

6. WORKSHOP FOR GLASSWARE AND INSTRUMENTS

The workshop provides facilities for

- (i). the repair of instruments and equipment
- (ii). the repair and small-scale production of the necessary glassware.

7. AUDITORIUM

The auditorium has a seating capacity of 200 people and serves to

- (i). organize lectures, meetings, conferences
- (ii). to present films

8. EXPOSITION ROOM

The exposition room carries a permanent exposition of current pharmaceutical specialite in use in Indonesia and provides ample floor space for the exhibition of progresses in the field of quality control.

9. METHODS AND PROCEDURES

The National Quality Control Laboratory holds a selective collection of

- (i). methods and procedures for the chemical, physical, physico-chemical, pharmaceutical, microbiological, pharmacological, toxicological, immunological, evaluation of drugs and chemicals.
- (ii). specific methods and procedures for the evaluation of the cancerogenicity; the teratogenicity; the mutagenicity of drugs and chemicals.
- (iii). methods and procedures for the clinical evaluation of drugs.
- (iv). operational methods and procedures for each instrument in the National Quality Control Laboratory.

All methods and procedures should be in the English language .

10. REFERENCE STANDARDS AND SUBSTANCES

The reference standards and substances comprise

- (i). selected drugs and chemicals
- (ii). antibiotics
- (iii). hormones
- (iv). pesticides
- (v). narcotics
- (vi). psychotropic drugs and chemicals
- (vii). pharmacological and toxicological test and reference substances.

IV. OTHER FACILITIES

Other facilities include the following.

1. PURE BRED COLONY OF LABORATORY ANIMALS

The animal breeding facility should start with a colony of pure bred rats and mice.

A colony of standardized breed of rabbits adapted to the purpose of the testing for pyrogens should be instituted.

2. WATER DISTILLATION AND PURIFICATION FACILITIES

A system to supply water of high quality in sufficient quantities at all times should be on hand and in good running condition at all times.

3. ASEPTIC ROOMS

Aseptic rooms should be provided within the National Quality Control Laboratory to provide for

- (i). the evaluation of the sterility of parenteral products
- (ii). the evaluation of antibacterial potencies of drugs
- (iii). the conduction of microbiological and bacteriological tests.

4. SPECIALLY DESIGNED ROOMS

Specially designed rooms should provide for

- (i). stability testing
- (ii). testing for pyrogens
- (iii). testing for specific pharmacological activities.

5. COLD ROOMS

Cold rooms provide for

- (i). the storage of sera and vaccines
- (ii). the storage of bacterial cultures
- (iii). the conduction of protein binding studies.

6. WASTE WATER TREATMENT AND DISPOSAL SYSTEM

A system for the treatment of waste water and its non hazardousness at disposal into the environment should be installed at

the location of the National Quality Control Laboratory.

7. ELECTRICAL FACILITIES

The electrical capacity should be sufficiently large to ensure the conduction of all quality control functions at optimum conditions.

V. TRAINING PROGRAM FOR QUALITY CONTROL

PERSONNEL

The training program for quality control personnel takes place at the National Quality Control Laboratory, at the Regional and provincial quality control laboratories and at Institutes of Quality Control abroad, in order to

- (i). achieve proficiency in the comprehension of equipments and their performance as well as in the interpretation of results obtained with those instruments;
- (ii). enable personnel to repair minor operational defects of equipment;
- (iii). become proficient in the maintenance of equipment;
- (iv). obtain specific training in animal breeding, care and handling and uses;
- (v). obtain training in specific techniques in the fields of pharmacology and toxicology; immunology; microbiology; pharmacy; advanced analytical chemistry; environmental chemistry.

The duration of training abroad depends on the specific field studied but will last in general for 3 months up to one year.

VI. EXCHANGE OF EXPERTS

An exchange of experts should be instituted toward the permanent and continuous development of the National Quality Control Laboratory to render consulting services, to conduct national training programs and to the expansion of building construction.

Short visits will extend from 2 weeks up to one month in order to:

- (i). become acquainted with the systems of quality control in the cooperating and collaborating countries;
- (ii). appreciate the physical design and lay-out of National Institutes/Laboratories of Quality Control ;
- (iii). appreciate animal facilities, the care, handling and usages of laboratory animals in the respective countries;
- (iv). visit and appreciate quality control facilities and activities of the respective countries.

VII. CRITERIA OF INSTRUMENTS

The instruments supplied to the National Quality Control , the Regional and Provincial Quality Control Laboratories should fulfill the following requirements.

- (i). instruments are adapted to the volume of analytical and experimental work to be carried out;
- (ii). instruments will maintain their good performance under the conditions of climate (humidity; temperature; instability of electrical supply) of the country;
- (iii). instruments should be of excellent accuracy and precision;
- (iv). instruments are properly guaranteed by the deliverer;
- (v). after sales services of the instruments can be assured by the deliverer;
- (vi). instruments delivered are in excellent running condition; are to be adjusted and checked for good performance by the deliverer and the receiver;
- (vii). maintenance and operational manuals for each instrument accompany each instrument supplied; these are presented in English;
- (viii). accessories and spare parts of the instruments can be easily procured.

VIII. SETTING OF PRIORITIES

- (i). The National Quality Control Laboratory should be equipped with all the facilities necessary to perform all quality control functions as stipulated; to act as a top referral laboratory and a laboratory for the certification of reference standards; to provide guidance and training to quality control personnel in the country;
- (ii). the activity, the volume as well as the type of quality control work of the regional and provincial laboratories should be assessed in order to make correct decisions on needed equipment, facilities and type of quality control work, guidance and training that must be established.

IX. ANNEX

1. PRODUCTS TO BE CONTROLLED

- Drugs
- Hazardous substances
- Additives
- Pharmaceutical dosage forms
- Traditional medicine
- Cosmetics
- Health products and toiletries
- Sera and vaccines
- Household products
- Birth control devices and pills
- Medical instruments and devices
- Food, beverages, including alcoholic beverages
- Packaging materials

2. FUNCTIONAL CAPACITIES OF THE NATIONAL QUALITY CONTROL LABORATORY

- (i). Top Referral Laboratory for the Quality Control of Food, Drugs, Cosmetics, etc.
- (ii). Testing and evaluation of Food, Drugs, Cosmetics, etc. in the registration process.
- (iii). Certification of National Reference Standards.
- (iv). Guidance and training of the national quality control personnel.
- (v). Development of methods of quality control in all its aspects of the promotion of human and environmental health.
- (vi). Revision of the Indonesian Pharmacopoeia and other official National Compendia under the authority of the Directorate General of the Quality Control of Food, Drugs and Cosmetics.

Activities:

- (i). Able to test and evaluate yearly
 - 2200 samples of drugs;
 - 2700 samples of food

- 1200 samples of cosmetics and medical devices
 - 900 samples of traditional drugs
 - 900 samples of narcotics and hazardous substances.
- (ii). Able to conduct twice yearly a training program in a specific field of quality control for simultaneously 30 participants of regional and provincial laboratories.
- (iii). Able to develop 100 assay/analytical/evaluation methods yearly, applicable to quality control activities.
- (iv). Able to develop and maintain 200 chemical reference substances each year comprising
- antibiotics
 - hormones
 - vitamins
 - cardiac glycosides
 - selected alkaloids
 - psychotropic substances
 - narcotics
 - hazardous substances
- (v). Effective floor space of the National Quality Control Laboratory is 6000 m² (4000 m² are to be added).

3. FUNCTIONAL CAPACITIES OF THE REGIONAL QUALITY CONTROL LABORATORY

- (i). Able to conduct chemical, physical, physicochemical, pharmacognostic, biopharmaceutical (in vitro test), microbiological (antibacterial activity; pollution; sterility); toxicity; pyrogenicity tests and evaluation of products.
- (ii). Able to carry out testing and evaluation of samples submitted by the provincial laboratory;
- (iii). Able to test and evaluate yearly
- 1500 samples of drugs
 - 1500 samples of food
 - 1000 samples of cosmetics and medical devices
 - 600 samples of traditional drugs
 - 400 samples of narcotics and hazardous substances

- (iv). Effective floor space of the Regional Quality Control Laboratory will be extended to approximately 1200 m².
- (v). Able to provide guidance and training for provincial quality control laboratory personnel at least once a year in a specified field of quality control.

4. FUNCTIONAL CAPACITIES OF THE PROVINCIAL QUALITY CONTROL LABORATORY

- (i). Able to test and evaluate yearly
- 600 samples of drugs
 - 600 samples of food
 - 400 samples of cosmetics and medical devices
 - 400 samples of traditional drugs
 - 100 samples of narcotics and hazardous substances
- (ii). Able to carry out the chemical, physical, physicochemical, pharmacognosy and microbiological testing and evaluation of products (potency and contamination).
- (iii). Extension of effective floor space to attain approximately 600 m².

5. EQUIPMENTS AND APPARATUS FOR PYROGEN TEST

Digital data logger	30 points	1
Thermistor sensor	0,01 digit	30
Rabbit fixing boxes with stand	for 6 rabbits	5
Electronic balance	min 10 g - max 6 kg	1
Electric oven	up to 260 ^o C	1
Ultrasonic glassware washer		1
One side experimental table for digital data logger		1
Experimental table with castor		2
Syringe container		4
Syringe box for sterilization		5
Climate recorder		1
Shelves for rabbit cages		
Rabbit cages		
Feeding container and drinking water bottle		

R/O system for high quality water	1
Deionizing resin, charcoal cartridge and microfilter	1
Animal feed fabrication system	1
Incinerator with deodorizing system	1
Sewage disposal facility	1
Air conditioner for animal room	2
(cf. BOD rabbit faeces 25000 ppm, rabbit urine 5000 ppm)	
Truck equipped air conditioner for cages	1

6. ROOMS AND FACILITIES FOR PYROGEN TEST

1. Rabbit room (150 rabbit cages)
 - area : 12 x 8 m
 - climate : temperature $23 \pm 2^{\circ}\text{C}$, humidity $50 \pm 5\%$
 - light : 150 - 300 lux (40 - 85 cm high from floor) light time control
 - ventilation: 12 - 15 times/hour; 100% fresh air
 - sound and vibration : 40 - 50 phon. (without animal)
2. Body temperature measuring room
 - area : 4 m x 8 m
 - all conditions are just the same as rabbit room except light control
3. Experimental room
 - area : 5 m x 8 m
 - all conditions are just the same as body temperature measuring room
4. Laboratory
 - area : 5 m x 8 m
 - all conditions are just the same as experimental room except air conditioning common air conditioning.
5. Rabbit breeding room (150 rabbit cages)
 - area : 12 m x 8 m
 - all conditions are just the same as rabbit room

6. Store room for samples
area : 4 m x 8 m with common air conditioner
7. Washing area and sterilizing room
area : 10 m x 15 m
with common air conditioner
pool, automatic cage washer, autoclave
8. Sterilized cage store room
area : 4 m x 4 m
9. Store room for spare Cage
area : 4 m x 8 m
10. Diet storage room
area : 4 x 4 m
room temperature controlled about 22°C
11. Rest room
area : 4 x 8 m
with common air conditioning
12. Machine room

CENTRAL FOOD AND DRUG CONTROL LABORATORY
DIRECTORATE GENERAL OF FOOD AND DRUG CONTROL
MINISTRY OF HEALTH

1. ORGANIZATION

Central Laboratory consist of 5 Laboratories ,and each Laboratory divided into 4 section as follows:

a. DRUG CONTROL LABORATORY

Section : 1. Physico Chemistry
2. Microbiology
3. Pharmacology
4. Biopharmacy

b. FOOD CONTROL LABORATORY

Section : 1. Physico Chemistry
2. Microbiology
3. Toxicology
4. Nutrition

c. COSMETICS AND MEDICAL DEVICES LABORATORY

Section : 1. CHEMISTRY
2. Microbiology
3. Toxicology
4. Physic

d. NARCOTICS AND DANGEROUS SUBSTANCES CONTROL LABORATORY

Section : 1. Narcotics
2. Psychotropics
3. Dangerous Sustances
4. Forensic

e. TRADITIONAL DRUG CONTROL LABORATORY.

