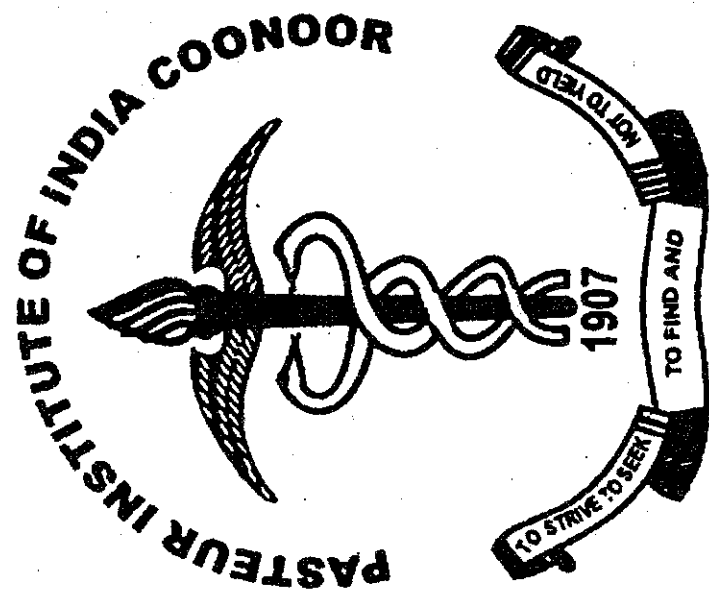


PASTEUR INSTITUTE OF INDIA
COONNOOR 643 103, NILGIRIS.
TAMILNADU



ANNUAL REPORT

2013 - 2014

DIRECTOR
Dr. B. SEKAR, M.D.,

DEPUTY DIRECTOR
Vacant

ASSISTANT DIRECTORS
Dr. K.N. Venkataramana, M.B.B.S, D.M.V.,
Dr. B. Sundaran, M.Sc., Ph.D.,

QUALITY ASSURANCE AND QUALITY CONTROL DEPARTMENT

SENIOR RESEARCH OFFICER
Shri C. Palaniappan, M.Sc., D.M.L.T.,

ASST. RESEARCH OFFICER
Dr. N. Sivananda, M.Sc., M.Phil., Ph.D., M.Ed., M.Phil., PGDCA, DIPC.,

SENIOR RESEARCH ASSISTANT
Shri T. Sekar, M.Sc.,

PRODUCTION DIVISION
TISSUE CULTURE ANTI RABIES VACCINE

RESEARCH OFFICER
Dr. A. Premkumar, M.Sc., Ph.D.,

ASST. RESEARCH OFFICERS
Shri Jason Muthukumar Jeyacross, M.Sc.,
Dr. S. Jagannathan, M.Sc., Ph.D.,

DPT GROUP OF VACCINES

SENIOR RESEARCH OFFICER
Dr. (Smt.) Jeeva Kalai Selvan, M.B.B.S.,

RESEARCH OFFICERS
Smt. Savithri Sundaran, M.Sc.,
Smt. Shanthi Mani, M.Sc.,
Shri R. Mohan, M.Sc.,

ASST. RESEARCH OFFICERS
Dr. K.C. Shivanandappa, M.Sc., Ph.D.,
Smt. T. Lalitha, M.Sc.,
Smt. Chandra Charles, M.Sc.,
Shri B. Annamalai, M.Sc., P.G.D.M.L.T.,

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ASST. TECHNICAL OFFICERS

Shri V. Manoharan, M.Com., PGDMM

Shri K. Krishnamurthy

Shri K. Nagarajan (superannuated on 31.01.2014)

ADMINISTRATIVE SECTION**ADMINISTRATIVE OFFICER**

Shri A. Vairamoorthy, M.A., M.L., M.H.R.M.,

SENIOR P.A. TO DIRECTOR

Shri P. Sasikumar, B.Com., M.A. PGD.M.M.,

ACCOUNTS DEPARTMENT**ACCOUNTS OFFICER**

Vacant

PURCHASE & STORES DEPARTMENT**STORES OFFICER**

Shri S. Chandrasekaran, B.Com., M.A.,

LABORATORY ANIMAL DIVISION**VETERINARY ASSISTANT SURGEON**

Dr. Anjan Jyoti Nath, M.V.Sc.,

ASST. RESEARCH OFFICER

Dr. C. Muniandi, M.Sc., Ph.D.,

LIBRARY**LIBRARY AND INFORMATION OFFICER**

Vacant

MAINTENANCE SECTION**MAINTENANCE OFFICER**

Shri J. Kamaludeen

DISPENSARY**SENIOR MEDICAL OFFICER**

Dr. (Smt) Sibani Barman, M.B.B.S.,

MEDICAL OFFICER

Dr. Samyak Sahu, M.B.B.S.,

**DIRECTOR'S MESSAGE**

In this reporting period our Institute has seen a series of developments towards a progressive growth. As the first step of the establishment of our Rs. 140 crores new GMP project for the production of DPT group of vaccine, the civil construction for the new facility has begun in June, 2013, after the receipt of statutory approval from the Government of Tamil Nadu. Concurrently actions have been taken to finalize the specifications of certain equipments and to place the purchase orders for certain critical equipments for the GMP project.

This year we continued the production of DPT vaccine in the existing facility and supplied 188.19 lakh doses of DPT vaccine to the Universal Immunization Programme (UIP).

The analysis of records available with the Anti Rabies clinic of our Institute and other health facilities and Animal Husbandry department of Nilgiris district revealed that Rabies case has not been reported from Nilgiris District for the past few years. Taking advantage of this situation, we organized a National Workshop on "Assessing Rabies free status of Nilgiris district", on 31.08.2013 in coordination with Department of Public Health of Government of Tamil Nadu. In the workshop, inaugurated by the District Collector, experts from different organizations debated and it has culminated into the formation of a coordination committee and identification of action plans both at human and animal level for taking forward the situation of Nilgiris District to declare Rabies free in future. Further, in commemoration of the death anniversary of Louis Pasteur, we celebrated 'World Rabies Day' on 28th September, 2013, by organizing a Rabies awareness rally, Essay writing and Quiz competitions for School children.

Our Rabies Diagnostic lab has received 230 samples from all over the country, for the estimation of Anti-rabies neutralizing antibodies by RFFIT using Murine Neuroblastoma-2A cells. As done in the previous years, in the reporting year also about 1811 patients received Anti Rabies Vaccines in our Anti Rabies Treatment Centre. Besides this we have undertaken Post graduate students course projects, industrial visits for college students and other academic activities. The outcome of some of the project works has been published as scientific articles in reputed journals. Many officers and staff of this Institute have undergone relevant training programme.

I sincerely thank the Secretary, Additional Secretary, Joint Secretary and all officials of Department of Vaccine Institute of Ministry of Health and Family Welfare, Government of India, for all the supports rendered during the reporting period. I thank all the officers and staff of PII, Coonoor for all the achievements witnessed in this year.

I wish the entire team of PII, Coonoor a great success in all their future accomplishments.

Dr. B. SEKAR,
DIRECTOR.

CONTROLLING OFFICERS

- 1. Director : Dr. B. Sekar, M.B.B.S., M.D.,
- 2. Assistant Director – I : Dr. K.N. Venkataramana, M.B.B.S., D.M.V.,
- 3. Assistant Director – II : Dr. B. Sundaran, M.Sc., Ph.D.,
- 4. Senior Research Officer-I : Dr. (Smt) Jeeva Kalai Selvan, M.B.B.S.,
- 5. Senior Research Officer-II : Shri. C. Palaniappan, M.Sc., D.M.L.T.,
- 6. Senior Medical Officer : Dr (Smt) Sibani Barman, M.B.B.S.,

