BASIC DESIGN STUDY REPORT
ON
THE PROJECT FOR STRENGTHENING
OF
DRUGS CONTROL
AND
TRADITIONAL MEDICINE CENTRE
LOCATED IN
THE NATIONAL INSTITUTE OF HEALTH
IN
THE ISLAMIC REPUBLIC OF PAKISTAN

NOVEMBER, 1989

JAPAN INTERNATIONAL COOPERATION AGENCY

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PREFACE

In response to a request from the Government of the Islamic Republic of Pakistan, the Government of Japan has decided to conduct a Basic Design Study on the Project for Strengthening of Drugs Control and Traditional Medicine Center located in the NIH and entrusted the study to Japan International Cooperation Agency (JICA).

JICA sent to Pakistan a Survey Team headed by Dr. Shozo Kamiya, Director, Division of Organic Chemistry, National Institute of Hygienic Sciences, Ministry of Health and Welfare from July 17th to August 5th, 1989.

The team exchanged views on the Project with the concerned officials of the Government of Pakistan and conducted a field survey. After the team returned to Japan, further studies were made. Then, a mission was sent to Pakistan in order to discuss the draft report and the present report has been prepared.

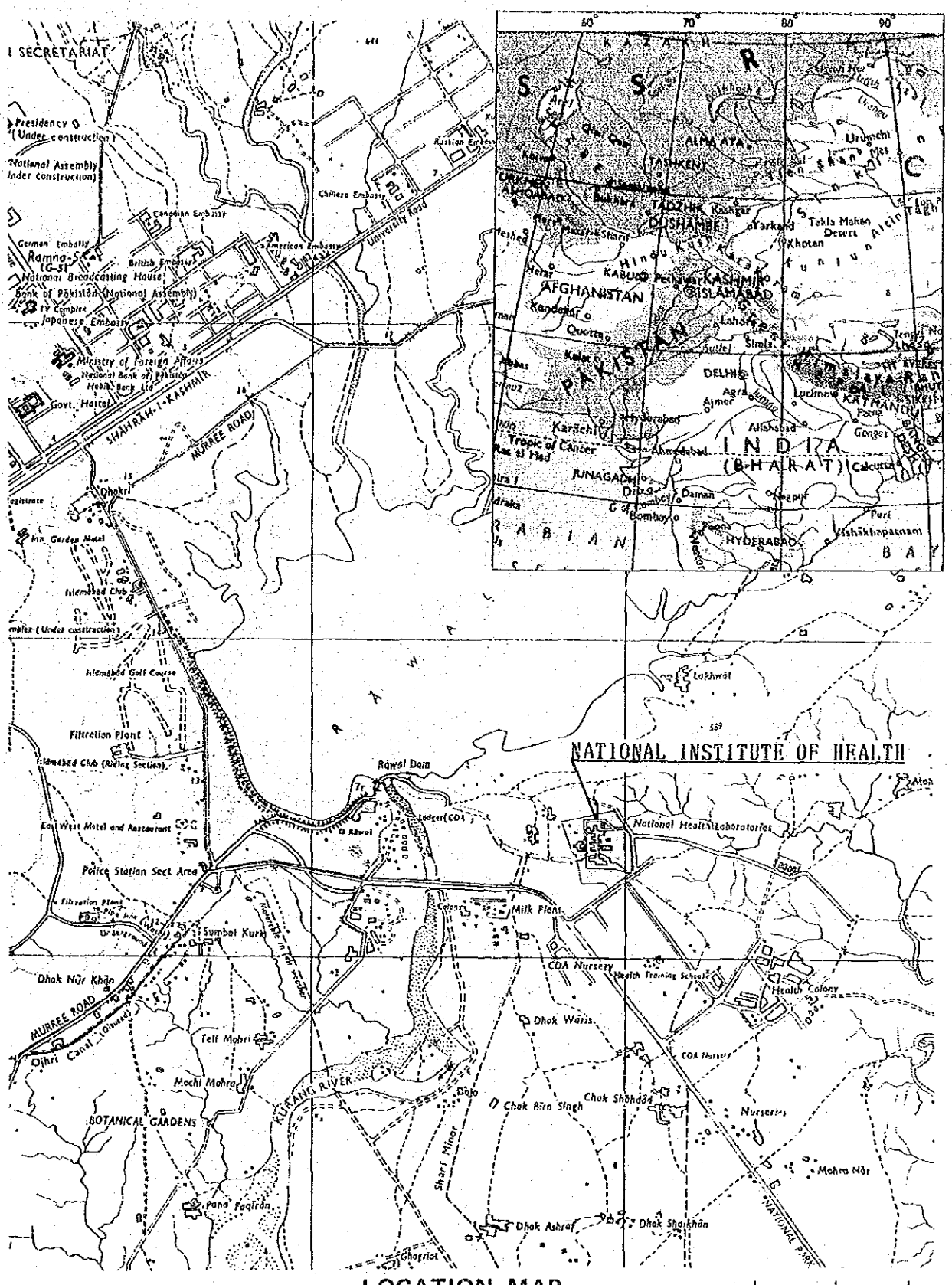
I hope that this report will contribute to the development of the Project and to the promotion of friendly relations between our two countries.

I wish to express my sincere appreciation to the concerned officials of the Government of the Islamic Republic of Pakistan for their close cooperation extended to the team.

November, 1989

Kensuke Yanagiya

Kensuke Yanagiya
President
Japan International Cooperation Agency


SECRETARIAT
Presidency
(Under construction)
National Assembly
(under construction)
Canadian Embassy
German Embassy
Ramna-5
National Broadcasting House
Bank of Pakistan (National Assembly)
TV Complex
Japanese Embassy
British Embassy
American Embassy
Chinese Embassy
Russian Embassy
University Road
Ministry of Foreign Affairs
National Bank of Pakistan
Habib Bank Ltd
Govt. Hostel
SHAHRAH-I-KASHMIR
MURREE ROAD
Dhokri
Inn Garden Motel
Islamabad Club
(Under construction)
Islamabad Golf Course
Filtration Plant
Islamabad Club (Riding Section)
East West Motel and Restaurant
Police Station Sect Area
Rawal Dam
Rawal
Ladies (CDA)
National Health Laboratories
Milk Plant
CDA Nursery
Health Training School
Health Colony
Dhok Waris
CDA Nursery
Sumbal Kurk
Dhok Nur Khan
MURREE ROAD
Ojhri Canal (Disused)
Tell Mohri
Mochi Mohra
BOTANICAL GARDENS
KURANG RIVER
Dajo
Chak Bira Singh
Chak Shahdad
Nurseries
Mohra Nur
Pano Faqiran
Dhok Ashraf
Dhok Shaikhan
NATIONAL PARK
Ghagriot
Shah-i-Mina
RAWAL
Lakhwal
NATIONAL INSTITUTE OF HEALTH
60°
70°
80°
90°
KAZAKH
S.S.R.
ALMA ATA
TASHKENT
TADZHIK
DUSHAMBE
Kashgar
Urumchi
Takla Makan Desert
Khotan
Hindu Kush
KABUL
AFGHANISTAN
KASHMIR
ISLAMABAD
Kandahar
Quetta
Lahore
Simla
PAKISTAN
DELHI
Agra
Jumna
Lucknow
KATHMANDU
Karachi
Tropic of Cancer
Hyderabad
Ahmedabad
Allahabad
Ganges
INDIA
(BHARAT)
Calcutta
JUNAGADH
Diu
Daman
Bombay
Puri
HYDERABAD
Vishākhapatnam
ARABIAN SEA
BAY
LOCATION MAP
0 km
1

SUMMARY

The Islamic Republic of Pakistan is located in the southwestern part of Asia. Its territory of 800,000 km^2 is twice as large as that of Japan, but the populations of the two countries are roughly the same at approximatery 110 million (according to the Pakistani census in 1988).

The Government of Pakistan is now promoting "The Medical Treatment Improvement Plan" to ensure good health for all Pakistani people by the year 2,000. Recently, a number of accidental deaths caused by the use of counterfeit drugs have been reported, and in the regions which have no means of treatment other than drugs, people are burdened heavily and unnecessarily by substandard drugs. For this reason, the side effects of drugs are a serious problem in this country. Therefore strengthening of the system of controling drugs is essential, and, as a first step, laws and regulations relevant to drugs should be drawn up. In 1976 the Drugs Act came into effect. As a result, drug examination methods (for quality control, safety, etc.) are now regulated according to the Drugs Act on the one hand, and the Traditional Medicines Act, which is about to be promulgated to control traditional medicines in common use among the masses, on the other. But the equipment of governmental research institutes is out of date and poor in quality. This makes it impossible to properly control the quality of drugs and traditional medicines as called for by the Drugs Act.

Consequently, the Government of Pakistan has been trying to effect equipment modernization, and has significantly reorganized the Drugs Control & Research Division (hereinafter referred to as the "Division") of the National Institute of Health (hereinafter referred to as the "NIH"), establishing the Drugs Control & Traditional Medicine Centre (hereinafter referred to as the "Centre") there, and is proceeding with the construction of its facilities.

At this point, the Government of Pakistan, whose revenues are limited, requested grant aid from Japan with the aim of procuring the testing equipment needed for the above-mentioned facilities. In response to this request, the Government of Japan decided to implement a basic design study on this project and the Japan International Cooperation Agency (JICA) undertook the study.

JICA dispatched the basic design study team to the site for 20 days from the 17th of July. The team studied the background of the project and the context of the request, and held discussions with the Pakistani side. After returning to Japan, the team analyzed the documents and information gathered

through the field survey and modified the basic design of this project. The contents of the basic design were compiled in the draft final report and explained to the Pakistani side by the basic design study team (explanation of the draft final report) dispatched for 10 days from the 29th of September, 1989.

The Division was inaugurated in the middle of the 1970s as one division of the NIH established in 1967, and is composed of eight sections: the Chemistry Section, Clinical Pharmacology Section, Pharmacology Section, Pharmaceutical Section, Botany Section, Microbiology Section, Unai Section and Homeopathic Section. In addition, it has an Animal House. The Division is, as an appellate laboratory, in charge of examinations and analyses related to the safety and effectiveness of a particular drug if the Provincial Drugs Laboratory judges that drug to be substandard and when its manufacturer appeals to the Drugs Court. This is a unique organization in Pakistan that deals with a scientific explanation of the efficacy of traditional medicines. But in reality such examinations and analyses are carried out with equipment that is 15 to 20 years old, and consequently the examination accuracy and sample treatment capacity are not adequate.

Under these circumstances, the improvement and expansion plan of the Division aims at decisively solving its problems and consists of constructing a new building in the corner of the NIH and renovating the existing building of the Division as well as the Animal House in order to establish the Centre. The outline of the arrangement and expansion plan of the Centre is as follows.

1.	Construction site	In the NIH
2.	Site area	26,500 m^2 (approx.)
3.	Buildings	New construction : The Centre
		Renovation 1 : The Division
		2 : The Second story of the Animal House
4.	Construction	Reinforced concrete
		Construction : Brick
		Construction : Two stories (same for all 3 buildings)
5.	Accessories	Electrical equipment, plumbing equipment, air conditioner, etc. , (same for all 3 buildings)

6.	Equipment to be installed	The Equipment for spectroscopy chemical reactions, physical tests, bacterial and botanical incubation, animal tests
7.	Total floor area	New construction : 1,904 m^2 Renovation 1 : 952 m^2 2 : 542 m^2
8.	Employees	77
9.	Executing agency	The Ministry of Health (M.O.H.)
10.	Design & supervision	The Public Works Department
11.	Execution	Sayd Hassan Imam Co. ltd.; four other builders for facilities
12.	Completion	New construction : by the end of October 1989, Renovation of the Division and Animal House : before delivery of equipment

This request covers the equipment to be installed in the new building of the Centre, in the existing buildings of the Division, and the Animal House. It includes a) equipment for Chemistry Tests, b) equipment for Microbiology Tests, c) equipment for Pharmacology Tests, d) equipment for Pharmaceutics, e) equipment for Pharmacognosy Tests, and f) equipment for research of Traditional Medicines. Judging from the results of the study, it is deemed appropriate that this project be implemented with Japan's grant aid. The following is the outline of the results of our analysis.

A manning plan was drawn up for the operation and maintenance of equipment and its contents were judged to be appropriate. As for the real operating capacity of the equipment, judging from the operating condition of the equipment in similar facilities such as the existing Virology & Immunology Departments in the NIH, the Central Drugs Laboratory in Karachi, etc, it can be said that the new equipment will be operated properly.

The basic design has been drawn up on the basis of the following principles.

1. Quality control and the development of traditional midicines, which are the subjects of the Centre, are taken into account for the selection of equipment.

2. Priority is given to the equipment used frequently for the improvement of drugs and traditional medicines.
3. Selection of the equipment for this project is taking into account the operating conditions of similar equipment, the plan to ensure a supply of expendables and reagents in the existing Division, and also the actual conditions at the Central Drugs Laboratory in Karachi.
4. The number of pieces of equipment to be installed in the Animal House under this project is determined according to the work plan and the operating condition.

The outline of the equipment selected for this project is as follows.

1. Equipment for Chemistry Tests ; Gas/Mass spectrophtometer, High-performance liquid chromatograph, Disintegration/Dissolution machine for tablets, Rotary evaporator, etc.
2. Equipment for Microbiology Tests ; Steam sterilizer, Digital colony counter, Pyrometer, Air sampler, etc.
3. Equipment for Pharmacology Tests ; Rotary evaporator, Kymograph, High-performance liquid chromatograph, IR, UV/VIS spectrophotometer, etc.
4. Equipment for Pharmaceutic / Narcotic Section ; High-performance liquid chromatograph, B.P. M.P. F.P. apparatus, Tabletting machine, Absorption/dissolution machine for tablets, etc.
5. Equipment for Pharmacognosy ; Rotary evaporator, Column chromatograph, Laminar flow, Thin layer chromatograph, etc.
6. Equipment for Research of Traditional Medicines ; Grinder, Soxhlet apparatus, Rotary evaporator, etc.

If this project is implemented under grant aid from the Japanese Government, the term of work for the project's execution is expected to be eight months from the conclusion of the contract with the agent supplying the equipment (hereinafter referred to as the "Supplier"). The Japanese side will be responsible for providing the consultant fees, cost of equipment procurement, and cost of supervision for equipment installation ; and the Pakistani side will be responsible for securing the cost of the equipment installation work.

The Ministry of Health, Special Education & Social Welfare of Pakistan has a overall responsiblity for the implementation of this project, and actual implementation agency is the NIH. The NIH is now strengthening its personnel through its manpower plan in order to ensure the stable functioning of the equipment introduced under the project and to ensure competent technicians to deal with its daily operation and maintenance, and also to carry out repairs based on the manuals included with the main equipment. As for the supervisor to be dispatched by the manufacturer of equipment installation, he will teach the researchers/operators operation methods and daily maintenance. If some difficulty occurs with the equipment that can not be settled by these researchers/operators, the repairs will be consigned to a dealer or the local agents assigned by the manufactures. The period covered by equipment guarantees is one year from the date of delivery and all repair costs for which the manufacturer is responsible will be covered by the supplier. But for the any troubles which occur due to operational error during the 5 years from the end of the term of guarantee, spare parts, expendables, and maintenance services necessary for repairs will be provided by the supplier upon payment therefore. This project aims at the arrangement of equipment for tests, analyses, research, study, etc., in the Centre to be established.

