceutical' or 'pharma' or any other words with similar connotation was under the purview of the Registration of Pharmacist Act 1951. Section 7 of the Act specifies the restriction on use of certain titles. Section 13 of the same Act specifies that companies involved in keeping, retailing, dispensing and compounding poisons, dangerous drugs or therapeutic substances must be registered as a body corporate with the Pharmacy Board prior to their being permitted to use the name/ pharmacy title including the words 'pharmaceutical'/ 'pharma'.

However, for companies that are involved in manufacturing/ importation/ distribution of traditional products, although it is not a requirement for the companies to be registered as a body corporate with the Pharmacy Board, such companies are not allowed to use the name/ pharmacy title including 'pharmaceutical'/ 'pharma' as stated in subsection 13 (6) of the Act. The meeting thus agreed that individuals (company owners) who are involved in a business of manufacturing/ importation/ distribution of traditional products but do not have recognised pharmacy qualifications are prohibited from using name/ pharmacy title including the words 'pharmaceutical'/ 'pharma'. Companies concerned are given a grace period of 6 months to abide by the ruling.

ADDITION OF ACTIVE INGREDIENT 13-C UREA INTO THE POISON LIST

The Drug Control Authority (DCA) at its 201st meeting held on 31st January 2008 decided that the active ingredient 13-C Urea is to be included in the Poison List.

ACTIVE INGREDIENT (PELARGONIUM SP) ADVERSE EVENTS REPORTS

The Drug Control Authority (DCA) at its 202nd meeting held on 28th February 2008 decided to permit the use of Pelargonium sidoides extract material in traditional product formulations only if the following warning statement on hypersensitivity adverse reactions is printed on the labels and package inserts for all products containing Pelargonium sidoides.

"IN VERY RARE CASES, PELARGONIUM SIDOIDES MAY CAUSE HYPERSENSITIVITY REACTIONS"

News and Announcements

NEW FEE STRUCTURE FOR GOOD MANUFACTURING PRACTICE (GMP) INSPECTION OF LOCAL AND INTERNATIONAL MANUFACTURING PREMISES

The Drug Control Authority (DCA) at its 186th meeting held on the 26th October 2006 has agreed to revise the GMP inspection fee for local and overseas manufacturers. .

The increase in GMP inspection fee is considered reasonable since this is the first time the rate has been revised since 1994, even though the cost of inspections have increased over the years.

The new rate has taken effect since 2nd January 2008.

New GMP inspection fee for local premise:

TYPE OF INSPECTION	FEE
Duration of inspection not exceeding one (1) working day	RM1000.00
Duration of inspection exceeding one (1) working day	RM1000.00 / personnel / working day
Inspection involving more than three (3) inspectors and/or duration of inspection exceeding three (3) working days.	RM10 000.00 (maximum rate)

New GMP inspection fee for overseas premise:

TYPE OF INSPECTION	FEE
Fee for each inspection*	EURO 5000.00

Travel costs, accommodation and food allowances will be financed by the local registration applicant and will be according to the qualification of the officers involved in the audit.

WARNING FROM THE U.S. FOOD & DRUG ADMINISTRATION (USFDA) ON THE USE OF MEDICINES TO TREAT COUGH AND COLD IN CHILDREN.

According to the information received from the USFDA and Health Canada recently, it is recommended that cough and cold products that can be dispensed without a prescription should not be used in children under 2 years of age. This is due to the potential risk of serious adverse events which could be fatal to these children.
The products involved are anti-histamines, anti-tussives and decongestants which are used in the treatment of cough and cold.

According to the two agencies, the use of cough and cold products is also seen to be ineffective in treating children below 6 years of age. However, an on-going study is done on the use of these products which may potentially produce the same risk in children aged between 2-11 years old.

In Malaysia, these products are categorised as Type C Poison whereby it can be only be dispensed by a professional medical practitioner and/or a pharmacist. These products cannot be sold in an open market. To date, only products containing promethazine include a warning statement informing the user that it should not be given to children below 2 years of age.

Following the above warning, the Drug Control Authority (DCA) wishes to inform all medical practitioners on the potential risk and recommends that the benefit/risk ratio must be considered before dispensing the cough and cold products to children below 2 years of age. As soon as the evaluation on the use of these products are completed, appropriate amendments are to be done on the product labels and package inserts to ensure the proper handling and safe use of the products.