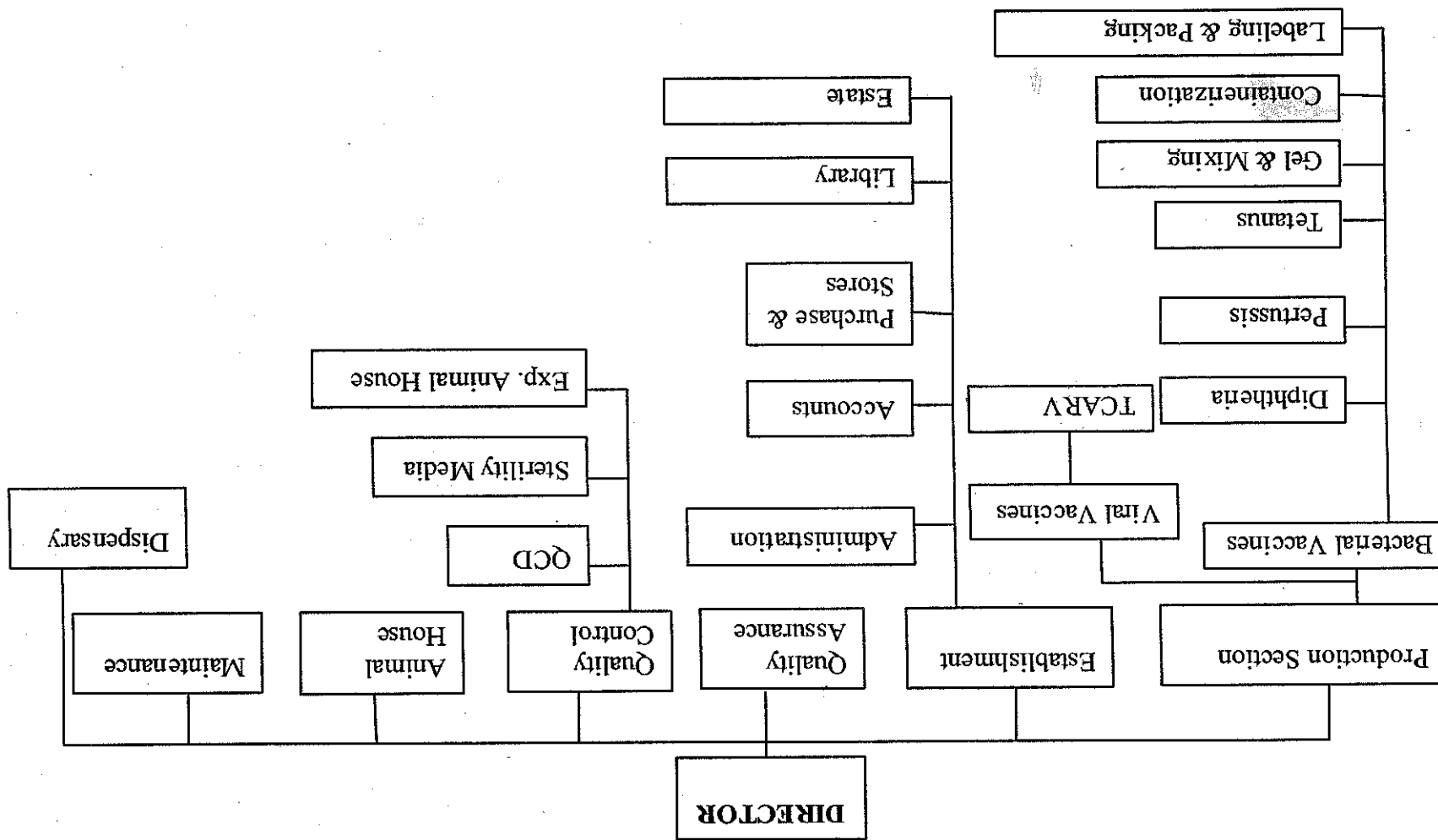
RESPONSIBILITIES OF CONTROLLING & OTHER OFFICERS

- 1. DIRECTOR : Chief executive officer of all activities associated with the Institute viz., Administration, Accounts & Finance, Production, QA, QCD, R&D.
- 2. ASSISTANT DIRECTOR-I : All activities associated with the production and supply of TCARV, Animal House, Maintenance section, Purchase, Stores Department, Estate Department and administrative duties assigned by the Director.
- 3. ASSISTANT DIRECTOR-II : All activities associated with the Quality Assurance Division, overall supervision of production & supply of DPT vaccines and administrative duties assigned by the Director.
- 4. SENIOR RESEARCH OFFICER-I : Production of Diphtheria, Tetanus, Pertussis, Gel & Mixing Section, Containerization & Inspection and Labelling, Packing and Dispatch section.
- 5. SENIOR RESEARCH OFFICER-II : All activities associated with QCD (QCD, Sterility Media Section, Rabies Diagnosis Lab and Experimental Animal House).
- 6. SENIOR MEDICAL OFFICER : All activities associated with Dispensary.
- 7. ADMINISTRATIVE OFFICER : All activities associated with Administration, Establishment, Security, Legal, Vehicle movement and also Accounts.

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ORGANOGRAM - PASTEUR INSTITUTE OF INDIA



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OVER VIEW

Pasteur Institute of India, Coonoor is one of the leading Institutions in the production of Antirabies Vaccine and DPT group of Vaccines for the Expanded Programme of Immunization of Government of India.

PREAMBLE

The Institute started functioning as Pasteur Institute of Southern India, on 6th April 1907 and the Institute took a new birth as the Pasteur Institute of India (registered as a Society under the Societies Registration Act 1860) and started functioning as an autonomous body under the Ministry of Health and Family Welfare, Government of India, New Delhi from the 10th of February, 1977. The affairs of the Institute are managed by a Governing Body. The Institute is functioning on a no profit no loss basis.

GENESIS

The death of a young English lady Lily Pakenham Walsh, due to hydrophobia in the year 1902 who could not get antirabies treatment in time led to the establishment of Pasteur Institute of Southern India. Mr. Henry Phipps, American Philanthropist donated to Lord Curzon, the then Viceroy of India a sum of Rs.50.00 lakhs for the development of Medical Institutions, out of which, a sum of Rupees one lakh was allocated to start the Pasteur Institute of Southern India at Coonoor.

The cool and equitable climate led to the choice of Coonoor as the most suitable location for the construction of the Institute. Spread over an area of 16 acres of land the Institute is situated on a grassy knoll on the upper reaches of Coonoor town amidst beautiful surroundings with lush greenery, manicured lawns and flower gardens. It has a glorious tradition of single minded dedication to alleviate the suffering of humanity by its contribution to the research and development of vaccines in the country.

SETTING THE PACE IN TECHNOLOGY

Pasteur Institute of India has consistently set the pace in innovating and adapting newer technology to suit Indian conditions and needs. It is this vast experience and expertise which makes it well equipped to meet the challenges of applying advanced technology in vaccine production. Among the major equipments available in the Institute are large bacterial fermentors, zonal centrifuge, industrial freeze drier, several bulk autoclaves, ovens, filling machines, large cold rooms, deep freezers, bioreactors, purified water system, WFI plant, TOC analyzer, column chromatography, oil & moisture free air compressor, Effluent Treatment Plant (ETP) and Sewage Treatment Plant (STP). Full fledged facility is available for Research and Development work which includes HPLC system, ultra centrifuge, ELISA equipment and equipment for molecular biology work.

The Institute is recognized by the Tamilnadu Dr. M.G.R. Medical University, Chennai for M.D degree in Microbiology and by the Bharathiar University for Ph.D in Microbiology, Biotechnology and Biochemistry in the faculty of Science.



INSTITUTE'S PRODUCT PROFILE

"Laboratories are the Temples of the future. It is there the man learns to read the works of nature" Louis Pasteur.

- ◆ Production of Tissue Culture Antirabies Vaccine (Vero Cell Purified)
- ◆ Production of DPT group of vaccines viz., Diphtheria-Pertussis-Tetanus (DPT) Vaccine, Diphtheria-Tetanus (DT) Vaccine and Tetanus Toxoid (TT) Vaccine.

OBJECTIVES

The objectives of the Society are to make available effective means of preventing the occurrence of rabies to spread the knowledge of such means among the public and to undertake research work on rabies, influenza, enteroviruses or any other diseases and for the following purpose.

- ◆ To prepare such other vaccines as may be in the National interest.
- ◆ To develop the Institute into an advanced service, post-graduate training and research center.
- ◆ To co-operate with International and National agencies engaged in biomedical research and training and arrange for inter-change of personnel, material and data.

IMPORTANT MILESTONES

- ▲ 1907 Manufacture of Neural Tissue Antirabies Vaccine.
- ▲ 1957 The isolation of Asian Flu Virus during the pandemic and development of Influenza vaccine against the same virus.
- ▲ 1970 The Development of BPL-inactivated Rabies Vaccine for the first time in India which made the treatment easier and cheaper with less dose and less injections with a vaccine of increased potency.
- ▲ 1970 Research, Development, Production and Supply of Trivalent(Sabin) Oral Polio Vaccine for the first time in India
- ▲ 1982 Release of DPT group of vaccines for the National Programme of Immunization.
- ▲ 1988 Release of Tissue Culture Anti Rabies Vaccine for Canine Prophylaxis
- ▲ 2001 Development and release of Vero Cell Derived Purified Rabies Vaccine for human use at an affordable price to common man for the first time in India by Government controlled Institutions.
- ▲ 2003 This is the first Government sector vaccine Institute awarded with ISO 9001-2000 certificate by BVQI, UK in Quality Management System.
- ▲ 2006 Renewal of ISO 9001:2000 certificate for further period of 3 years by BVQI, UK for QMS.

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FUTURE PLAN

- Creation of cGMP facilities for Tissue Culture Antirabies Vaccine.
- Research and Development of newer cost effective vaccines like Pentavalent vaccine.

INTERNATIONAL ACCREDITATION

This Institute has been accredited with International Organisation for Standardization (ISO) Certification 9001-2000 for adopting Quality Management System during the year 2003-2004. This is the first Institute in the Public Sector which has been accredited with ISO 9001-2000 in the vaccine manufacture by International accrediting organization namely Bureau Veritas Quality International (BVQI), London. The certificate was valid upto 22.02.2009. The ISO standards are complementary in line with Good Manufacturing Practices (GMP) norms. The Certificate is issued only after conducting a series of audits to check whether all the standards of ISO are in compliance.

PRESENT ACTIVITIES

- Production of DPT group of vaccines and TCAR vaccine in compliance with the revocation of production licence by the Ministry of Health and Family Welfare, New Delhi in February, 2010.
- Academic programmes like Ph. D. Microbiology, Biochemistry and Biotechnology (Part time & Full time) affiliated to Bharathiar University, Coimbatore and M.D (Microbiology) affiliated to Tamilnadu Dr. M. G. R Medical University, Chennai.
- Breeding of Mice and Guinea pigs for Experimental purpose like Quality Control of DPT group and TCAR vaccines.
- Institute has a Rabies Diagnostic Lab and treatment center to cater the need of the general public.

INSTITUTE'S QUALITY POLICY

"We are committed to produce Safe, Potent and Cost effective vaccines with continual improvements in our Quality system."