This project will greatly improve quality control accuracy and treatment capacity by arranging for testing and analytic equipment. The Centre will serve as an institute for establishing a scientific basis for traditional medicines, related to which a legal provision will go into effect soon. And its research on the standardization of safety tests and the efficacy and the composition of traditional medicines will contribute greatly to the safety of the traditional medicines that more than 60% of the people are using. In addition, in these new facilities, the training of pharmaceutical supervisors and drug control technicians can be carried out, training that will contribute to the improvement of drug and traditional medicine quality at the provincial level. As a result, usage of substandard drugs and spurious traditional medicines by the people will be controlled, so that they will no longer buy useless drugs, and their economic burden will be reduced. Thus this would be a very important contribution to people in Pakistan. In order to implement this project smoothly and to realize effective testing and analytic activities after the installation of the equipment, the Pakistani side should prepare the buildings and facilities so that there are no obstacles to the equipment installation work, complete its own work as previously arranged, provide

operation and maintenance personnel according to the manning plan before delivery of the equipment, and make budgetary arrangements for equipment operation. These arrangements will surely enable the project to attain its initial objectives.

CONTENTS

CHAPTER 1

CHAPTER 1 INTRODUCTION

The Islamic Republic of Pakistan is located in the southwestern part of Asia. Its territory of 800,000 km^2 is twice as large as that of Japan, but the populations of the two countries are roughly the same at about 110 million (according to the census in 1988).

The Government of Pakistan is now promoting "The Medical Treatment Improvement Plan" to ensure good health for all people in Pakistan by the year 2000. In the past, a number of accidental deaths caused by the use of counterfeit drugs have been reported, and in the regions which have no means of treatment other than drugs, people are burdened heavily and unnecessarily by substandard drugs. For this reason, the side effects of drugs are a serious problem in this country. Strengthening of the system of controling drugs is therefore necessary, and, as a first step, laws and regulations relevant to drugs should be drawn up. In 1976 the Drugs Act came into effect. As a result, drug examination methods (for quality control, safety, etc.) are now regulated according to the Drugs Act on the one hand, and the Traditional Medicines Act, which is about to be promulgated to control traditional medicines in common use among the people in Pakistan, on the other. But the equipment of governmental research institutes are out of date and poor in quality. This makes it impossible to properly control the quality of drugs and traditional medicines as called for by the Drugs Act and the Traditional Medeicines Act. Consequently, the Government of Pakistan has been trying to effect equipment modernization, and has significantly reorganized the Division of the NIH, establishing the Centre there, and is proceeding with the construction of its facilities.

At this point, the Government of Pakistan, requested grant aid from Japan with the aim of procuring the testing equipment needed for the above-mentioned facilities.

In response to this request, the Government of Japan decided to implement a basic design study on this project and the Japan International Cooperation Agency (JICA) undertook the study.

JICA dispatched the basic design study team to the site for 20 days from the 17th of July, 1989, headed by Dr. Shozo Kamiya, Chief of the Organic Chemistry Division, National Institute of Hygienic Sciences to confirm the details of the request and to examine the necessary and appropriateness of the Japanese cooperation.

Through this field survey, the team studied the background of the project and the context of the request, discussed with the Pakistani side, and agreed on the main point of the project. The Minutes of Discussions was thus exchanged between the Pakistani side represented by Dr. Qazi Abdus Saboor Khan, Deputy Director General of the Health Division, Ministry of Health, Special Education & Social Welfare and Mr. Akthar Iqbal, Deputy Secretary, Economic Affairs Division, Ministry of Finance and Economic Affairs, and the Japanese side represented by Dr. Shozo Kamiya.

The Study team, after returning to Japan, analyzed the result of the field survey and of the discussions with the Pakistani side to elaborate the basic design of this project.

The contents of the basic design were compiled in the draft final report and explained to the Pakistani side by the basic design study team (for explanation of the draft final report) dispatched for 10 days from the 29th September, 1989. This study team in its turn confirmed the contents of the basic design with the Pakistani side, and the Minutes of discussions on the draft final report was exchanged between Dr. Saboor and Mr. Tanigawa, the resident representative of JICA Pakistan Office.

This report recapitulates these results. The list of study team member, schedule of field survey, list of attendants and copies of the Minutes of Discussions are attached in the Annex 1, 2, 3 & 4.

CHAPTER 2

CHAPTER 2 BACKGROUND OF THE PROJECT

2-1 Curret Medical Situation in the Islamic Republic of Pakistan

2-1-1 Medical Situation

1) Actual situation concerning drugs hazards

The consumption, production, supply and distribution of drugs are not organized into rationalized structures, either at the official level or the private level. For instance, personnel that administer medicines are usually poorly trained, and laws that govern treatment with traditional medicines which are used by the people during the initial stages of many diseases do not even exist. The amount of medicine consumed by a single citizen amount to 47 Rupees, or approximately 2.2% of daily spendings. This means that the people of Pakistan consume more drugs than other countries with similar economic level.

Pakistani newspapers occasionally report on harmful drugs. However, nothing has ever been officially compiled on the subject and thus it is hard to determine the extent of the dangers that actually exist. However, according to the Central Drugs Laboratory in Karachi, the results of nationwide sampling test of drug produced in a year shows that 3.5 to 4% are substandard and 86% of those samples are below standard, 5% adultrated, and 9% are spurious.

In Japan and other western countries, where a drug control system is established, there is almost no problem of drugs hazards except for excessive use of them. If the drug hazard should happen, the drug-maker takes the responsibility socially. Thus 3.5 to 4% of substandard drugs will be a serious problem. From this point of view, the occurence of problems of drug toxicity in Pakistan is just related to the situation where the drug manufacuring and control are done freely for the unimprovement of its own drug control system.

Although Pakistan spends 1% of its GNP on medicine, the people of Pakistan usually end up buying substandard medicines.
This can only be attributed to the fact that quality control for drugs are unorganized.

2) Situation concerning medicine production and distribution

The current demand for medicines in Pakistan amounts to approximately 6 billion Rupees and is increasing by 20% each year. There are 10,000 types of medicines registered and three quarters of that amount are produced by 206 different manufacturers. 27 of those manufacturers are multi-national companies. The total amount of medicines imported by trading companies between 1987 and 1988 was 2 billion Rupees, while the total imports of raw materials by manufacturers amounted to 3 billion Rupees.

2-1-2 Health and Medical Standards

Life expectancy at birth and vital factor statistics are often used as an index to estimate health and medical standards. According to the 6th Five Year Plan, those statistics for Pakistan are as follows.

Table 2-1-2 (1) Physical Achievement in Vital Health Indices

	1978	1982-1983 (5th plan targets)	1983 (June) (Achievement)
Crude death rate	14	10.2	12
Infant mortality rate (age 0 - 1)	105	79	100
Maternal mortality rate	6 - 8	-	6 - 8
Life expectancy at birth (Male)	54	60	55
(Female)	53	57	54
			(per 1,000)

(Source : The 6th Five Year Plan)

At the beginning of the 20th century, the general death rate was 40 out of 1,000 people. This figure declined to 30 by 1950 and the figure dropped to 16 by mid-1960, the figure has leveled at 12.

The maternal mortality rate shifts between 6 and 8. The fact that there have not been any drastic drops on this mortality rate can be attributed to poor nursing skills during deliveries.

The infant mortality rate in 1950 was 178. This declined to 136 in 1960 and continues falling to the current rate of 100. As for causes, children before school age mainly die from diarrhea or pneumonia. And children attending school die mainly because of accidents, tuberculosis, cardiovascular disorders, and malignant tumors.

As for diseases, contagious diseases have a high attack rate. the most common causes for diseases in children are measles, whooping cough, tetanus, and diarrhea.

Approximately 1.6 million people have dormant tuberculosis, radiologically, and 250,000 of those cases are open tuberculosis. Evidently vaccines, medications, and other medication should be administered. In fact, projects to produce and spread vaccines are underway. However, this has yet to reach local rural areas.

The following table shows health indexes comparing Pakistan with countries that have a similar economic level.

Table 2-1-2 (2) Health Related Statistics

	Pakistan		Countries of middle income economies (Sri Lanka)	
	1965	1978	1983	1987
Life expectancy at birth (Male)	47	54	55	70
(Female)	45	53	54	70
Infant mortality rate (age 0 - 1)	140	105	100	36
Child death rate (age 1 - 4)	12	-	10	2
Crude death rate	16	14	12	4
				(per 1,000)

(Source : The 6th Five Year Plan)

2-1-3 Drug Testing Facilities

1) Outline

The Government of Pakistan is responsible for examining whether drugs used by consumers meet standard quality levels, comply with established standards, and guaranteeing the safety and effectiveness. The only two facilities that can carry out these responsibilities are the drugs laboratory controlled by the provincial government of Punjab in Lahore and the central drugs laboratory in Karachi which is a subordinate organization under the Ministry of Health. Other appellate laboratories, subject to the basic design study team include the Division located in the NIH. Every Year, approximately 9,500 samples are examined at these research facilities.

The testing capacity of these facilities are limited to chemical tests using analytical equipment and microbiological tests including pyrogenic and sterility tests.

However, these facilities are incapable of pharmacological examinations and analysis. A full scale drug testing laboratory would require pharmacological analysis functions as well as chemical microbiological testing functions. If one of these functions were to be omitted, the entire testing system would be insufficient.

2) Outline of similar facilities

The following is an outline of a similar facility studied, the central drugs laboratory in Karach. This laboratory uses an old British colonial era's building. It is divided and managed as two sections. The section (I) is chemical, pharmaceutical and physical section and the other section (II) is microbiological and pharmacological section.

Major duties and equipment used are given below.

-1 Section I

Chemical/Pharmaceutical/Physical section

This section has following main areas of work:

a. General testing laboratory involving routine titrametric analysis.
b. Physical instrumrnts laboratory
c. Chromatographic testing:
   Thin layer chromatograph
   Paper chromatograph
   Column chromatograph
   Gas/liquid chromatograph
   High-performance liquid chromatograph (HPLC)

The chief personnel for each equipment has the technical knowledge necessary to operate his equipment. There are three personnel (director, two supervisors) that are thoroughly versed in the use of the high performance liquid chromatograph and seven technical assistants can use the other equipment satisfactorily.

-2 Section II

Bacteriological (Microbiological)/Pharmacological section

This section deals with microbiological/pharmacological testing of drugs as below:

a. Microbiological anarysis
b. Sterility testing
c. Pyrogen testing
d. Short term toxicity tests
e. Redial walker test
   Zone reader
   Equipment for tests with animals

The pharmacological section and toxicological section exist under the same management. Although equipment for biological tests, such as pyrogenic tests and short term toxicological tests, are close to being obsolete, the testing method are carried out in close adherence to British and US pharmacopoeias. The testing system itself is well organized.

2-1-4 Medical Practitioners

According to the statistics in 1988, there are 2,066 patients per doctor, and 62,372 patients per dentist, 6,304 patients per nurse, and 2,774 patients per paramedics. The table below gives the health Indices for medical practitioners during 1955-1988.

Table 2-1-4 (1) Health Indices during 1955-1988

	1955-60	1960-65	1965-70	1970-78	1978-83	1983-88
Doctors & Dentists	1,351	3,691	3,561	9,362	10,203	52,710
Nurse	275	800	1,681	4,311	4,246	16,722
Paramedics	3,800	4,520	4,653	9,756	13,576	38,000
Basic Health Units	70	340	250	1,183	1,617	2,600
Rural Health Centres	-	73	14	81	206	355
Hospital Beds	2,500	3,750	4,300	14,308	5,308	11,770
Population (1000)	33,780	42,880	-	65,309	84,253	105,409
	(1951)	(1961)		(1972)	(1981)	(1988)

(Source : Economic Survey 1987-88)

Rural areas face the shortage of doctors due to bad employment conditions, and the lack of roads, communication facilities, electlicity, schooling, and simple water services. 30% of the population live in urban areas where there are 6,000 doctor posts. However, 70% lives in rural areas where there are less than 1,000 doctor posts. To fill the gap between rural areas and urban areas, traditional medicine practitioners numbering 52,000 carry out medical activities.

The breakdown of traditional practitioners registered is 36,881 Tabib practitioners using Unani traditional medicines, 15,786 Homeopaths, and 539 Vaid practitioners using Ayruvadic traditional medicines. A separate table that compares the 5th Five Year Plan with current license holders and their amount of experience is attached as below. The duty of these traditional medicine practitioners is to treat patients according to the traditional medicines act. This means to administer medication according to treatment programmes and diagnosis results. Some practitioners buy traditional medicines while most usually prepare these medications by themselves.

Table 2-1-4 (2) The Break Down of Traditional Practitioners

	Qualified and Resistered	Category(A)	Category(B)	Total	5th Plan period
Tabibs	4,807	3,459	28,415	36,881	35,090
Homeopaths	2,819	11,997	970	15,786	14,240
Vaids	Nil	146	393	539	539
	7,626			53,206	49,869

(Source : Data from Ministry of Health, Special Education & Social Welfare)

Note 1 : 1) Category (A) unqualified and resistered with 7 years or new experience.

2) Category (B) unqualified and registered with less than 7 years experience.

Note 2 : 1) Unani System

In this system diseases are treated by medical plants and a number of metallic oxides i.e. lead, calamine sulphates etc. The medicinal drugs are combined according to their elementary qualities of heat, cold, moisture and dryness as shall render them effective in combating or over-coming the conditions which exist in different diseases.

2) Ayurvedic System

This is mainly based on treatment with medical olants and their complexes with metals. The drugs belonging to this system are classified in three groups.

-1 Vegetable Drugs :

In this plant extract & their extracts are used.

-2 Animal Drugs :

They are derived from various organs of animals.

-3 Minerals Drugs :

Include silver, lead, zinc, arsenic & antimony, etc., Minerals like tale, miea, Cinnabar. Precious stones such as emerald, ruby, are used as drugs after giving them proper treatment.

3) Homoeopathy System

In a system in which similar effects are produced by medicines given in micro doses which is claimed to possess very high potency.

2-1-5 Pharmaceutical Training

There are seven universities that provide education in all aspects of pharmaceuticals, such as microbiology, pharmaceutical chemistry, and pharmacology. Students may obtain degrees in the study of pharmaceuticals at these universities. There are 14 colleges that instruct pharmacology, and another 14 medical colleges that instruct microbiology and chemistry.

The curriculum for Pharmacy comprise of studies for four years of the following subjects:

-1 Mathematics
-2 Pharmaceutics including Pharmaceutical technology
-3 Pharmaceutical and Dispensing Chemistry including medicinal and analytical Chemistry
-4 Pharmacology
-5 Physiology
-6 Microbiology

In three major institutions, a two years of further studies and researches lead to Master's degree in some of the major disciplines such as Pharmaceutical Chemistry, Pharmaceutics, Pharmacology & Microbiology.

These degree are recognised all over the world and the graduates of Pharmacy from Pakistan go for jobs in U.K. & U.S.A. where their degrees are fully recognised.

Two of the Universities have also started enroling students for Ph.D. degree.

Apart from these institution, the post-graduate University of Quaid-e-Azam at Islamabad is awarding higher degrees of M.Phil (Master's degree in Philosophy in the relevent subject) & Ph.D. in different science subjects including Chemistry and Analytical Chemistry.

Every year some 700 graduates are qualifying who are being absorbed in various fields including:

-1	Pharmaceutical Industry in	(60 %)
	a. Production	
	b. Quality Control	
	c. Sales Promotion	
-2	Government Agencies:	(5 %)
	Quality Control of Pharmaceuticals in	
	a. Inspection	
	b. Laboratories	
	c. Administration	
	d. Research	
-3	Hospitals:	(1 %)
	a. Hospital Pharmacy	
-4	Retail:	(1 %)
	A small number is going into retail Pharmacy.	