- Section : 1. Physico Chemistry
2. Pharmacognosy
3. Toxicology
4. Galenics

2. FUNCTIONS.

- a. As Top Referral(National) Laboratory for quality control of drug, food and Cosmetics, and as referral testing body in matter of disputes relating to quality of drug, food and cosmetics
- b. As training Laboratory in advanced technique of drug, food and cosmetics analysis.
- c. Undertaking research and development in method of analysis
- d. Establishing National Reference Substances and Standards
- e. As testing Laboratory in connection with compulsory registration of drug, food and cosmetics

3. SCOPE OF PRODUCTS TO BE TESTED.

a. Drug and vaccines control

- (1). Raw materials
- (2). Supporting materials
- (3). Additives
- (4). Containers and packaging materials
- (5). Finished products(drug)
- oral solid doses form
 - oral liquid doses form
 - dermatologicals
 - parentheral preparation
 - others finished products
- (6). Sera and vaccines
- (7). Biologicals

b. Food and Beverages Control

- (1). Raw materials

(2). Food Additives

(3). Packaging materials

(4). Food Commodities

- Canned food
- Food for Infants and Children
- Milk and milk products
- Fish and fish products
- Meat and meat products
- Fat and fat products
- Cereal and cereal products
- Sugar and sugar products
- Non alcohol beverages
- Alcoholic beverages
- Salt, spices and condiments
- Fruits, vegetables and products
- Others food products

c. Cosmetics and medical devices control

(1). Cosmetics

- Raw materials
- Finished products
- Packaging materials

(2). Household goods

- Raw materials
- Finished products
- Packaging materials

(3). Medical device

- Medical supplies
- Medical Instruments

d. Traditional Drug Control

(1). Simplicia

(2). Additives

(3). Finished Products

- Herbs

- Powders
- Oral solid dosage form (tablets, pills, trochises)
- Liquids, alcoholic and non-alcoholic
- Dermatologicals

4. EXISTING LABORATORY

The existing Central Laboratory was designed mainly as chemical and physico chemical laboratory and located in two floors building with total space of 2000 m². There is not enough space for microbiological testing and no facility for pharmacological examination.

5. PLAN OF LABORATORY DEVELOPMENT

a. Working space and other facilities.

The following laboratories and other facilities need to be developed or established at Central Laboratory:

(1). Pharmacology and toxicology Laboratory	
including animal house	- 1500 m ²
(2). Microbiology laboratory	- 600 m ²
(3). Biopharmacy laboratory	- 100 m ²
(4). Training laboratory	- 300 m ²
(5). Reference Standard laboratory	- 150 m ²
(6). Library	- 100 m ²
(7). Workshop, service and repairment	- 100 m ²
(8). Store room	- 300 m ²
(9). Meeting room	- 100 m ²
(10) Offices	- 100 m ²
(11) Toilet, locker etc.	- 550 m ²

Total space - 4000 m²

b. Laboratory furniture and services

Furniture including fume cupboard suitable for their purpose should be furnished in the laboratories

Laboratory services including piping, wiring, central AC, central vacuum etc should be installed

c. Apparatus & Instrument

The following laboratories should be equipped with appropriate instruments

- (1) Physico Chemistry
- (2) Biopharmacy
- (3) Pharmacology & toxicology (including animal house)
- (4) Microbiology
- (5) Teaching Laboratory
- (6) Reference standard Laboratory

d. Personnel skill

- (1) Central Laboratory must provide a training course program for the personnel from Provincial laboratory .

Every year 2 training programs should be conducted each for 30 participants last for 1 month .

- (2). The Central Laboratory personnel should be sent abroad to get training in certain field of analytical problem, especially in

- Instrumental analysis
- Biopharmaceutic
- Pharmacology & toxicology
- Microbiology
- Sera and vaccine control
- Establishing reference standard

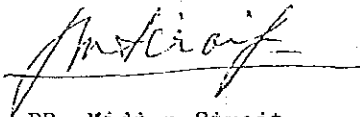
d. Estimated number of samples to be tested.

Drug and Vaccines	:	2300
Food and Beverages	:	2700
Cosmetics and Medical devices	:	1200
Narcotics and dangerous Substances	:	900
Traditional medicine	:	900

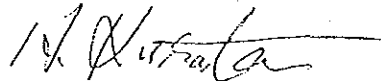
Minutes

The Japanese expert team organized by the Japan International Cooperation Agency and headed by Dr. H. Kurata, Head of Division of Microbiology, National Institute of Hygienic Sciences, visited Central Food and Drugs Laboratory of Indonesia and discussed with the Indonesian authorities concerning detailed program on the possibility of cooperation for the project on the Strengthening of the National Quality Control Laboratory from November 16 to November 27, 1982. Through the discussion and exchange of views between both parties, the following points were recognized as to be noted.

Jakarta, November 27, 1982



DR. Midian Sirait
Director General
Drug and Food Control
Ministry of Health,
Indonesia



Dr. H. Kurata
Head of Expert Team
(Head, Division of Micro-
biology, National Institute
of Hygienic Sciences)

1. Subject to the authorization of the Japanese Government technical cooperation and Grant Aid for the construction of new laboratory building would concentrate mainly on the Central Quality Control Laboratory.

2. For the Strengthening of Central Quality Control Laboratory, construction of new Laboratory Building is essential due to the facilities and space limitation of the existing laboratory.

3. The main priority areas to be strengthened in the Central Quality Control Laboratory particularly includes microbiological, pharmacological and toxicological laboratories and establishing reference standards.

4. Technical Cooperation to be extended from the Government of Japan to this project includes dispatch of Japanese experts, provision of machinery and equipment, and training of Indonesian personnel in Japan.

5. Among the three types of the cooperation as mentioned above, the training of Indonesian personnel is extremely important to both parties.

6. Technical cooperation could start on the 1st of April, 1983 for the period of three years, and for this purpose record of discussion should be set up under negotiation of the both Governments by the end of February, 1983.

7. To make final record of discussion for the technical cooperation, the preliminary draft R/D (see Annex 1) could be utilized as a basic reference.

8. As for the plan of new building, Indonesian side has the following idea.

- (1) Construction site will be in just between the present central laboratory and main administration

- office and just east side of water tower (see Annex 2)
- (2) Building is three stories high and total area is 4,000 m².
Layout of the building is shown as Annex 3.
 - (3) New building will be used mainly for microbiological, pharmacological and toxicological examination, establishing of reference substances and Animal House and breeding.
 - (4) All the additional running cost as well as cost for increase of the number of personnel should be taken care by the Indonesian side.

In addition to these items pointed out above, the followings were confirmed as for National Health development programme.

Five top priority programme areas in Ministry of Health in National Development Programme are :

- (1) Health Service
- (2) Manpower Development
- (3) Policies and Management of Drug and Food
- (4) Environmental Health and Nutrition and
- (5) Management of Health Law.

And as for Policies and Management of Drugs and Food, there are three programmes that is to say, (1) Formulation and distribution of essential drugs, (2) local production of raw materials and (3) Strengthening of quality control of drugs and food. Out of above mentioned three programmes, No. (3) Policies and Management of Drugs and Food is with highest priority to Ministry of Health.

THE PRILIMINARY DRAFT ON THE RECORD OF
DISCUSSIONS BETWEEN THE JAPANESE IMPLEMENTATION
SURVEY TEAM AND THE AUTHORITIES CONCERNED OF
THE GOVERNMENT OF THE REPUBLIC OF INDONESIA
ON THE JAPANESE TECHNICAL COOPERATION FOR
THE PROJECT ON THE STRENGTHENING OF THE NATIONAL
QUALITY CONTROL LABORATORY

The Japanese Implementation Survey Team (hereinafter referred to as the Team) organized by the Japan International Cooperation Agency (hereinafter referred to as JICA), and headed by (

, visited the Republic of Indonesia from , 1983 for the purpose of working out the details of the technical cooperation program concerning the Strengthening of the National Quality Control Laboratory in the Republic of Indonesia.

During its stay in the Republic of Indonesia, the Team exchanged views and had a series of discussions with the Indonesian authorities concerned in respect of the desirable measures to be taken by both Governments for the successful implementation of the above-mentioned project.

As a result of the discussions, the Team and the Indonesian authorities concerned agreed to recommend to their respective Government the matters referred to in the document attached hereto.

Jakarta,

DR. Midian Sirait
Director General,
Drug and Food Control
Ministry of Health,
Indonesia

Head of Japanese
Implementation Survey
Team

THE ATTACHED DOCUMENT

I. COOPERATION BETWEEN BOTH GOVERNMENTS

1. The Government of Japan and the Government of the Republic of Indonesia will cooperate with each other in implementing the Project on the Strengthening of the National Quality Control Laboratory (hereinafter referred to as the Project) for the purpose of the promotion of public welfare in the Republic of Indonesia.

2. The Project will be implemented in accordance with the Master Plan which is given in Annex 1.

II. DISPATCH OF JAPANESE EXPERTS

1. In accordance with the laws and regulations in force in Japan, the Government of Japan will take necessary measures through JICA to provide, at its own expense, services of the Japanese experts as listed in Annex II through the normal procedures under the Technical Cooperation Scheme of Japan.

2. The Japanese experts referred to in 1. above and their families will be granted in the Republic of Indonesia the privileges, exemptions and benefits as listed in Annex III and will be granted privileges, exemptions and benefits no less favourable than those granted to experts of third countries or international organizations performing similar missions.

III. PROVISION OF MACHINERY AND EQUIPMENT

1. In accordance with the laws and regulations in force in Japan, the Government of Japan will take necessary measures through JICA to provide, at its own expense, such machinery, equipment and other materials necessary for the implementation of the Project as listed in Annex IV, through the normal procedures under the Technical Cooperation Scheme of Japan.

2. The articles referred to in 1. above will become the property of the Government of the Republic of Indonesia upon being delivered c.i.f. to the Indonesian authorities concerned at the ports and/or airports of disembarkation and will be utilized exclusively for the implementation of the Project in consultation with the Japanese experts referred to in Annex II.

IV. TRAINING OF INDONESIAN PERSONNEL IN JAPAN

1. In accordance with the laws and regulations in force in Japan, the Government of Japan will take necessary measures through JICA to receive, at its own expense, the Indonesian personnel connected with the Project for technical training in Japan, as listed in Annex V, through the normal procedures under the Technical Cooperation Scheme of Japan.

2. The Government of the Republic of Indonesia will take necessary measures to ensure that the knowledge and experience acquired by the Indonesian personnel from technical training in Japan will be utilized effectively for the implementation of the Project.

V. MEASURES TO BE TAKEN BY THE GOVERNMENT OF THE REPUBLIC OF INDONESIA

1. In accordance with the laws and regulations in force in the Republic of Indonesia, the Government of the Republic of Indonesia will take necessary measures to provide, at its own expense :

- (1) Services of the Indonesian counterpart personnel and administrative personnel as listed in Annex VI
- (2) Offices and other incidental facilities in the Project area
- (3) Supply or replacement of machinery, equipment, instruments, vehicles, tools, spare parts and any other materials necessary for the implementation of the Project other than those provided through JICA under III above
- (4) Transportation facilities and travel allowance for Japanese experts for the official travel within the Republic of Indonesia
- (5) Suitably furnished accommodations for the Japanese experts and their families

2. In accordance with the laws and regulations in force in the Republic of Indonesia, the Government of the Republic of Indonesia will take necessary measures to meet

- (1) Expenses necessary for the transportation within the Republic of Indonesia of the articles referred to in III above as well as for the installation, operation and maintenance thereof
- (2) Custom duties, internal taxes and any other charges imposed in the Republic of Indonesia on the articles referred to in III above
- (3) All running expenses necessary for the implementation of the Project.

VI. ADMINISTRATION OF THE PROJECT

1. The Japanese experts will give necessary technical guidance and advice to Indonesian staff associated with the Project pertaining to the implementation of the Project, and Indonesian authorities concerned will be responsible for the administrative and managerial matters pertaining to the Project.

2. For the successful implementation of the Project, the Joint Committee will be established with the members as listed in Annex VII.

The Committee will meet at regular intervals.

The functions of the Committee are as follows :

- (1) To formulate plans for this Project;
- (2) To review the Project budget, fellowship and equipment requests;
- (3) To advise to the Indonesian authorities concerned about the implementation of the Project at all stages and at all levels.

VII. CLAIMS AGAINST JAPANESE EXPERTS

The Government of the Republic of Indonesia undertakes to bear claims, if any arises, against the Japanese experts engaged in the Project resulting from, occurring in the course of, or otherwise connected with the discharge of their official functions in the Republic of Indonesia, except for those arising from the willful misconduct or gross negligence of the Japanese experts.

VIII. MUTUAL CONSULTATION

There will be mutual consultation between the two Governments on any major issues arising from, or in connection with this Attached Document.

IX. TERM OF COOPERATION

The duration of the technical cooperation for the Project under this Attached Document will three years for the time being from April 1st, 1983. During which time the two Government will have mutual consultation regarding further cooperation.