DETAILS OF GRANT-IN-AID RECEIVED FROM THE MINISTRY OF HEALTH AND FAMILY WELFARE, NEW DELHI AND THE EXPENDITURE INCURRED, ETC., DURING 2013-14

The Ministry of Health and Family Welfare, New Delhi has released a total sum of ₹ 40.00 Crores to this Institute during the financial year 2013-14 vide the under mentioned Sanction Orders:

Sl. No.	Sanction Letter No. and Date	Amount (in ₹)	Head
1.	Letter No. V.11011/01/2013-VI/1 dated 27.06.2013	5,00,00,000	General
2.	Letter No. V.11011/01/2013-VI/2 dated 27.06.2013	5,00,00,000	Salaries
3.	Letter No. V.11011/01/2013-VI/3 dated 27.06.2013	10,00,00,000	Capital
4.	Letter No. V.11011/01/2013-VI/1 dated 19.11.2013	7,00,00,000	General
5.	Letter No. V.11011/01/2013-VI/2 dated 19.11.2013	6,00,00,000	Salaries
6.	Letter No. V.11011/01/2013-VI/3 dated 12.12.2013	7,00,00,000	Capital
	TOTAL	40,00,00,000	

While releasing the Grant-in-Aid, the Ministry has, vide above letter informed that the normal expenditure of the Plan scheme including the administrative expenses of grantee institutions may be met from the above amount. The details of the head wise expenditure incurred are given below:

Sl. No.	Head of Account	Amount (₹ in lakhs)
1.	Grants-in-General	10,38,80,179
2.	Grants for creation of Capital Assets	7,00,00,000
3.	Grants-in-Aid Salaries (new)	8,92,29,522
	TOTAL	26,31,09,701

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ACTIVITIES UNDERTAKEN IN RESPECT OF ESTABLISHMENT OF GREEN FIELD MANUFACTURING GMP FACILITY FOR PRODUCTION OF DPT VACCINE AT PIIC

- The Govt. proposed to create Green Field GMP facility for manufacturing DPT group of vaccines at PIIC. In this regard, HLL Lifecare Ltd., Trivandrum has been identified as Project Consultant. EFC has recommended for a total estimated non-recurring expenditure of ₹137.02 crores plus the Project Management Consultancy Fee for HLL.
- In Nilgiris, the height of new building is restricted to 7 mts. and any proposal above 7 mts. requires approval of Architectural & Aesthetics Aspects (AAA) Committee and Hill Area Conservation Authority (HACA) committee. Accordingly, the layout has been submitted to the local municipal authorities for recommendation of the AAA/HACA committees. AAA Committee recommended and referred the proposal to HACA committee and the HACA has also approved in principle and the proposal has been forwarded to the Municipal Administration and Water Supply Department (MAWS) for final Orders. The MAWS have issued order relaxing the height restriction on 1-3-2013 and the final order is received during May, 2013 from the Local Municipal Authorities, Coonoor.



- Civil work for the new GMP project was initiated in the month of June, 2013.
- HLL has proposed to complete the construction of GMP establishment by October, 2014.
- After that Equipment Validation and Process validation will be undertaken. Then production of vaccine from the new facility will be initiated and completed with the certification of initial 3 consecutive batches by CDL.
- The proposed annual supply from the new facility will be: DPT- 60 Mld; TT -55 Mld; DT- 15Mld (Total- 130 Mld).

PROGRESS OF CIVIL CONSTRUCTION

- Basic infrastructure required for the construction of Diphtheria & Pertussis block has been initiated. As on date 100% of the basic infrastructure work required for DP block has been completed.
- 26% of the work for Diphtheria and Pertussis block has been completed in the form of concreting work up to plinth beam & Retaining walls.
- 5% of the work for Formulation block has been completed in the form of footing concrete work.
- 28% of the work for Sterility and Microbiology Lab has been completed in the form of concreting up to plinth beam & retaining wall.
- 45% of the work for the Animal Experiment Block has been completed in the form of footing work.
- Tender value for civil construction is around Rs.24.67 crores out of which, in the reporting year civil work amounting to Rs.3.05 crores worth of work has been completed which is 12.35% of the total civil project cost.

OTHER GMP RELATED ACTIVITIES

- The User Requirement Specifications (URS) in respect of Dry Heat Sterilizer, Autoclave cum Bung processor, Sterilization Autoclave, De-contamination-Autoclave have been finalized and signed on 08.11.2013.
- The kick off meeting on supply, installation, commissioning and validation of production scale fermentors and blending vessels held on 13.12.2013. The qualified and successful vendor made a presentation on quality policy of the company.
- Filter Integrity testing machine URS approved on 22.02.2014.



PRODUCTION DIVISION

The Pasteur Institute of India has been producing the DTP group of vaccines viz., DTP, DT and TT vaccines as its main product, along with sheep brain anti rabies vaccine. The Institute has successfully developed indigenous technology for manufacturing of Vero cell derived and purified vaccine for human use. The Sheep brain anti rabies vaccine, usually referred as ARV (NT) was phased out.

Prior to suspension of the Drug Licence this organization has been producing the DPT group of vaccines viz., DPT, DT and TT vaccines as its main product, as well as Tissue Culture Anti Rabies Vaccine (TCARV). No production work carried out during the suspension period. On receipt of the revocation order, this Institute concentrates to produce and supply of DPT group of vaccines and TCARV in the existing facilities with due modification as well as creation of newer cGMP infrastructure for vaccine production.

A. BACTERIAL VACCINE DIVISION

The bacterial vaccine division comprises of three basic functional units, which has been producing bulks for the production of DPT group of vaccines.

- ◆ Diphtheria
- ◆ Tetanus
- ◆ Pertussis

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The DPT vaccine production units have adopted modern fermentor technology to produce the toxin (Tetanus and Diphtheria) and bacterial mass (B. pertussis), which are the components of DTP group of vaccines. *PIIC is the first Institute in the country both in public and private sectors to adopt and install the PROSTAK system for clarification of toxin and concentration of formal treated toxin prior to ammonium sulfate fractionation step and concentration of Pertussis organisms.* The crude toxoid of both tetanus and diphtheria are purified as per GMP norms adopting latest technology of Tangential flow principles using appropriate membrane and cassettes (Micro filtration & ultra filtration). Further the Membrane filters successfully replaced the old fiber shedding EKS filters in the final polishing filtration process.

DIPHTHERIA

This section is adopting fermentation technology for the cultivation of Diphtheria organisms. The capacity of the fermentor is 400 lts. The crude toxoid of diphtheria is purified as per adopting latest technology of Tangential flow principles using appropriate membrane and cassettes (Micro filtration & ultra filtration). Membrane filters were successfully replaced the old fiber shedding EKS filters.

During the period from 2013 to 2014, 10.5 million doses of Bulk Purified Diphtheria Toxoid (BPDT) has been produced and issued for formulation. About 1.5 million doses of BPDT is available as buffer stock. This department has successfully completed the allotted target in time.



TETANUS

The tetanus section is adopting both pot culture and fermentor culture for the cultivation of Tetanus organisms. For the clarification of the toxin prostack modules with 0.22 µm membrane filters have been standardized and used. Toxoid concentration was done by Pellicon Cassette system.

During the period about 30.18 million doses of Tetanus Toxoid at purified level prepared by processing 48.78 million doses crude material. Required purified material supplied for formulation. After achieving the target the laboratory was handed over for demolition for construction of new laboratory. Meanwhile a Tetanus lab has been established in the adjacent old building to continue the production in future.

PERTUSSIS

This division is adopting fermentor technology for the bulk production. The total capacity of the fermentor is 400 lts. The concentration of bacterial mass involves the use of Tangential Flow Filtration system utilizing 0.45 µm open channel modules – (micro porous membranes) fitted to Prostack system.

During the reporting period, 10.8 million doses of Pertussis concentrate were produced and completed the allotted target in time.

B. VIRAL VACCINE DIVISION

The Institute has the facilities to produce the Vero cell derived purified antirabies vaccine.

VERO CELL DERIVED PURIFIED ANTI RABIES VACCINE

Tissue culture Anti Rabies Vaccine project was started in 1981 funded by WHO/UNDP. In 1982 PV-3462 strain of rabies was adopted in BHK and Vero cell lines. In 1983 PV-11 strain was adopted in Vero cell lines. From 1984 onwards-regular batches using Vero cell based PV-11 strain of rabies virus have been produced.

Further the clinical trials have been carried out on 6 batches. During 2001-2002 CDL, Kasauli declared and certified that the vaccine produced by this Institute is of standard quality.

During the reporting period standardization of purification by affinity chromatography utilizing cellulose sulphate matrix and lyophilisation were carried out prior to preparation of three validation batches.



QUALITY CONTROL DIVISION

The Quality Control Division comprised of the following divisions

1. Quality Control Department
2. Rabies Diagnosis Laboratory
3. Sterility Media Section
4. Experimental Animal House

The following processes were carried out in Quality Control Division.

- a) Quality Control Tests on Bacterial Vaccines (DPT group of vaccines) and Tissue Culture Anti Rabies Vaccine
- b) Sterility media preparation and supply to different laboratories.
- c) Rabies Diagnostic Tests
- d) In vivo tests and Regular Maintenance of Experimental Animal House

a. QUALITY CONTROL TESTS

16 batches of DPT final bulks, 58 batches of DPT final lots, 4 batches of BPDT, 3 batches of BPDTI, 12 batches of B.P. Pool, 1 batch of TCARV CON samples, 3 batches of TCARV lot samples and 8 batches of Aluminium phosphate gel samples were carried out in QCD.

b. STERILITY MEDIA PREPARATION DIVISION

During this period the Sterility Media section was engaged in the preparation of sterility media to rule out the microbial contamination on various samples and also for the checking of microbes in the classified sterile area in vaccine production. The following table shows the figures of various bacteriological media prepared and utilized.