The present number of Pharmacists in the country is estimated to be about 3000. The job opportunities are relatively less than the qualifying number of Pharmacists and as such many of them go abroad for work. (Middle East, U.K., U.S.A.)

The 14 Universities of the country are also offering courses of studies leading to Master's degree in Chemistry and some to Ph.D. also and therefore a large number of Chemists are also available in the country.

2-1-6 Trends and Contents of Foreign Aid

1) Data pertaining to the changes in foreign aid and yen loans to Pakistan are attached to ANNEX 6.

Analysis and background of the data is mentioned as follows. There is a tendency of increment of foreign aid for Pakistan that USA and other free nations have recongnized geopolitical significance of Pakistan and she also thinks much of relationship with free nations.

For Pakistan, Japan is one of the countries providing most overseas development aid classed with USA, and has been providing aid for more than 3 million Afghan refugees through WFP and UNHCR. It has lightened economic burden which Pakistan bears. As a result, much contribution has been given to Pakistani economy directly & indirectly.

2) The contents of aid from international agencies toward the Division in the NIH are given below.

-1 Monitoring project of harmful substances in cigarettes.

This project monitors harmful substances in cigarettes distributed domestically with the cooperation or WHO.

An air/liquid chromatograph that condenses tobacco smoke has been brought in to measure the amount of condensed nicotine and tar.

-2 US PNCB (Pakistan Narcotic Control Board) Forensic Drug Laboratory project.

This project was set up acording to a US planned project to identify and analyze narcotics confiscated by the PNCB.

-3 Cooperation with WHO for drug quality control.

WHO has contributed funds to training projects concerned with drug quality control and research. WHO also provides an opportunity for many personnel to study abroad and thus learn about the advances in today's quality control field.

As a result, some have obtained higher degrees and others occupy important posts in the NIH.

WHO also helps improve drug quality control by allowing personnel to attend international and domestic seminars, symposiums, and techinical meetings. WHO provides the forum for opinions on drug quality control with the object of expanding the quality control project and rationalizing theories.

2-2 Related Plan and Programme

2-2-1 National Development Plan

1) 6th Five Year Plan (1983-1988)

The Planning commision, Government of Pakistan reflects on page 2 of "7th Five Year Plan 1988-93 and Perspective Plan 1988-2003" as follows.

It may be recalled that the 6th Five Year Plan had aimed at rapid and equitable development and had been based on economic growth combined with policies to benefit the poor through their participation in economic life. The 6th Plan strategy, therefore, was to revive private-sector investiments by progressive deregulation, to increase the production base, to diversify the agriculture into high value crops, to move towards self-sufficiency in oil seeds, to improve industrial efficiency; and to expand exports. While some of these objectives have been realized, the 6th Plan has only partially succeeded in some areas and has not performed too well in others.

Accroding to the "7th Five Year Plan 1988-93 and Perspective Plan 1988-2003", the short coming of the 6th Plan has been the failure of the Government to implement structural changes in the economy envisaged in the plan which are notably the diversification of agriculture into high value added crops, shift of industry towards more efficient and export-oriented industries, and changes in the composition of exports and a basic strengthening of the fiscal situation to cope with the growing finantial obligations. These structural changes are essential for sustaining healthy growth in the long run.

2) 7th Five Year Plan (1988-1993)

Reflecting on the 6th Plan, the ideas of the 7th Plan were elaborated. Its principle is that all people in Pakistan should enjoy a comfortable and modern life, and this principle is penetrating through the social works in the 7th Plan.

The basic aims of the 7th Plan would be as follows:

-1 Movement towards full employment, specially of the educated.

-2 Provision of nutrition, shelter, health, education and transport and other public services through maximum coverage of population.

-3 Development of human resources, with emphasis on education and training of manpower.

-4 Progressive achievement of self-reliance in all spheres of life, including the gradual reduction of dependence on foreign loans, technology and know-how.

-5 Promotion of private sector activity to the fullest extent consistent with social responsibility, through further deregulation of the economy, so as to transfer the bulk of the financial burden of investment and growth from the governmnet's budgetary resources to the private sector's own resources.

-6 Restoring equilibrium in public finances by a concrete programme of balancing the revenue budget, and eliminating the imbalance between the Government's expenditure requirement and its revenue raising capacity.

-7 Strengthening the balance of payments by aggressive promotion of expoerts, through indeusrial, commercial and exchange rate policy and to achieve a better balance between imports and exports.

-8 Pursuing a restrained monetary policy to ensure continued price stability.

As mentioned above, the 7th Five Year Plan is characterized by the attempt to raise the standard of life through converting policies on public investment, taking the activation of a private sector into policies, and by the attempt to realize the above mentioned objectives through penetrating the public works, especially education and health into the whole society.

2-2-2 Project Concerning Medical Sector

The project concerning Medical Sector in the 7th Five Year Plan takes up most of the less successfull programme in the 6th Plan. As a new programme at least one standard quality control laboratory per province will be established, and budget necessary to schieve this objective are planned.

Another programme is the establishment of drugs control laboratory to act as a high level institution above the provincial standard quality control laboratory. This is also a long term policy indicating that as organized quality control system, meaning the establishment of a quality control council should be done.

The following projects are planned in the medical sector of the 7th Five Year Plan.

-1 Solve space, equipment and bed insufficiencies existing amongst all university and regional hospitals.

-2 Prevent, treat, and rehabilitate mental health diseases by way of Mental Health Programme.

-3 Enhance welfare benefits to the handicapped by executing the projects in the 5th, and 6th Plan continuously.

-4 Strengthen and expand existng centers to treat and rehabilitate drug addicts by way of a Drug Detoxification Programme.

-5 As for the traditional medicines, with the intention of controlling the manufacturing, sales, efficacy and quality of unani, ayurbadic and homeopethy medicines, the Traditional Medicines Act is being prepared.

2-2-3 Positioning of this Project

In the background of the programmes of the establishment of the standard quality control laboratory at the provincial level and the high level institution above the laboratories, there is an increase of the side effects of the drug, which has been taken up as the important problem in recent years and the recognition that the quality control system is poor against substandard drugs.

In the 7th Five Year Plan, prior to establishment of the laboratories at the provincial level, the establishment of the laboratory at the national level is materializd, this decision is connected with the thought to have to complete the drugs control laboratory which corresponds to the higher organization in the quality control system.

With completion of the drugs control laboratory, promoting the technical level of the personnel to be engaged in the quality control services at the provincial level through execution of the education of quality control and the quality control level.

Concerning the positioning of the drugs control laboratory, namely the Centre in the national development plan, the Government of Pakistan has taken such policy to spread the public work especially for education and health to the whole area in the society, and it can be said that this project is the materialized work of the policy.

2-3 Current Situation Concerning the NIH and the Division

2-3-1 National Institute of Health

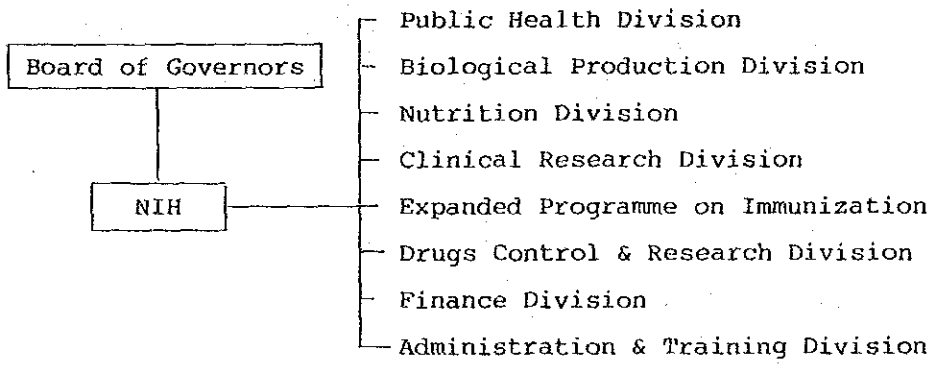
The NIH was founded in 1967 at the cost of 400 million rupees. The consolidation of independent sevices carried out in the NIH by the government of Pakistan in 1973 led to the progress of the NIH was designated as an investigation and development institution independent both in personnel and budget from the jurisdiction of the Ministry of Health, Special Education & Social Welfare. Ever since the institute became self governed on September 10, 1980, many achievements have been made through procuring the diagnostic research equipment and vaccine production equipment.

2-3-2 Infrastructures

1) Organization of the NIH

The organizaitional drawing of the NIH, which operates the Division, is given below.

Table 2-3-2. Organization Chart of the NIH



-1 Public Health Division

This division must study and research contagious deseases, and to establish research theories and standards most suitable for Pakistan. The public health division must convey this technology to other research centers.

-2 Biochemical Production Division

This division handles the production and supply of vaccines, anti-viotics, and other drugs used to suppress contagious diseases, Pakistan's most important health problem.

-3 Nutrition Division

This division advises the Pakistani government on food and nutritional projects and helps set up future projects.

-4 Clinical Research Division

This division makes use of modern medicines, similar medicines, and Unani traditional medicines to conduct clinical inspections.

-5 Expanded Programme on Immunization

This division, in cooperation with high level WHO officials, handles training courses for upper and middle management workers, monitors health education programs, and all other adjustment and assessment projects.

-6 Drugs Control & Research Division

This division is the object of this project and is described within this report.

-7 Finance Division

This division handles the accounting for the NIH.

-8 Administration & Training Division

This division manages medical techinical schools, the central library, and conducts workshops.

2) Functions of the Board of Governors of the NIH.

The Board of Governors is the highest dicisions making institution within the NIH.

The functions of the Board of Governors covers general direction and adiministrative duties. The following list indicates the members of the Board of Governors.

-1	Secretary, Ministry of Health, Special Education & Social Welfare	- Chairman of BOG
-2	Director General, Health, Health Division	- Member of BOG
-3	Financial Adviser, Health Division	- Member of BOG
-4	Surgeon General, or his nominee	- Member of BOG
-5	Chairman of Pakistan Medical Research Council, or his nominee	- Member of BOG
-6	Vice-Chanceller, Quaid-i-Azam University, or his nominee	- Member of BOG
-7	Two Representatives from the Public to be nominated by the Federal Government	- Member of BOG
-8	One Representative of the College of Physicians and Surgeons	- Member of BOG
-9	Executive Director of the NIH	- Member/ Secretary of BOG

2-3-3 *Personnel Organization of the Division*

The following shows the allocation of personnel affiliated with the Division.

(number of staff)

Chief

Chemistry Section	:	S.S.O.	(1)
		S.O.	(2)
		Tech. Asst.	(4)
		Technician	(2)
		Lab. Attendant	(4)
Clinical Pharmacology / Pharmacology Section	:	S.O.	(4)
		Technicial	(1)
		Lab. Attendant	(3)
		Animal Attendant	(1)

Pharmaceutical / Narcotic Section	:	S.S.O.	(1)
		S.O.	(1)
		Tech. Asst.	(2)
		Technician	(2)
		Lab. Attendant	(3)
Parmacognosy Section	:	S.S.O.	(1)
		S.O.	(1)
		Tech. Asst.	(1)
		Lab. Attendant	(2)
Microbiology Section	:	S.O.	(1)
		Technicial	(2)
		Lab. Attendant	(3)
		Animal Attendant	(1)
Unani / Homeopathic Section	:	A.S.O.	(2)
		Lab. Attendant	(2)

For Administration 12 staffers exist.

2-3-4 Current Situation Concerning the Division

1) Outline

The Division has participated actively in drugs quality control and research. This Division was designated as an appellate laboratory in 1976, in accordance to the Drugs Act, which was granted the right to test the quality of samples inquired by the drugs court and provincial Quality Control Boards. Reference standards of WHO are used to analyze medicines. In cooperation with international aid agencies, drug testing facilities have been set up and based on the urinal tests are being conducted for drugs abusers. WHO also provides aid to encourage quality control and the monitoring of harmful substances in tabacco.

Currently, the Division occupies the second floor of a two story buildings concerned for the public health department. The total floor area is 930 m^2.

2) Function of each section

This Division is entrusted with the following functions shown classified by each section.

-1 Chemical Section

a. Main functions

a-1 To perform appellate testing for the drug samples sent by the Drugs Courts, Provincial Quality Control Boards and Central Licencing and Registration Boards.

a-2 Organized monitoring of drugs for Qulity Control.
To collect and test drugs from a city market and manufacturing plant and to report to Registration Boards that manufacturers of substandard drugs should be deprived of a lisence.

a-3 To test and analyze the drug samples referred by the Ministry of Health and other governmental organizations such as social security department and Pakistani Institute of Medical Sciences.

a-4 Research in quality control of drugs.

a-5 Maintenance of reference standards based on British Pharmacopoeia and US Pharmacopoeia.

a-6 Maintenance of specification and methods of testing.

b. Projects in hand

b-1 Project on survey and monitoring of "Anti-malarial Drugs" is in progress.

b-2 Determination of harmful constituents in cigarette is in progress.

b-3 Research on "Chemical Studies for the Genus Artemisia", leading to Ph.D. Degree.

-2 Microbiological Section

a. Main functions

To conduct quality control test following the examinations mentioned below.

a-1 Potency test : Microbiological analysis for antibiotics and other drugs.

a-2 Sterility test for Bacteria and Fungus, etc.

a-3 Pyrogen test : Determination of temperature in animal before and after injection of drugs.

b. Research projects

b-1 Antimicrobial activity of Medicinal plants.

b-2 Drugs monitoring (Potency test), from Market and Hospitals on National level.

b-3 A comperative study on the efficacy of antibiotics from different manufacturers.

-3 Pharmacology Section

a. Routine Analysis

a-1 Testing of biological products including hormonal drugs.

a-2 Toxicity studies of different synthetic and crude drugs and agents according to B.P. ; B.P.C. and U.S.P. or any official book.

a-3 Establishing methodologies for toxicity testing/efficacy of substances which are not included in various pharmacopoeias or other official books.

b. Other projects

b-1 Search for new antidiabetic agents, screening of indigenous plants and traditional medicines.

b-2 Adverse Drug Reaction Monitoring.

b-3 Drug Utilization studies.

-4 Pharmaceutical & Narcotic Section

a. Test and analysis of Drugs of Abuse/Psychoropical drugs.

To identify and analyza Drugs of abuse seized by law enforcement organizations, under a project US-INM and PNCB. The drug examination provinces necessary basis for the execution of legal proceedings against clandestine manufacturers, traffickers and pushers of drugs.

b. Test and analysis of Drugs of unknown origin e.g. steroids.

Steroids are prohibitted from putting into ordinal medicines because of its adverse reaction. The identification of those are conducted for Quality control.

c. Test and analisis of Pharmaceutical Products following Blitish Pharmacopoeia.

Drugs referred are tested for qulity control as an Appelate Laboratory.

d. Isolation and characterization of chemical constituents of indigenous medicinal plants in Pakistan.

Through extraction and concentration of chemical constituents of those plants with organic solvents crude extracts are obtained.

Active constituents are isolated from crude extracts and identified.

e. Test antiepileptic drugs in biological fluids e.g. serum and urine.

-5 Pharmacognosy Section

a. Main functions

a-1 To standardize the crude used in the indigenous system of medicines which will be a national reference standard.

a-2 To collect and categorize pollen grains from all over the country for the preparation of Allergy vaccines against Pollen Allergy.

a-3 To collect, and identify herbs of Pharmacological, Pharmaceutical and microbiological interest, special emphasis on herbs used in idigenous system of medicines.

a-4 Phytochemical screening of indigenous plants.

a-5 Establishment of Herbarium of medicinal plants for National Reference purposes.

b. Other Projects

The work load in view of the shortage of staff is increasing and also inview of the new assignments such as:

b-1 Phyto chemical screening of indigenous plants used in herbal medicines.

b-2 Standardization of crude drugs used in Herbal medicines.