ANNEX I MASTER PLAN

The Government of Japan will cooperate with the Republic of Indonesia in carrying out the Project on the Strengthening of the National Quality Control Laboratory through dispatch of Japanese experts, acceptance of Indonesian personnel for technical training in Japan and provision of equipment.

The Project is intended :

- (1) to Strengthening a system of laboratory services,
- (2) to strengthen the function of drug and food examination, and
- (3) to Strengthen the quality of drug and food

by conducting

- microbiological examination (drug, food)
- pharmacology and toxicology (drug)

and

by establishing

- reference standards (drug)

for drugs and color materials

ANNEX II JAPANESE EXPERTS

1. Expert in microbiological examination of drugs and food.
2. Expert in pharmacology and toxicology of drugs.
3. Expert in reference standards
4. Expert in other related fields as necessary to mutually agreed upon.

ANNEX III

PRIVILEGES, EXEMPTIONS
AND BENEFITS

1. Exemptions from income tax and charges of any kind imposed on or in connection with the living allowances remitted from abroad.
2. Exemptions from import and export duties and any other charges in respect of personal and household effects, including one motor vehicle per-family, which may be brought into the Republic of Indonesia from abroad.
3. Free medical service and facilities to the Japanese experts and their families.

ANNEX IV

PROVISION OF MACHINERY
AND EQUIPMENT

1. Equipment for microbiological examination of drugs and food such as multiple-usage microscope, digital colony counter, Air sampler and others.
2. Equipment for pharmacological and toxicological examination of drugs and food such as digital data logger with thermister sensor, animal cages and shelves, animal diet fabricator and others.
3. Equipment for reference standards such as high pressure liquid chromatograph, infrared spectrophotometer, high speed TLC scanner and others.
4. Equipment for other related fields of the drug quality control as necessary to be mutually agreed upon.
5. Vehicles.

ANNEX VII

COMPOSITION OF THE JOINT
COMMITTEE

Japanese side :

Japanese experts
(Representative (s) from the Embassy of Japan in
Indonesia will be able to attend this Committee as
observer (s)).

Indonesian side :

Dr.
Director of Central Food and Drugs Laboratory

Dr. M. Sihombing
Drugs Directorate
Ministry of Health

Dr. M. Sirait
Director General of Food and Drugs Control
Ministry of Health

ANNEX V

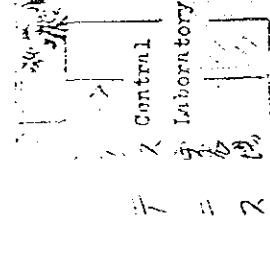
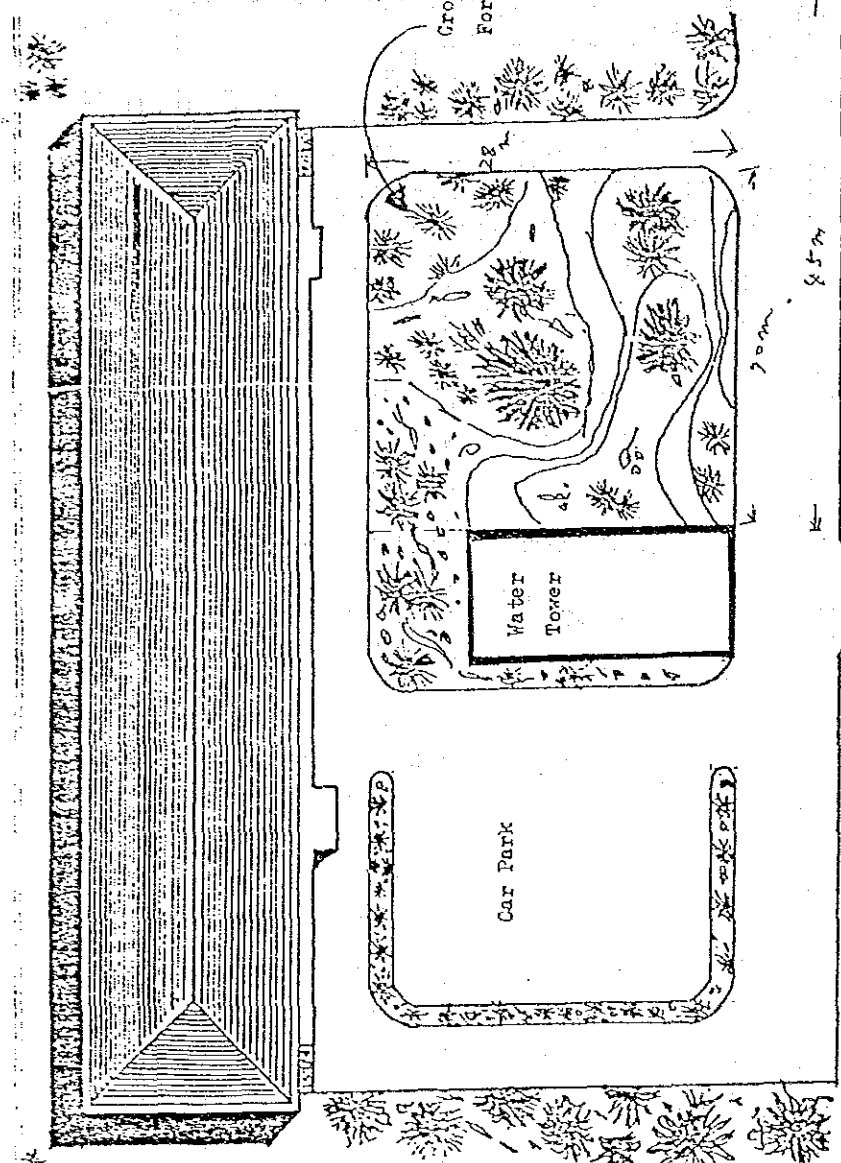
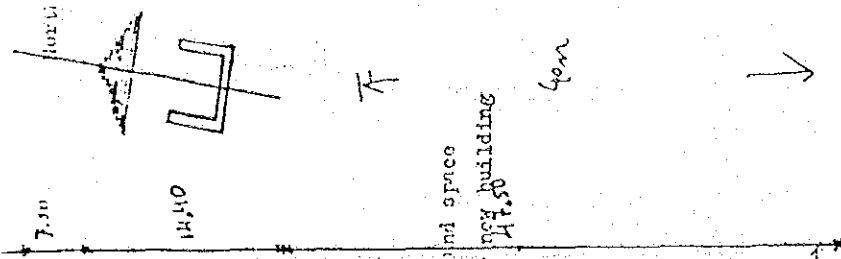
TRAINING IN JAPAN

1. Personnel in microbiological examination of drugs and food.
2. Personnel in pharmacology and toxicology of drugs.
3. Personnel in reference standards
4. Personnel in other related fields as necessary to be mutually agreed upon.

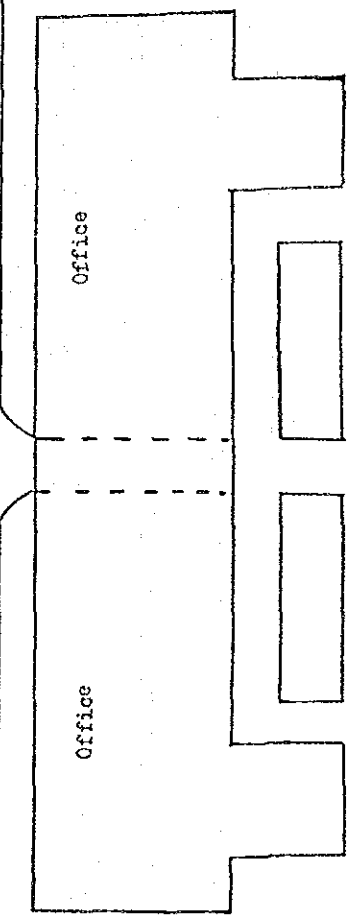
ANNEX VI

COUNTERPART PERSONNEL AND
ADMINISTRATIVE PERSONNEL

1. Counterpart personnel in microbiological examination of drugs and food.
2. Counterpart personnel in pharmacology and toxicology.
3. Counterpart personnel in reference standards.
4. Counterpart personnel in other related fields as necessary to be mutually agreed upon.
5. Clerical and service employees.