Nutrient Agar	66.50 Litres	Prepared in Petri dishes and used for various testings
Sabourauds Agar	57.25 Litres	Prepared in Petri dishes and used for various testings
Alternate Thioglycollate broth fluid medium	632.00 Litres	Used in the sterility testings as per I.P.
Soyabean Casein Digest broth	721.00 Litres	Used in the sterility testings as per I.P.
Fluid Thioglycollate Broth	81.50 Litres	To use in the sterility test as per I.P.

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c. RABIES DIAGNOSIS LAB

230 sera samples both from Human and Domestic animals were subjected to Rapid Fluorescent Focus Inhibition Test (RFFIT) for the detection and quantification of Rabies Neutralizing Antibodies using Murine Neuroblastoma-2A cells and 96 well flat bottom Micro titre plates. This includes the samples received from our Dispensary from the patients reporting for consultation and to assess the post vaccination sero conversion for the protection against rabies infection.

d. EXPERIMENTAL ANIMAL HOUSE

Production Labs and Quality Control Department conducted in vivo tests in the experimental animal house. These experimental animals were maintained in the Experimental animal house during the test period as per test procedure.

LABORATORY ANIMAL DIVISION

Number of animals supplied to internal users:

Mice : 9980 Nos.
Guinea Pig : 956 Nos.

Number of animals supplied to other institutes:

Mice : 1900 Nos.
Guinea Pig : 316 Nos.

GEL & MIXING SECTION

During the period 8 batches of Aluminium Phosphate Gel were prepared. This is enough to prepare approximately 8 million doses. 16 final bulks were formulated (apprx. 8.00 million doses).

DPT CONTAINERIZATION, LABELLING & PACKING SECTION

During the period 58 lots of DPT vaccine filled and processed

DPT VACCINE SUPPLY TO UIP

April, 2013 to September, 2013 : 181.19 lakh doses
December, 2013 : 7.00 lakh doses
Total : 188.19 lakh doses

**RABIES TREATMENT CENTRE & DISPENSARY**

Rabies treatment center established in 1907 for treatment of dog bite cases is continuously functioning for the last 100 years or more effectively and efficiently. For the benefit of the long distance patients coming from far of places this hospital is working round the clock. During day time the dispensary is also providing basic health care facilities to employees of Pasteur Institute of India and their dependents. Rabies treatment centre is also engaged in collecting epidemiological data of animal bite cases and also efficacy of antirabies vaccine. In order to minimize the cost and quantity of tissue culture vaccine intra dermal administration is also being practiced.

DISPENSARY PERFORMANCE STATISTICS

Staff and family : 6294
Diabetes patients : 42
Hypertensive patients : 58
Asthma patients : 10

PATIENTS TREATED WITH TCARV

Sl. No.	Details	Nilgiris	Other than Nilgiris	Total cases	In percentage (%)
1.	Class - I	16	63	79	4.37
2.	Class - II	133	29	162	8.95
3.	Class - III	527	1043	1570	86.7
4.	A.R.S.	356	797	1153	73.44
5.	Adult Male	335	607	942	52.02
6.	Adult Female	173	264	437	24.13
7.	Child Male	121	172	293	16.18
8.	Child Female	47	92	139	7.68
	TOTAL	676	1135	1811	
	Hydrophobia	2	5	7	

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COST WISE DETAILS

Total cost of TCARV sold (2749 doses) worth ₹ 2,72,720.00
Antirabies serum sold (1444 vials + 3.9 ml) ₹ 6,84,378.00
Total ₹ 10,13,848.00



QUALITY ASSURANCE

“Quality Assurance” is a wide – ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality Assurance therefore incorporated GMP and other factors. The following activities were carried out in Quality Assurance Section.

- ❖ Regular monitoring of seed stock in cold storage for bacterial vaccines (DPT group of vaccine) and issue to the production laboratories based on the requirement.
- ❖ Maintaining the Standard Operating Procedures (SOPs) for all sections of our organization and made amendments based on the request.
- ❖ Batch Processing Records (BPRs) were issued based on the request from the different section and reviewed the same after the completion of the work.
- ❖ Revisions made in organogram and responsibility for all sections as and when warranted.
- ❖ Environmental monitoring (viable & non viable particle count) at DPT filling unit and other critical area undertaken.
- ❖ Calibration of temperature and pressure gauges available in different section was organized.
- ❖ Monitoring of vehicles during the vaccine loading, fixing of data logger and vehicle temperature documentation.
- ❖ DPT vaccine samples (representing batches from 3A-2596 to 3A-2655) sent to Central Drug Laboratory, Kasauli for inspection and final release. It amounted to 139.7 lakh doses.

LIBRARY

The Institute has a well stocked library with 4257 books and 12604 bound volumes, 8 International journals, 9 Indian Journals and WHO publication (Periodicals and Selected Series subscription).

List of Books added to library during the reporting period :

1. Good Clinical Laboratory and Manufacturing practices – P.A. Carson
2. Theapeutic Oligonucleotides – Jens Karreck
3. Annual Review of Biochemistry Vol. 81
4. Annual review of Immunology Vol. 30
5. Annual review of Microbiology Vol.66
6. British Pharmacopoeia 2013
7. British Pharmacopoeia 2013 (Veterinary)
8. Indian Pharmacopoeia 2014
9. Prescott Microbiology 9th Edition

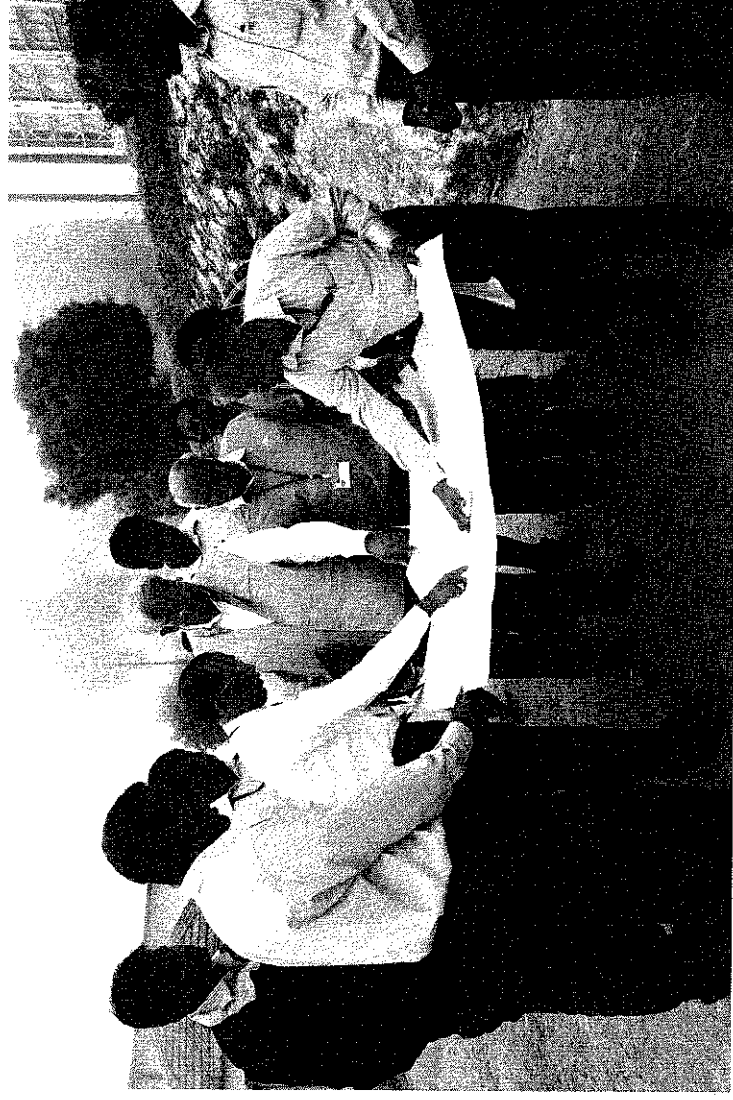
List of Foreign Journals Purchased:

1. Biologicals
2. Human Vaccines
3. JAMA



photo gallery

VISIT OF SHRI KESHAV DESIRAJU, SECRETARY (HEALTH) TO ASSESS THE PROGRESS OF CIVIL CONSTRUCTION OF GREEN FIELD cGMP DPT PROJECT ON 31st DEC 2013