-6 Unani/Homeopathic Section

a. Literature survey of medicinal plants from the books of unani system of medicine as well as some scientific publication.

b. Extraction of medicinal plants.

c. Preparation of unani medicines to conduct clinical trials or as may be needed for other research purposes.

3) The transition of number of samples tested & expected number of samples in future

-1 Transition of number of samples tested

Table 2-3-4 Transition of Number of Samples Tested

SOURCE	1984	1985	1986	1987	1988
Appellate Testing	55	32	12	76	44
Routine Testing for Qulity Control	100	99	302	365	281
Narcotics	48	179	162	331	691
Testing for Steroids, etc.	40	81	105	138	136
Total Samples:	243	391	581	910	1152

Note : 1) For appellate testing, the samples are received from Provincial Governments and Drug Courts.

2) Sample for Narcotic testing are received from Customs, Pakistan Narcotics Control Boards, Police Stations, Pakistan Coast Guards, etc.

3) For other testing the samples are received from Federal Government, Hospitals, Provincial Governments, Drug purchasing agencies and private individuals.

-2 Expected number of samples in the future

In this division, as mentioned above, number of necessary equipment is not enough to conduct large scale testing, and most of the equipment is out of date.

Therefore, it is expected that the capacity of testing will be remarkablly improved with the equipment which will be provided through this project.

Pakistani side is expecting approximately 5,000 samples for testing per year. However, with the strengthening of the capacity for quality control of drugs in the near future, the number is increased sharply since these samples would be collected or received from the Federal Government Agencies relating to drugs control and purchase and similar Provincial Government Agencies as well as from the private sector of Pharmaceutical trade and industry.

2-3-5 Maintenance Control System for Existing Equipment

One of the sections within the NIH has a workshop with electronic, electric and mechanical engineers that can perform common repairs.

To evaluate capability of the workshop engineer an interview was made to him showing the existing equipment in this Division. The basic study team understood through the interview that he can manage to repair and maintain most of the existing equipment properly, provided circuit diagram, service manual and necessary spare parts. In addition, existing tool and equiment in the workshop are well arranged even though they are relatively old and the manpower of the workshop is properly organized. However, since a relativly new electronic equipment needs special knowledge to be made repairs and maintenances, service engineers from agents of equipment manufacturers are left to conduct repair and maintenance.

A list of the workshop engineers and the organization chart of the workshop is attached as ANNEX 9.

2-3-6 Situation of Existing Equipment and Countermeasures

The situation of existing equipment classified by each section is mentioned as follows.

1) Chemical Section

13 units are 20 years old out of 19 units which exist at the present time and are used still now except for units out of order. However since most of equipment is superannuated and spare parts to be replaced are not available it's deemed that the accuracy of those equipment is not very reliable. Although another 6 units are 3 - 4 years old and relatively new, only 1 unit of High-performance Liquid Chromatograph (HPLC) is included as a spectrophotometric equipment necessary for present functions. There is no problem about maintenance for these new equipment as service engineers conduct maintenance services.

Conclusively it's clarified that since most of existing spectrophotometric equipment is inferior in accuracy as well as efficiency.

This section can not carry out the functions well as mentioned before.

The existing equipment list of this section is shown in ANNEX 5, P172.

2) Microbiology Section

Most of equipment are 20 years old superannuated except for digital Colony Counter. Moreover the existing equipment does not include fine equipment e.g. Water Distiller to keep the accuracy of test, Zone Reader to improve efficiency of test. Therefore it's concluded that the increment of samples for the future can not be coped with by those existing equipment.

The existing equipment list is shown as ANNEX 5, P173.

3) Clinical Pharmacology / Pharmacology Section

This section contains 33 units in total. 7 units are unrepairable because of lack of spare parts. 6 units were procured 2 - 5 years ago, relatively new but contain only 2 units of frequently used equipment, or Glucometer and Stimulator, which are very necessary to carry out tests. Most of the frequently used equipment is 15 - 20 years old and superannuated. More over it's understood that necessary equipment e.g. Laminar Flow, Incubator, etc. is not contained or in shortage.

The existing equipment list is shown in ANNEX 5, P174.

4) Pharmaceutical / Narcotic Section

The existing equipment contained 9 units not functioning out of 23 units in total. These 9 units are 20 years old, unrepairable because spare parts are not available.

14 units functioning contain of 2 units of physical test equipment, 10 units for Pilot Plant and 2 units of spectrophotometric equipment.

The equipment in Chemistry Section is utilized also bacause the existing equipment in this section is not sufficient enough to carry out functions entrusted.

However, since necessary equipment e.g. Gas Chromatograph unit with various detectors, preparative Thin Layer Chromatograph, etc. is not available all of test items described in Pharmacopoeia can not be conducted. Although the latent work load is reported to be much higher than the work load of referred section is 2 - 3%. That concludes that many samples referred connot be tested bacause of absence of necessary equipment.

The existing equipment list is shown in ANNEX 5, P175.

5) Pharmacognosy Section

The existing equipment contains only one equipment, that is a dissecting microscope. Therefore laboratory officers have been conducting researches utilizing of equipment in other institute i.e. Pakistan Agricultural Research Institute.

6) Unani / Homeopathic Section

In this section basic study for standardization of medicinal plants are carried out. However existing equipment inthis section does not include some necessary equipment e.g. Grinder to grind medicinal plants, Rotary Evaporator to concentrate extract, etc.

Therefore it's concluded that since some constituents contained in medicinal plants cannot be extracted. The abovementioned researchs are not conducted sufficiently.

The existing equipment list is shown in ANNEX 5, P176.

The following three project have been set forth as measures to meet the abovementioned duties satisfactorily.

-1 Obtain a building that can house all related sections (Currently, the division cannot be expanded and thus work efficiently.)

-2 Obtain analysis and experiment equipment that will enable the division to meet its obligations and objectives.

-3 Distribute personnel that can successfully operate the above analysis and experiment equipment and carry out detailed procedures.

2-4 Expansion Project

2-4-1 Project Objective

To improve and expand the existing Division in order to make quality control drugs, and to improve and standardize the quality of traditional medicines.

2-4-2 Content of the Project and Implementation Programme

1) Content of the Project

This project is comprised of a new construction project to build a new building and install equipment, and a project to install equipment in the two existing facilities.

Site : NIH
Total site area : 26,500 m^2
Excuting agency : The Ministry of Health

-1 New construction project for the NIH

a. Structure and stories : Steel reinforced concrete structure, elixir, two story building

b. Incidental facilities : Electricity, water supply and sanitary facilities, air conditioning, etc.

c. Equipment to be installed : Equipment shall cover extract test of effective ingredient in traditional medicines, production of test sample for safety tests, microbiological quality control of medicines, and control of narcotics.

d. Total floor area : 1,904 m^2

e. Number of personnel : 77

f. Project costs : 2,243 million Rupees (not including equipment)

-2 Project to install equipment in the existing facilities of the division

a. Structure and stories : Steel reinforced concrete structure, elixir, two stoty building

b. Incidental facilities : Electricity, water supply and sanitary facilities, air conditioning, etc.

c. Equipment to be installed : Equipment shall cover quality control and standardization of efficacy of traditional medicines, and production of reference samples.

d. Floor to be installed : 2nd floor

e. Floor area : 952 m^2

f. Number of personnel : 61

-3 Project to install equipment in the existing animal house

a. Structure and stories : Steel reinforced concrete structure, elixir, two stoty building

b. Incidental facilities : Electricity, water supply and sanitary facilities, air conditioning, etc.

c. Equipment to be installed : Equipment shall cover toxic tests of medicines used in animals.

d. Floor to be installed : 2nd floor

e. Floor area : 542 m^2

f. Number of personnel : 5

2) Implementation programme

The Ministry of Health is the general supervisory agency for the project. However, the chief in charge of implement action of the project is the Director of the NIH.

-1 Development progress

a. Designing : Pakistan public works department

b. Supervision : Pakistan public works department

c. Construction : Domestic construction companies are working on each different type of construction.

Construction work
Electrical work
Sanitary work
Air conditioning work
Boiler

d. Equipment procurement : The three materials necessary for this construction (steel, lumber, cement) and special materials (sashes, steel products, etc.) are all procured domestically.

e. Tentative completion date : Pakistan states that construction will end by millde of October in this year. However, the design study team judges the construction will end before equipment is procured and installed.

-2 Implementation budget and fund raising methods

The project costs are to be taken from the Pakistani national budget. The breakdown is as follows.

a. New construction costs	1,692.0
b. Road construction costs	30.5
c. Furniture manufacturing costs	210.0
d. Test tube procurement costs	184.0
e. Overhead costs	126.5
Total	2,243.0 (milliion rupees)

2-5 Outline of the Request

2-5-1 Outline of the Request

Tasks imposed upon the Division of the NIH have increased so much since 1976 when Drugs Act was enacted. However, it can hardly catch up with improvement of the inspection and experimental facilities, and building.

To save this situation, the said division and the government authorities such as the Ministry of Health worked out a plan in the 7th five year plan to improve and expand "Drugs Control and Research Division" at a total of 83,827 million rupees. As breakdown of the total amount, funds to be supplied by the Japan's Grant Aid are expected to be used for purchasing inspection and experimental equipment whose cost accounts for major part of the budget. Pakistan will bear the cost of the remaining, new centre construction and facility costs.

2-5-2 Detailes of the Request

1) General description of the project

The sections classified by works of this centre to be surveyed are (1) analytical chemistry, (2) medicine, (3) narcotics, (4) trial production of medical supplies, (5) pharmacology, (6) toxicity, (7) poison, (8) herb medicine and traditional medicin, (9) microorganism, and (10) animal house. Pakistani facilities improvement project is as described below.

-1 New building [(2), (3), (4), (9)]

The facilities to extract and experiment the efficacy and ingredients of traditional medicines, and the facilities to produce medicine out of efficacy ingredients in as experimental scale (mainly productionof test specimens for safety tests) and to control quality of medical supplies through a microbiological method, and control narcoties.

-2 New building [(1)]

The facilities to control quality of medical supplies by means of chemical reaction, properties reaction and various sorts of special apparatuses and control information on toxicity (poisoning).

-3 Second floor of the existing facilities [(6), (7), (8)]
(remodelling of the interior of the building currently used as "The Division" has been planned)

Facilities to control quarily with a focus placed on their toxicity; facilities to control traditional medicine quality, standardization of medicine efficacy and preparation of specimens, etc.

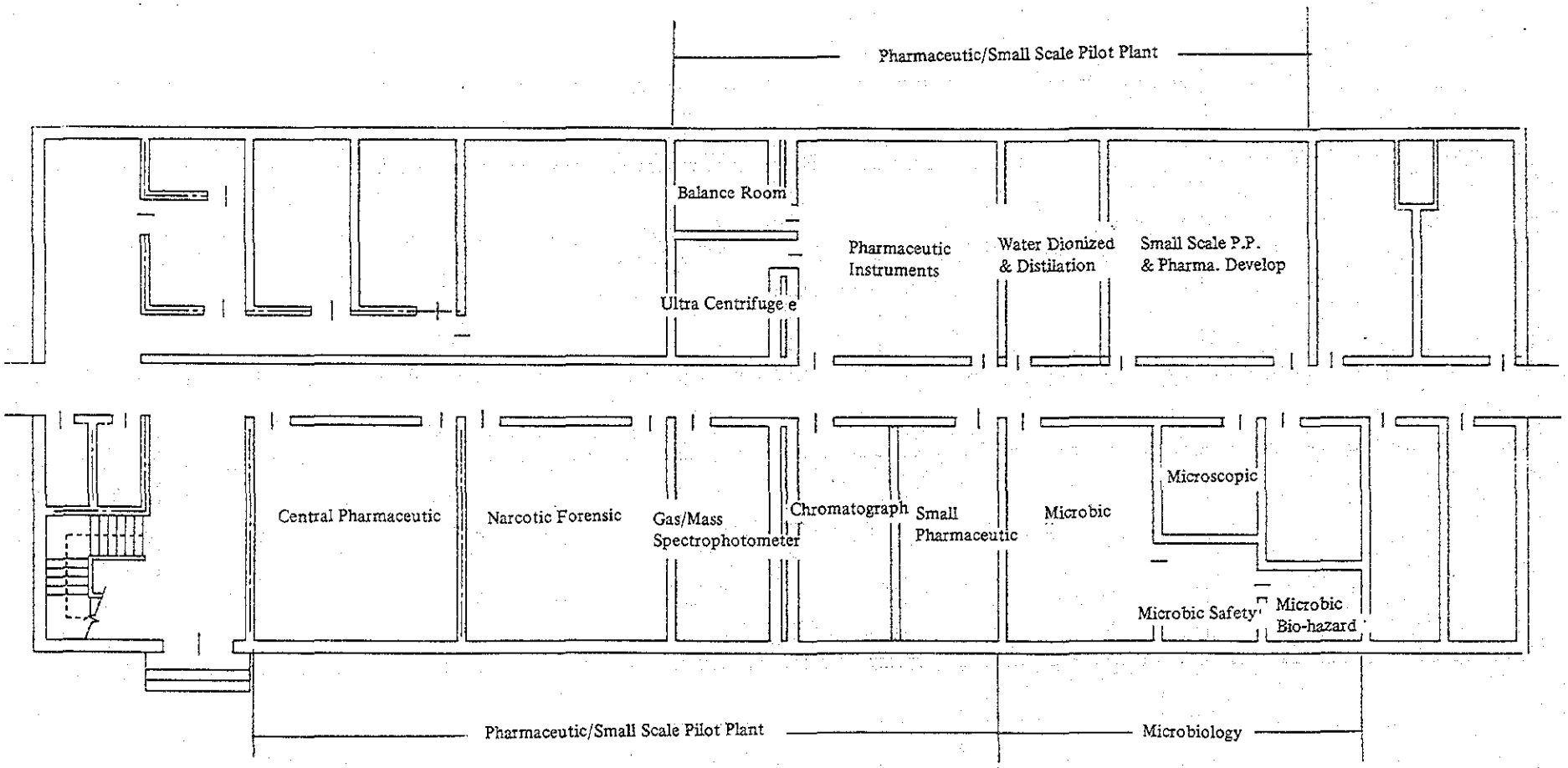
-4 Existing experimental animal feeding building [(5), (10)]

Facilities to conduct toxicity tests of medical supplies, by using experimental animals.

