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DEVELOPMENT OF THE PHARMACEUTICAL INDUSTRY IN THAILAND

DP/THA/88/018

THE KINGDOM OF THAILAND

Terminal report*

Prepared for the Government of the Kingdom of Thailand by the United Nations Industrial Development Organization, acting as executing agency for the United Nations Development Programme

Based on the work of Mr. J. P. Beelen, chief technical adviser and reviewed by Dr. Prasan Dhumma-Upakorn, national director

Backstopping Officer: Z. Csizer Chemical Industries Branch

United Nations Industrial Development Organization Vienna

^{*} This document has not been edited.

TABLE OF CONTENTS

	PAGE
ABBREVIATION	4
ABSTRACT	5
1.0 OBJECTIVES	6
. Problems to be Solved	6
Types of Technical Assistance Needed Development Objective	7 8
2.0 PROJECT DESIGN AND APPROACH	9
3.0 OUTPUTS SOUGHT AND PRODUCED	11
. Immediate Objectives #1	11
Output to be Achieved	11
. Achievements and Impact of the Project	11
	11
. Results	12
. Favorable Factors	
. Immediate Objectives #2	13
Output to be Achieved	13
. Achievements and Impact of the Project	13
. Results	13
. Favorable Factors	14
n 1- Objectives #3	15
. Immediate Objectives #3	15
Output to be Achieved	15
. Achievements and Impact of the Project	15
. Results	15
. Favorable Factors	
	16

5.0 CHANGES IN PROJECT ENVIRONMENT	18
. Adverse Changes . Positive Changes	18 18
6.0 REMAINING ACTIVITIES OF THE PROJECT	19
7.0 LESSONS LEARNED	20
3.0 OTHER ISSUES OF GENERAL INTEREST	21
9.0 FINDINGS AND OBSERVATIONS	22
10.0 RECOMMENDATIONS	23
. PTSC/University . BOD/PIC/TPMA	23 25
EXHIBITS	26

ABBREVIATIONS

BOD Board of Directors of the Service Center

CTA Chief Technical Advisor

DTEC Development of Technical and Economic Cooperation

FDA Food and Drug Authorities

FTI Federation of Thai Industry

GLP Good Laboratory Practices

GMP Good Manufacturing Practices

MOI Ministry of Industry

PIC Pharmaceutical Industry Club

PPER Project Performance Evaluation Report

PTSC Pharmaceutical Technology Service Center

QA Quality Assurance

QC Quality Control

QIT Quality Improvement Team

TPMA Thai Pharmaceutical Manufacturer Association

UNDP United Nations Development Program

UNIDO United Nations Industrial Development Agency

WFI Water For Injection

ABSTRACT

Country

: Kingdom of Thailand

Title

: Development of Pharmaceutical industry in Thailand

Project No.

: DP/THA/88/018

Contributions

: UNDP US \$ 868,728

Government

N/A

Executing Agency

: UNIDO

Title of Report

: TERMINAL REPORT

Prepared by

: J.P BEELEN - C.T.A

DR. P. Dhumma - Upakom - NATIONAL DIRECTOR

Dated

: Oct. 25, 1994.

TERMINAL REPORT

1. OBJECTIVE

1.1 Problems to be solved

Some problems encountered by the local pharmaceutical industry did include:

- Limited pharmaceutical technology.
- Lack of " know how " to improve product quality.
- Lack of skilled or qualified personnel in some areas of the pharmaceutical production.
- Lack of engineering consultants familiar or experienced with GMP regulations as opplicable to plant layouts, material specifications or construction requirements.

The Food and Drug Administration (FDA) of Thailand in cooperation with the Industry and the Academic Institution, established the Quality Improvement Team (QIT) in 1987.

The QIT team visited about 60 pharmaceutical plants of which the majority were believed to be in need of technical assistance.

Plant visits were also conducted by a UNIDO mission and, during a subsequent meeting with some pharmaceutical executives of the Pharmaceutical Industry Club (PIC) and Thai Pharmaceutical Manufacturer Association (TPMA), several large volume manufacturers of drugs expressed the intention to renovate their existing plants or to relocate from the residential area to the industrial estates.

1.2 Type of Technical Assistance Needed

The most immediate problems which had to be addressed by the pharmaceutical industry and for which different types of technical assistance was required included:

- Plant layouts in compliance with GMP guidelines.
- Effective environmental control and monitoring of production areas in terms of temperature, humidity, air pressure, dust and air ventilation.
- Clean Room technology.
- Development of comprehensive GMP training programs for different levels of the plant personnel.
- Validation Techniques applicable to production &
 QC operations.
- Manufacturing of Purified Water USP and Water For Injection. (WFI)
- Treatment of waste water at the plant site.

Different problems or constraints identified " at the outset of the project " were clearly stated in the project document.

The inputs and activities necessary to resolve these problems were summarized in the revised workplan which covered a time frame of 36 months.

The perception of the different problems " at the end of the project " which had to be solved remained the same as at the outset of the project with the exception of the need of preparing a manual of GMP guidelines which was issued by the FDA / Thailand prior to the start up of the project.

1.3 Development Objective

"The Development Objective of this project was to ensure that the quality of locally manufactured drugs meet International standards and thereby enhances their exportability."

- This project effectively contributed to improve the quality of the locally manufactured drugs due to the implementation of more stringent GMP standards as recommended by the Service Center and the FDA / Thailand.
- A total of about 30 local pharmaceutical companies received the GMP Certificate from FDA authorities between 1991 and
 1994 and approximately 8 to 10 companies presently export pharmaceutical products within the ASEAN Region, Africa and Central America.
- . In view of the above encouraging results, the Service Center is investigating the possibility to obtain additional funds from the Government to further enhance the exportability of the locally manufactured drugs.

2. PROJECT DESIGN & APPROACH

- . As a result of the difficulties faced by Pharmaceutical Industry in Thailand, the Royal Government in conjunction with the United Nations Development Program (UNDP) / UNIDO and members of the Industry and the University of Chulalongkorn set up the framework for a Pharmaceutical Technology Service Center. (Exhibit #1)
- . The project was initiated by the Federation of Thai Industries (FTI) in close cooperation with the PIC who has close ties with the TPMA. Both associations are managed by the same Executive Committee.
- . The PIC represents the industry at Government levels and proposes measures for the advancement of its industry to the Ministry of Industry (MOI) in Thailand.
- The project was implemented by the office of the FTI / FIC, executed by the UNIDO and financed by the UNDP.
- . A National Project Director, who was appointed by the FTI/PIC, coordinated the project on the national side whereas the Chief Technical Advisor (CTA) represented the UNIDO.
- . The PIC was responsible to nominate the entire staff for the PTSC including the staff for QC laboratories and the National Experts.
- The project was carried out by the PTSC in very close cooperation with the Chulalongkorn University - Pharmaceutical Science Department and the PIC/TPMA Association.
- The PIC/TPMA appointed several industry representatives to facilitate the transfer of the available information regarding pharmaceutical technology to its members.