**PROGRESS OF CIVIL CONSTRUCTION OF
GREEN FIELD cGMP DPT PROJECT
BEFORE**

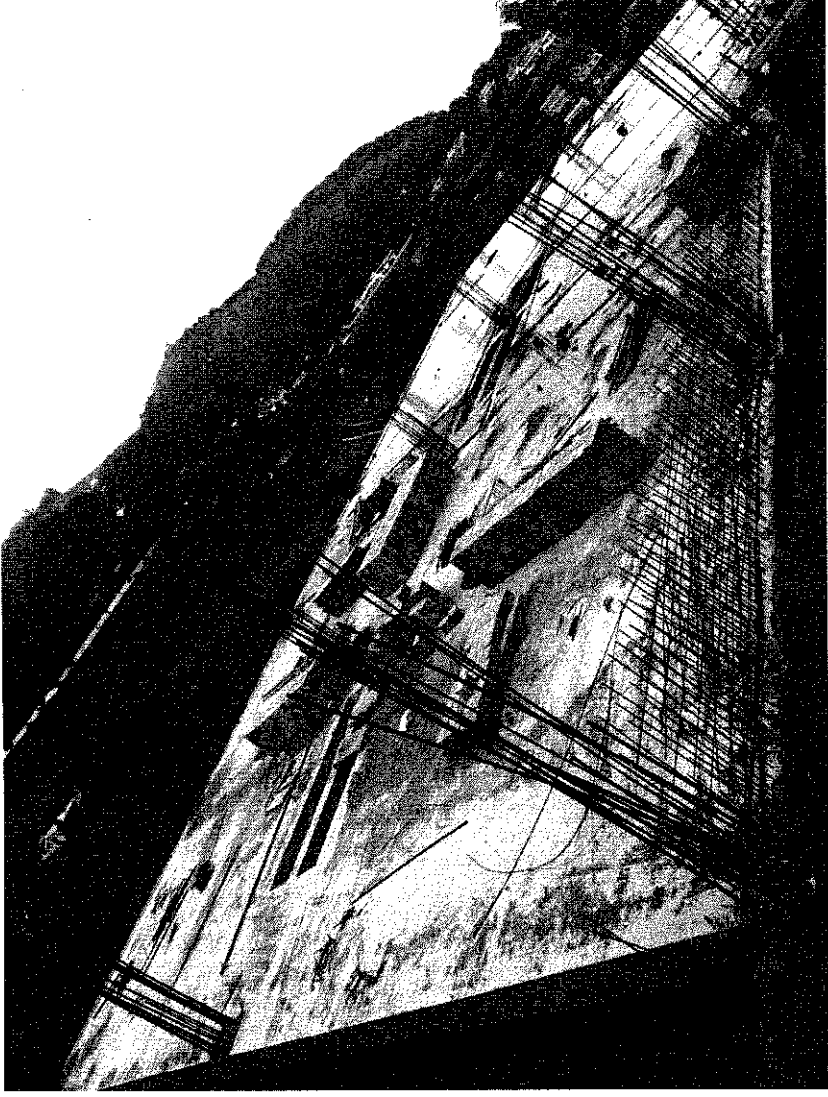


AFTER

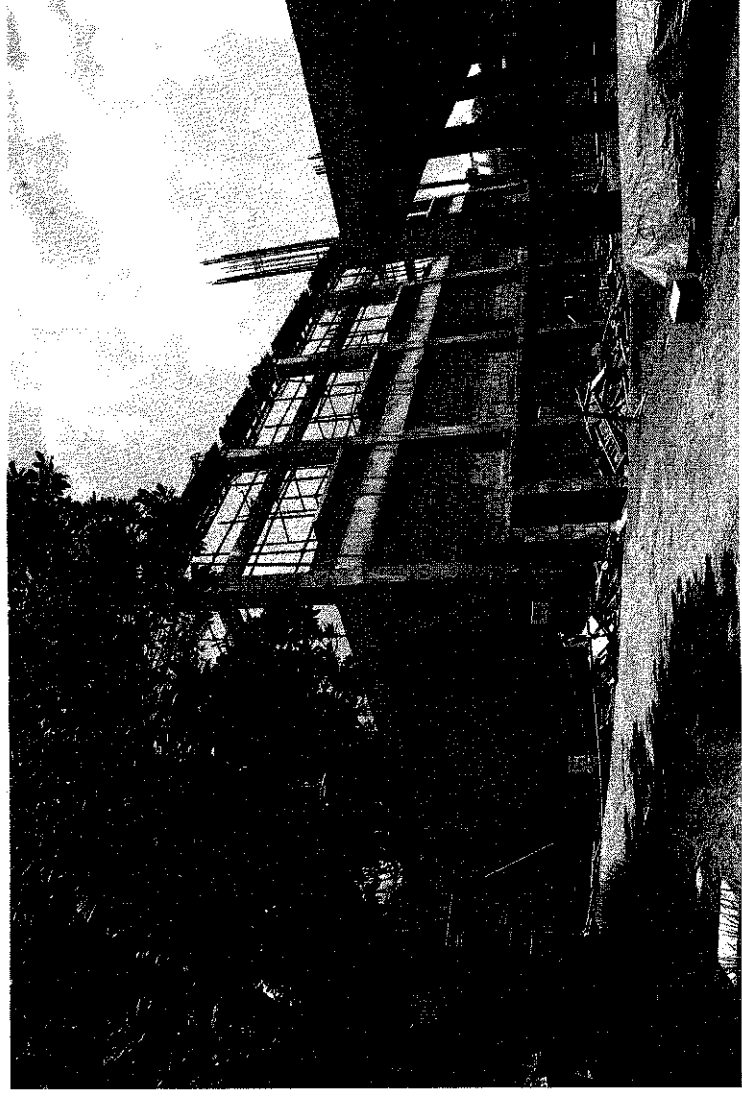


EXPERIMENTAL ANIMAL BLOCK, MICROBIOLOGY BLOCK & UTILITY BLOCK

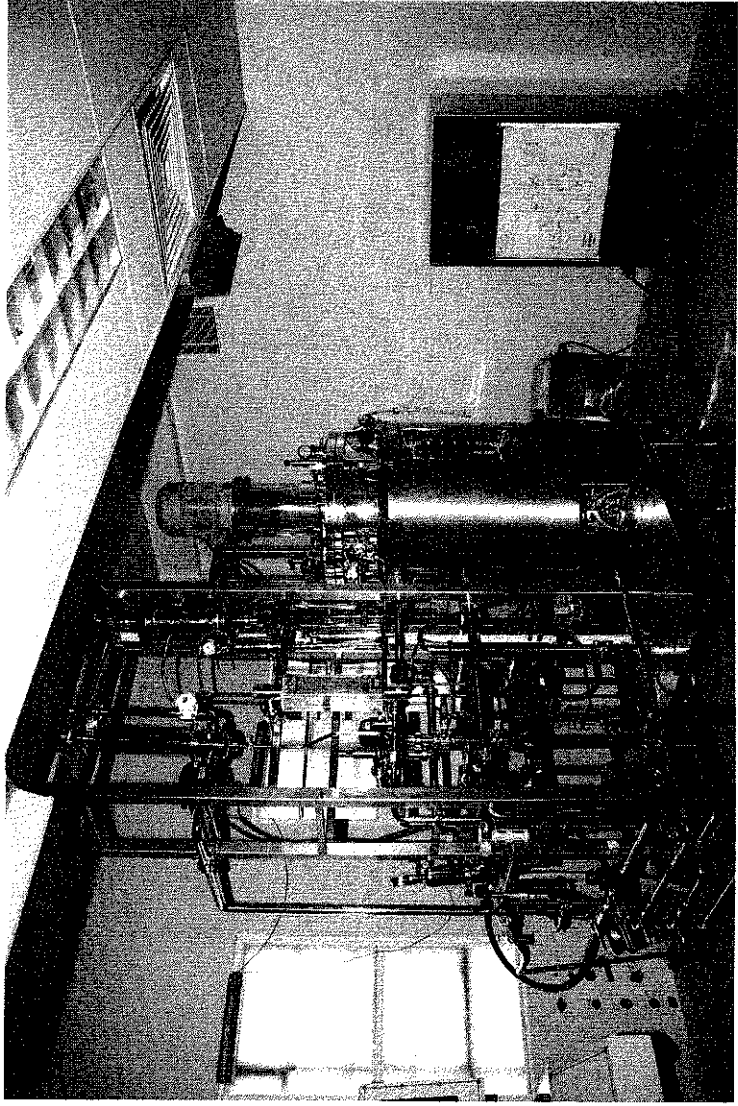
**PROGRESS OF CIVIL CONSTRUCTION OF
GREEN FIELD cGMP DPT PROJECT**