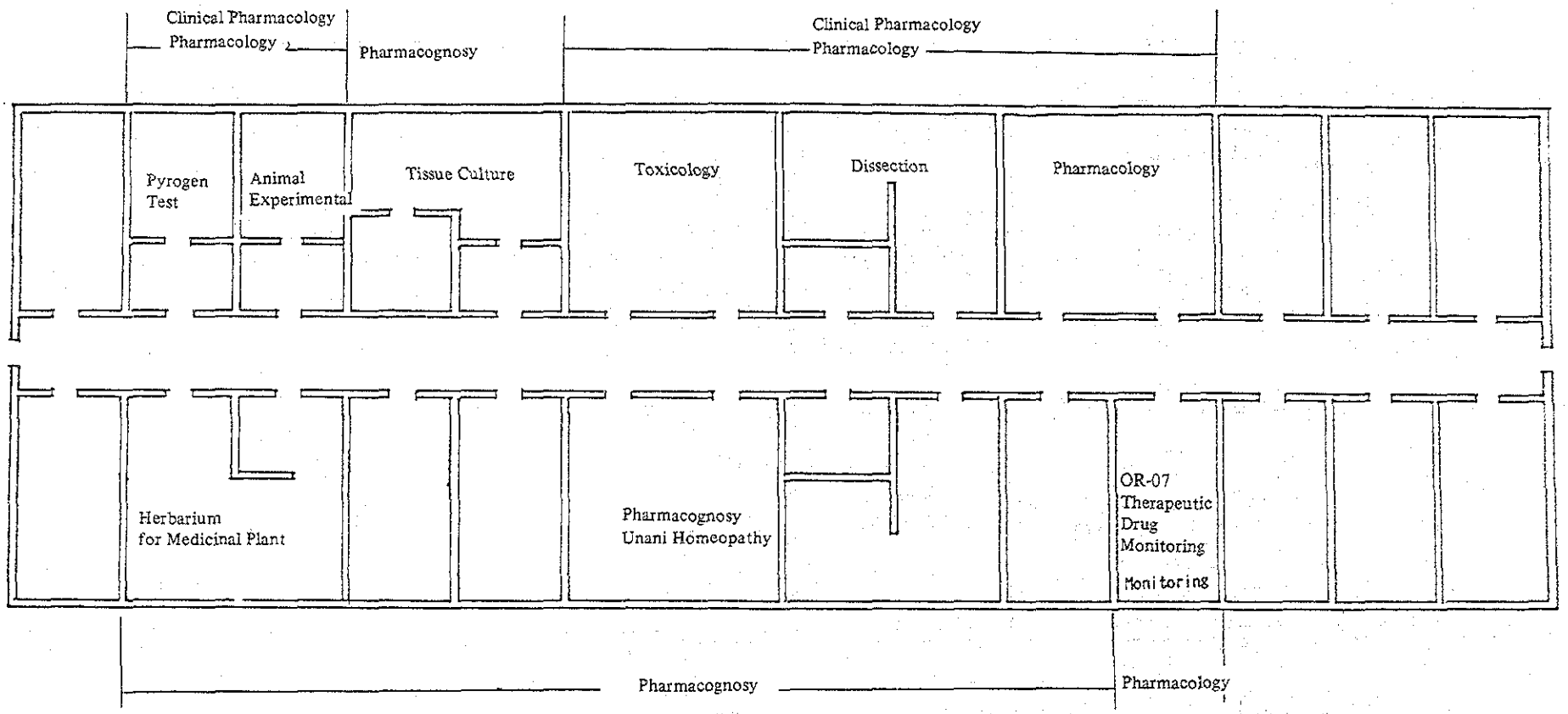
At the moment, the building is completed, and it can be immediately made available for use as soon as examination equipment and tools are available for use in the building.

Current request comprises verification equipment and tools requied for performing signed duties which are related to the above facilities program.

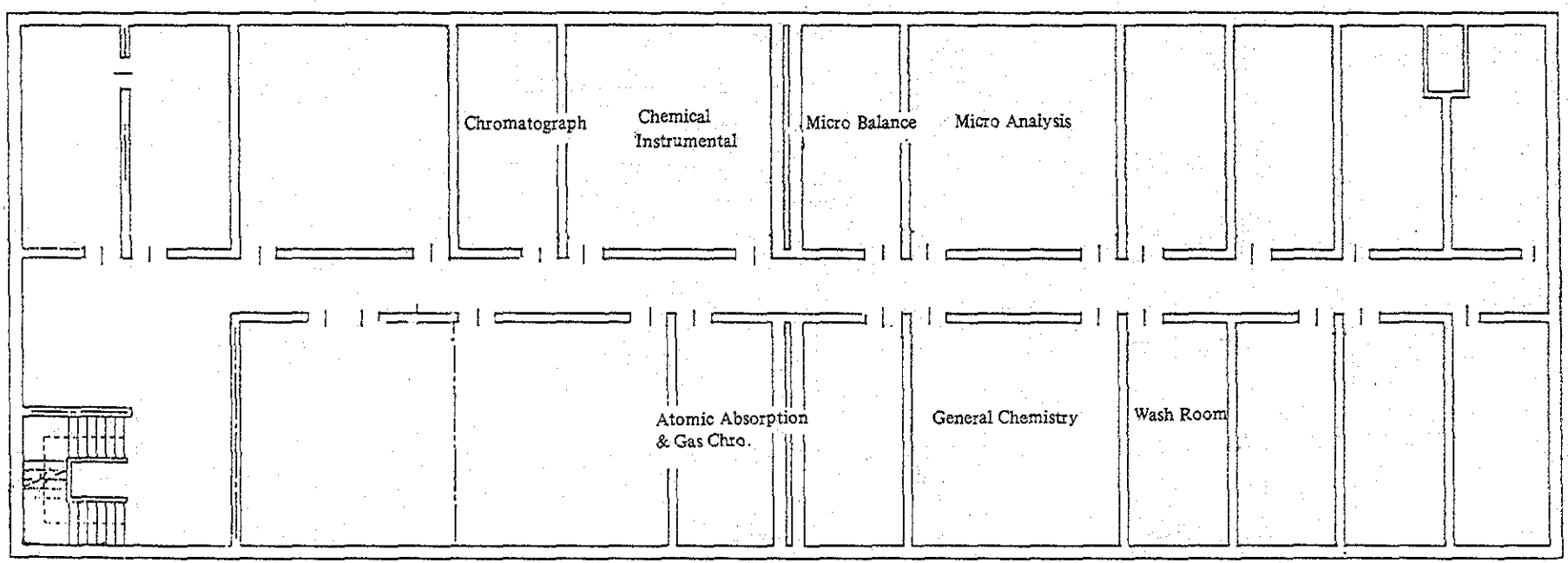
Floor drawings indicating each testing room are shown as follows.



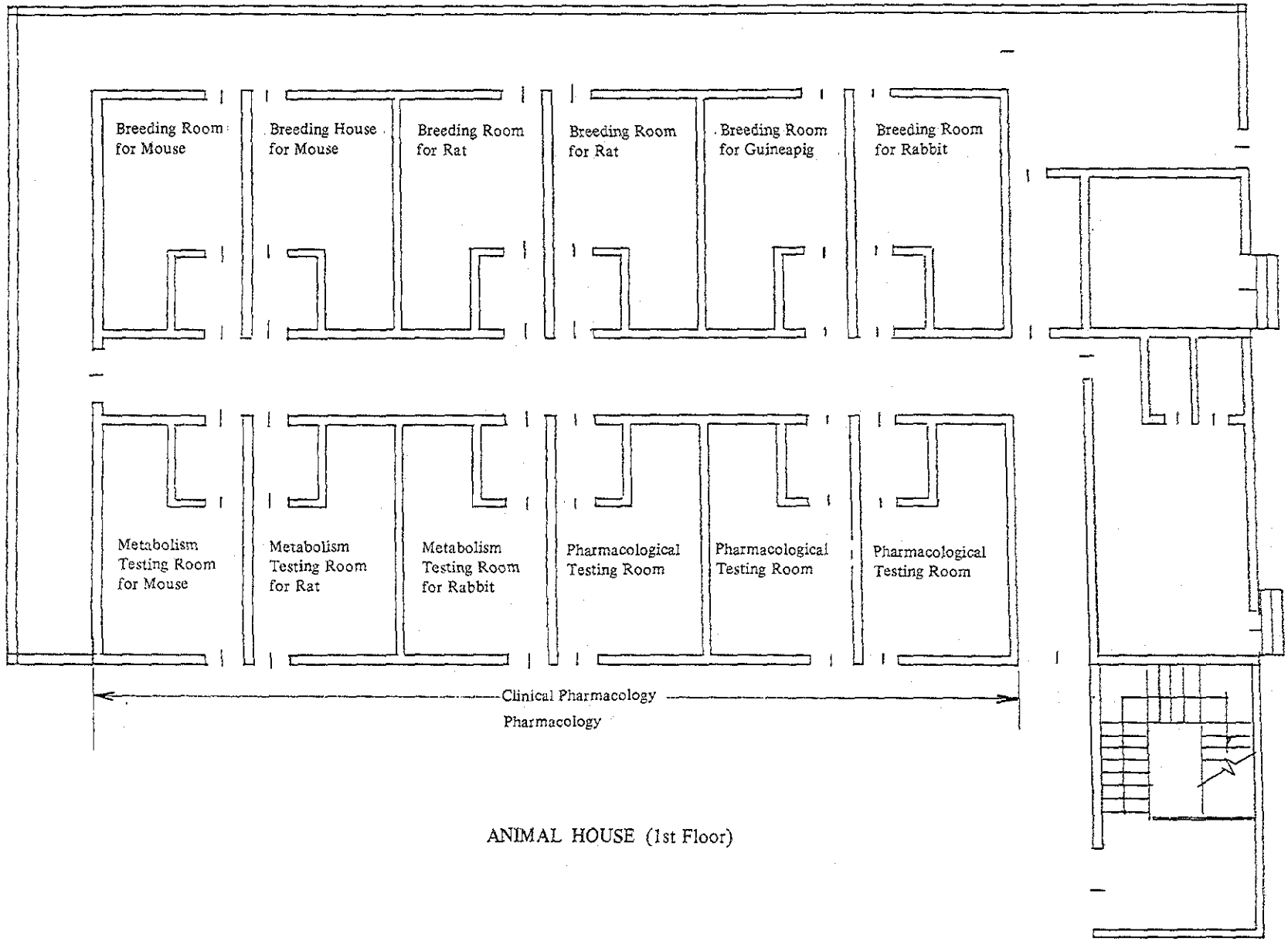
Ground Floor


Clinical Pharmacology
Pharmacology
Pharmacognosy
Clinical Pharmacology
Pharmacology
Pyrogen Test
Animal Experimental
Tissue Culture
Toxicology
Dissection
Pharmacology
Herbarium for Medicinal Plant
Pharmacognosy Unani Homeopathy
OR-07 Therapeutic Drug Monitoring
Monitoring
Pharmacognosy
Pharmacology

First Floor



First Floor – Chemistry



ANIMAL HOUSE (1st Floor)

CHAPTER 3

CHAPTER 3 DESCRIPTION OF THE PROJECT

3-1 Purposes of the Project

At the present, the Division has the three (3) duties of functioning as the appellate laboratory subject to the Drugs Act enacted in 1976, performing inspections and analyses of drugs and performing investigations and research on traditional medicines. However, the duties of the inspection and analysis of drugs for the legal inquiry organization have not been sufficiently executed up to the present time, and moreover, the responsibility to execute standardization and evaluation of traditional medicines, as added by a regulation in 1981, is also not being completely carried out. One problem is that all of the existing equipment of the Division was manufactured 15 to 20 years ago so that it is inefficient and inaccurate. In addition, it should be mentioned that the required testing materials are in short supply. To establish a system which enables the supply of cheap and safe drugs for the Pakistani people, first of all, it is necessary to arrange matters so that the functions which have been assigned to the Division, can be performed. Under such circumstances, the equipment for the Division should be arranged to enable it to accomplish its function.

3-2 Work Plans and Management Budget

3-2-1 Work Plans

1) Chemical Section :

(Work plan for 1989)

-1 Routine Work :

Quality Control, evaluation and standardization are to be advanced in the Centre. Work plans are shown for each section as below.

Quality control testing and analyses of samples of drugs received from :-

a) Provincial Quality Control Boards.

b) Drugs Courts.

c) Federal Government Institution.

d) Army.

e) Medical Store Department.

-2 Research Projects :

Project No.1 Monitoring of Drugs for Quality Control :

This project aims at organized monitoring of the quality of some of the most commonly used drugs in the country including stability and bioavailability studies.

Project No.2 Training in Poisons :

A training programme in the field of poisons testing has arranged for officers of the Forensic Laboratory, Peshawar. This will last for about four weeks and is expected to be held in the month of April.

Project No.3 Phytochemical Studies into the Genus Artemisia :

The work involves detailed study of the Artemisia plant of Pakistani origin and its chemical consitituents of therapeutic importance.

This forms a part of the project of one of the research officers for his Ph D degree.

Project No.4 Cigarette Smoking :

A detailed study is to be conducted for the qualitative and quantitative determination of carcinogenic substances present in the smoke of various brands of cigarettes available in the market.

-3 Other Projects :

1. Maintenance of Reference Standards :

Presently only a few reference standards are present in the Division. It is therefore planned to collect and maintain Reference Standards of all important drugs and chemicals and to prepare Working Standards for distribution to other laboratories.

2. Maintenance of Specifications of Pharmaceutical Products :

Presently no Specifications are maintained in the Division. Whatever is available is only rudimentary. This is causing great difficulty in conducting tests and analyses of drugs received.

It is planned to obtain authenticated specifications of all registered drugs and maintain them in the Division for ready reference and use.

3. Establishment of method of testing of pharmaceutical products :

2) Pharmaceutical Section :

(Work plan for 1989)

-1 Routine Work :

Routine testing and analyses of the followings :-

1. Identification of steroidal drugs in the samples of unani and homeopathic remedies received from government institutions and other sources.
2. Testing and analyses of narcotics and psycotropic drugs from
   a) samples of materials received from the Pakistan Narcotics Control Board, Airport Customs and other government agencies.
   b) samples of blood and urine received from hospitals and rehabilitation centres in Pakistan.

-2 Research Projects :

1. Isolated of active constituents from indigenous medical plants for pharmacological testing for antidiabetic activity.
2. Studies into bioavailability of drugs. The drugs' bioavailability is of great concern to the medical practitioners of the country. There is therefore a need to develop procedures for estimating the variability in the dosage requirments of various drugs, to achieve a steady state of plasma concentration produced a fixed dose.

3) Clinical Pharmacology / Pharmacology Section :

(Work plan for 1989)

-1 Research Projects :

The following summary details the status of projects being carried out in the pharmacology section of the Division for the year 1989.

Project No.1 Adverse Drugs Reaction Monitoring :

A pilot project establishing a nationwide adverse drug; reaction monitoring system.

Participating physicians have been contacted and further preparations are under way.

Project No.2 Drug Utilization Studies :

These studies are aimed at ascertaining the prescribing patterns and dispensing practices of practicing physicians and pharmacists.

Support or this is being sought from WHO and UNICEF.

Project No.3 Drug Therapeutic Monitoring :

Determination of safe and effective blood levels for

Theophylline, digoxin and phenytoin in Pakistani patients. This is a WHO funded project and equipment is awaited. Preliminary groundwork has been completed.

Project No.4 Screening of Herbs for Antidiabetic Activity :

Project in cooperation with the unani, pharmaceutical and chemical section of the Division is among to identify herbal drugs with possible antidiabetic activity.

The work plan involves identification, purification, chemical analysis, toxicological analysis and patient administration.
Work is well underway.

-2 Routine Work : Pharmacological testing of samples of drugs received for quality control.

4) Pharmacognosy Section :

(Work plan for 1989)

-1 Research Projects :

Project No.1 Collection and Categorization of Pollen Grains from the country for Clinical Allergy Centre.

Till now, the pollen grains for the production of allergy vaccines in the NIH were collected locally in a haphazard manner without any categorization and irrespective of the seasonal changes.

The project aims at collecting pollens separately for each of the four categories of plants, i.e., herbs, shrubs, trees and grasses during different seasons of the year from throughout the country.

The objective is to collect the pollens for the separate preparation of mono-valent as well as polyvalent vaccines.

The pollen-bearing plants with allergy treatment potential will be properly photographed, preserved, categorized and documented for this purposes.