- . The project was carried out almost entirely under a single subcontract by the PTSC and was designed to:
 - (a) Provide laboratory services to the industry.
 - (b) Organize consultancy services and provide technical assistance to the industry.
 - (c) Play important role as mediator or facilitator between the FDA and the industry.
 - A Workplan was prepared to schedule the activities required to achieve the results or outputs outlined in the project document proposal, DP/THA/88/A/02/37.
- The active involvement of the industry was intended to facilitate the cooperation with the Service Center and the counterparts of the industry as well as to ensure the financial sustainability of the project in the long term.

3. OUTPUTS SOUGHT & PRODUCED

The status concerning the outputs sought and produced as applicable to the immediate objectives stated in this Project Document can summarized as follows:

Immediate Objective # 1

"Enable the local pharmaceutical companies to introduce "Good Manufacturing Practices" in their production plants in order to insure that the pharmaceutical products comply with International quality standards."

Output to be achieved

" Top managers, technicians and production personnel of 28 pharmaceutical production plants will be trained and able to introduce Good Manufacturing Practices at different levels."

Achievements and Impact of the Project

- . A total of at least 105 pharmaceutical companies attended or participated the seminars or workshops organized by the PTSC on several topics related to GMP aspects. Continued genuine interest has been shown by the industry as large as illustrated in Exhibit #2
- . The industry at large has acquired a clear understanding of the different GMP aspects which must be implemented in order to qualify for the GMP certificate of the FDA / Thailand.
- The number of companies approved for GMP certification by the FDA/Thailand increased gradually from 95 to 125 plants which represents an increase of 30 companies. (Exhibit #3)
- . The FDA encourages the non certified plants to contact the PTSC to obtain GMP training.

Results : As per " Outputs to be achieved "

Favorable Factors

The main factors which facilitated the achievement of the above output are :

- The formal approval obtained by all participating partners (PIC/FTI/MOI/DTEC/UNIDO/UNDP) to extend the time period for completion of this project from 15 t, 36 months is considered a major factor of the success achieved as it enabled the PTSC to complete the outputs via a step by step approach.
- The Establishment of different task force groups for the preparation of the technical information in combination with the valuable assistance given by the national experts from the university and the industry.

Immediate Objective #2

" Establish and operate a Service Center for the Pharmaceutical Industry."

Outputs to be Achieved

" A newly established Service Center to provide the required technical services needed by the pharmaceutical industry."

Achievements and Impact on the Project

- The Service Center did implement an action plan to develop positive GMP awareness attitude within the local pharmaceutical industry.
- The technical advice given by the International Experts via Workshops, Seminars or Plant Visits greatly contributed to overcome some of the initial resistance to changes regarding the effective implementation of stricter GMP standards.
- . The representatives of the Pharmaceutical industry at large regularly attend the seminars and workshops organized by the Service Center.
- . A two-day seminar was organized by the PTSC aimed at the Executives of the local pharmacies in order to stimulate the potential interest for the Center.
- . Suitable audio visual training material and equipment was acquired for the GMP training of production personnel at the plant site or at the Center.
- A comprehensive technical library has been set up which includes several international technical journal, GMP manuals and Guidelines as well as textbooks on different related pharmaceutical technology subjects.
- . Many companies contacted the Service Center to obtain technical assistance in terms of plant layouts, QC testing methods and GMP training of personnel.

Results : As per " Outputs to be achieved "

Favorable Factors

- The Subcontract between the UNIDO and the National Expert representing the Chulalongkorn University greatly facilitated the hiring and selection of the most appropriate experts on some specific technical subjects.
- The authorization obtained from UNIDO / Vienna to select National experts from the industry contributed to strenghten the technical team.
- Several pharmaceutical companies requested their technical staff to provide technical assistance to the Service Center while remaining on the payroll of the company.

Immediate Objective #3

" To maintain quality assurance in the industry through a well documented Good Manufacturing Practices (GMP) Manual as well as a Manual on Standard Operating Procedures (SOP)."

Output to be achieved

A comprehensive GMP Manual and SOP Guidelines for the industry.

Achievements and Impact of the Project

 Representatives of the University industry and the Service Center meet at regular intervals to develop technical documents on subjects such as Validation, SOP's - Water Treatment, Good Laboratory Practices ect.

Results: As per " Outputs to be achieved "

Note: Manual of GMP was issued by the FDA prior to start up of the Service Center.

Favorable Factors

- . The invitation extended by th FDA to the Center to actively participate in their 5 years Development Program towards the implementation of the GMP Guidelines. (Exhibit #5)
- . The support exhibited by the DTEC/UNIDO/UNDP towards the recommended Revised Workplan which was extended from 15 to 36 months.

4 MAJOR CONSTRAINTS

Introduction of VAT System

The increased cost of drugs resulting from the introduction of the VAT System (7%) has been absorbed by the local industry because of the fierce competition prevalent within the market places.

A decrease in the profit margins does not motivate the manufacturers to allocate new operating expenses for the implementation of GMP related projects. (GMP training - New equipment - Hiring of additional personnel, etc.)

Routing Procedure for approval of changes to the original project document

- . The routing procedure which must be followed to obtain approval of proposed changes regarding the "inputs" did require several months (e.g. extension of the project from 15 to 36 months).
- . Some activities could not be implemented unless a modification of the project was formally approved by all partners.

Volume and Complexity of technical issues

Insufficient time was allocated at the *outset of the project* to ensure adequate completion of all activities, inputs and outputs.

Social & Cultural Environment

- Some cultural, social and academic practices prevented the hiring of a full time National Director from the University. The appointed professor must indeed continue to give lectures throughout the entire University calendar year can and therefore only devote his energies towards the Center on a part time basis.
- . The time required to overcome the attitude of "Resistance to Change" and social & cultural constraints were underestimated.

5. CHANGES IN THE PROJECT ENVIRONMENT

Some of the changes encountered during the life cycle of the project which had a <u>negative</u> or <u>positive</u> impact on the outcome of the expected results include:

Adverse Changes

- . Introduction of VAT System during 1991.
- . Price control on drugs during approximately one year.
- Pressure exercised by the Government to avoid any price increase on drugs.
- . Introduction of Patent Protection for pharmaceutical products.

Positive Changes

- The Service Center has been granted the status to become a "reference laboratory" pending complete compliance with GLP and Government Regulations.
- The FDA invited the Service Center to actively participate in their 5 years development program. (Exhibit # 5)
- The Service Center has gradually increased its reputation and credibility within the local pharmaceutical industry and the FDA authorities.
- Expansion of the technical services provided by the Center to the Cosmetic and other related industries by the Service Center.

6. REMAINING ACTIVITIES OF PROJECT

The main activities which remain to be initiated to meet the workplan include:

- Documentation regarding QA Management systems.
- Systems and Procedure necessary to achieve GMP compliance regarding Production Records.
- Guidelines to facilitate Product Development.

7. LESSONS LEARNED

Communication Channels

- . A specific routing procedure (Exhibit #11) had to be followed to ensure that all partners remain properly informed during the project about all important aspects or changes.
- The minimum lead time necessary to obtain formal approval from all participating partners regarding required changes to the project were definitely underestimated.