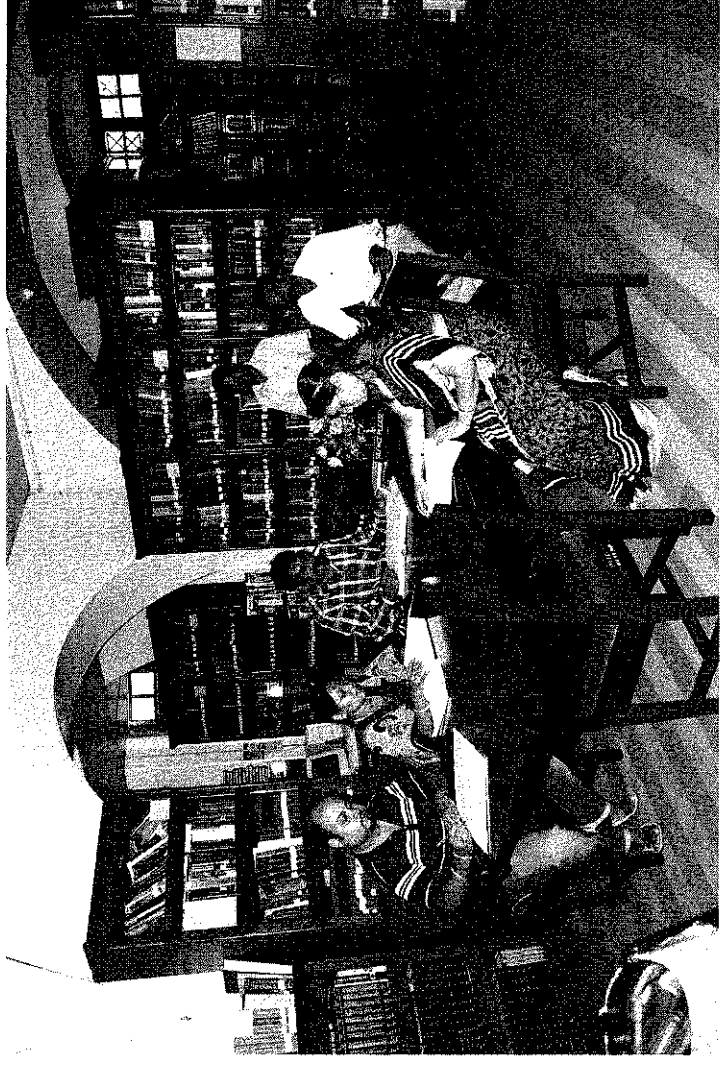
DIPHTHERIA & PERTUSSIS BLOCK



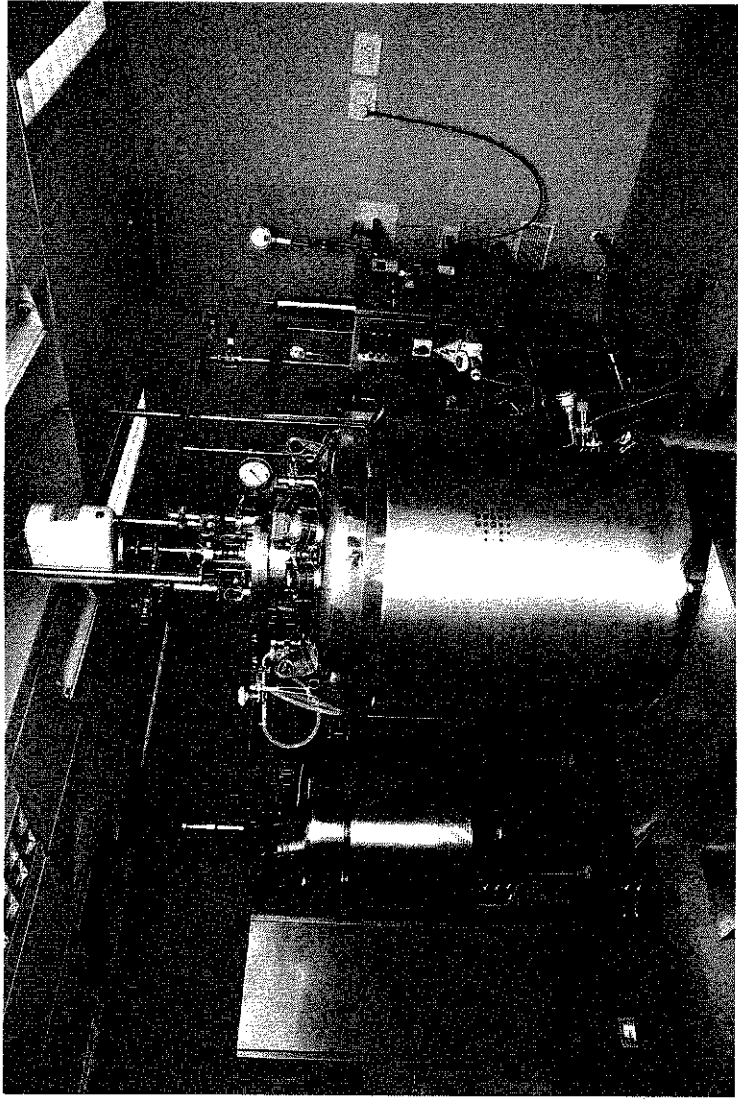
EXPERIMENTAL ANIMAL BLOCK & MICROBIOLOGY BLOCK



**FERMENTATION TECHNOLOGY FOR THE
CULTIVATION OF PERTUSSIS ORGANISMS**



LIBRARY

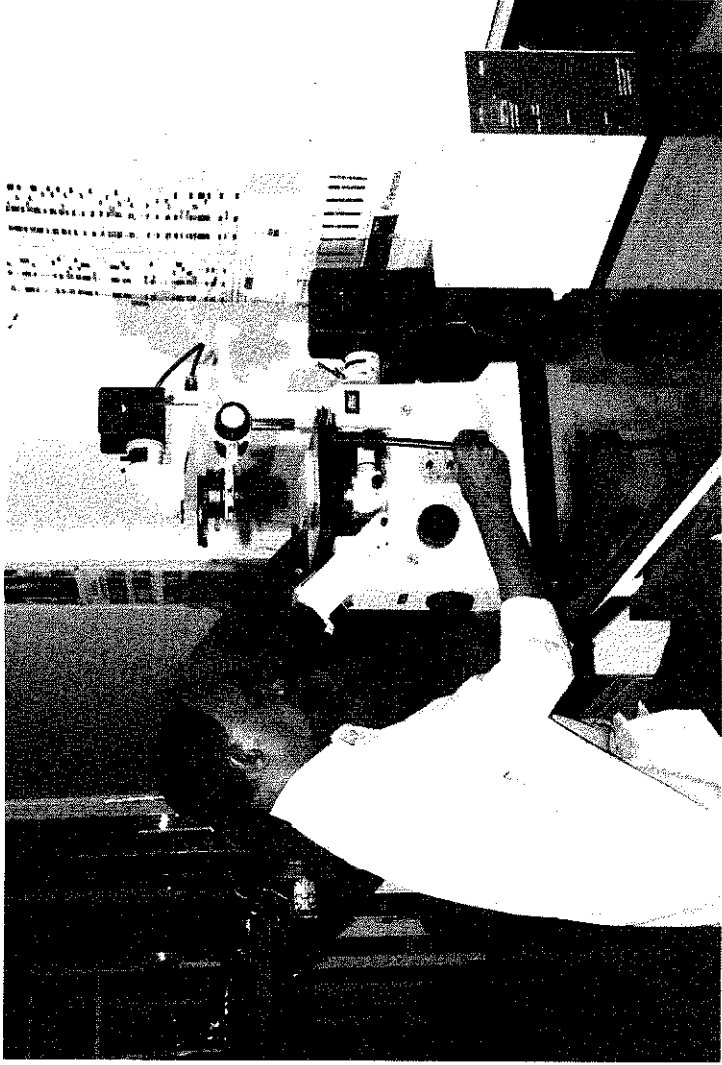
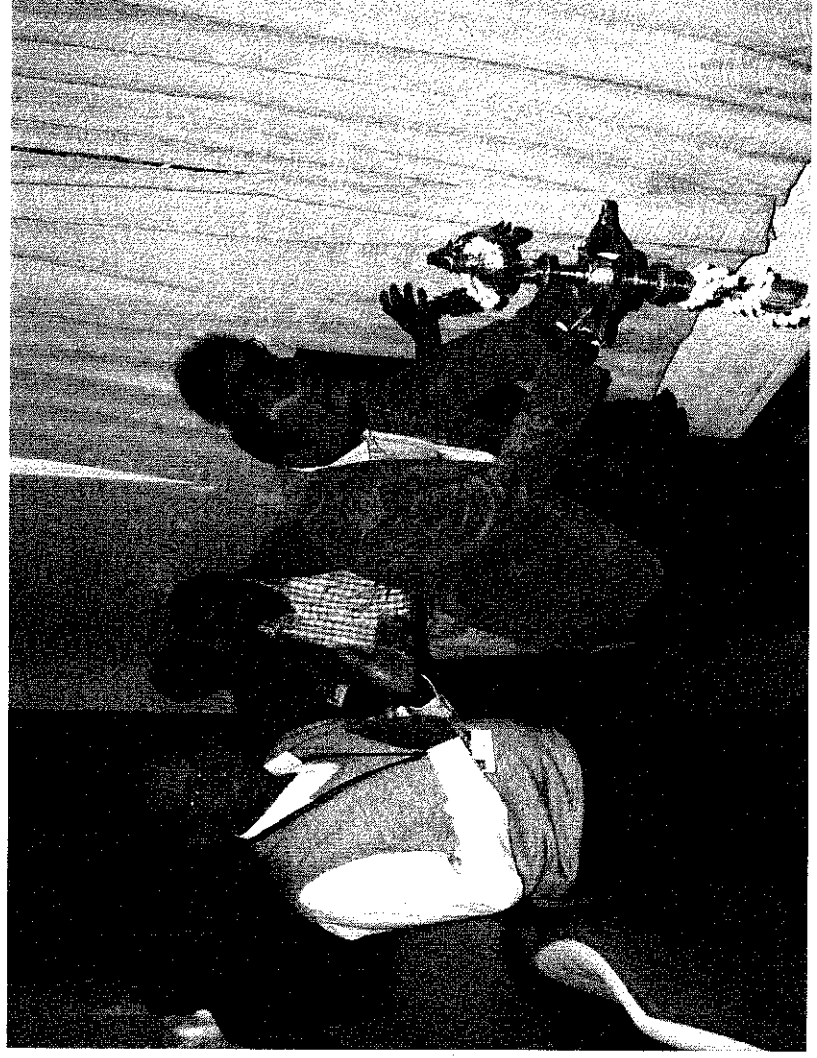
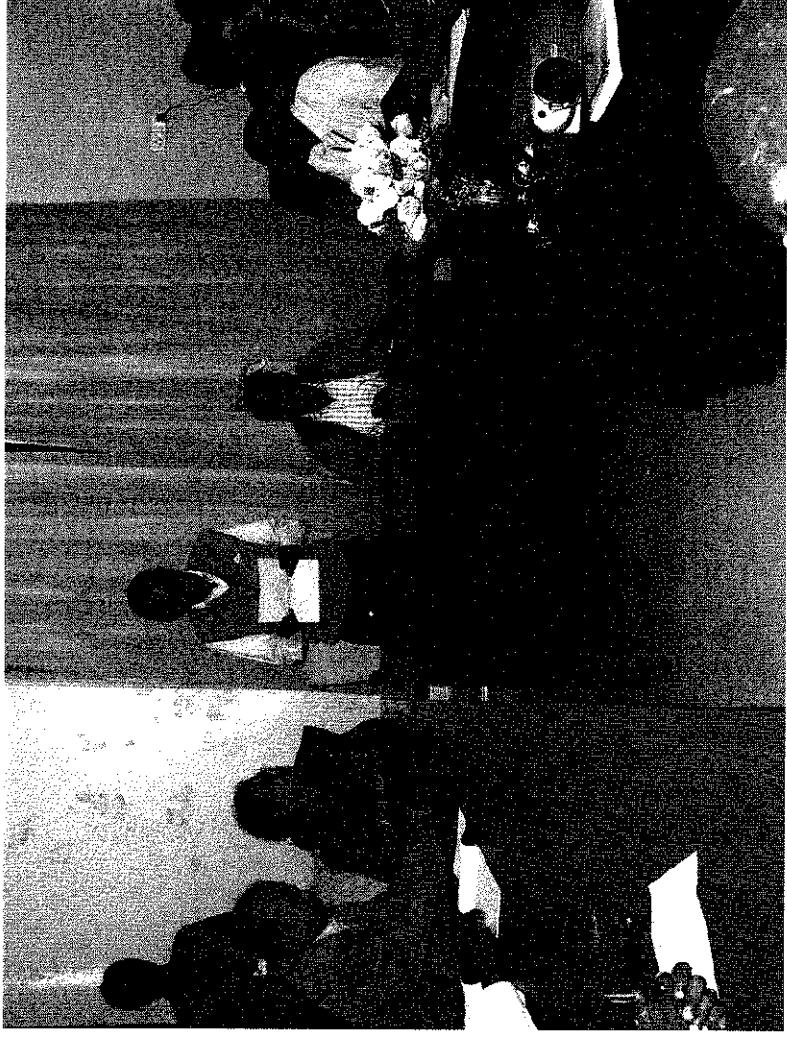