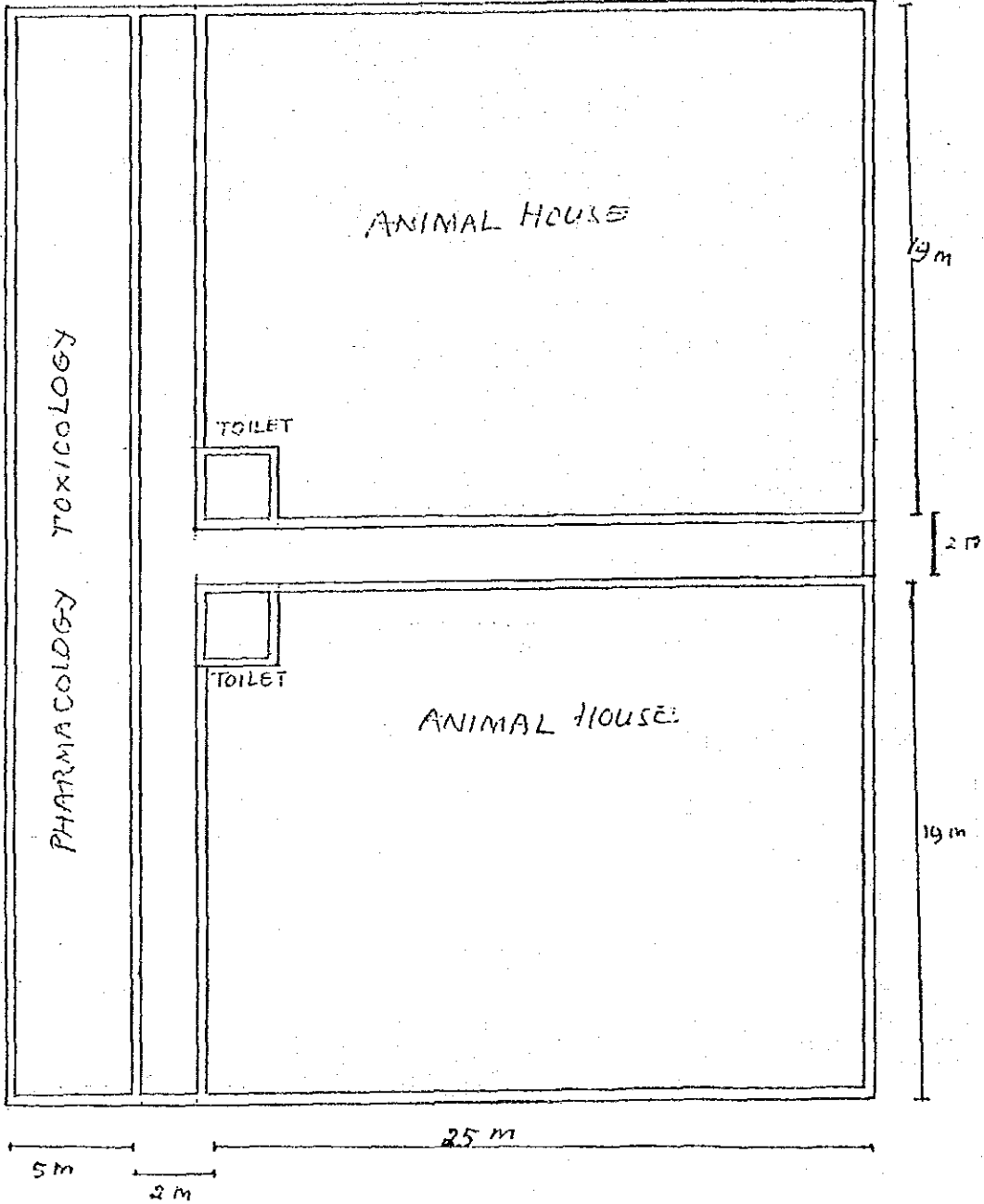
東京利師林塾
教育研究所



Annex 3

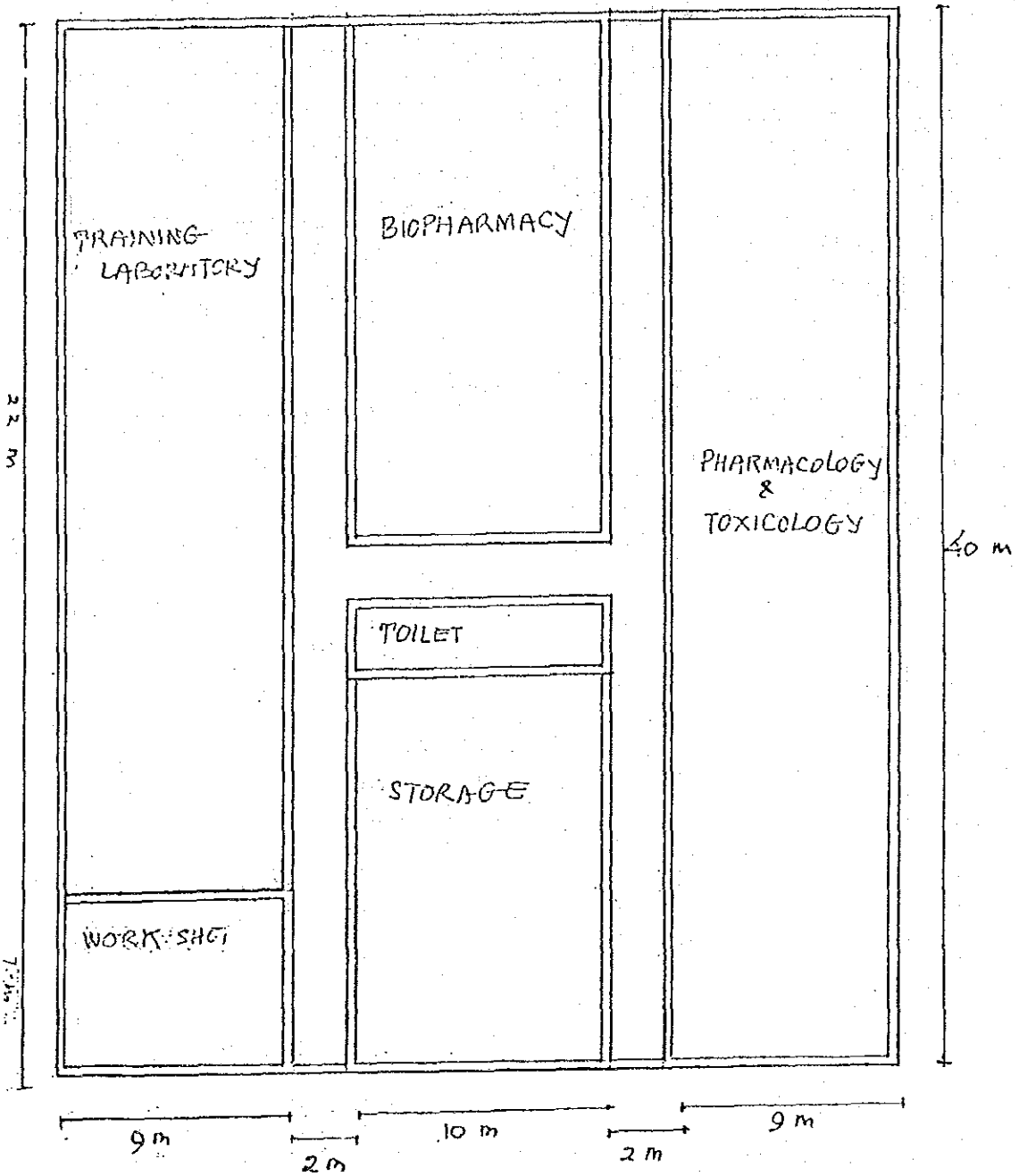
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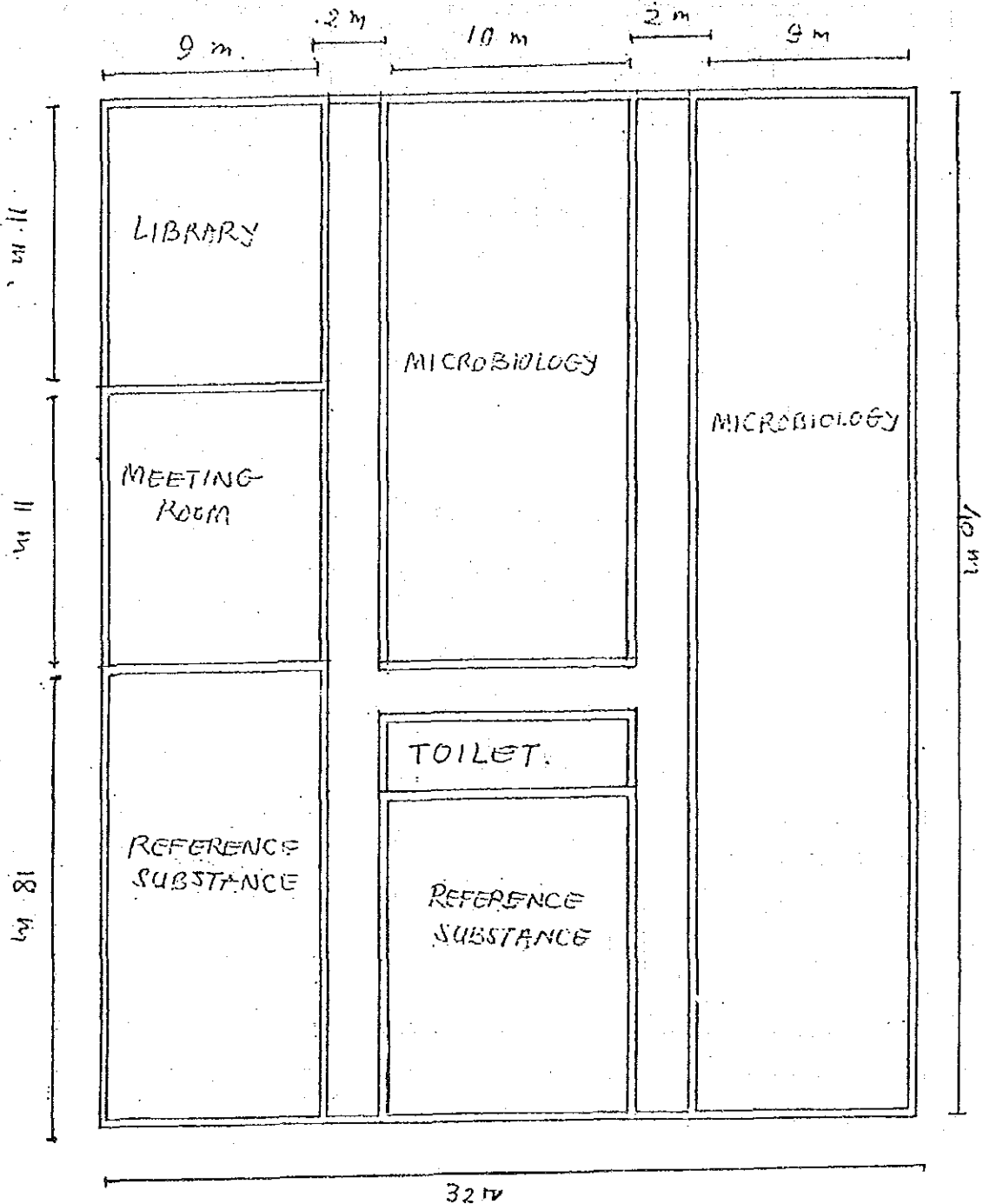
2nd floor

SCALE = 1 : 200



SCALE = 1:200

3rd floor



List of participants

Indonesian side :

- | | |
|----------------------------|---|
| (1) Dr. M. Sirait | D.G. of Food and Drugs Control
Ministry of Health |
| (2) Drs.M.P. Sihombing | Drugs Directorate,
Ministry of Health |
| (3) Drs. Sumitro | Acting Director of Central
Food and Drugs Laboratory |
| (4) Dr. J. Wattimena | Consultant from ITB |
| (5) Drs. David Sumantri | Central Food and Drugs Laboratory |
| (6) Drs. Masna Supratna | ' ' |
| (7) Drs. Rivai Muhibat | ' ' |
| (8) Ir. Tien Gartina | ' ' |
| (9) Dra. Aminah Abdulsalam | ' ' |
| (10) Dra. Syamsimar | ' ' |

Japanese side :

- | | |
|---------------------|---|
| (1) Dr. H. Kurata | Director of National, Institute of
Hygienic Sciences |
| (2) Dr. T. Kawamura | Ditto |
| (3) Dr. A. Takanaka | ditto |
| (4) Mr. M. Abe | Ministry of Health |

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I N D U S T R I F A R M A S I**D.K.I. JAKARTA :**

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| 2. ABDI PT | Jln. Percetakan Negara V, P.O. Box 17/Jtg Tlp. 881794 |
| 3. ARCO INDONESIA PT | Jln. Raya Jakarta Bogor Km. 32, Cimanggis P.O. Box 2304/Jkt Tlp. 870548 (Pab)
Jln. Arjuna No. 28 Kav. 11 Tomang Barat Tlp. 593573 - 593672 (Ktr) |
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| 5. ARTOPHARMA PT | Jln. |
| 6. BINTANG TOEDJOE PT | Jln. Jend. A. Yani No. 63 (Cempaka Putih) P.O. Box 172/Jkt Tlp. 341649 - 360709 - 361764 - 363707 |
| 7. BRISTOL-MYERS INDONESIA PT | Jln. Raya Jakarta Bogor Km. 51,5 Ciluar Bogor Tlp. 642 (Pab)
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Jln. Cikini Raya No. 97 P.O. Box 3098 Tlp. 346733/3 - 347817 (Ktr) |
| 9. BISON PT | Jln. Raya Mangga Besar No. 18.A Tlp. 278099 (Pab)
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| 10. BROMO PHARMACEUTICAL INDUSTRIES PT (BROPHARIN) | Jln. Kartini VIII No. 5 Tlp. 273063 |
| 11. BUNGA PUTIH PHARMA PT | Jln. Melawan No. 69 (P. Jayakarta) |
| 12. CORSA INDUSTRIES LTD PT | Jln. Letjen M.T. Haryono Kav. 10 Tlp. 884171 (Pab)
Jln. K. Satsuit Tubun II C/30 Tlp. 348343 (Ktr) |
| 13. CIBA-GEIGY PHARMA INDONESIA PT | Jln. Raya Jakarta Bogor Km. 27,3 Tlp. 870411 - 870413 - 870543 (Pab)
Jln. Letjen M.T. Haryono 58 (e Five Pillars Office Park) (Ktr)
Pancoran Jakarta Selatan P.O. Box 259 Tlp. 777847 - 777851 Telex: 47110 |

14. **DUPA PT** Jln. Gillitan Rawajati Kalibata Tlp. 883982 (Pab)
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71. SQUIBB INDONESIA PT
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278687 - 270006 (Ktr)

82. WARNER-LAMBERT PARKE-DAVIS INDONESIA PT
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 Jln. Jend. Sudirman No. 2 Arthaloka Building, 9th Floor Tlp. 583442 - 583443 (direct) 583281-5 583321-5 Ext. 286
83. WYETH LABORATORIES INDONESIA PT
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P.T. Merapi Utama Farma
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1057
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7. **GANDHA NV** Jln. Merdeka No. 42
8. **HIMAJAYA RAYA PT** Jln. Raya Ujungberung No. 113--114 Tlp.
40--41 U.b.
9. **HOLI FARMA (NDAHOLI) PT** Jln. Leuwigajah Cimindi No. 100, Cimindi

- | | |
|---|--|
| 10. INPHA (INDONESIA PHARMASI) PT | Jln. Gempol Wetan No. 207 |
| 11. KERTADJAGA PT | Jln. Jend. A. Yani No. 240 |
| 12. KIMIA FARMA PT | Jln. Pajajaran P.O. Box 12 Tlp. 51041-4 |
| 13. KIMIA FARMA PT (Terbatas) | Jln. Braga No. 6 |
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| 15. KARUMBI PT | Jln. Cihampelas No. 160 |
| 16. LUKAS JAYA PT | Jln. Cibangkong No. 83.A Tlp. 71293 |
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| 33. TECACIN PT | Jln. Halteu Selatan No. 71 & Veteran
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| 34. RINDU SEHAT PT | Jln. Dr. Setia Budi No. 270 |
| 35. SIDOLA PT | Jln. Purnawarman No. 34 |
| 36. OTTO PHARMACEUTICAL IND. PT | Jln. Lembang No. 38 |
| 37. WIWACO LTD PT | Jln. Dr. Setia Budi No. 25 |