Employment of Qualified Staff

- The Government Regulation stipulate that the head of Production and QC/QA departments require a licensed pharmacist.
- . A serious shortage of qualified pharmacists combined with a limited number of newly graduated pharmacist results in a high turnover of pharmacist within the industry. Difficulties to identify experienced and qualified technical staff are often experienced.

8. OTHER ISSUES OF GENERAL INTEREST

- . An International Expert from Japan visited the Service Center during 1994 to provide advise on the Waste Water Treatment to protect the environment.
- Very positive comments were received at the Service Center for the technical assistance given to several pharmaceutical companies.

9. FINDINGS / OBSERVATIONS

- Social, cultural and economic factors explain the reluctance exhibited by several local pharmaceutical manufacturers to implement GMP standards.
- The local FDA in Thailand does gradually impose stricter requirements for GMP compliance.
- Several companies at the end of the project intend to implement new plant layouts or upgrade their manufacturing facilities.
- The Government Pharmaceutical Organizations (GPO) supplies
 most of the drugs for the Government Health Institution.
 However, they are not subjected to similar FDA inspections for
 GMP compliance.
- The preparation of technical material for training session on all subject related to GMP topics depend greatly on the impact and cooperation of National Experts of the industry with the Center.
- . It is anticipated that the approval of the QC laboratory to obtain a government GLP certificate, will require more time than anticipated.
- . The FDA decision to invite the Service Center to actively participate in their 5 year CMP Development Plan, represents a challenging opportunity to enhance the image and reputation of the Center to the Government and Industry.
- . All aspects regarding the financial management of the Center are currently subjected to Government & University Regulations which prevents the Center to become an independent financial entity.

10 RECOMMENDATIONS

Recommendations to Pharmaceutical Technical Services / University

- Complete the preparation of the technical manual documentation regarding the manufacturing of Purified Water and Water for Injection.
- a technical manual regarding all aspects related to environmental control for sterile and non sterile production operation. (HVAC Dust Control Clean Room technology, etc.)
- Update on a continuos basis all reference technical information files regarding the Validation of pharmaceutical operation.
- Continue the preparation of GMP training material for plant personnel.
- . Develop technical documentation for workshops regarding plant layouts.
- Expand The physical facilities of the PTSC to accommodate an efficient library room, area for GLP training and additional space for the administration.
- Develop a comprehensive action plan to explore the possibility of funding a project on a regional basis (Vietnam - Laos).
- . Submit as per standard procedure operating budgets for 1995 and 1996 to the BOD based upon planned activities or services which will be provided to the industry.
- . Investigate together with the University the feasibility & merits to obtain the status of an " Independent Service Center " as a financial entity.

• Continue to promote a harmonious rapport with the FDA/Thailand and participate actively in their 5 year GMP Development Plan.

the feasibility of hiring on a full time basis a qualified person for the preparation of all technical documentation and the review of technical journal and/or text books available in the library. (Water systems, SOP's, Plant layout, Validation, Manufacturing record, ets.)

. Organize at regular intervals visits of the Service

Center for the benefit of the executives of the Pharmaceutical, Cosmetic and Food Industries.

. Circulate to the industry at regular intervals the "Fee Schedule" for all Technical or Consultancy Services available at the Center.

• Give top priority to meet GLP compliance in order to qualify for the FDA Certification as a Reference QC Laboratory.

. Concentrate activities within the laboratory on training activities or workshops related to:

- GLP training
- Validation of QC equipment
- Operating instruction for QC equipment
- Routine testing of RM

• Pursue the strategy of organizing activities which meet the urgent needs of the industry at large to ensure the financial sustainability of the Center.

Recommendations to BOD/PIC/TPMA

. Continue to encourage the PIC/TPMA members to utilize extensively the technical assistance of the Service Center.

. Promote the visibility of the PTSC via special information meetings between the Service Center and members of the PIC/TPMA.

• Provide continued management advice and support to the Service Center and monitor the progress of activities designed to achieve all the established objectives.

• Investigate the merits of rotating at regular intervals (e.g 2 years) the management team of the Service Center between an Academic & a Business Director.

The above approach would facilitate the implementation of new business strategies or systems to assist the dynamic growth and expansion of the Center.

. Investigate the possibility to obtain additional funds from the Governments to further enhance the exportability of the locally manufactured drugs.

LIST OF EXHIBITS

- Exhibit #1 Organizational chart of PTSC .

 Relationship of PTSC to other organizations.

 Exhibit #2 Companies participating in PTSC activities.

 Exhibit #3 Number of Pharmaceutical Companies.

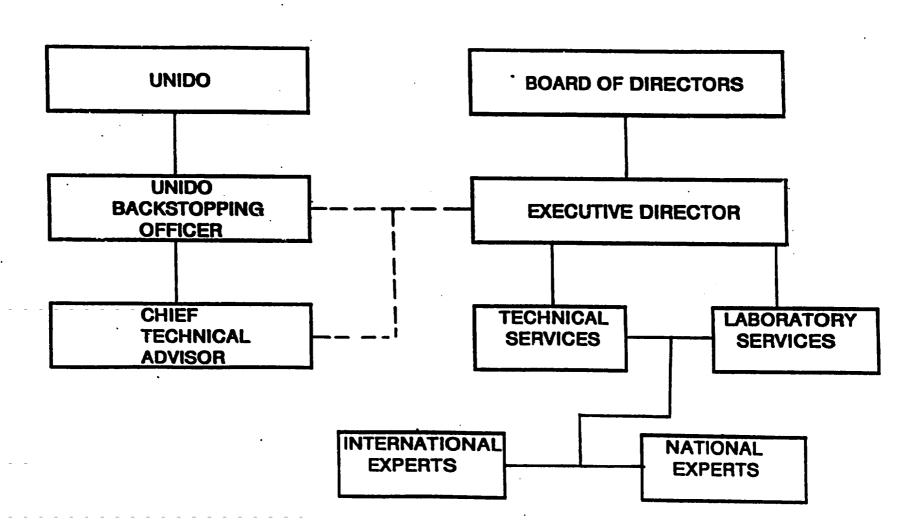
 Exhibit #4 Summary of Activities during Oct. 91 Sept.94

 Exhibit #5 Correspondence with FDA / Thailand.

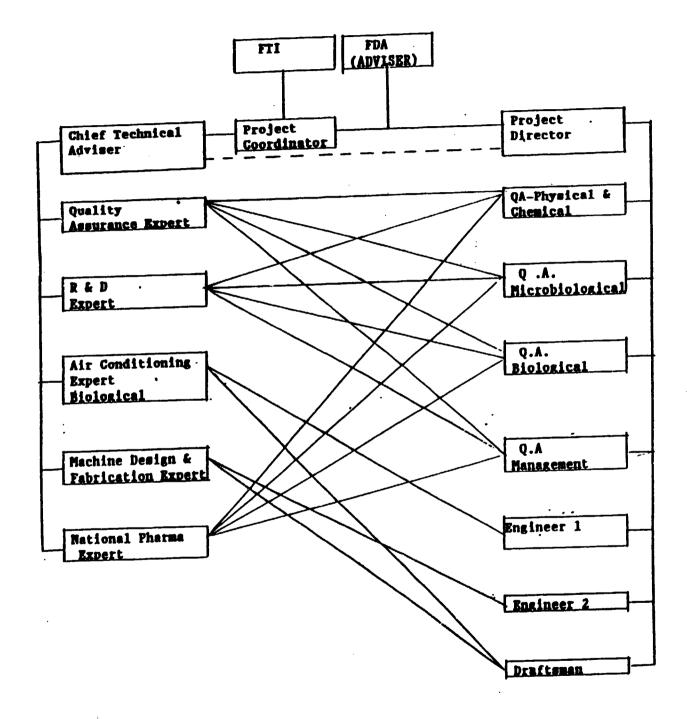
 Exhibit #6 Plant visits and inspections by CTA.