GEL & MIXING SECTION

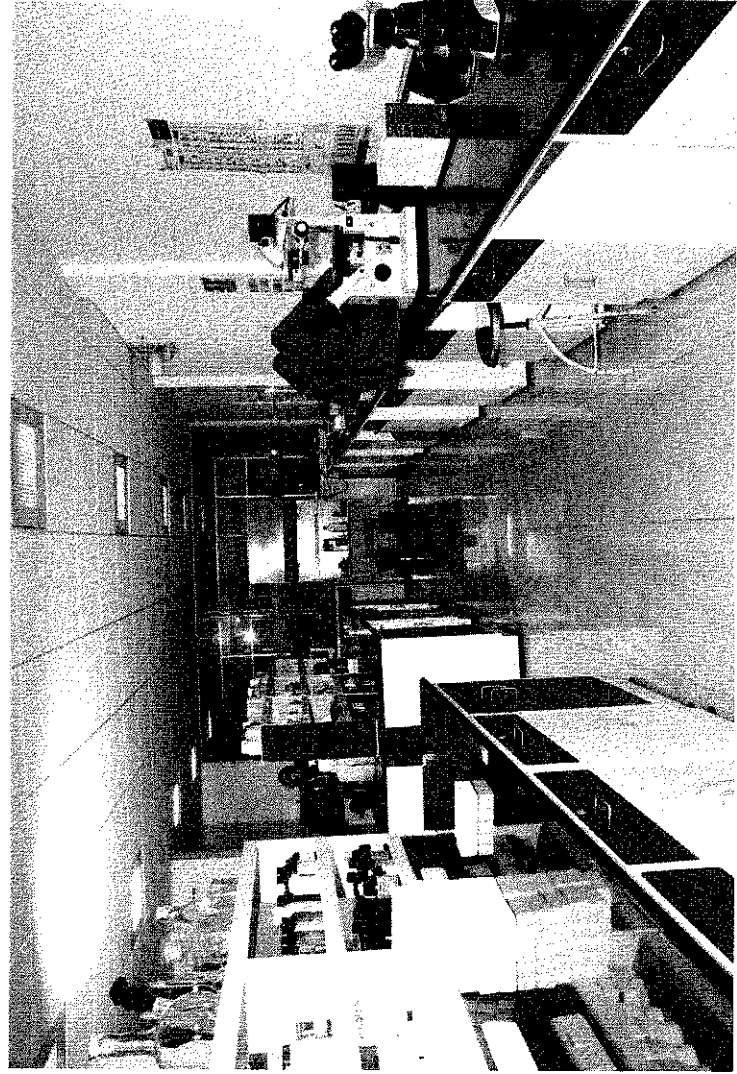


Breeding of Mice and Guinea pigs for Experimental purpose

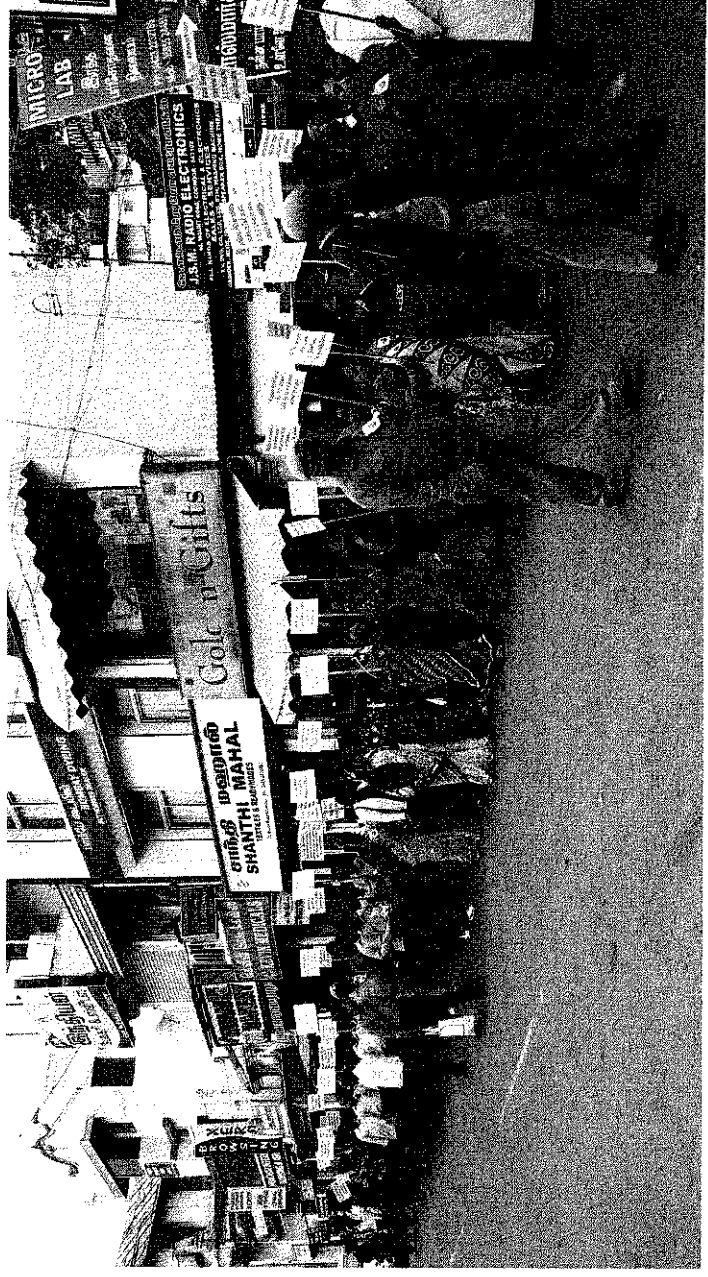
HINDI DAY OBSERVED ON 23 - 09 - 2013



QUALITY CONTROL LABORATORY



**WORLD RABIES DAY RALLY
HELD ON 28 - 09 - 2013**



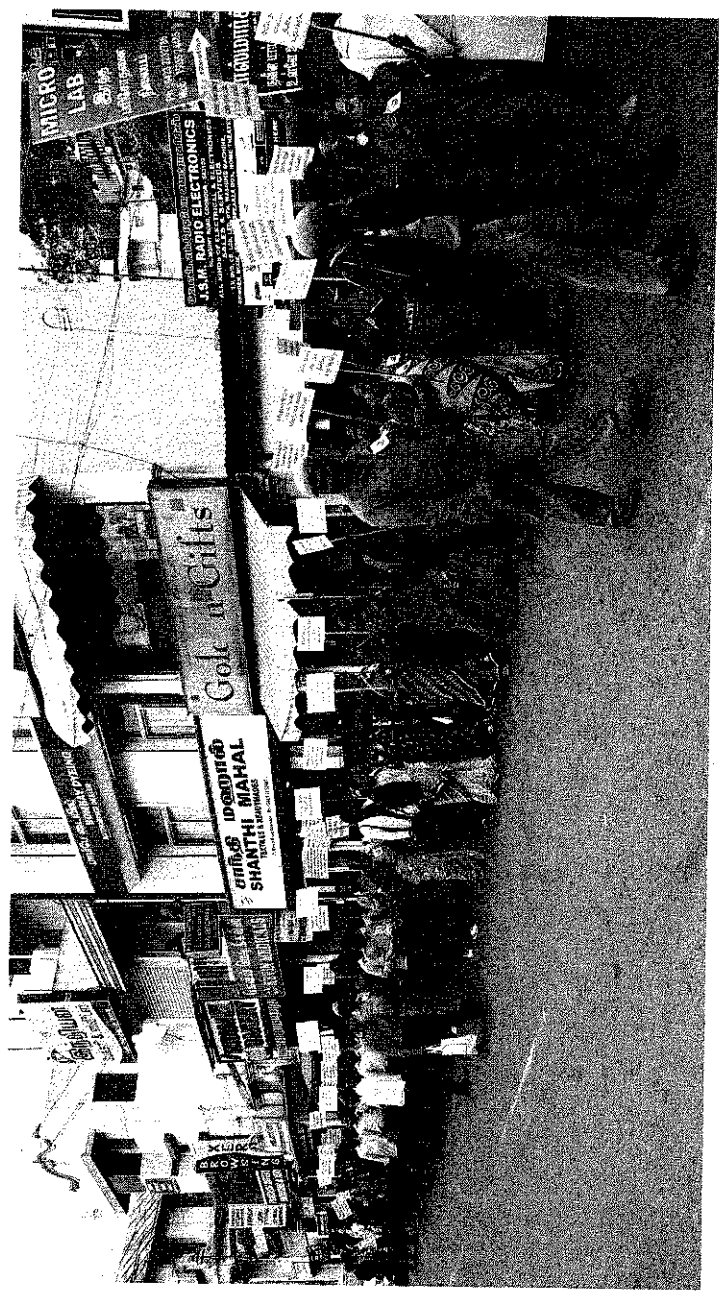
**WORLD RABIES DAY
QUIZ COMPETITION CONDUCTED
ON 07 - 11 - 2013**



**WORLD RABIES DAY
QUIZ COMPETITION CONDUCTED
ON 07 - 11 - 2013**



**WORLD RABIES DAY RALLY
HELD ON 28 - 09 - 2013**



Enlisting Youth's Support for Rabies-free Nilgiris District

and Family Welfare, is enlisting the support of school children to eradicate rabies in the Nilgiris district. The initiative is part of a larger campaign to make the district rabies-free by 2015. The campaign involves educating children about the dangers of rabies and the importance of vaccination. The children are also encouraged to spread the message to their families and friends. The initiative is being implemented in all schools in the district. The children are given small pamphlets and stickers to use as a means of spreading awareness. The initiative is being implemented in all schools in the district. The children are given small pamphlets and stickers to use as a means of spreading awareness.

Nilgiris to Become 'Rabies Free' Soon

By P S Sundar
Coimbatore: Nilgiris is close to being declared rabies-free, thanks to concerted action by officials and public. The district has been free of rabies for the last 10 years. The initiative is being implemented in all schools in the district. The children are given small pamphlets and stickers to use as a means of spreading awareness.

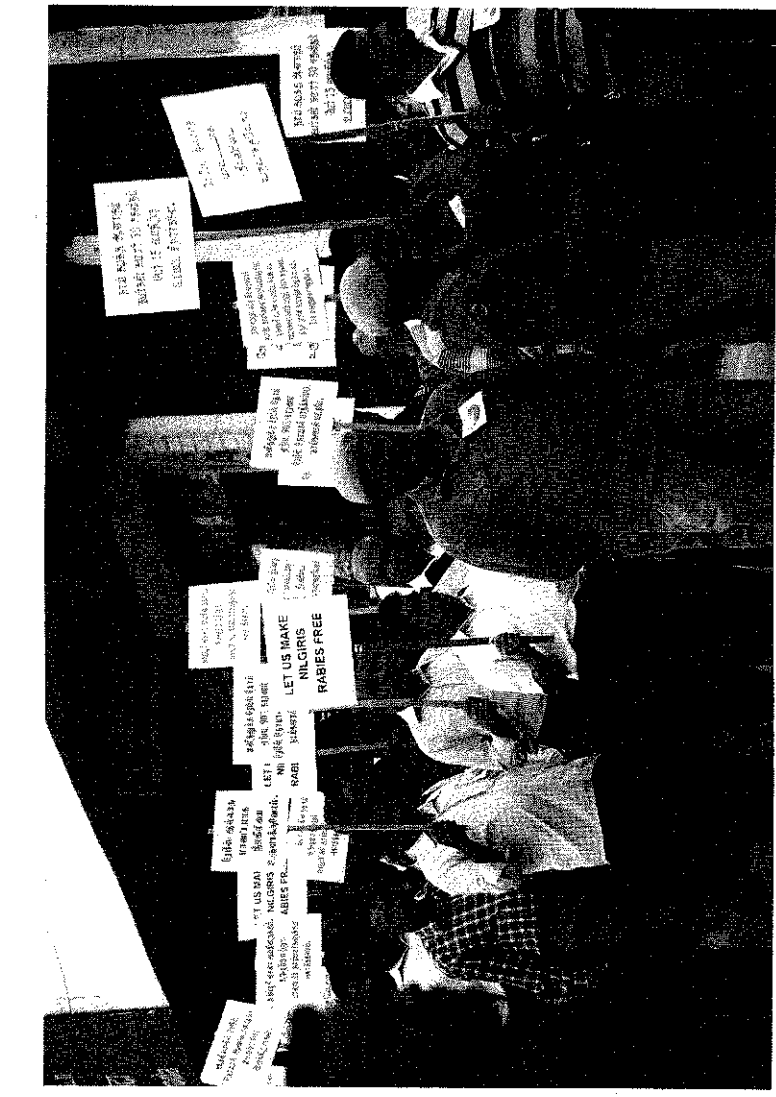
QUIZ COMPETITION FOR STUDENTS
The quiz competition conducted by the P.I.C. Coimbatore is an autonomous body under the Ministry of Health and Family Welfare, has launched a contest for school children. The contest is aimed at raising awareness about rabies among school children. The contest is being implemented in all schools in the district. The children are given small pamphlets and stickers to use as a means of spreading awareness.

Mission on to Make Queen of Hills a Rabies-free District

Express News Service
Coimbatore: The Pasteur Institute of India (PII) is on a mission to make the Nilgiris district rabies-free. The initiative is part of a larger campaign to make the district rabies-free by 2015. The campaign involves educating children about the dangers of rabies and the importance of vaccination. The children are also encouraged to spread the message to their families and friends. The initiative is being implemented in all schools in the district. The children are given small pamphlets and stickers to use as a means of spreading awareness.

PII Calls for Vaccinating Dogs