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- | | |
|---------------------------------|---------------------------------|
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| 2. SEKAR MIRAH PT | Jln. Jend. M.T. Haryono No. 800 |
| 3. CIUBROS FARMA PT | Jln. Raden Patah No. 141 |
| 4. DEGEPHARM PT | Jln. Raden Saleh No. 106-108 |
| 5. EMPECO PT | Jln. Jend. M.T. Haryono No. 872 |
| 6. ERLIMPEX PT | Jln. Dr. Setia Budi No. 130 |
| 7. ERLANGGA EDI LABORATORIES PT | Jln. Eriangga No. 11 |
| 8. GRATIA PT | Jln. Gajah Mada No. 101 |

- | | |
|---|--|
| 9. GAMAFARMA PT | Jln. Dr. Cipto No. 200 |
| 10. INDUSTRI DJAMU & PHARMASI
CAP "DJAGO" PT | Jln. Setia Budi No. 179 |
| 11. INDUSTRI JAMU & FARMASI SIDO
MUNCUL PT | Jln. Mlaten Trenggulan No. 106--108 |
| 12. IRECO FARMA PT | Jln. Majapahit No. 73 |
| 13. INTRASAL PT | Jln. Simongan No. 96 |
| 14. LIBRACAL PT | Jln. Bratajaya Timur No. 18 |
| 15. META RATNA FARMA PT | Jln. Mataram No. 815 |
| 16. NYONYA MENEER PT | Jln. Raden Patah No. 195--197 |
| 17. PHARCO PT | Jln. Petek No. 23--23A |
| 18. PHAPROS PT | Jln. Simongan No. 131 P.O. Box 234
Tlp. 2558 SM |
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22878 |
| 20. UNKRES KARYA PHARMACEUTICAL
(Sapta Usaha) PT | |
| 21. VERAP PT | Jln. Pemuda No. 149 |
| 22. ZENITH PHARMACEUTICAL PT | Jln. Wotgandul Barat No. 16 |

TEGAL :

- | | |
|------------------------|----------------------|
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|------------------------|----------------------|

KLATEN :

- | | |
|--------------------|---------------------|
| 1. MERBABU FALA PT | Jln. Merbabu No. 14 |
|--------------------|---------------------|

WONOGIRI :

- | | |
|---|-----------------------|
| 1. PERUSAHAAN JAMU CAP "AIR
MANCUR" PT | Jln. Palembang No. 51 |
| 2. DELTOMED PT | Jln. Raya No. 267.B |

SURAKARTA :

- | | |
|--------------------|-------------------------------------|
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| 2. GRAHA FARMA PT | Jln. Gajah Mada No. 148 |
| 3. YAKKUM FARMA PT | Jln. Jend. A. Yani No. 2 |
| 4. TRIBATA PT | Jln. Kemasan No. 28.A |
| 5. KONIMEX PT | Jln. Urip Soemaharjo No. 108--111 |

YOGYAKARTA :

- | | |
|-------------------|-------------------------------------|
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| 2. MIROTA CV | Jln. Jend. A. Yani No. Tlp. 4620 |
| 3. ITA FARMA PT | Jln. Ambarukmo Jln. Solo |
| 4. NOVIMEX PT | Jln. Dongkelan No. 49 Tlp. 2264 |
| 5. CANGKAKALA PT | Jln. Jagalan No. 6.P.A |

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- | | |
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| 4. BERKAT PT | Jln. Kedungsari No. 36 Tlp. 41523 |
| 5. BERNOFARM LABORATORIES PT | Jln. Raya Darmo No. 143 Tlp. 68007 |
| 6. BUSANA UTAMA PT | Jln. Bibis No. 4 |
| 7. CORONET SYNDICATE PHAMACEU-
TICAL | Jln. Bibis No. 14 |
| 8. DASA ESA FARMA PT | Jln. Nginden No. 102 |
| 9. DUPA PT | Jln. Danakarya No. 37-39 Tlp. 21135 |
| 10. FIRST MEDIPHARMA PT | Jln. Kenjeran No. 83 Tlp. 23890 |
| 11. HEROIC PHARMA PT | Jln. Sidodadi IV/40-A Tlp. 279518 |
| 12. INTERBAT PT | Jln. Semarang No. 58 Tlp. 43596 |
| 13. INFARMIND FARMASI INDUSTRI PT | Jln. Pesapen Kali No.4 Tlp. 279755 |
| 14. IRAWAN JAYA AGUNG PT | Jln. Kalimati Tengah No. 4-6 Tlp. 26219 |
| 15. IE DJIEN SAN PT | Jln. Kembang Jepun No. 78 Tlp. 26177 |
| 16. JAMU IBOE JAYA PT | Jln. Ngaglik No.3-5 Tlp. 41479 |
| 17. KALIROTO PT | Jln. Sidorame No. 19 Tlp. 279440 |
| 18. KASA HUSADA PT | Jln. Kalimas Barat No.17-19 Tlp. 26051 |
| 19. KEMBANG JEPUN PT | Jln. Demak Jaya No. 129 Tlp. 270341 |
| 20. MOENTE PT | Jln. Songoyudan No. 53 Tlp. 23489 -
278702 |
| 21. NOVA PHARMACEUTICAL IND. PT | Jln. Walikota Mustadjab No. 37-39 Tlp.
43823 |
| 22. PARI ANOM PT | Jln. Gembong Tebasan No. 18 Tlp. |
| 23. P.I.M. PT | Jln. Rangkah II/51 Tlp. 20785-21332 |
| 24. P.M.H. PT | Jln. Kutai No. 21 |
| 25. RITA CHEMICAL INDUSTRI PT | Jln. Alun-alun Rangkah No. 4-6 Tlp.
26131 - 21766 |
| 26. SANDAI FARMA PT | Jln. Kenjeran No. 401 Tlp. 25397 |
| 27. SUMBER KESEHATAN BARU PT | Jln. Welirang No. 18 Tlp. 41545 |
| 28. SINTEN NYONO PT | Jln. Raya Wonokromo No. 16 Tlp. 46611 |
| 29. SEGER WARAS PT | Jln. Pandegiling No. 314-316 Tlp. 470614 |
| 30. U.S.F.I. PT | Jln. Kapasan No. 8 Tlp. 279224 |
| 31. VITA PT | Jln. Karet No. 80-86 Tlp. 21515 |
| 32. SURABAYA INDAH PERMAI PT | Jln. Jagir Sidomukti Gg. V/49 |

SIDOARJO :

- | | |
|--------------------|---|
| 1. BUSANA UTAMA PT | Jln. Waru Gedangan (Lihat Surabaya No.6) |
| 2. BERNOFARM PT | Jln. Desa Banjar Kemantren, Buduran (Li-
hat Surabaya No. 5) |
| 3. INTERBAT PT | Jln. Desa Buduran, Km. 20 Jalan Raya
Surabaya Sidoarjo (Lihat Surabaya No. 12) |

MADIUN :

1. IDOS PT

Jln. Pahlawan No. 81 Tlp. 2636

PASURUAN :

1. P.I.M. PT

Jln. Candi Wates Prigen (Lihat Surabaya No. 23)

2. MEIJI INDONESIA PHARMACEUTICAL INDUSTRIES PT

Jln. Mojoparon No. 1, Bangil

MALANG :

1. BALATIF PT

Jln. Tenaga No. 5

2. NEON FARMA PT

Jln. Lamongan No. 8 Tlp. 3549

PANDAAN :

1. ESSEX INDONESIA PT

Jln. Raya Pandaan, Pandaan Jatim (Pab)
Cilandak Commercial Estate Jakarta Selatan P.O. Box 62/Kebyb Tlp. 760601 - 760603 Jakarta Telex : 44515 BHUSEK (Ktr)

2. I.C.I. FARMASI INDONESIA PT

Jln. Raya Pandaan, Pandaan Jatim (Pab)
Jln. Gunung Sahari XII/6-7 P.O. Box 2158/Jkt Tlp. 354710 - 340775 Jakarta Pusat (Ktr)

3. OTSUKA INDONESIA PT

Jln. Lawang Tlp. 234-244

4. JOHNSON & JOHNSON INDONESIA PT

Jln. Stadion No. 6 Tlp. 87-94 (Pab)
Jln. Patrice Lumumba No. 20 P.O. Box 3200 Tlp. 357367 Telex : 44298 JANDJI (Ktr)

UJUNG PANDANG :

1. KIMIA FARMA PT

Jln. Jend. A. Yani No. 17

2. TAWON JAYA MAKASSAR PT

Jln. Irian No. 10 Tlp. 7382

PONTIANAK :

1. MEDICAL PONTIANAK PT

Jln. Karel Satsuit Tubun No. 9

MANADO :

1. INDUSTRI FARMASI JEMPOL SPECIAL PT

Jln. Panjaitan No. 57

BANDA ACEH :

1. TENAGA TANI FARMA PT

Jln. Meduati No. 84.A

MEDAN :

1. AROINDO PT

Jln. Pekan Baru No. 4 Tlp. 22395

2. ARIS FARMA PT

Jln. Puri No. 301

3. BINA FARMA PT

Jln. Rachmansyah No. 225.A

4. DEWI TANJUNG PT

Jln. Semarang No. 34 Tlp. 29268

5. GARU PT

Jln. Samosir No. 37 Tlp. 21713

- | | |
|-----------------------------|---|
| 6. KIMIA FARMA PT | Jln. Tanjung Morawa Km. 9 Tlp. 23818 |
| 7. MULIA FARMA PT | Jln. Sambas No. 46 Tlp. |
| 8. MOHAR PT | Jln. Amaliun No. 26.F |
| 9. PHEPARIN RIA PT | Jln. Glugur By Pass No. 68 Tlp. 22871 – 26885 |
| 10. SINABUNG PT | Jln. Surabaya No. 58 Tlp. 25755 |
| 11. SINAR MANJUR PT | Jln. Pekantan Baru No. 10 Tlp. 26693 |
| 12. SUN STAR CHEMICAL | Jln. Sutomo No. 480 Tlp. 24669 |
| 13. UNIVERSAL PT | Jln. P. Brayan Km. 6 No. 347 BB Tlp. 26542 |
| 14. YANTHIE PT | Jln. Sutomo Dalam No. 22 Tlp. 20772 |
| 15. SEJATI PT | Jln. Kampung Baru No. Tlp. 23190 |
| 16. VARSE PHARMACEUTICAL PT | Jln. Jend. Gatot Subroto No. 168 Tlp. 22052 |

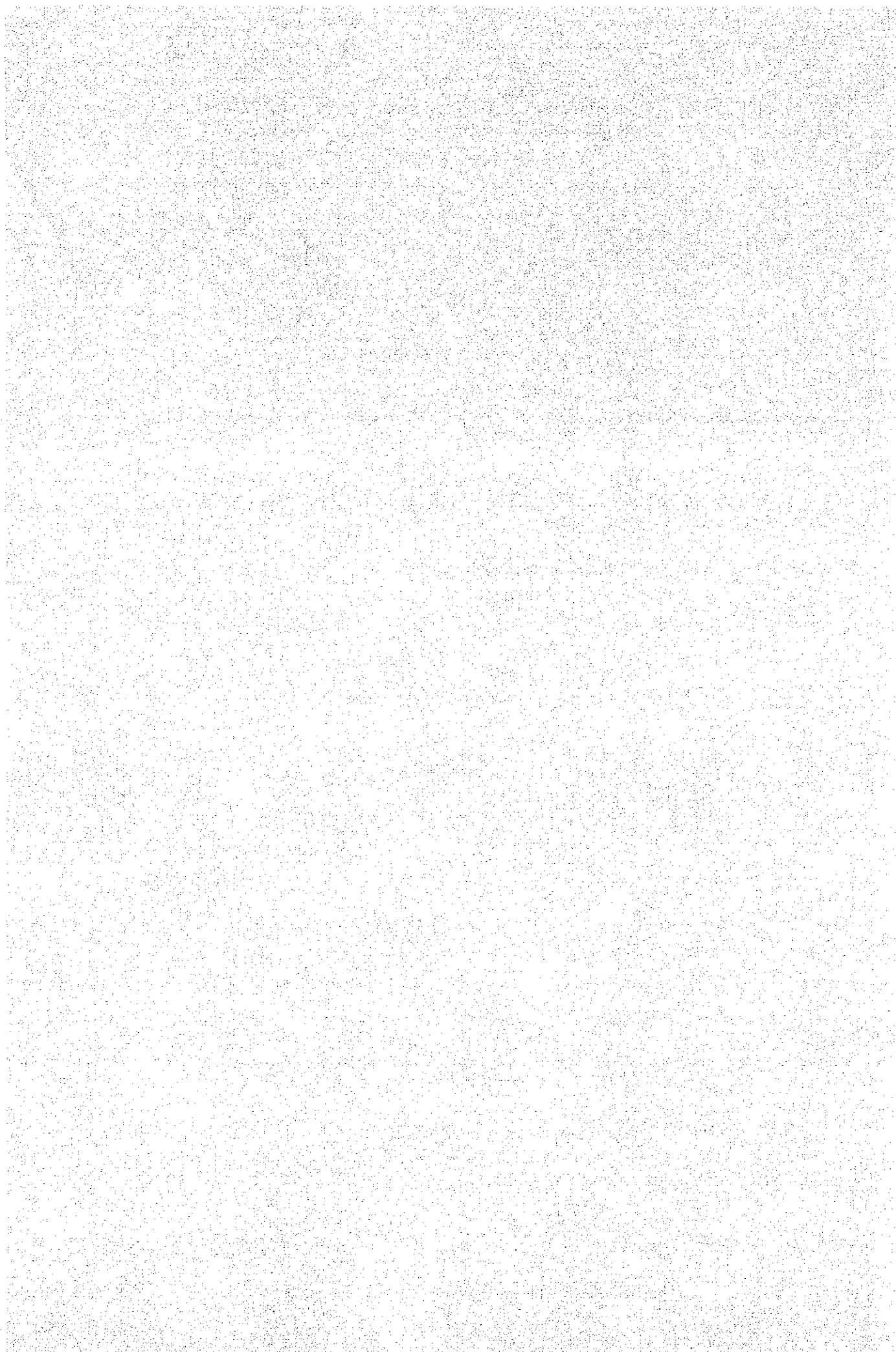
BUKITTINGGI :