 Exhibit #7 Seminars and Workshops 1991 1994.
- EASIDITE # 7 COMMING COMMING COMMING
- Exhibit #8 Workshops with Industry / Center / University 1991 1994.
- Exhibit #9 Study Tour Canada 1993.
- Exhibit #10 Fellowship Program 1994.
- Exhibit #11 Routing channel of communication between PTSC and other organization.
- Exhibit #12 Correspondence of evaluation by pharmaceutical companies concerning the technical services provided by the PTSC.
- Exhibit #13 List of SOP's.
- Exhibit #14 List of Laboratory Equipment.

Organizational Chart for the Pharmaceutical Technology Science Centre



ORGANIZATION CHART OF PROJECT INSTITUTIONAL FRAMEWORK



Companies participating in PTSC activities.

- 1. A.N.B. LABORATORIES CO.,LTD.
- 2. A.N.H. PRODUCTS
- 3. ACDHON CO.,LTD
- 4. AMORNKIAT TRADING LTD. PART.
- 5. ATLANTIC LABORATORIES CORP. LTD.
- 6. B.B.PHARMA CO.,LTD.
- 7. B.J. LIMITED PARTNERSHIP
- 8. B.L. HUA & CO.,LTD.
- 9. B.L. LIMITED PARTNERSHIP
- 10. BERLIN PHARMACEUTICAL INDUSTRY CO.,LTD.
- 11. BETERSCORF (THAILAND) CO.,LTD
- 12. BETTER PHARMA CO.,LTD
- 13. BIOLAB CO.,LTD.
- 14. BRYWOOD PHARMACEUTICAL LTD. PART.
- 15. BUKALO PHARMACY CO.,LTD
- 16. BURAPHA DISPENSARY CO.,LTD.
- 17. CATHAY CHEMICAL LTD, PART.
- 18. CHAROEN BHAESAJ LAB CO.,LTD.
- 19. CHEMEPHAND MEDICAL (FACTORY)
- 20. CHEW BROTHERS & CO.,LTD. PART.
- 21. CHINTA TRADING CO.,LTD.
- 22. COMBINE CO.,LTD
- 23. COMMUNITY PHARMACY PUBLIC COMPANY LIMITED
- 24. CONTINENTAL PHARM CO.,LTD
- 25. COX LABORATORIES LTD. PART.
- 26. DUMEX LIMITED
- 27. F.E.ZUELLIG (BANGKOK) LTD.
- 28. FACTORY OF PHARM CO.,LTD
- 29. FIVE PAGODAS PHARMACY CO.,LTD.
- 30. GENERAL DRUGS HOUSE CO.,LTD.
- 31. GLAXO-VIDHYASOM LTD.
- 32. GOLD MINTS PRODUCTS
- GREATER PHARMA LTD. PART.

- 34. HI-PEX CO.,LTD
- 35. HOECHT PHARMACEUTICAL INDUSTRIES LTD.
- 36. JACK CHIA INDUSTRIES (THAILAND) LTD.
- 37. K.B. LABORATORY LTD.
- 38. KENYAKU (THAILAND) LTD.
- 39. KRUNGDHEB PHARMACY LTD. PART.
- 40. L.B.S. LABORATORY LTD, PART.
- 41. L.P. STANDARD LABORATORIES LTD.
- 42. LACHMANN CO.,LTD.
- 43. LAM THONG KARNPHATAYA PHARMACEUTICAL PRODUCTS
- 44. LART SINGH
- 45. LUPIN CHEMICALS (THAILAND) LIMITED
- 46. M & H MANUFACTURING CO.,LTD.
- 47. MEDICAL SUPPLY CO.,LTD.
- 48. MEDICAP LIMITED
- 49. MODERN MANY CO.,LTD.
- 50. NAKORN PATANA PHARM CO.,LTD.
- 51. NAM KOK DISPENSARY CO.,LTD.
- 52. NEOPLAST COMPANY LIMITED
- 53. NIDA PHARMA CO.,LTD
- 54. OLAN-KEMED CO.,LTD.
- 55. OLIC (THAILAND)LED.
- 56. OSOTH INTER LABORATORIES CO.,LTD.
- 57. OSOTHSAPHA (TECK HENG YOO)CO.,LTD.
- 58. P.P. LABORATORIES CO.,LTD.
- 59. PARAR LAB. LTD, PART.
- 60. PATANAKARN BHAESAI LTD, PART.
- 61. PHARMACARE CO.,LTD.
- 62. PHARMASANT LABS CO.,LTD.
- 63. POLIPHARM CO.,LTD
- 64. POND'S CHEMICAL (THAILAND) R.O.P.
- 65. PURE CHEM CO.,LTD.
- 66. RHONE-POULENC THAI INDUSTRIES LIMITED

- 67. ROTALABORATORIES CO.,LTD.
- 68. S.M. PHARMACEUTICAL
- 69. SCHERING CHEMICALS LTD.
- 70. SENG THAI COMPANY LTD. PART.
- 71. SEVEN STARS PHARMACEUTICAL CO.,LTD
- 72. SIAM BHEASACH CO.,LTD.
- 73. SIAM PHARMACEUTICAL CO.,LTD
- 74. SIAMERICAN PHARMACEUTICALS CO.,LTD.
- 75. SILOM MEDICAL CO.,LTD.
- 76. SOMCHITT DISPENSARY CO.,LTD.
- 77. SRIPRASIT PHARMA CO.,LTD.
- 78. SUPHON BHESAJ FACTORY
- 79. T.O. CHEMICALS (1979) LTD.
- 80. T.P. DRUG LABORATORIES (1969) CO.,LTD
- 81. T.P. DRUG LABORATORIES (1969) CO.,LTD
- 82. TAKEDA (THAILAND) LTD.
- 83. THAI MEIJI PHARMACEUTICAL CO.,LTD.
- 84. THAI NAKORN PATTANA CO.,LTD.
- 85. THAI NAKORN PATTANA CO.,LTD.
- 86. THAI OTSUKA PHARMACEUTICAL CO.,LTD.
- 87. THAI P.D. CHEMICALS CO.,LTD.
- 88. THAI PHARMED (1942) CO.,LTD.
- 89. THAIRED CROSS (SCIENCE DIVISION)
- 90. THE BOOTS MANUFACTURING CO(THAILAND) .TD.
- 91. THE BOOTS MANUFACTURING CO., (THAILAND) LTD.
- 92. THE FORTY-TWO LABORATORIES LTD.
- 93. THE GOLDEN CUP PHARMACEUTICAL CO.,LTD.
- 94. THE GOVERNENNT PHARMACEUTICAL ORGANIZATIO
- 95. THE JAWARAD CO.,LTD.
- 96. THE SERMMITR CO.,LTD.
- 97. THI OTSUKA PHARMACEUTICAL CO.,LTD.
- 98. TOPDERM CO.,LTD.
- 99. TRUST MAN PHARMAR L.P.