Project No.2 Pharmacognostical Investigation of Plants Containing Flavonoids

The project aims at screening indigenous plant meterials from a selected family for the presence of flavonoids as anti-bacterial agents. The work will involve isolation of the active constituents of the plant material, their identification & charactorization followed by investigation of antimicrobial activity.

Project No.3 Micropropagation of Artemisia Species

Pharmaceutical interest is growing in the artemisia species. One of the artemisia species (A.annua) has recently been found to contain an antimalarial constituent, whereas in Pakistan another species (artemisia maritina) is grown in abundance indicating that the climate in Pakistan is suited to the cultivation of artemisia annua & other species. This project aims at conducting micro-propagation which is a new technique for the large-scale cultivation of A.annua.

-2 Routine Work : Collection, identification and preservation of medical plants of the country.

5) Microbiology Section :

(Work plan for 1989)

-1 Routine Work : Microbiological analyses of drugs, i.e., potency tests, sterility tests and pyrogen tests of antibiotics and other drugs.

-2 Research Project :

Screening of indigenous plants, their extracts and various constituents for antimicrobial activity, especially against strains resistant to the commonly available antibiotics.

6) Unani / Homeopathic Section :

(Work plan for 1989)

-1 Research Work :

1. Assistance in conducting literature survey for Antidiabetic, Antihypercholesterolaemic and Antibacterial drugs.
2. Survey of literature on Unani System to find out the concepts and misconceptions about the following diseases and their treatment in the Unani System of medicine.
   a) Diabetes.
   b) Hypercholesterolaemia.

3-2-2 Management Budget

The proposal for budget for this Centre is submitted to the Finance Division of the NIH every October to November where the requirements of all other Divisions are consolidated and the combined proposals are submitted to the Ministry of Health, Special Education & Social Welfare of Government of Pakistan which in turn takes up with the Ministry of finance for approval of budget. This is usually approved sometimes during the month of March and is announced in June.

For the management of this centre two (2) million rupees are added to one (1) million rupees alloted as ordinal budget for this fiscal year (July 1989 - June 1990).

The breakdown of this budget is 0.9 million rupees for purchase of chemicals, 0.9 million rupees for purchase of glasswares and 1.2 million rupees for furniture in new building. The management budget is consisted of cost of procurement of expendable, of cost of periodical check-ups, of utility cost and of personnel expenses, whose estimation is shown in 4-7. Since personnel expenses and utility cost are paid from the main NIH budget it's not necessary for this centre to secure these cost. And also the increased amount is estimated to be five thousand rupees for annual utility cost by procurement of equipment, 0.5 million rupees for personnel expenses, which are to be appropriated in its budget for the coming year.

Therefore, it's necessary for this centre to secure the cost of purchase of chemicals, cost of procurement of expendable and cost of periodical check-ups.

The breakdown of management budget necessary for this centre is shown below.

Cost secured by this Centre	
Cost of procurement of expendable	1,565,000 rupees
Cost of periodical check-ups	1,280,000 rupees
Cost of purchase of chemicals	900,000 rupees
Sub total	3,745,000 rupees
Cost of dealt with as whole NIH	
Utility cost	5,000 rupees
Personnel expenses	2,100,000 rupees
Sub total	2,105,000 rupees
Grand total	5,850,000 rupees

Accordingly this Centre needs to secure 3,745 thousand rupees as management budget for its own.

It has been confirmed that the budget proposal including above mentioned 3,745,000 rupees that shall be prepared for the next fiscal year and shall be submitted to the relevant quarter for approval. And also it has been confirmed that the funds will be raised by the Executive Director, who is the official from Pakistani side responsible for all the expenses concerning its management budget.

The confirming documents signed by the executive Director of the NIH have been received.

As mentioned above, the required budget for the operation of the centre secured with a firm promise by the men responsible such as chief of the Centre and the Executive Director of the NIH and the Deputy director General of Planning and Development of the Ministry of Health, Government of Pakistan who is a person designated for coordination and sponsoring the project on behalf of the Ministry. The budget for the NIH is 40 million rupees in total composed of the funds from the Government amounting 20 million rupees and income from Biological Production Division amounting 20 million rupees.

The present earning of the Division for testing of samples is about 50,000 rupees annually. Such an income is consolidated by Finance Division and is spent as budget for the NIH.

3-3 Study and Examination on the Request

3-3-1 Survey Method

A survey of the equipment to be supplied under this project was conducted by interviewing full-time researchers of respective departments in order to fully ascertain the appropriateness of their request for equipment and to check out the reasons for its necessity and the purpose of its use. They were also asked to show equipment installation sketches with clearcut indications of the equipment's locations. With such a survey as the background, the survey team prepared a list of equipment by room interviewed full-time researchers, and confirmed again the locations of these equipment. Additionally, a survey was conducted on the existing equipment which is currently being used in the facilities of the Division of the NIH, and the survey team used its finding as materials for passing judgement on the selection of equipment.

In parallel with the said interviews, the team requested the preparation of a list of persons responsible for equipment operation and such a list was obtained. The list consists of the names of the persons in charge, information on their experience using the requested equipment, their basic knowledge of individual equipment, and detailed of the existing equipment being used.

3-3-2 Request and Findings of the Survey

The list of equipment intended for the improvement and reinforcement of the present facilities was attached to the written request and it considered of (a) equipment for Chemistry Tests, (b) equipment for Microbiology Tests, (c) equipment for Pharmacology Tests, (d) equipment for Pharmaceutics, (e) equipment for Pharmacognosy, and (f) equipment for research of Traditional Medicines.

The requested number of spectrophotometric equipment listed under (a) was one (1) unit each.

It is the most urgently needed type of equipment in conducting modernized quality control of drugs.

The British and US Pharmacopoeia are adopted as quality control method in this country. For these methods spectrophotometric eqiupment is most frequently used for analyses and separation and required accuracy.

Accordingly, one (1) unit of this equipment should be installed at each section (e.g., pharmacological examination, chemical analysis of drugs, analysis of traditional medicine, and others) when controlling drugs other than those that require a Gas/Mass spectrophotometer, which is another type of high performance analytic device.

As a result of the survey, the quantities of the requested equipment, details and inspections, and the objectives of the research work utilizing (b), (d), (e) and (f) above were cross-checked and indivisual experimental facilities were found to be appropriate.

As equipment for experiments with animals, various animal cages made of plastic, metal, ets., feeding silos, an anatomy stage for experimental purposes, a metabolism cage to check metabolic functions, etc., are requested. The animal cages, which have already been built at the site of the NIH, become an included item because animal will be bred there also for the project.

Too many cages are included in the list of equipment to be procured. it's been determined that there is no place to put all of them. Though the existing cages are fairly old and the environment for breeding animals for use in experiments is not good, it's considered that the animals kept in the existing cages are satisfactory for the quality control tests (e.g., pyrogen test) mentioned in the work plan.

3-3-3 Request for Additional Equipment

1) Number of equipment requested additionally classified in section

-1	Chemistry Section	33 units
-2	Microbiology Section	14 units
-3	Clinical Pharmacology / Pharmacology Section	81 units
-4	Pharmaceutical / Narcotic Section	53 units
-5	Pharmacognosy and Unani / Homeopathic Section	43 units

There are 224 units of equipment requested additionally in total by each section. Most of them are composed of basic equipment necessary for the Drugs Control, Pharmacognosy, and Unani / Homeopathic Section. Since most of the requested equipment overlaps with the equipment for the Quality control mentioned in the Letter of Request (PC-1 form), conclusively they are not necessary, and the recommended number of equipment is shown as follows, which is considered appropriate to add to the basic design.

2) Number of equipment added to basic design upon additional request

-1	Chemistry Section	15 units
-2	Microbiology Section	7 units
-3	Clinical Pharmacology / Pharmacology Section	30 units
-4	Pharmaceutical / Narcotic Section	16 units
-5	Pharmacofnosy and Unani / Homeopathic Section	18 units

3) Analysis of additional request

Additional request includes 8 units of high performance equipment such as FT/NMR (Nuclear Magnetic Resonance) and XRD (X-ray Diffraction). Since these are considered dispensable for Drugs Control, but necessary for the structure analysis of unknown substances in molecular biological research, genetic engineering, fine chemical analysis, etc. these units of equipment are excluded from the basic design.

Concerning equipment for Pharmaceutical research and study, the equipment is planned for Pilot production and Development and consist of large scale equipment for Pharmaceutics. As a result of the study of the additional request, it's clarified that the laboratory scale pilot production is aimed at extracting the active constituents out of herbal medicines and traditional medicines, and establishing thier formulas. The additional request was made to procure the equipment necessary for the abovementioned research. since the research and study on herbal medicine and on traditional medicine is indispensable for the health of the people of Pakistan and for securing safe medical treatment, which should be achived by the Pakistani side without delay.

The equipment requested additionally for Pharmacognosy and Traditional medicine research is not included in the initial letter of request.

The equipment for these sections is necessary to extract active constituents from herbal medicines found in the domestic ecosystem, to clarify scientifically the efficacy of them, and to set basic standards for them because the people of Pakistan have no quality control standards at the moment. The equipment is also necessary to conduct tissue culturing and to grind plants to find out the possible constituents for synthesizing them.

Prior to the study of the equipment plan, the basic design team surveyed the function of each section and made out the list of equipment allotting the equipment to each testing room according to its purpose while considering the equipemnt requested in the letter of request and additional request. As a result of the study, the adopted equipment is shown with code number as APPENDIX 3.

3-3-4 Equipment Recommended by the Basic Design Study

In Addition to the study mentioned in 3-3-2 and 3-3-3 of the requested equipment, the basic design study team considers the following equipment to be indispensable in order to implement researches of this Centre :

-1 Reverse Osmosis Water Purification Unit to pre-treat crude water for Water Distillation Unit which provides distilled water necessary for preparation of media, reagent and for extraction of herbal medicines.

-2 Chemical Waist Water treatment Unit to prevent public pollution which may be caused by disposal of chemicals such as reagent.

-3 Weight Scale for experimental animal for testing Metabolism Rotary Machine for plant cell culture necessary for research of herbal medicines and traditional medicines and others.

Concerning 3-3-2 to 3-3-4 study of major equipment is shown as Table 3-3-4.

Table 3-3-4 Study point of major equipment requested

Name of equipment	Initial request	Additional request	Result of field survey	Analysis at home	Result of Draft report explanation	Study points
High performance liquid chromatograph	1 NO. (Chemistry Section)	1 NO. (Clinical Pharmacology /Pharmacology Section)				. necessary for confirmation of safety for pharmaceutical drugs e.g. separative and identical analysis, existence of foreign material and conformation of specification. . possible to conduct multipurpose analysis. . requested to add from Pharmacology Section to help measure concentration of toxicity in blood and to conduct separation and analysis of toxicity quantitatively.
Gas chromatograph	1 NO.	1 NO. (Pharmaceutical/ Narcotic Section)				. effective to analyze drugs composed of constituents having similar property. . necessary for quantitative analysis of pure material and analysis of element requested to add from Pharmaceutical Section which needs to conduct structural analysis of natural products e.g. herbal medicines.
Gas/mass spectrophotometer	1 NO. (For all Sections)					. necessary for structural analysis of herbal medicines.narcotics. psychotopics.toxicity & escepially steloids contained in herbal medicines.

Name of equipment	Initial request	Additional request	Result of field survey	Analysis at home	Result of Draft report explanation	Study points
Atomic absorption spectrophotometer	1 NO. (Chemistry Section)					. to conduct qualitative & quantitative analysis for pharmaceutical drugs and herbal medicines. . to supplement spectroscopy since photoelectric analysis (Inflared, Fluorescence) enables to deal with difficult substances to be analysed.
I.R. Spectrophotometer	1 NO. (Chemistry Section)	NO.1 (Clinical Pharmacology /Pharmacology Section)				. to analyze organic substances. . to conduct quantitative and qualitative analysis of molecules absorbing Inflared spectrum of its own. . indispensable for drugs quality control since effective to detect isomers. . requested to add by Pharmacology Section in order to detect isomers of molecules of active constituents in pharmaceutical drugs, herbal medicines and traditional medicines in the phase of gas, liquid and solid for quality control.
Digital Polarimeter	1 NO. (Chemistry Section)					. indispensable for quality control to detect polysaccarides containing toxic substance known as pyrogen.

Name of equipment	Initial request	Additional request	Result of field survey	Analysis at home	Result of Draft report explanation	Study points
Spectrophotometer, fluorescent	1 NO. (Chemistry Section	1 NO. (Pharmaceutical/Narcotic Section)				. to conduct identification & analysis of fatty acids, amino-compounds and amines. . necessary for analysis of constituents of drugs and herbal medicines and has characteristics that enable to detect substances which is hard to analyze by ordinal spectrophotometer. . requested to add by Pharmacology Section in order to analyze cardiotonic glucosides in herbal medicines, antiepileptic medicines etc.
Spectrophotometer	1 NO. (Chemistry Section	1 NO. (Charmaceutical/Narcotic Section)		1 NO. (Clinical Pharmacology/ Pharmacology Section)		. analyze and measure atomic emission spectrum for innorganic substances & absorption spectrum for organic substances. . multipurpose and indispensable for quality control of drugs and others. . requested to add by Pharmaceutical Section and disposed to Pharmacology Section at the result of analysis at home. For, basic for analysis and used most often, Pharamacology Section is located away from Chemistry Section.

Name of equipment	Initial request	Additional request	Result of field survey	Analysis at home	Result of Draft report explanation	Study points
Dissolution testing machine for tablet	1 NO. (Chemistry Section)					. basic as equipment for quality control . to measure dissolution of tablet to judge potency of tablets, or absorption to body.
Fraction collector	1 NO. (Chemistry Section)	1 NO. (Pharmaceutical/Narcotic Section)				. to collect active constituents as fraction extracted, dissolved and concentrated by solvents from herbal medicines. . requested to add by Pharmaceutical Section for Pilot plant in order to obtain much enough extract, or active constituents from herbal medicines and to make drugs experimentally.
Tensile testing unit for Sutures & Bandage	1 NO. (Chemistry Section)					. to test tensile strength of suture, bandage & gause. . indispensable to check if coated drugs on them affect their strength.

Name of equipment	Initial request	Additional request	Result of field survey	Analysis at home	Result of Draft report explanation	Study points
Particle counter for liquid	1 NO. (Pharmaceutical/Narcotic Section)					. to detect foreign material in drug, in liquid form, such as injection, eye drops and oral vaccines available in city market for quality control . to capture optically and count bigger particles than specified.
Particle counter in the air					1 NO. (Microbiology Section)	. to count numbers of particles in the air . to confirm cleanliness of the clean bench before using it In case it's not clean as designated the accuracy of quality control test may be affected. . to check and instruct cleanliness of private drug manufacturing plants for safety. . possible to take to sites since portable. . requested to add during explanation of draft final report since indispensable to support quality control.

Name of equipment	Initial request	Additional request	Result of field survey	Analysis at home	Result of Draft report explanation	Study points
Densitometer, TLC/ electrophoresis			1 NO. (Chemistry Section)			. to quantify substance separated by TLC or electrophoresis. . recommended by basic design team since indispensable for aforementioned units.
Water distillation unit, (30L/H)	1 NO. (For All Sections)					. to provide hihgly purified water needed for smaple preparation, extraction of herbal medicines and pharmaceutical preparation.
Zone reader		1 NO. (Microbio-logy Section)				. indispensable to examine potency in drugs quality control. · especially useful to the potency test for antibiotics.
Biomicroscope with camera system	1 NO. (Microbio-logy Section)					. to clarify structure of microbe and microscopic substances. . attached with function of phase difference and fluorescence apparatus. . needed one each unit for micro biological test, for examination of animal organs used for toxicological test.