- | | |
|------------------------|---------------------------------|
| 1. USAHA BROS UTAMA PT | Jln. Prof. Moh. Yamin SH No. 35 |
|------------------------|---------------------------------|

PALEMBANG :

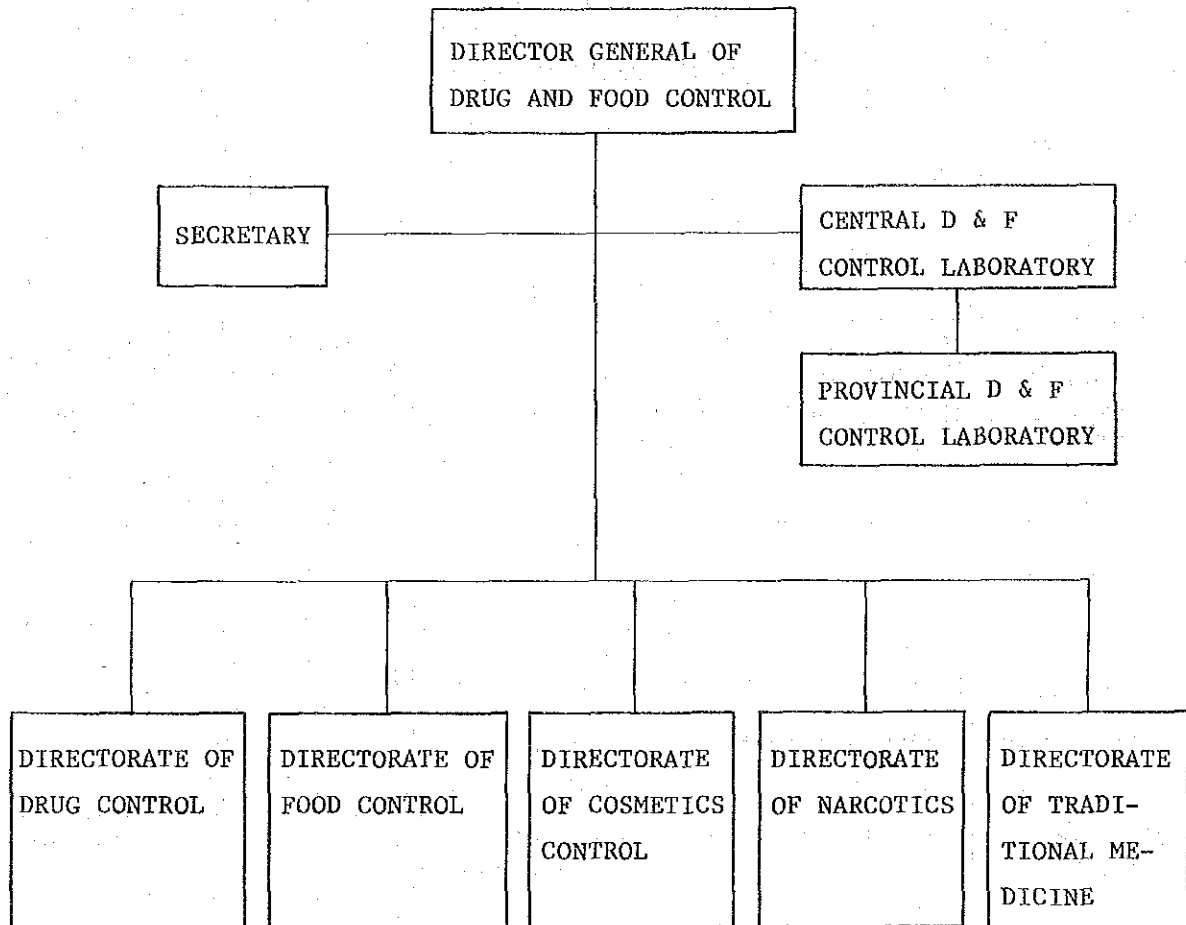
- | | |
|------------------------------|---------------------------------|
| 1. GEMINI NV | Jln. Mahkota No. 603 |
| 2. DEXA MEDICA PT | Jln. Dukuh No. 8 |
| 3. KINOL NV | Jln. Jend. Sudirman No. 269 abc |
| 4. MARUCO FARMA PT | Jln. Jend. Sudirman No. 1053 |
| 5. MASA KARYA SAKTI PT | Jln. Madang, 20 ilir 6824 |
| 6. SOYOSAN PHARMACEUTICAL PT | Jln. Mayor Santoso No. 1707 |

VI. 別 表 (資 料 2)



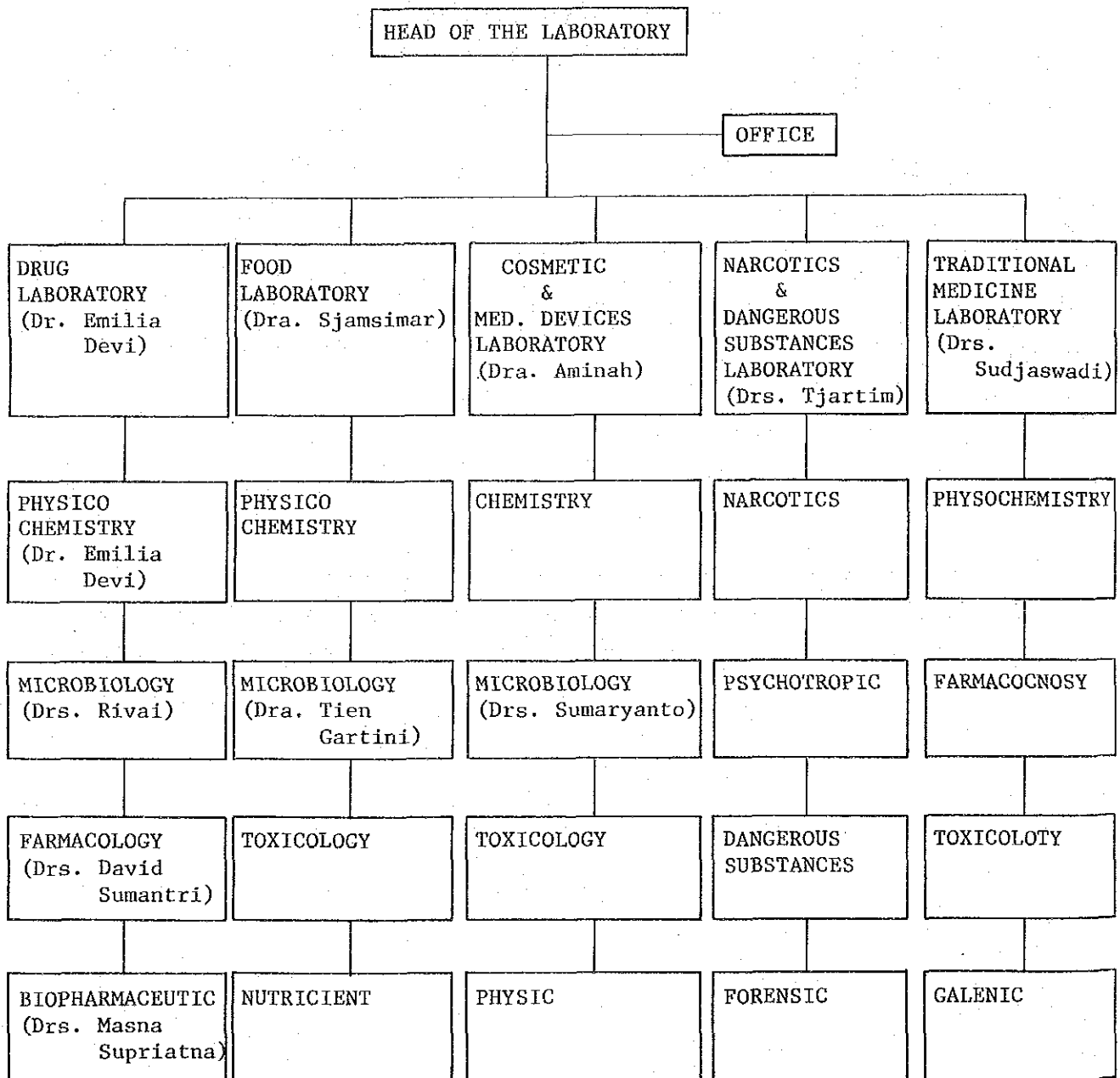
(別表1)

保健省食品・薬品総局機構図



N:Q. N:Q.C.L機構図

CENTRAL DRUG AND FOOD CONTROL LABORATORY



N.Q.C.L. 試験・検査取り扱い数

No.	Description	Present Situation (m ²)	Technical cooperation	New building (m ²)
1	2	3	4	5
<u>I. Space</u>				
	1. Chemistry	560		N.A.
	2. Physical Chemistry	470		N.A.
	3. Biopharmacy	0		190
	4. Pharmacology, Toxicology and Biologics	55		1,560
	5. Microbiology	275 *		550
	6. Training laboratory	0		300
	7. Reference standards	20		150
	8. Library	70 *		100
	9. Store room	150		150
	10. Office room & locker	270		190
	11. Workshop and mechanical plan	0		60
	12. Meeting room	30		100
	13. Toilet, corridor, stairs	100		650
		<u>2,000</u>		<u>4,000</u>
	* borrowed spaces			
<u>II. Activities</u>				
	1. Chemistry	+++	+++	+++
	2. Physico-Chemistry	++	+++	+++
	3. Microbiology	+	++	+++
	4. Biopharmacy	+	++	+++
	5. Pharmacology and Toxicology	None	+	+++

1	2	3	4	5
	6. Biological (sera, vaccen)	None	None	+++
	7. Reference standards	+	++	+++
	8. Training	+	+	+++
	9. Methods and procedures	+	++	+++
<u>III. Estimated number of samples per year</u>				
	1. Drug	1.250	2.000	2.300
	2. Food and beverages	1.250	2.000	2.700
	3. Cosmetics, toiletries and health products	700	1.000	1.200
	4. Narcotics and Hazardous substances	400	500	900
	5. Tradisional medicine	400	500	900
		<u>4.000</u>	<u>6.000</u>	<u>8.000</u>
<u>IV. Number of personnel</u>				
	1. University degree	33	33	60
	2. Technician	<u>44</u>	<u>44</u>	<u>90</u>
		77	77	150
	3. Others	50	50	50

Explanation

Explanation

1. Physico-Chemistry

- ++ : Identification, assay and purity test for single/simple preparation by chromatography, spectrometry and others.
- +++ : Identification, assay and purity test for complex preparation by more sophisticate instruments.