- 100. UDOMPHON (PHIHALAB) CO.,LTD
- 101. UNICHEM PHARMACEUTICALS CO.,LTD
- 102. UNION DRUG LABORATORIES LTD.
- 103. UNISON LABORATORIES CO.,LTD
- 104. UTOPIAN CO.,LTD.
- 105. VIDHYASOM CO.,LTD.

* The figure in 1994 is estimated by the end of the year.
As of the mid of August 1994, 119 plants have received GMP certificate.

4. SUMMARY OF ACTIVITIES DURING THE LIFE SPAN OF THE PROJECT BETWEEN OCTOBER'91 UNTIL SEPTEMBER'94

Exhibit Total # 6 . Plant visits or inspections by the CTA 125 # 7 35 . Workshops or Seminars . GMP Training sessions for plant personnel 12 . Working Sessions of PTSC / Industry / # 8 92 University # 9 . Number of Study Tours #10 . Fellowship Programs # 2 105 . Participating Companies . Liaison Meetings with the FDA 4 . Meetings of Board of Directors 36 . Waste Water Treatment . Regionalization of the project 3



No. 0802/ 14513

Food and Drag Administration Ministry of Pablic Health Devaves Palace, Bangkok 10200 Thailand

September 2, B.E. 2535(1992).

Mr. Beelen

Pharmaceutical Technology Service Centre

Faculty of Pharmaceutical Sciences

Chulalongkorn University

Bangkok 18338

Dear Mr. Beelen.

Thank you very much for your letter of August 31, 1992, in which you explain the main objectives and activities concerning the Pharmaceutical Technology Service Centre at Chulalongkorn University.

Please find enclosed a copy of the English translation of the GMP 5-Year Action Program which the FDA authorities will enforce to achieve GMP compliance on a step by step basis throughout the entire pharmaceutical industry.

We are quite interested about your suggestion to arrange meetings at regular intervals between the Service Centre and the FDA authorities to discuss subjects related to GMP training.

The 5-Year GMP Action of the FDA assumes that the Service Centre will cooperate with the authorities to assure that a suitable GMP training program will be offered throughout the entire cycle of our Action Plan.

We very much appreciate the efforts made by the Service Centre in order to achieve all our common goals as it applies to the manufacturing of high quality products in Thailand

Yours sincerely,

Dr. Morakot Kornkasem

Yhoobe his

FDA Secretary-General

ACTION PLAN OF PHARMACEUTICAL GMP FOR 1992-1996

		Ī	irget (for budg	ret jea	r)		Responsible Agency
Activities s	Vait	1992	1993	1994	1995	1996	Total	werhoustate weent
1. Inspect, advise and assess	plant	109	134	156	157	173		QIT & Inspection Div.
GEP compliance 2. Seminars	time	1	1	-	1	. -		Drug Control Div.
3. Training	l							a tar a mutaa
- Officials	time	•	2	1	1	1		Drug Control Div. & UNIDO
- Batrepreneurs	time	-	1	-	1	•		Drug Control Div.+ Paculty of
								Pharmacy, Mahidol U. + UNIDO
1. Nake and publicise technical	sabj.	4	q -(¢{			Drug Control Div + commended
kandbooks								persons from private sector
								+ academia
5. Nake slides and VDO on GMP	subj.	-	44		2	-		Drug Control Div.+ <u>UNIDO</u>
6. Overses training on GMP for	person	2	2	2	2	2		Drug Control Biv.+ UNIDO +
officials	·		'					Inspection Div. + Provincial
								Health Office + Health Con-
			'				Ċ	sumer Protection Div.
7. Inspect and drug sampling	place	25	60	40	20	15		Inspection Div.
from non-GMP manufacturers								
strictly according to the law								
8. Revise GHP and asend	1	4 j						Drug Control Div.
Hinistry's regulations								
9. Suspension or mon-renewal of				¢				Drug Control Div.
license till corrections be				}				
asde.	1							
10. PR on GMP data		4						Drug Control Div. + Public
								Relation & Advertisement
,				· ·				Control Division
RIPECTED OUTCOME								
- More GMP compliance	plant	2	25	21	4	14	65	Drug Control Div. (QIT)
- Complaince with GMP in	plant	1	fina 🛊	i o -	// .		:	Brug Control Div. (QIT)
every category (increased)	1	7.4	料	1	W.	100	W.	Inspection Div.
- Reassessment of GMP	plant	10%	3.000	1	张	243	1949 F.	THE PERCENT DIV.
complying manufacturers	12	1	***			3	*	

Plant Visits and Inspections by CTA and National Experts Exhibit #6

Year	Number of Visits
1991 (Oct - Dec)	11
1992 (Jan – Sep)	51
1993 (Oct - Dec)	31
1994 (Jan - Oct)	42
·	
	135
	2222

Seminars & Workshops Exhibit #7

Year	Seminars	Workshops	Number of Participants
1990	1	_	107
1991	3	-	369
1992	7	· 3	525
1993	4	8	650
1994	1	10	500 to date
	16	21	2,151
	=======	222222	*======

Workshops with Industry/Center/University Exhibit #8

Year	Total
1991	ML
1992	12
1993	52
1994 (Jan - Sep)	28
	92
	-

SCHEDULE

RE

STUDY TOUR/ CANADA

MAY 15 - 30 / 92

DAY	DATE	ACTIVITY	TIME
1.	15th-Fri	Departure: via CPA- Bangkok Arrival: Montreal/CANADA	08.30AM. 11.: 7PM.
2	16th-Sat	Weekend	
3	17th-Sun	Weekend	
4	8th-Mon	Holiday	
5	19th-Tue	- Hoechst Pharmaceuticals	10.00AM.
6	20th-Wed	-Bristol- Squibb	10.00AM.
7	21st-Thu	-ICN Pharmaceutical	09.30AM.
		_ Rougier Inc.	02.00PM.
8	22nd-Fri	-Abbott -Cyanamid	10.00AM. 02.00PM.
9	23rd-Sat 24th-Sun	Weekend Weekend	
10	25th-Mon	-Rhone-Poulenc -Health Protection Branch	09.30AM. 02.00PM.
11	26th-Tue	-Schering Corporation -Burroughs Wellcome -University of Montreal	09.00AM. 02.00PM.
12	27th-Wed	-Merck-Frossi -Ciba - Geigy	09.30AM. 02.00PM.
13	28th-Thu	-Ayerst -Marion	09.30AM. 02.30PM.
14	29th-Fri	-Health Protection Branch	09.30AM.
15	30ths-Sat	Departure via CPA - Montreal Arrival in Bangkok on 31 st.	06.30 AM. 08.35 PM.