Name of equipment	Initial request	Additional request	Result of field survey	Analysis at home	Result of Draft report explanation	Study points
Centrifuge, high speed, cooling system	1 No. (Micro-biology Section)					. to separate microbes and substance of very little quantity with high speed centrifuge under low temperatures. . necessary for separation of samples as a pretreatment of quality control test. . attached with rotors for vertical and swing use as accessory.
Drug analyzer (Drug therapeutic monitor)					1 NO. (Clinical Pharmacology /Pharmacology Section) 1 NO. (Pharmaceutical /Narcotic Section)	. indispensable to conduct aforementioned tests for herbal medicines and traditional medicines used by many Pakistani people. . to confirm potency and safety of abovementioned medicines by means of determination of concentration of medicine in blood from experiments with animals.
Centrifuge, ultra high speed, 80,000 rpm	1 NO. (Parma-ceutical /Narcotic Section)					. to extract very little active constituents in herbal medicines by ultra high speed centrifuge. . indispensable for separation/ extraction to confirm safety of herbal medicines.

Name of equipment	Initial request	Additional request	Result of field survey	Analysis at home	Result of Draft report explanation	Study points
Tabletting machine, portable	1 NO. (Pharma-ceutical /Narcotic Section)					. to manufacture tablets with active constituents crystallized to confirm the safety through experiments with animals. . used for tabletting active constituents of herbal medicines, synthesized to conduct safety test for the purpose of determination of Pharmaceutical formulation.
Thin layer flash evaporator	1 NO.					. to extract and crystallize active constituents in herbal medicines and traditional medicines. . necessary to extract substance heat-sensitive and easty to dissolve under high temperature.
Paraffin oven		1 NO. (Clinical Pharmacology /Pharmacology Section)				. to embed organs of animal used for safety test into paraffin as one process of making sample for examination. . necessary to analyze result of safety test of drugs.

Name of equipment	Initial request	Additional request	Result of field survey	Analysis at home	Result of Draft report explanation	Study points
Immuno assay analyzer			1 NO. (Clinical Pharmacology /Pharmacology Section)			. to analyze immuno reaction between antigen-antibody and to judge immuno effect of anti-biotics made from microbes. . to determine immuno reaction in cerum taken through experiment with animals.
Distillation/ reaction apparatus					1 NO. Pharmaceutical /Narcotic Section	. to crystallize active constituents extracted and concentrated from herbal medicines and traditional medicines, and to synthesize active constituents to stabilize. . to separate toxins and active constituents which co-exist in herbal medicines and traditional medicines and to secure safety of these medicines.

3-4 Organization of the Centre

3-4-1 Organization of the Centre

The following shows the allocation of personnel affiliated with the Centre.

			(number of staff)
Chief			(1)
Chemistry Section	:	S.S.O.	(2)
		S.O.	(3)
		A.S.O.	(1)
		Tech. Asst.	(5)
		Technician	(2)
		Lab. Asst.	(1)
		Lab. Attendant	(4)
Clinical Pharmacology/ Pharmacology Section	:	S.S.O.	(1)
		S.O.	(1)
		Technicial	(1)
		Lab. Attendant	(3)
		Animal Attendant	(1)
Pharmaceutical/ Narcotic Section	:	S.S.O.	(2)
		S.O.	(2)
		A.S.O.	(1)
		Tech. Asst.	(3)
		Technician	(2)
		Lab. Attendant	(5)
Pharmacognosy Section	:	S.S.O.	(1)
		S.O.	(1)
		Tech. Asst.	(1)
		Lab. Attendant	(2)

Microbiology Section	:	S.S.O.	(1)
		S.O.	(1)
		A.S.O.	(1)
		Tech. Asst.	(1)
		Technician	(2)
		Lab. Attendant	(3)
		Animal Attendant	(2)
Unani/Homeopathic Section	:	A.S.O.	(2)
		Tech. Asst.	(1)
		Packer	(1)
		Mali	(1)

3-4-2 Manning Plan

The present number of staff of this section is more than adquate in relation to its work load. However, in preparation of the project, the posts created for strengthening of this Division are being filled one by one.

In the recent past, appointments have been made of some of the technical staff including a Senior Scientific Officer in Pharmacology, one (1) Senior Scientific Officer in Microbiology and one (1) Scientific Officer for Pharmacology. Appointment of a Senior Scientific Officer for Chemical Research is under active process. The rest of the posts enumerated in the PC-1 form shall be filled by the end of this fiscal year putting the time of procurement of equipment into considerataion. The contents of posts for strengthening is shown below.

Post	Number
Principal Scientific Officer	1
Senior Scientific Officer	3
Scientific Officer	2
Assistant Scientific Officer	4
Technical Assistant	4
Laboratory Attendant & Assistant	3
Attendant	1
Total	18

Fulfillment of abovementioned 18 personnels has been approved by the Government and also has been promissed positively by Dr. Fazli, Chief of this Centre.

3-5 Concept of the Project

The concept of this project is to execute the functions required of the Centre such as medicine quality control, research on traditional medical treatment, high grade inspection and analysis, legal inquiry functions and development.
Therefore, following the request of the Pakistani side, the most necessary and suitable equipment will be selected with reference to function and business details.

As mentioned previously, major equipment to be covered by this project is as follows :

-1 Equipment for Chemical Tests
- a. Gas/Mass Spectrophotometer
- b. High-performance Liquid Chromatograph
- c. Disintegration/Dissolution machine for tablets
- d. Rotary Evaporator

-2 Equipment for Microbiology Tests
- a. Steam Sterilizer
- b. Digital colony Counter
- c. Pyrometer

-3 Equipment for Pharmacology Tests
- a. Rotary Evaporator
- b. Kymograph
- c. High-performance Liquid Chromatograph
- d. IR, UV/VIS Spectrophotometer

-4 Equipment for Pharmaceutical/Narcotic Section
- a. High-performance Liquid Chromatograph
- b. B.P. M.P. F.P. Apparatus
- c. Tabletting Machine
- d. Absorption/Dissolution Machine for Tablets

-5 Equipment for Pharmacognosy
- a. Rotary Evaporator
- b. Column Chromatograph
- c. Laminar Flow
- d. Thin Layer Chromatograph

-6 Equipment for Research of Traditional Medicines

a. Grinder

b. Soxhlet Apparatus

c. Rotary Evaporator

3-6 Relationship with International Assistance Organizations

WHO has rendered positive assistance such as materials for the quality control being performed in health research, furnishing reference standards and assistance with the funds required for training the employees of the NIH, etc.

Through WHO's good offices, many scientists active in drug quality control and research have taken training overseas or joined in seminars, symposium and learned societies. These have been very helpful for the business of drug quality control.

WHO has been active in the spread and development of traditional medicine in developing countries, and its role in accomplishing this target is very great.

WHO's activities have the following three (3) policies :

-1 Evaluation of treatment with traditional medicines and consultation.

-2 Traditional medicines as a part of the national health system

* WHO has particularly cooperated with reference to the traditional system of medicines being utilized at the level of 1st stage health and medical treatment.

-3 Training :

WHO has furnished training facilities.

The training mainly details traditional medicines and standardization of the dosage of medicines which are extracted from substances such as herbs and which are being used in 1st stage health and medical treatment. The goal is to improve the safety of medicines and their effectiveness as a medical treatment method.

In the building to be newly constructed, five (5) rooms are included for use of WHO, but these rooms do not provide any technology and education for the centre, and they are only to replace the Pakistan WHO office which had been located inside the NIH.

CHAPTER 4

CHAPTER 4 BASIC DESIGN

4-1 Basic Design Object

As a result of consultations held between Japan and Pakistan, as well as internal analyses, it has been decided that equipment selection shall be made based on the following basic policy:

1) Attention shall be paid so that what is selected will provide satisfactory conditions for the present Division to perform its duties as regulated by law.

2) Items procured through the project shall be the equipment for pharmaceutical quality control management and research mutually agreed upon by Japan and Pakistan as below.

-1 Equipment for analytical chemistry tests
-2 Equipment for microbiology tests
-3 Equipment for pharmacology tests
-4 Equipment for pharmaceutical tests
-5 Equipment for pharmacognosy tests
-6 Equipment for research of traditional medicines

3) To pursue a rational selection procedure, item of equipment currently used by the Division shall be fully reviewed to avoid any redundancy.

4) Before the actual equipment selection phase, a preliminary study on equipment used at other laboratories which is similar or identical to what the project is to procure shall be conducted with reference to operation of conditions, the business plan, supply of reagents, etc.

5) The quantity of equipment shall be selected taking into account service volume, operational efficiency, test purpose, etc.

4-2 Equipment Plan Description

4-2-1 Equipment for Chemistry Tests

Equipment requested in this field is concentrated on analytical chemistry equipment. Analytical chemistry equipment is composed of extraction/concentration units e.g. evaparator and identification separation units e.g. high-performance liquid chromatograph for traditional medicine examination and development, experimental test units for quality control management of pharmaceuticals that have been in the market following pharmacopoeia of the USA, England, and other advanced countries, physical test units for quality control tests such as tablet/capsule solubilization tests, disintegration tests, fragility tests, viscosity tests, etc.

Relations between test procedures and application equipment in this field are shown in Appendix 1, P89 - 92.

4-2-2 Equipment for Microbiology Tests

Equipment requested in this field is composed of the following units dealing with microbiology :

1) For potency tests on antibiotics under research/study and quality control, tests of the efficacy of medicinal plants:

   Sterilizer, unit necessary for growing fungus cultures, thermostat, etc.; digital cluster measuring instrument to measure fungus reproduction, etc.

2) For pyrogen test under quality control test:

   Automatic balance for experiment animals, pyrometer, etc.

3) For sterility tests, anti-virus/bacteria tests, as well as quality control tests:

   Sterilizer, unit necessary for reproduction in thermostat, etc.

   For measurement of fungus reproduction:

   Air sampler, digital colony counter, etc.

Relations between test procedures and application equipment in this field are shown in APPENDIX 1, P93 - 95.

4-2-3 Equipment for Pharmacology Tests

1) Test requirements concerning traditional medicines in this field shall be put into the pharmacological classification under quality control tests.

During the classification process, eqiupment shall be alloted for each requirement as below.

Scientific balance for measurement during traditional medicine refining process, sample grinding unit to grind samples, rotary evaporator to extract pharmaceutically effective ingredients, soxhlet apparatus, refining unit to refine ingredients, kymograph & dynamometer to check pharmaceutical effectiveness, spectrophotometer to check blood sugar level, high performance liquid chromatograph, infrared spectrophotometer, ultraviolet/visible spectrophotometer, etc., to analyze pharmaceutical contents at blood level for pharmacological surveillance of pharmaceutical such as gentamycin, digoxin, etc., under quality control test, and steam sterilizer, thermostat, culture use glassware devices, etc., for tissue cultures.

2) Equipment in this field is composed of microtomes for sample cutting and processing to test acute, quasiacute, chronic, and long-term toxic characteristics, a microscope, etc., to conduct identification, etc.

3) Therefore, it's considered sufficient to procure enough cages to keep experimental animals in the experimental room for 3 - 4 months and reasonable to procure related equipment.

Equipment such as a metabolism cage and a dissecting table are supposed to be located in the Toxicology Section.

However, the room is too narrow to keep this equipment, and therefore it is planned to keep it in the Animal House.

Relations between test procedures and application equipment in this field are shown APPENDIX 1, P96 - 100.

4-2-4 Equipment for Pharmaceutics & Narcotics Tests

1) While some of the tests normally conducted include analytical chemistry tests, the following equipment is requested for pharmaceutics tests:

For legal inspection equipment for narcotics, a high performance liquid chromatograph with ultraviolet/infrared detector unit, gas chromatograph, analyzer such as ultraviolet/visible spectrophotometer, etc.; material test units such as for measurement of melting point, boiling point, and freezing point, etc.

2) This section has been conducteing Narcotics Testing judging from abovementioned situation at the moment, the high-performance liquid chromatograph (HPLC), gas chromatograph and UV/VIS spectrophotometer with detectors are procured newly. This will enable the conducting of comprehensive studies, e.g., the body fluids of narcotics addicts can be examined to detect narcotics as mentioned in the work plant.

3) For the pilot plant, an extraction unit to separate the active ingredients of herbs, a tablet/powder pharmaceutics unit for test purposes, a laboratory scale; and for pharmaceutic material tests, a pharmaceutics absorption/dissolution unit, etc., are disposed.

Relations between test procedures and application equipment in this field are shown in Appendix 1, P101.

4-2-5 Equipment for Pharmacognosy Tests

Equipment disposed in this field is composed of the following units dealing with Pharmacognosy/Botany.

1) Study concerning Biological/Microbiological activities.

Balance and oven for collection, preparation and weighing of material, water bath, glasswares for Hydrolysis, Rotary evaporator for preparation or extraction/drying of plant extract, spectrophotometer for identification of natural drugs, gas chromatograph, thin layer

chromatograph, column chromatograph and paper chromatograph for identification for different natural compunds, high-performance liquid chromatograph for further identification by producing spectra of different components in natural compounds, laminar flow, zone reader for test of Biological/Microbiological activities of the isolated compounds.

2) Research for Tissue culture

Cuttres, scissors and oven for cutting, washing and sterilization, autoclave, mixer, etc., for preparation of culture media, laminar flow to make aseptic conditions, incubator/growth chamber for growth of the natural, etc.

As abovementioned, this section having little necessary equipment, new equipment requested are procured.

Relations between procedures and application equipment in this section are shown in APPENDIX 1, P102, 103.

4-2-6 Equipment for Research of Traditional Medicines

Equipment requested in this section is shown as follows.

Top loading balance for weighing, grinder for grinding, electric balance for precise weighing, extractors for extraction, rotary evaporator for concentration, vessils for crystallization, reaction vessils for reaction, Tabletting machine.

As abovementioned, necessary equipment is not contained in this section. Therefore new equipment is procured following the content of equipment requested.

Relations between procedures and application equipment in this section are shown in APPENDIX 1, P104.

4-2-7 Other Accessory Equipment

On the occasion of the field survey, the Pakistani side said that they had no intention of treating the experiment wastewater including toxic reagents such as mercury compounds and cyanides, and used solvents such as chloroform, etc. Then, so as not to allow the free run off of experiment wastewater, a wastewater disposer should be installed at each section under this grant aid.

And also, three personal computers are procured in order to accumulate quality control information for each drug, so that analysis is made easier. Each one (1) unit is disposed to Chemical Section, Clinical Phamacology/Pharmacology Section and Pharmaceutical/Narcotic Section.

As a result of the abovementioned study, the equipment list is shown as APPENDIX 4.

4-3 Implementation of the Project

4-3-1 Implementation Organization

1) Implementation Organization

The general administrative organ of this project shall be the Ministry of Health, Special Education & Social Welfare (Planning and Development Section) which shall cooperate with the NIH, Pakistan Public Works Department, Central Board of Revenues, Economic Affairs Department, and other organs concerned, and take complete responsibility for the implementation of this Project. The Deputy Director General of the Health Division shall make the necessary arrangements for the project and ask opinions from related organs including the Director of the NIH.

2) Consultant

Upon the signing of the official Exchange of Notes by the Governments of Japan and Pakistan, a Japanese consultant shall immediately enter into a Consultant Contract with the Ministry of Health, Special Education & Social Welfare in accordance with the Grant Aid Program, procedures laid down by Japan.

Based on the contract, the Consultant shall carry out the following work:

-1 Implementation design stage :

Preparation of implementation design, specifications of equipment and other technical documents.

-2 Tendering stage :

Selection of Equipment Supplier and business cooperation in relation with Suppliers Contract in general.