2. Microbiology

- + : a. Sterility testing
b. Antibiotic assay (petridisk plate method)
c. Bacterial count, pathogenic bacteria
d. Phenol coefficient
e. Microbiological examination on drug, cosmetics, medical supplies, sanitary goods, and imported and domestic good.
- ++ : a. As above (+)
b. Enumeration and identification of both aerobic and anaerobic bacteria
c. Antibiotic assay (turbidimetry)
d. Vitamine assay
- +++ : a. As above (++)
b. Supply of strain micro organism standard culture
c. Supply of fungal standard culture
d. Enteropathogenicity and enterotoxigenicity of bacterial isolated from foodstuff
e. Bioproduction of mycotoxins and their micotoxigenicity.

3. Pharmacology

3. Pharmacology

- + : Pyrogen test
- +++ : a. Pyrogen test
 - b. Testing of the toxicity of substance/products
 - c. Testing of the efficacy of new products/traditional medicine :
 - 1) central nervous system
 - 2) autonomous nervous system
 - 3) cardiovascular system
 - 4) respiratory system
 - 5) psychotropic agents
 - 6) blood coagulation
 - 7) anti inflammation
 - d. Testing of the toxicity of drugs :
 - 1) subacute and chronic toxicity
 - 2) testing of teratogenicity of drugs
 - 3) testing of the mutagenicity of drugs
 - 4) testing of the carcinogenicity of drugs
 - 5) testing for allergy and irritation.

4. Biopharmacy

- + : Invitro testing for tablet and capsule preparation
 - 1) hardness testing for tablet
 - 2) disintegration testing for tablet and capsule
 - 3) dissolution testing for tablet and capsule.
- ++ : Invitro testing for tablet, capsule, powder, ointment and liquid preparations.
 - 1) hardness testing
 - 2) disintegration testing, *dissolution testing*
 - 3) absorption simulator testing
 - 4) release rate of active ingredient from dosage form
 - 5) particle size determination
 - 6) rheology of powders
 - 7) stability of active ingredient.

+++ :

- +++ : a. Invitro testing as above (++)
- b. Invivo testing
 - 1) testing of drug bioavailability
 - 2) blood and urinary level determination of active ingredient and metabolites
 - 3) computer simulator of drug pharmacokinetics.

5. Biological (sera, vaccines)

- +++ : Laboratory for the testing of sera and vaccines
 - 1) testing for efficacy
 - 2) testing for allergenic properties
 - 3) testing for toxicity.

6. Reference standard

- + : Chemical test substance
- ++ : a. Chemical test substance
- b. Microbial test substance
- +++ : a. Chemical test substance
- b. Microbial test substance
- c. Biological test substance
- d. Pharmacological test substance

7. T r a i n i n g

- + : 1 x 30 participants per year
- +++ : 2 x 30 participants per year

8. Method and procedures

- + : Simple procedures (Chemical & physico Chemical)
- ++ : More advanced method
- +++ : Chemical, Physico Chemical, Biological methods.

NOCCにおける機器について

(別表4)

PHYSICO CHEMICAL LABORATORY

NO.	Instruments/Apparatus	Existing Number	Demanded Number	Total Number
1.	Gas Chromatograph	3	1	
2.	Atomic Absorption Spectrophotometer	1	1	
3.	Uv - Vis Spectrophotometer	5		
4.	Infra - Red Spectrophotometer	2	1	
5.	Fluorescence Spectrophotometer	1	1	
6.	Karl - Fischer Titrator	2	2	
7.	p H - meter	6	3	
8.	Polarimeter	2	2	
9.	Refractometer	2	2	
10.	Thin Layer Chromatography Apparatus	2	1	
11.	Melting point Determination Apparatus	4	1	
12.	Moister Content Determination Apparatus		2	
13.	Alcohol Content Determination Apparatus		3	
14.	Kjedahl Apparatus	2	2	
15.	S i e v e s	1	3	
16.	Analytical Balance	14	6	
17.	Top Loading Balance	5	5	
18.	Electronic Micro Balance		2	
19.	Microscope	7	3	
20.	Microscope phase contrast		3	
21.	Water bath	9	3	
22.	Constant Temperature Water Bath	4	2	
23.	Muffle Furnace with thermostat		2	
24.	Vacuum Drying Oven	2	2	
25.	Constant Temperature Oven	10	3	
26.	Coolmix Circulator		5	

No.	Instruments / Apparatuses	Existing Number	Demanden Number	Total Number
27.	Refrigator Explosion Proff	-	5	5
28.	Freezer	3	3	6
29.	Centrifuge 5000 RPM	1	3	4
30.	Rotary Evaporator	4	5	9
31.	Oil Bath	-	3	3
32.	Shaker	4	4	8
33.	Blender Explosion Proff, high speed	-	4	4
34.	Clean Bench	-	3	3
35.	Cup Dropper	-	3	3
36.	Fume Hood	-	7	7
37.	Ultrasonic Washer	1	5	6
38.	Sink Unit	-	-	-
39.	Electric Drying Oven	-	-	-
40.	Stop Watch	3	7	10
41.	Timer	12	8	20
42.	Fractional Distillation Apparatus	3	3	6
43.	Extraction Apparatus	2	5	7
44.	Dark Room Kit	-	2	2
45.	Calculator	15	10	25
46.	Calculator Programmer	-	5	5
47.	High Performance Liquid Chromatography (HPLC)	1	2	3
48.	Dehumidifier	5	3	8
49.	Integrator	1	2	3
50.	Diluter Apparatus	1	4	5
51.	Polarograph	1	3	4
52.	Electro Phoresis Apparatus	-	2	2
53.	Glassware washing Machine	-	5	5
54.	Mass Spectrophotometer	-	1	1
55.	N M R	-	1	1
56.	Automatic fraction collector	-	2	2
57.	Grinding mill	-	2	2
58.	Vacuum Pump	2	2	4
59.	Tensile strength testing apparatus for condom surgical suture	-	1	1
60.	Water destillation	-	5	5
61.	Water demineralizer	1	5	6

CENTRAL DRUG AND FOOD CONTROL LABORATORY
MINISTRY OF HEALTH OF THE REPUBLIC OF INDONESIA

INSTRUMENT AND APPARATUS

BIOPHARMACEUTICS LABORATORY.

No.	Instruments/Apparatus	Existing Number	Demanded Number	Total Number
1.	Disintegration Tablet Tester	1	2	1
2.	Dissolution Tablet Tester	1	2	1
3.	Absorption Simulator	1	1	1
4.	Dissolution Simulator	1	2	1
5.	Peristaltic Pump	2	2	1
6.	Programmer for Peristaltic Pump	1	2	1
7.	UV-VIS Spektrofotometer, six beams (single) with printer and recorder	1	1	1
8.	Calculator Programmer	1	2	1
9.	Automatic Diluter Machine	1	2	1
10.	Particle-Size Determination Apparatus	1	1	1
11.	Recorder	1	2	1
12.	Plastic flask for Dissolution Tablet Tester	1	12	1
13.	Air Conditioning 2 pK	1	4	1
14.	Refrigerator	1	2	1
15.	Stabilizer Voltage 5 KVA	1	1	1
16.	Tachometer Electronic	1	1	1
17.	Electronic Micro Balance	1	2	1
18.	pH Meter	1	2	1
19.	Water Determination Apparatus	1	2	1
20.	Ultrasonic Cleaner Bath	1	2	1
21.	Water Demineralisator Apparatus	1	2	1
22.	H.P.L.C.	1	1	1
23.	UV, VIS Spektrofotometer	1	1	1
24.	Constant Temperatur Water Bath	1	2	1
25.	Coolmix Circulator	1	2	1

CENTRAL DRUG & FOOD CONTROL LABORATORY
INSTRUMENT/ APPARATUS/ EQUIPMENT

PHARMACOLOGY & TOXICOLOGY LABORATORY

No	Instrument/Apparatus/Equipment	Existing N.	Demanded N.	Total Number
1	Pyrogen Test Processor	1 set	1 set	2 set
2	Rabbit Fixing Box	8 15 boxes	30 boxes	45 boxes
3	Rabbit Cage	7 cages	53 cages	60 cages
4	Shelves for Rabbit Cages	-	-	-
5	Electronic Balance 1.0-6,660 g	6	1 pc	1 pc
6	Electric Oven, 250°C	1 pcs	1 pc	2 pcs
7	Ultrasonic glassware washer	-	1 pc	1 pc
8	Syringe container	-	4 pcs	4 pcs
9	Syringes box for sterilization	-	5 pcs	5 pcs
10	One side exp. table for digital Data logger	-	1 pc	1 pc
11	Experimental Table with caster	-	2 pcs	2 pcs
12	Air Conditioners for Animal room & measuring room	-	2 pcs	2 pcs
13	Air Conditioning Car/Minibus for carrying rabbits	-	1 pc	1 pc
14	Climate Recorder	-	1 pc	1 pc
15	R/O system for high quality water, deionizing resin & char- coal cartridge & microfilter	-	1 set	1 set
16	Animal feed fabrication system	-	1 set	1 set
17	Incinerator with deodorizing system	-	1 set	1 set
18	Sewage disposal facility	-	1 set	1 set

CENTRAL DRUG AND FOOD CONTROL LABORATORY
MINISTRY OF HEALTH OF THE REPUBLIC OF INDONESIA

INSTRUMENT AND APPARATUS

Microbiology Section :

No.	Instrument / Apparatus	Existing number	Demanded number	Total.
1.	Anaerobic jar	3	4	7
2.	Anaerobic cabinet	-	2	2
3.	Anaerobic incubator	-	3	3
4.	Analytical Balance	2	2	4
5.	Antibiotic zone reader	2	2	4
6.	Autoclave	2	2	4
7.	Bacteriifilter	1 units	2 units	3 units.
8.	Biophoto recorder	-	1	1
9.	Blender	2	2	4
10.	Centrifuge	2	2	4
11.	Calculator Programmer	-	1	1
12.	Colony counter	3	1	4
13.	Dispenser (automatic pipetter)	1	1	2
14.	Drying Oven	4	4	8
15.	Freezer (Deep Freezer)	2	1	3
16.	Hot Plate	4	3	7
17.	Incubator	6	4	10
18.	Laminar air flow (Bench)	2	2	4
19.	Microscope	3	3	6
20.	Pipet washer	2	3	5
21.	Repipet	1	1	2
22.	Refrigerator	6	4	10
23.	Shaking waterbath	1	2	3
24.	Spectronic 20.	1	-	1
25.	Waterbath	1	2	3
26.	Top loading balance	3	3	6
27.	Vacuum drying oven	-	1	1
28.	Stomacher	-	2	2
29.	Incubator with refrigerator system.	-	2	2
30.	Absolutely sterilitiam room	-	2	2
31.	U V Biophotometer	-	1	1
32.	Vacuum liophylisation	-	1	1
33.	New closed system for sterilisation.	-	2	2
34.	Ultra centrifuge 6.000.000 rpm	-	1	1
35.	Ultra centrifuge 1.500.000 rpm	-	1	1
36.	Automatic washing machine	-	2	2

No.	Instrument /Apparatus	Existing number	Demanded number	Total
(37)	Incubator with refrigerator system.	0	1	1
(38)	Air sampler machine	0	1	1
(39)	Automatically autoclave	0	1	1
(40)	Gas Pack			
(41)	Super ultra microscop	0	1	1
(42)	Ultra electric microscop	0	1	1
(43)	Ultra electric microscop (canning type)	0	1	1
(44)	Digital colony counter	0	1	1
(45)	Automatic balance	0	1	1

CENTRAL DRUG AND FOOD CONTROL LABORATORY
MINISTRY OF HEALTH OF THE REPUBLIC OF INDONESIA

INSTRUMENTS AND APPARATUS

ESTABLISHMENT REFERENCE SUBSTANCES.