<mark>ตูนซ์บริการเทดโนโลซีเทสัชอุตสาหทรรม</mark> PHARMACEUTICAL TECHNOLOGY SERVICE CENTRE

Exhibit #10

คณะเภสัขศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ปทุมวัน กทม. 10330 โทร. 2511871-7 คือ 273 FACULTY OF PHARMACEUTICAL SCIENCES CHULALONGKORN UNIVERSITY BANGKOK 10330 THAILAND

To Mr.K.HANSELMANN

From

Dr.Prasan, NPD

UNIDO, Vienna

Fax

662-255-8227

Fax

43-1-237280

NO. of pages(including this pages).4

Date

February 8, 1994

FILE REF. DP/THA/88/018

Ref. to the facsimile from HANSELMANN/ARAKELY from Vienna dated 3 February 1994 sent to DR. MEIXNER, UCD

• We send you again the Fellowship Program of :-

DR. PRASAN

DHUMMA-UPAKORN

- DR. SUREERAT

CHAIAMNUAY

- MR. SARUN

GORSANAN

- Firstly, we would like to get UNIDO Letter informed that we get the fellowship.
- Please give top priority for the approval of the estimate cost to in order to buy the International flight tickets on time for MR.SARUN GORSANAN who will travel on March 12, 1994

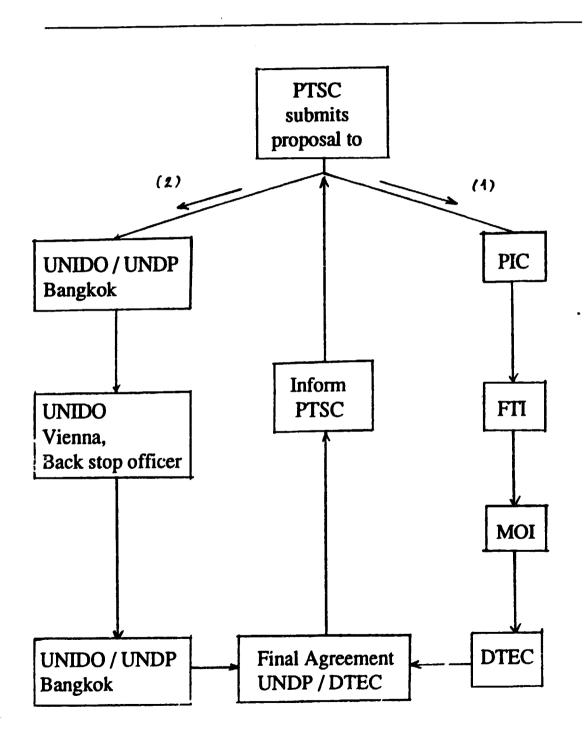
Best regards.

Dr. Prasan Dhumma-upakorn

Ranau Hummaphon

Director of PTSC

Routing Channel of
Communication of
PTSC and Participating Organizations



Correspondence of evaluation by pharmaceutical companies

concerning the technical services provided by the PTSC.



BIOLAB CO., LTD.

625 Soi 7A Bangpoo Industrial Estate Samutprakern 10280, Thailand.

Telephone : 317-7773, 377-2456,3240775-7

Cable : BIOPHARM BANGKOK Telex No. 87278 BIOPHAR TH

Ref: ADM001/94

January 27th, 1994

Attn: Mr. Joseph Beelen. Chief Technical Advisor

Pharmaccutical Technology Service Center

Faculty of Pharmaceutical Sciences

Chulalongkorn University

Bangkok, Thailand

From: Mr. Rachod Thukulsri

Director of Administration of Biolah

I would like to congratulate you for the impressive and outstanding training and advises that you provided to us during your ten day sessions. You have not only informed and advised my colleagues on the knowledge that they required but you have changed their attitude about how to work together and the real concept of Good Manufacturing Practices which you could not have done if I would have send my colleagues to the center.

You have gained our acceptance and we honor you as the first technical and managerial advisor for our factory. We hope that the center will concentrate on such services for the industry and keep the magic going.

Sincerely Yours.

Rechod Thakolari



Mailling Address: G.P.O. Bax 4O1 Bangkok 10501. Thailand. Office Address: 384 Sol & Pattana 3 Road. Bangpoo Industrial Estate. Samutprakarn 10280. Thailand Tet 324-0681, 324-0847-8 Th: 22575 GEEPEE TH Fax. (662) 324-0451 324-0537

REF: MXT/ML-93-064

March 29, 1993

Dr. Prasan Thamaupakorn
Pharmaceutical Technology Service Centre
Faculty of Pharmaceutical Sciences
Chulalongkorn University
Bangkok 10330 Thailand.

Dear Dr. Prasan,

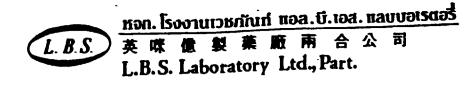
We are proud to inform you that Medicap Ltd. has received GMP Compliance from Australia and Denmark. Our company is grateful to you and your team for the help and training provided to us, without which we would not have been able to achieve international standards.

We hope that you will continue to provide new services and training programme for the benefit of pharmaceutical and health industry in Thailand.

Thanking you.

Yours sincerely,

Managing Director



Jan 21, 1994.

Dear Dr. Prasan,

We would like to express our sincere appreciation towards Mr. J.P Beelen, chief technical advisor of UNIDO, for his dedication to our company during his plant visits and audits from Dec. 14/93 - Jan 21/94.

His efforts to evaluate our company's system and procedures together with plant design and layout proved very beneficial.

His advice for corrective actions was extremely practical and will undoubtedly also contribute towards the long-term success of our company in several areas of our plant operations.

We would very much appreciate to arrange another opportunity to welcome Mr. Beelen in order to benefit from his consultancy services.

Best Regards,

Piya Tiragarn

President of L.B.S. Laboratory

REILIN BERLIN PHARMACEUTICAL INDUSTRY CO., LTD.

January 27, 1994

Dear Mr. Beelen.

We would like to express our appreciation for your valuable assistance in providing your support to our company in various aspects applicable to the plant operation.

We feel that your "on site" plant visits and training sessions have greatly contributed to improve our GMP and QA standards within our plant. These plant visits are very effective as they allow: us to investigate the specific areas for improvement and permit valuable discussions both in scope and depth.

We thank you very much for all the technical support and are looking forward to your next visit in Thailand in order to benefit again from the UNIDO consulting services.