-3 Prodrement stage:

Management of equipment procurement work by supplier.

3) Equipment Supplier

Equipment Supplier shall ensure that the supplier selected by the tender carry out fabrication, supply and delivery of required equipment in accordance with the contract and provide technical instruction on installation and operation of the equipment to be carried out under the responsibility of the Pakistani side.

4-3-2 Scope of Work

The project shall be implemented by mutual cooperation between Japan and Pakistan. Business items to be carried out by the Japanese government and those which are Pakistan's responsibility are listed as below:

1) Scope of Work to be covered by the Japanese government

-1 Consultant activities

Japanese side shall be responsible for work concerning consulting operations and equipment procurement as listed below.

a. Preparation of Details Design documents and tender documents.

b. Selection of equipment supplier and cooperation in contract work.

c. Management of equipment procurement work

-2 Equipment procurement work

a. Procurement of the project equipment and shipment to designated location of the NIH.

b. Instruction on the project equipment's installation and trial operation & adjustment.

c. Instruction and explanation of the project equipment's operation, maintenance, and control.

2) Scope of Work to be covered by the Pakistani side

Pakistani side shall be responsible for equipment installation and necessary tax exemption procedures of the project which are not included in the Japanese side work items as listed below.

-1 Supply and installation of equipment setting anchor, support steel, and concrete foundation, etc., for large size project equipment.

-2 Installation of infrastructure supply lines including water, drainage, power, gas, etc., up to designated area as well as air conditioning work necessary for the project equipment's operation.

-3 Site transportation of the project equipment from temporary storage area to installation area as well as installation work.

3) Duty exemption procedure

-1 Exemption from import duties, internal taxes, or other financial charges in Pakistan ("Other financial charges" here shall include indirect expenses applied in Pakistan on the installation of imported items) or, if such duties are unavoidable, payment of them.

-2 Quick and efficient customs clearance and inland transportation of equipment and materials imported from Japan.

-3 Provision of storage area for the project equipment until the installation work

-4 Arrangements for entry to and stay in Pakistan of Japanese nationals to work for implementation of the project.

-5 Issue or approval of necessary certificates, tax exemption, and other permission while observing Pakistan's laws.

-6 Responsibility for all necessary expenses incurred except for those borne by Japanese side.

4-3-3 Details Design and Management

Consultant shall be responsible for the Details design work and administrative management of the equipment arrangement plan in accordance with the contract entered into with Pakistan.

Under the details design work, the consultant shall determine and prepare detailed equipment specifications based on this basic design study, a building procedure text and tender documents consisting of an equipment procurement contract proposal, etc., including cost estimations for the procured equipment.

Under the administrative management, the consultant shall verify that work specified in the contract is duly conducted by the supplier, ensure fulfillment of the contract, and, taking an impartial position, provide necessary instructions, advice, and arrangements consisting of the following:

-1 Paper work necessary for equipment supplier selection and attendance at the time of tender as well as contract signing.

-2 Review and approval of working diagrams, equipment specifications, and other documents.

-3 Review and approval of quality control and performance report on equipment before delivery.

-4 Managemant & control of equipment supply and installation.

-5 Report on work progress.

-6 Attendance at the time of delivery.

In addition to the work listed above, the consultant shall submit to the Japanese government a report on the percentage-of-completion payment procedure, matters about delivery after work completion, etc.

4-3-4 Equipment Procurement Method

1) Supplier selection and contract

Open tender shall be held for equipment procurement work on the condition that qualified bidders, whether individual or corporate, shall have Japanese nationality. Selection shall be made based on tender documents evaluation.

As for the contract method, the bulk sale method shall be adopted for equipment items specified in the contract. Assigned contract work shall include supply, fabrication, and delivery of contract equipment, as well as instruction on installation, adjustment, trial operation and complete technical guidance concerning maintenance and control.

2) Shipment method

Japan inland transportation shall be by truck, and from Japan to Pakistan, shipment shall be by sea to Karchi port. From Karachi to Islamabad, truck tranportation shall be used again.

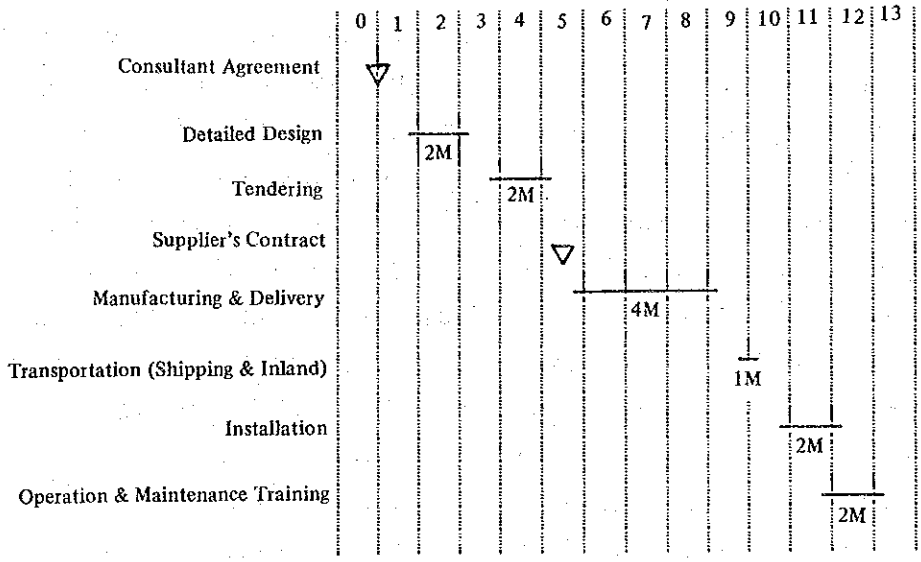
4-4 Implementation Schedule Plan

After completion of the Exchange of Notes between the two parties, the period required for each work phase by the Japanese side shall be as below.

1)	From official Exchange of Notes till tendering	4	months
2)	Contract, certificate, etc.	0.5	month
3)	Equipment fabrication, procurement	4	months
4)	Transportation	1	month
5)	Installation, operation and maintenance training	3	months

The implementation schedule plan listed above is shown in Table 4-4.

Table 4-4 Implementation Schedule Plan



The Pakistani side expressed that it is necessary for the Pakistani staff who will be engaged in equipment operation to be trained in Japan in advance. They have requested the Japanese side to review the possibility of staff of Division in the NIH visiting Japan for training after supplier's contract is signed.

However, the basic design study team judges that it's not necessary to give the training to the staff. For, supervisors from manufacturers teach them well how to conduct daily maintenance as well as to operate after installation of the equipment.

4-5 Expenses Borne by Pakistani Side

Expenses to be borne by the Pakistani side for implementation of the project shall be equipment installation costs.

Estimated total cost of the equipment installation is Rps. 276,900 and its breakdown is as below.

Man-day and manpower costs for installation work:

1) Unpacking and carrying-in
Total M^3 x (man/M^3) = 321M^3 x 2.5man/M^3 = 802.5 men

2) Installation	Rps. 200 x 802.5 men	= Rps.160,500.-
Technical engineer	3 plumber x 30 days	= 90 days
	90 x Rps. 600	= Rps. 54,000.-
Assitant engineer	4 electric engineer x 15 days	= 60 days
	60 x Rps. 600	= Rps. 36,000.-
	3 engineer x 44 days	= 132 days
	132 x Rps. 200	= Rps. 26,400.-
Total		Rps.276,900.-

Installation of the equipment shall be conducted under the installation of a supervisor dispatched from the manufacturer.
Manpower costs incurred for the installation work shall be borne by the Pakistani side.

Expected work period is about 4 months.

Because some of the equipment contains up-to-date electronic circuits, a supervisor of the technical engineer class will be dispatched.

4-6 Maintenance & Control System and Method

Daily and periodic check-ups necessary for the proper maintenance of test equipment shall be conducted as the responsibility of specified personnel. Technical know-how for the maintenance work shall be acquired together with operation procedures from technical engineer dispatched from the manufacturer at the time of equipment installation.

Should repair work be necessary but be unable to be handled by the specified maintenance personnel, and technical knowledge is unnecessary, workshop technicians of the NIH shall conduct it.

For a period of five (5) years after the warranty period for one year after hand-over, periodic check-ups, repairs, and spare parts shall be provided but at the Pakistani side's expense.

4-7 Maintenance & Control Cost Estimation

4-7-1 Cost of Procurement of Expendable

Calcualtion of the cost of the expendables necessary for equipment operation is affected by application length and frequency. It is necessary, therefore, to estimate an adequate cost based on experiences over a certain fixed trial period.

Regretably, however, expendables cost records for existing test equipment is unavailable. Accordingly, expendables cost calculation was done referring to records of projects in countries at approximately the same development level as Pakistan, as well as to accounts of the percentage of expendables in general type equipment costs.

Cost estimation of expendables is calculated as 3% of total cost of equipment and, that is, 1.6 million rupees.

4-7-2 Cost of Periodical Check-ups

The project equipment includes precise analyzers that require periodical check-ups by an engineer from the manufacturer in addtion to daily check-ups.

Periodic check-ups shall be carried out to enable the equipment to perform fully under optimum conditions for long years. Costs of technical services and parts replacement shall incur each time. These costs need to be accounted for in the annual fiscal budget under the title of operation costs.

The rough estimate of periodic check-ups presented below was calculated on the assumption that the personnel in charge of each piece of equipment will carry out satisfactory daily check-ups. The equipment for which periodic check-ups can be performed by the personnel in charge is excluded.

-1 Equipment quantity

Analysis type : Quantity and quality analysis, high performance liquid chromatograph and others.
Total 52 units

-2 Engineer's daily allowance : Rps. 4,400/day

-3 Cost calculation :

Total equipment quantity by model is 30 and by item 52.

In general, the average number of check-ups perfromed by one engineer is estimated at approx. 0.5 per day. The figure 0.5 is obtained on the assumption that every two years periodical check-ups with a measuring instrumrnt such as an oscilloscope shall be performed each piece of equipment.

From this, the total number of days required for maintenace check-ups will be : 52 is divided by 0.5 = 104

Therefore, manpower costs shall be calculated as below assuming maintenance check-ups are performed twice per year.

Rps. 4,400 x 104 x 2 = Rps. 915,200.-

During periodic check-up work, some parts replacement will be required. The cost of spare parts replacement tends to increase as time passes making a cost easimation extremely difficult to conduct. Yet, from manufacturer's technical data, allocation of approx. 0.7% of the cost of a piece of equipment's main body seems to be adequate starting from 8 years after the time of delivery.

Parts to be replaced : original cost of equipment x 0.007
= Rps. 370,000.-

In sum, the annual cost of periodic check-ups for one precision analyzer set will be Rps. 128,500.-

4-7-3 Increment of Personnel Expenses

Total amount of present personnel expenses is 1,600,000 rupees annually. With adding 18 members of following manning plan for the Centre 500,000 rupees is estimated to be increased.

However the personnel expenses are paid by the main budget of the NIH. Therefore the NIH needs to add this increased amount to the proposal for budget for the coming fiscal year.

4-7-4 Estimation of Utility Cost

1) Cost for water supply

There are 7 units of water consuming equipment composed of 1 unit of RO Plant, 1 unit of Water Distiller (30 lit/h) and 5 units of Water Distiller (1.8 lit/h). Other units consume very little and their amount can be ignored.

The breakdown of hourly amount of water consumption is shown below.

Equipment Name	Consumption Amount	Number	Total Amount
RO Plant	250 lit/h	1	250 lit/h
Distiller (30 lit/h)	300 lit/h	1	300 lit/h
Distiller (1.8 lit/h)	18 lit/h	5	90 lit/h
		Total	640 lit/h

Assuming that above equipment is used 8 hours a day, the yearly consumption amount is calculated as follows.

The yearly consumption amount (lit)

= hours consumption amount (lit/h) x 8 h/day
x 25 days/month x 12 months/year

= 640 lit/h x 8 h/day x 25 days/month x 12 mounths/year

= 1,536,000 lit

The unit cost of water consumption is 1.75 rupees/3.785 lit, the year cost is calculated as follows.

The yearly cost = 1,536,000 lit x 1.75 rupees/3.785 lit

= 710 rupees

Conclusively the yearly cost of water supply is estimated 710 rupees.

2) Cost for power supply

Assuming that average power consumption amount is equal to 60% of power consumption amount of equipment consuming most power and equipment runs 8 hours a day, the yearly cost of power consumption is calculated.

Average power consumption amount

= Amount of equipment consuming most power x 0.6

= 20 x 0.6

= 12 kW/h

Average yearly consumption amount

= Average power consumption amount (kW/h) x number of units
x 8 h/day x 25 days/month x 12 months/year

= 28.8×10^5 kW/year

Accordingly, as the unit cost is 1.5 rupees/10^3 kW, the yearly cost is calculated as follows.

The yearly cost = 28.8×10^5 kW/year x 1.5 rupees/10^3 kW
= 4,320 rupees

Conclusively, the yearly cost is estimated 4,320 rupees.

3) Cost for gas supply

There is no equipment consuming gas supply.

As calculated total of utility cost is estimated 5,030 rupees, it is scheduled that the utily cost is added to the budget for coming year as a part of management budget for the NIH.

CHAPTER 5

CAHPTER 5 EFFECTS OF THE PROJECT AND CONCLUSION

5-1 Effects of Project Implementation

The effects of the project's implementation are envisaged as follows.

1) At present, the main analysis work at the Division of the NIH is done with the old equipment introduced 15 to 20 years ago, and under the circumstances, it is extremely difficult to improve their accuracy and specimen testing capacity. But once modern instruments for analysis are procured through this project, it is certain that the division's accuracy and specimen testing capacity will be improved considerably. The Centre will serve adequately as a research institute on the scientific basis of traditional medicines under the Traditional Medicines Act which will come into effect soon.

With this, through the safety tests on traditional medicines and the determination of their medicine properties at the centre, the way will be open to offer to the people, safer traditional medicines which are utilized freely by more than 60% of the people. It is reported that under the present circumstances women and children are in poorer health than men, and that they do not enjoy good health care. As a large part of household budget is expended for medicines for infants, quality drugs which can be obtained easily and dependably will surely reduce the economic burden of the people.

2) As for the problem of drug toxicity (not available statistically, but reported so often by the media), its causes are;

-1 With high temperatures and humidity, drugs easily deteriorate and decompose.

-2 Traditional medicines whose efficacy and toxicity are unknown, are widely used.

-3 There are many cause of counterfeit drugs without any medicine properties being sold by wicked manufacturers

The completion of this centre will make possible the practice of scientific quality control tests on pharmaceuticals, and it will enable the authorities to block the circulation of the inferior drugs mentioned in items -1 and -3 above, and to make clear by scientific chemical analysis the efficacy of traditional medicines and confirm their safety by toxicological tests.

And through its function as a referral laboratory, the centre will be able to contribute to the improvement of drugs and traditional medicines in the provinces.

5-2 Conclusions

As described before, some important positive effects are expected of this project, and as it will contribute greatly to the improvement of the Pakistani people's lives, the implementation of this project is judged to be very significant. But this project involves some problems as noted below and if they are not resolved, the project cannot be smoothly managed.

1) The completion of construction of the facilities by the Pakistani side was initially scheduled for the end of June, but the field survey revealed that the completion would actually be at the end of October. The pace of construction of the facilities by the Pakistani side is expected to be accelerated so as to smooth the way for the installation of the materials of this project.

2) It is requested that the manning plan for strengthening of this Division is completed before delivery of equipment.

3) It is necessary to make budgetary arrangement for cost for expendable and periodic check-ups.