No.	Instruments/Apparatus	Existing Number	Demanded Number	Total
1.	High Performance Liquid Chromatography (HPLC)	-	1	1
2.	Infra red Spectrophotometer	-	1	1
3.	Thin Layer Chromatography Scanner	-	1	1
4.	Moisture Content Determination Apparatus, Micro Analysis	-	1	1
5.	Karl Fischer Water Determination Apparatus	-	1	1
6.	Electronic Micro Balance	-	2	1
7.	Thermo - Hygrometer	-	1	1
8.	Glove Box (Climate Chamber)	-	1	1
9.	Calculator Programmeter	-	1	1
10.	Refrigator	-	4	1
11.	Freezer	1	2	1
12.	Dry Ice Machine	-	1	1
13.	Vacuum Drying Cooler	-	1	1
14.	Integrator	-	1	1
15.	Timer	-	5	1
16.	Constant Temperature Oven	-	4	1
17.	Constant Temperature Water Bath	-	2	1
18.	Coolmix Circulator	-	2	1
19.	Shaker	-	2	1
20.	Dehumidifier	-	4	1
21.	Muffle Furnace	-	1	1
22.	Storage Room for Reference Substances	-	1	1

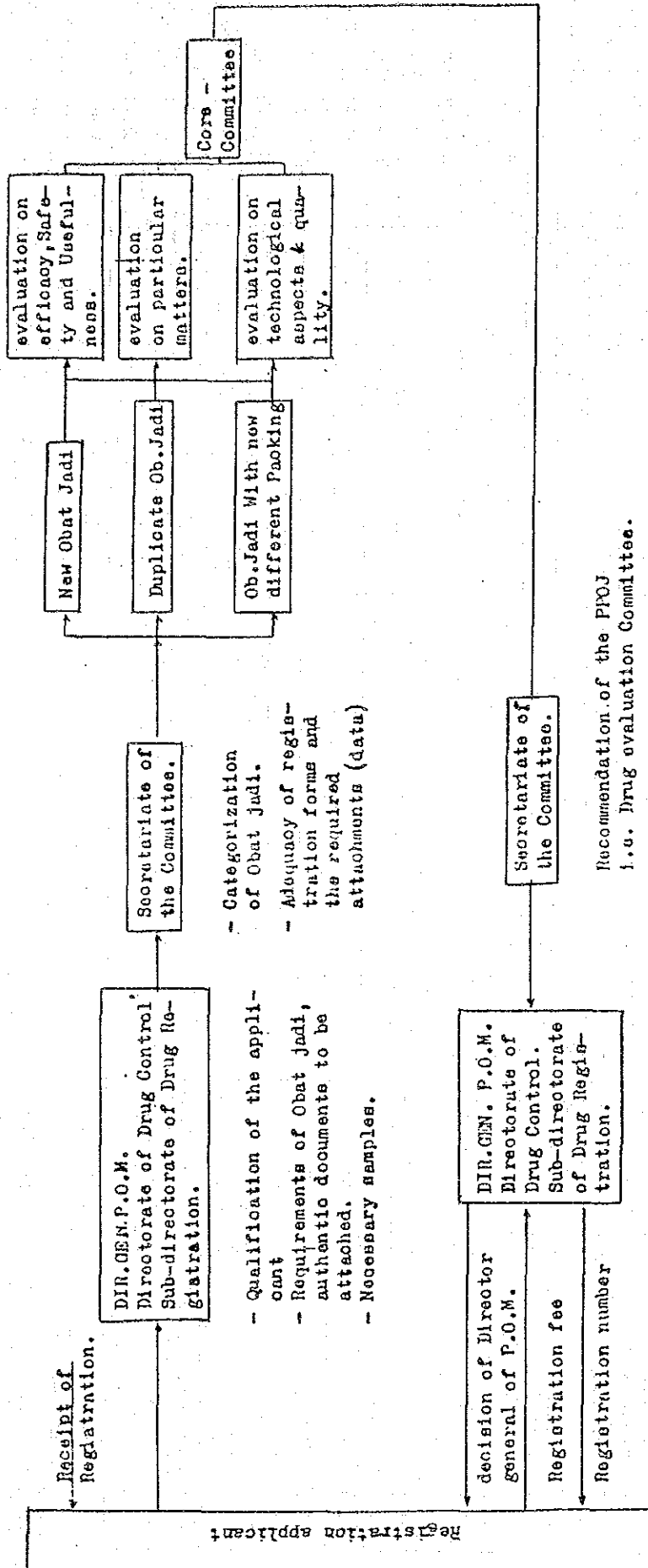
(別表5)

LABORATORIUM P. O. M. DAERAH
P. Q. C. I. L.における機器リスト

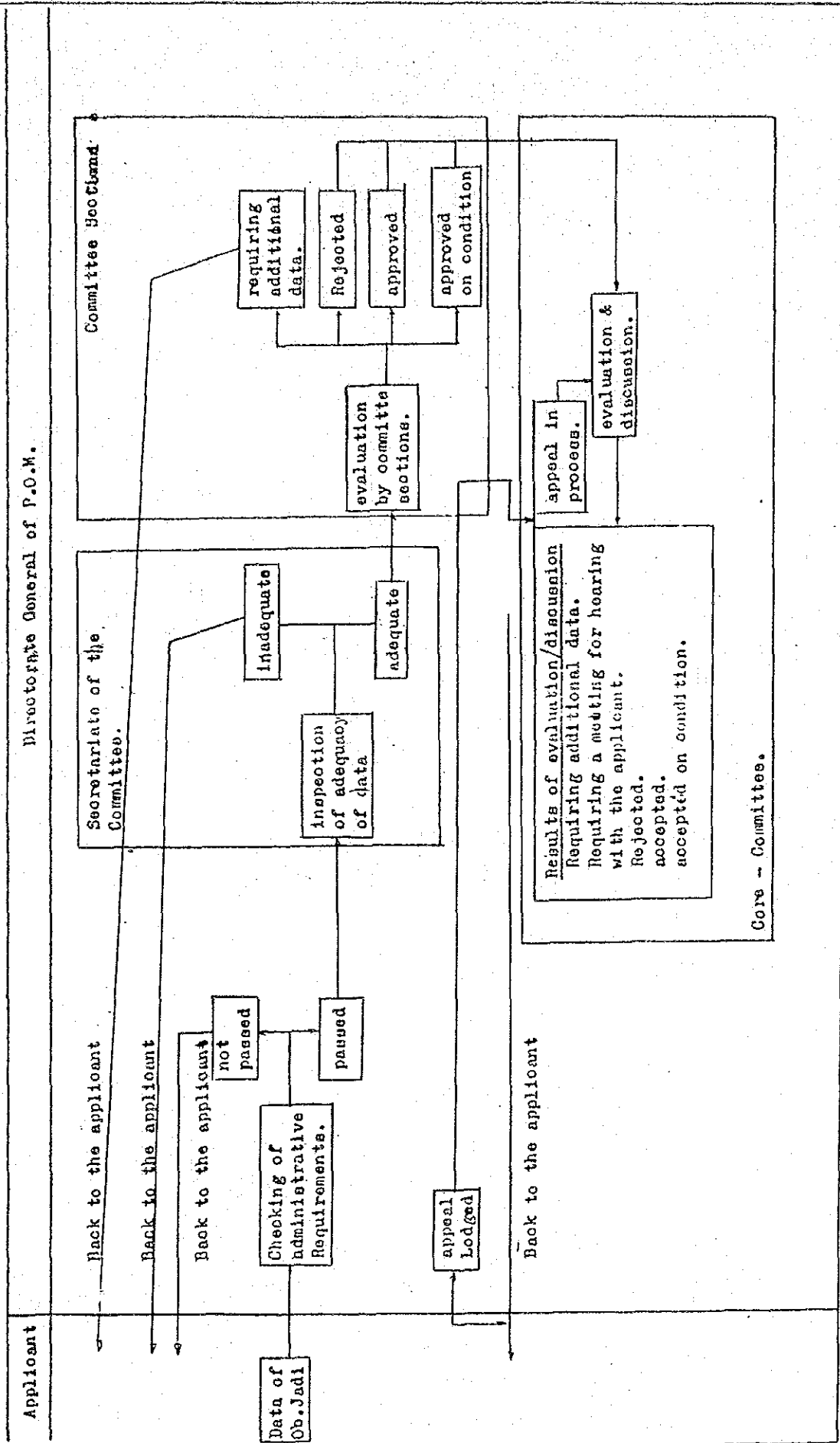
プランク:不要
ー:必要がない
±:not good condition

No. Urut	P R P P I N S I	Tipe		Luas Bangunan (m ²)			Peralatan Kimia Fisika										Peralatan Mikrobiologi		KETERANGAN
		B	C	Target	Yang Penam ada bahan	Spaktro foto meter	Wlnord meter	Gas Kro meter	Densito meter	XII meter	Potensip Polu meter	Refrak to meter	PH meter	Mik-ro-skop	Oven	B	C		
1.	D.I. Aceh		+	400	320	80	+								+	+		+	Lihat catatan
2.	Sumatera Utara		+	300	400	400	+		-										Lihat catatan
3.	Sumatera Barat		+	400	120	280	+												Lihat catatan
4.	R i a u		+	400	320	80	+												Lihat catatan
5.	J a m b i		+	400	200	200	+												Lihat catatan
6.	Sumatera Selatan		+	800	170	630	±		-										Lihat catatan
7.	Bengkulu		+	400	200	200	+												Lihat catatan
8.	Lampung		+	400	320	80	+												Lihat catatan
9.	D.K.I. Jakarta		+	800	480	320	+												Lihat catatan
10.	Jawa Barat		+	800	740	60	+												Lihat catatan
11.	Jawa Tengah		+	500	600	200	+												Lihat catatan
12.	D.I. Jogjakarta		+	400	400	-	+												Lihat catatan
13.	Jawa Timur		+	800	400	400	-												Lihat catatan
14.	B a l i		+	400	320	80	±												Lihat catatan
15.	Kusa Tenggara Barat		+	400	320	80	±												Lihat catatan
16.	Kusa Tenggara Timur		+	400	200	200	+												Lihat catatan
17.	Kalimantan Barat		+	400	320	80	+												Lihat catatan
18.	Kalimantan Selatan		+	400	320	80	±												Lihat catatan
19.	Kalimantan Tengah		+	400															Lihat catatan
20.	Kalimantan Timur		+	400	320	80	+												Lihat catatan
21.	Sulawesi Utara		+	400	350	50	+												Lihat catatan
22.	Sulawesi Tengah		+	400	200	200	+												Lihat catatan
23.	Sulawesi Selatan		+	800	540	260	+												Lihat catatan
24.	Sulawesi Tenggara		+	400															Lihat catatan
25.	M a l u k u		+	400	200	200	+												Lihat catatan
26.	Irian Jaya		+	400	200	200	-												Lihat catatan
27.	Timur Timur		+	400															Lihat catatan

Scheme of The Steps of Evaluation at new registration.

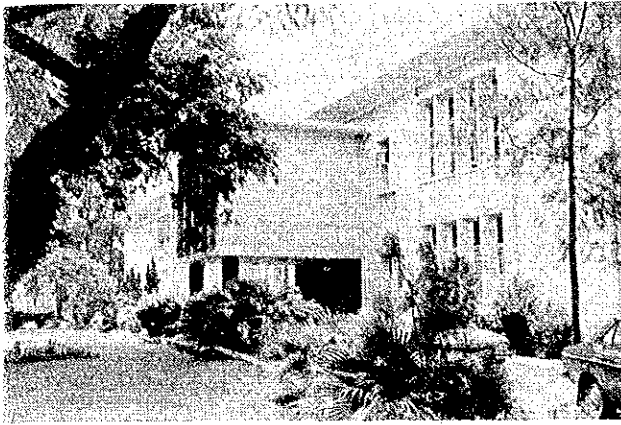


Scheme of Registration & Evaluation of Dosage Form Drugs.



Ⅶ. 関連写真（資料 3）

1. 保健省薬品・食品総局/N.Q.C.L.(P.POM) Jakarta.



保健省薬品・食品総局 (POM)



中央薬品・食品試験所 (N.Q.C.L.)にて
(左より, 江島団員, 鈴木団長, 川村団員, Mr.Sumitro)



POMにて, 表敬・協議
(左より, Dr. Sirait, MR. Sihombing, Mr. Sumitro, 手島記官)



NQCLにて
(左より田辺, 江島, 川村各団員, MR.Sumitro, 市川団員)



POMにて
(右端, 鈴木団長)



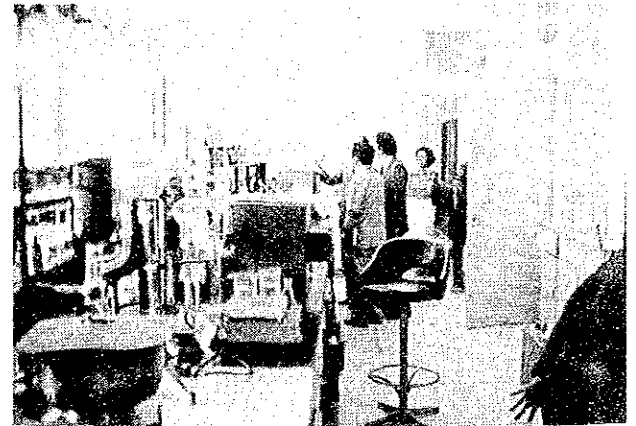
NQCLにて協議 (1)



NQCLにて(2)



NQCLにて(3)



1. POM Yogyakarta .