Sincerely yours,

Vanida Chainuveti

Managing Director



mida Chainwali

LIST OF SOPS PREPARED BY THE SERVICE CENTRE

			Page 1	of 2
	COR Tale	Area	Code No.	P.
#	SOP Title	Manufacturing	15-0001	17
1	Dispensing an weighing of raw material		15-0003	12
2	Cleaning of manufacturing equipment		15-0020	12
3	Preparation and use of batch manufacturing record Gowning procedure for non-clean areas		15-0023	3
4	Quantile brocessie in the			
	Guideline for preparation of SOPs	Quality Assurance	60-0000	5
1	Raw material specification document		60-0001	10
2	Sampling of raw materials		60-0002	14
3	Guidelines for review, revision and		60-0003	6
4	deletion of SOPs			
_	Assignment of product code number		60-0007	5
5	Assignment of product code names			4
6	Returned goods policy		60-0013	9
7	Stability program Preparation of master formula and		60-0017	12
8				
_	manufacturing method		60-0018	4
9	Handling of product complaints		60-0029	2
10	Sampling of water system			
	- · · · · · · · · · · · · · · · · · · ·	Warehousing	65-0007	8
1	Receipt of raw materials	War (110 a.m.)	65-0005	6
2	Assignment of receiving control			
	numbers (lot numbers)		65-0007	9
3	Raw material inventory control			
1	Gowning procedure for clean areas	Sterile production	70-0001	5

LIST OF SOPS PREPARED BY THE SERVICE CENTRE

Page 2 of 2

1	Organization of validation set-up	Validation	75-0008	5
_	Calibration of instruments	Vandation	75-0013	12
2	Organization of retrospective validation		75-0013 75-0014	5
3	-		75-0014	,
4	program Organization of prospective validation		75-0015	7
~			75-0015	•
5	program Prospective validation of pre blending		75-0016	5
,	•		73-0010	,
	process of Ethiny Estradiol 10 μg tablets			
6			75-0017	14
	Validation of spectrophotometer		75-0017	6
7	Installation Qualification of Equipment and Instruments		73-0018	O
8	OQ of pH meter # Electrode / PG of pH		75-0019	12
	measurement			
9	Validation of High Performance Liquid		75-0020	27
	Chromatography and system suitability			
1	Measurement of pH	Quality control	80-0002	10
1	Operation and maintenance of a	Air Handling	25-0001	4
1	packaged air conditioning unit	•	23-0001	4
2		Systems	25-0002	7
2	•		23-0002	,
	procedures for air handling systems in			
_	pharmaceutical applications		05 0000	
3	Specifying environmental conditions in		25-0003	4
	pharmaceutical applications		25 0004	
4	Procedure for the leak testing of HEPA		25-0004	4
	filters in clean room installations			

Project No.

DP/THA/88/018

THAILAND Country

PRICE	MORE	THAN	US\$5.	000
				7.7

Purchase order Number	No.	Description	Stock-on-hand in US\$	Cond	Qty on Hand	Remarks
15-0-00427	1	Let of HPLC * WATER MULTIPLE-PUMP GRADIENT HPLC COMPLETE WITH: U6K INJECTOR.	1,884.00	G	1	}
15-0-00427	2	M5 10 SDS 100-240 50/60 SERIAL# 510139906, 510139878	11,320.00	G	2	
15-0-00427	3	M680 AGC CONTR 100-240V SERIAL # 680008154	3,189.00	G	1	
15-0-00427	4	M490 PMD 220V	10,909.00	G	1	*
15-0-00427	5	470 FLUOROMETER W/MANUAL	7,010,00	G	1	
15-0-00427	6	746 SINGLE CHANL DATA MOD.	2,629.00	G	1	
15-0-00<27	7	WISP M712 1G0/240 50/60HZ SERIAL # 712007457	10,514.00	o	1	
15-0-00427	8	ACCESSORIES	3,854.00	0	1	

Project No.
Country

DP/THA/88/018

THAILAND

Purchase order Number	ltem No.	Description	Stock-on-hand in US\$	Cond	Qty on Hand	Remarks
15-0-00428	1	AUTOMATIC TITRATOR 1 Set of Coulter Multisizer Particle *	19,018.00	G	1	,
15-0-00428	2	COULTER MULTISIZER PARTICLE ANALYZER WITH ACCUCOMP SOFTWARE	47,102.00	G	1]-u
15-0-00428	3	ACCUCOMP SOFTWARE COULTER 9904421	1,874.00	G	1	1
15-0-00428	4	VACUUM OVEN CAPACITY	8,320.00	G	1	
15-0-00428	5	TABLET HARDNESS TESTER	6,497.00	G	1	
15-0-00428	6	DISSOLUTION APPARATUS 6-STATION, HANSON SR 2.	7,437.00	G	1	
15-0-00428	7	LAMINAR FLOW CABINET, BASSAIRE MODEL AGHB	8,449.00	G	1	
]. 	<u> </u>		<u> </u>	

Project No.

DP/THA/88/018

Country THAILAND

Purchase order Number	Item No.	Description	Stock-on-hand in US\$	Cond	Qty on Hand	Remarks
15-0-00592	1	1 set of Spectrophotometer * DÙ-68 SPECTROPHOTOMETER W/INTERFACE 230 V S/N 0004293098	11,790.00	G	1	7
15-0-00592 15-0-00592 15-0-00592 15-9-01986	2 3 4 1	AUTO 7 SAMPLER ACCY, PRINTER FX85-230V. ASSY, D2 LAMP DU-70. GENMARK/HERAEUS-VOETSCH CLIMATIC (HUMIDITY) TEST CABINET MODEL HC 7005	1,665.00 945.00 1,062.00 21,527.00	G G G	,1 1 2	}*
19-0-09259	1	(MACKINTOSH, APPLE LASER WRITER) COMPUTER	16,000.00	G	1	

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Project No. Country

DP/THA/88/018 THAILAND

PRICE LESS THAN US\$ 5,000.-

Purchase order Number	Item No.	Description	Stock-on-hand in US\$	Cond	Qty on Hand	Remarks
15-0-00428	1	VISCOMETER WITH UL ADAPTER FOR LOW VISCOSITY	4,365.00	G	1	
15-0-00428	2	CONSTANT TEMPERATURE BATH SIMILAR TO MODEL EX 200 BUT WITH COOLER AND ACC. NO. WK14-1DS	2,461.00	G	i	
15-0-00428	3	OVEN TEMPERATURE CONTROL DIGITAL TEMPERATURE READ-OUT ACCURACY 0.1 DEGREE CELSIUS CAPACITY ABOUT 115 LITER BINDER MODEL B 115	3,928.00	G	4	
15-0-00428	4	ANALYTICAL BALANCE CAPACITY 205 G METTLER AE 200 S	2,362.00	G	1	
15-0-00428	5	TOP LOADING BALANCE, METTLER MODEL PM 1200	2,490.00	G	1	

PRICE MORE THAN 5000 US \$

#	Item	Quantity	Supplier	Purchase no.	Condition (*)	Price (US S)
1	Infrared Spectrophotometer	1 set	Perkin - Elmer (Thailand) Ltd.	93 / 09	G	53,050
2	Cryoscopic Osmometer "Osmomat 030"	1 set	Scientific Promotion Co. Ltd	93 / 05	G	7,614
3	Accupye 1330 Gas Pycnometer	1 set	Engineering & Science Assoc.Co. Ltd.	93 / 10	G	12,566