CHANGE OF CONTACT NUMBER

To further enhance its services, NPCB recently upgraded its telephone system and effective 15 January 2008, the main line is 603-7883 5400. Calls can now be made direct to the relevant sections or units if the extension number is known. A list of important contacts are as follows:

Director

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Fax: 603-79562924

Deputy Directors

1 Abida Haq Syed M Haq
(Deputy Director of Centre for Product Registration)
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2 Dr. Sulaikah Moideen
(Deputy Director of Centre for Quality Control)
Tel: 603-7883 5429; 603-7883 5430 Fax: 603-79567075

3 Sulaiman Ahmad
(Acting Deputy Director of Centre for Compliance and Licensing)
Tel: 603-7883 5566 Fax: 603-79571200

Administrative Centre

Tel: 603-7883 5400 Fax: 603-7956 7634

Zuraidah Zainudin (Executive Officer) 603-7883 5412

Centre for Quality Control

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Dr. Sulaikah Moideen (7883 5429)
Head of Centre for Quality Control

1 Pharmaceutical Chemistry Testing Section

Faridah Abd Malek (7883 5456)
Acting Head of Pharmaceutical Chemistry Testing Section

Chromatography Unit
Dr. Hasenah Ali (7883 5450)
Acting Head

Dosage Performance Unit
Faridah Abd Malek (7883 5456)

Spectroscopy / General Chemistry Unit
Muhammad Nasir Hashim (7883 5462)

Chemical Research Unit
Dr. Hasenah Ali (7883 5450)

2 Pharmaceutical Biology Testing Section

Noorul Akmar Mohd Nur (7883 5446)
Head of Pharmaceutical Biology Testing Section

Microbiology Unit
Noorul Akmar Mohd Nur (7883 5446)

Pharmacology / Toxicology Unit
Ida Syazrina Ibrahim (7883 5447) (Acting Head)

3 Natural Product Testing Section

Mazli Muhammad (7883 5471)
Head of Natural Product Testing Section

Adulteration Screening Unit
Mazli Muhammad (7883 5471)

Toxic Compound Detection Unit
Mazli Muhammad (7883 5471) (Acting Head)

Herbal Monograph Unit
(vacant)

4 Reference Standards Unit

Ahmad Zakhi Bin Ramli (7883 5468)

5 Laboratory Services Unit

Tan Ann Ling (7883 5431)

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Head of Generic Medicine Section

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Mazuwin Zainal Abidin (7883 5490)

Non-Prescription Unit
Abdullah Hisham Ahmat Yaya (7883 5497)

Veterinary Unit
(vacant)

2 New Drug Section
Noorizam Ibrahim (7883 5514)
Head of New Drug Section

3 Biotechnology Section
Arpah Abas (7883 5518)
Head of Biotechnology Section

4 Complementary Medicine & Cosmetic Section
(7883 5522)
Head of Complementary Medicine & Cosmetic Section

Health Supplement Unit
Asnida Mat Daud (7883 5528) (Acting Head)

Traditional Unit
Seetha a/p Ramasamy (7883 5523) (Acting Head)

Cosmetic Unit
Nik Shamsiah Nik Salleh (7883 5534) (Acting Head)

5 Regulatory Coordination Section
Rosilawati Ahmad (7883 5502)
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Sulaiman Ahmad (7883 5566)
Acting Head of Centre for Compliance and Licensing

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Muhammad Lukmani Ibrahim (7883 5569)

Head of Section for GMP 2
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Bariah Ab. Rani (7883 5554)

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Quality System Section
Nurulfajar Mohd Jamid (7883 5556) (Acting Head)

1st Announcement

NATIONAL REGULATORY CONFERENCE 2008

25th -27th AUGUST 2008

SHERATON SUBANG HOTEL
PETALING JAYA, SELANGOR
MALAYSIA

In Collaboration with:
Pharmaceutical Association of Malaysia (PhAMA)
Malaysian Organisation of Pharmaceutical Industries (MOPI)
Malaysian Pharmaceutical Society (MPS)
Chinese Medicine Manufacturers Association of Malaysia (PPUCM)
Traditional Malay Medicine Manufacturers Association (PURBATAMA)
Malaysian Dietary Supplement Association (MADSA)
Malaysian Biotechnology Corporation Sdn Bhd (BIOTECHCORP)

Objectives:
To disseminate information on new developments and regulatory issues pertaining to pharmaceuticals and complementary medicines

To strengthen the cooperation and understanding between regulators and the pharmaceuticals and complementary medicines industries

To increase the competitive capabilities of pharmaceuticals and complementary medicines industries in line with global trade developments

Who should attend:
This conference is aimed to benefit Regulators, Industry Representatives (Pharmaceuticals & Complementary Medicines Industries), Researchers and Academia

Registration Fee per participant:
RM 1200 (local participants)
USD 500 (foreign participants)

Kindly log onto www.bpfk.gov.my for updates

CONTACT & MAP

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Centre for Product Registration	5457
Section 1 Generic Medicines Section	5489
Section 2 Complementary Medicine & Cosmetics Section	5522
Section 3 New Drug Section	5514
Section 4 Biotechnology Section	5518
Section 5 Regulatory Coordination Section	5502
Centre for Post Registration	5538
Centre for Organisational Development	5553
Centre for Compliance and Licensing	5565
Centre for Quality Control	5429
(i) Reference Standard Unit	5468
(ii) Laboratory Services Unit	5431
(iii) Pharmaceutical Chemistry Testing Section	5450, 5456, 5462
(iv) Bio-Pharmaceutical Testing Section	5442, 5446
(v) Natural Product Testing Section	5471
Administrative Centre	5412

National Pharmaceutical Control Bureau (NPCB)
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