(*) G = Good

Project No. Country

DP/THA/88/018

THAILAND

Purchase order Number	liem No.	Description	Stock-on-hand in US\$	Cond	Qty on Hand	Remarks
15-0-00428	6	STÄNDARD SIEVE FOR PARTICLE ANALYZER RETSCH TYPE VIBRO ORDER NO. 355	635.00	G	1	
15-0-00428	7	STERILITY TEST UNIT "SARTORIUS"	967.00	G	1	
15-0-00428	8	LABORATORY VACUUM PUMP	692.00	G	1	¥.
15-0-00592	1	DISSOLUTION TUBING KIT	1,634.00	G	2	
15-2-01370	1	TOYOTA COROLLA 1300CC, 4-DOOR STD. SEDAN/ COOLER	. 3,621.00	F	1	TRANSFERRED FROM DP/THA/
15-9-01987	1	MISTRAL 3000E CENTRIFUGE	4,228.00	a	1	86/010

PRICE LESS THAN 5000 US \$

#	Item	Quantity	Supplier	Purchase no.	Condition (*)	Price (US S)
1	Accessories for Coulter Multisizer II	1 set	Meditop Co., Ltd	93 / 11	G	715
2	Desiccator Model D-BOX	1 set	Sithiporn Assoc Co., Ltd	93 / 08	G	548
3	Fume Hood, size 1.2x2.35x0.85 m ³	1 set	Bangkok Chemart	93 / 06	G	4,648
4	Silicon Automation Voltage Stabilizer	3 units	J.S. General Supply Co., Ltd	93 / 07	G	1,289
5	Computer with printer for Coulter Multisizer II	1 set	Sahaviriya OA Group	93 / 13	Ğ	1,786
6	Computer "NOAH" Model 386 and printer Epson Model LQ 1170	1 set	J.S. General Supply Co., Ltd	93 / 12	G	2,930

(*) G = Good

Accessories for alternatives HPLC column (6 columns) not received yet.

List of locally purchased Training Equipment

#	Item	Supplier	Purchase no.	Condition (*)	Price (US \$)
1	Video Camera Recorder (SHARP, Model VL-MX98GY)	SHARP Thebnakorn Co. Ltd	92 / 14	G	1,091
2	Video Cassette Recorder (SHARP, Model VC-95HT)	SHARP Thebnakorn Co. Ltd	92 / 14	G	555
3	Colour Television (SHARP, Model 25N42-E1)	SHARP Thebnakorn Co. Ltd	92 / 14	G	754
4	Photocopy Machine (Model SF-7800)	SHARP Thebnakorn Co. Ltd	92 / 009	G	2,344
5	Electronic Typewriter (NAGAJIMA, Model AX-60)	O.M.A. Ltd	92 / 10	, G	547
6	Overhead Projector (KODAK, Ektalite L-5)	Chai Sayam Trading Co., Ltd	92 / 11	G	714
7	Slide Projector (KODAK, Caroussel S-AV 1030)	Chai Sayam Trading Co., Ltd	92 / 11	G	926
8	DA-LITE Tripod Screen 60 x 60	Chai Sayam Trading Co., Ltd	92/11	G	174
		-			<u> </u>

G = Good

List of locally purchased Training Equipment

#	Item	Supplier	Purchase no.	Condition (*)	Price (US \$)
 1	Video Camera Recorder	SHARP Thebnakorn Co. Ltd	92 / 14	G	1,091
2	(SHARP, Model VL-MX98GY) Video Cassette Recorder (SHARP, Model VC-95HT)	SHARP Thebnakorn Co. Ltd	92 / 14	G	555
3	Colour Television (SHARP, Model 25N42-E1)	SHARP Thebnakorn Co. Ltd	92 / 14	G	754
4	Photocopy Machine (Model SF-7800)	SHARP Thebnakorn Co. Ltd	92 / 009	G	2,344
5	Electronic Typewriter (NAGAJIMA, Model AX-60)	O.M.A. Ltd	92 / 10	G	547
6	Overhead Projector (KODAK, Ektalite L-5)	Chai Sayam Trading Co., Ltd	92 / 11	G	714
7	Slide Projector (KODAK, Caroussel S-AV 1030)	Chai Sayam Trading Co., Ltd	92 / 11	G	926
8	DA-LITE Tripod Screen 60 x 60	Chai Sayam Trading Co., Ltd	92 / 11	G	174
	DR-MIN	Co., Ltd			

G = Good

PRICE LESS THAN 5000 US \$

†	Item	Quantity	Supplier	Purchase No.	Price (US\$)
l	E 55013 MINIPLUS 3 MODEL MP 8	1 SET	QUALITECH INSTRUMENTS	94/01	3,098
	GILSON PERISTALTIC PUMP, 220-240		Co.,LTD.		
	V/50 Hz with Standard				
2	Piv. 537094 Pump Control Board	1 SET	QUALITECH INSTRUMENTS	94/01	1,215
		* -	Co.,LTD.	1	
3	PN. 598274 RS 232 C INTERFACE	1 SET	QUALITECH INSTRUMENTS	94/01	745
		- [Co.,LTD		
4	IMMERSION MEASURING CELL	1 SET	SCHMIDT SCIENTIFIC	94/02	422
	K = 0.8		(THAILAND) LTD.		
5	Temperature Sensor	1 SET	SCHMIDT SCIENTIFIC	94/02	186
			(THAILAND) LTD.		1
6	ULT RASONIC BATH	1 SET	SAHAVIRIYA PURE SCIENCE	94/03	1,476
			Co.,LTD.		
7	ULTRAVIOLET LAMPS	1 SET	SAHAVIRIYA PURE SCIENCE	94/04.1	440
	Model UVGL-58		Co.,LTD.	Ì	
8	CAPILLARY DISPENSER	1 SET	DIETHELM & CO.,LTD	94/04.2	690.40
9	NANOMAT	1 SET	DIETHELM & CO.,LTD	94/04.3	1,184
10	15 MICRON APERTURE TUBE WITH	1 SET	MEDITOP CO.,LTD.	94/07	1,145
]	CALIBRATION STANDATD				

PRICE_LESS THAN 5000 US \$

#	Item	Quantity	Supplier	Purchase No.	Price (US\$)
11	280 MICRON APERTURE TUBE WITH CALIBRATION STANDATO	1 SET	MEDITOP CO.,LTD.	94/07	725
12	ERWEKA DISINTEGRATION TESTER	1 SET	HAVE LINK LTD.	94/10	2,200
13	MELTING POINT APPARATUS	1 SET	SAHAVIRIYA PURE SCIENCE Co.,Ltd.	94/11	1,480
14	POLARIMETER MODEL D2	1 SET	Bang Trading 1992 Co.,Ltd.	94/12	4,569

[&]quot; ON ORDER " as of Sep 25/94

PRICE MORE THAN 5000 US \$

#	Item	Quantity	Supplier	Purchase No.	Price (US\$)
1	TSP: CONSTA METRIC FLUID METERING PUMPS MODEL CM 3200	1 SET	SCITRONIC CO.,LTD.	94/06	6,000
2	GAS CHROMATOGRAPHY TREMETRIC USA	1 SET	SCITRONIC CO.,LTD.	94/08	24,108
3	TSP: VARIABLE - WAVELENGTH U/VIS DETECTOR MODEL SM 3200	1 SET	SCITRONIC CO.,LTD	94/09	6,500

[&]quot;ON ORDER" as of Sep 25/94