The Pasteur Institute of India (PII) is calling for the vaccination of dogs in the Nilgiris district. The initiative is part of a larger campaign to make the district rabies-free by 2015. The campaign involves educating children about the dangers of rabies and the importance of vaccination. The children are also encouraged to spread the message to their families and friends. The initiative is being implemented in all schools in the district. The children are given small pamphlets and stickers to use as a means of spreading awareness.

WORLD RABIES DAY RALLY HELD ON 28 - 09 - 2013



THE HINDU • MONDAY, DECEMBER 24, 2012

Rabies awareness programme held

Doctors, nurses, paramedics, self-help groups, students, and teachers took part

Special Correspondent
UDHAGAMMALAI: Having made a mark in presenting a variety of dance, drama and music programmes ever since it came into being, the Coimbatore based Nilgiris Cultural Association (NCA) commemorated its 15th Foundation Day by organising a different kind of culture related programme at Coimbatore on Saturday. Teaming up with the Family Planning Association of India (FPAI), the Nilgiris chapter and the Pasteur Institute of India (PII), the NCA presented a programme promoted as 'Health Culture', which featured an interactive session on the most needed and common aspects of vaccines for rabies and child care.

With many doctors, nurses, paramedics, self-help groups, it. With no side-effects even pregnant women can take vaccination. Underscoring the need to vaccinate all the dogs, he regretted that nearly 20,000 people die in India annually due to rabies. About 96 per cent of the rabies comes from dog-bites and half the victims are children. Stating that the Institute offers 24-hour service, he stressed the importance of first aid. NCA president P.S. Sundar said that the objective of the programme was to change the attitude of the people to-

School Essay Contest Results

Coimbatore: The results of the inter-school essay contest on rabies, organised by the Pasteur Institute of India (PII) Coimbatore, were declared on Tuesday. According to the winners are: P. Ashwin (St. Joseph's Higher Secondary School, Coimbatore) with the first prize of Rs. 1,000; M. Koushalya (St. Ann's Girls' Higher Secondary School, Aravankulam) with the second prize of Rs. 500; A. Akilan (Govt. High School, Kattalbert) and Anvitha (St. Ann's Girls' Higher Secondary School, Aravankulam) shared the third prize of Rs. 250 each. The contest was held at the P.I.I. Coimbatore on Tuesday. The contest was held at the P.I.I. Coimbatore on Tuesday. The contest was held at the P.I.I. Coimbatore on Tuesday.

Pasteur Institute to Raise Capacity

By P S Sundar
Coimbatore: The Pasteur Institute of India (PII), Coimbatore, an autonomous institution under the Union Ministry of Health and Family Welfare, is getting ready to increase its installed capacity by over 50 percent in three years.



Recently the Tamil Nadu Government had accorded approval for constructing new buildings for establishing laboratories conforming to General Manufacturing Practices (GMP). "We will commence construction works soon. We expect to finish construction, install equipment and procure validation for vaccine manufacture in three years," Dr. B. Sekar told Express on Tuesday. "The Union Government has sanctioned Rs. 7 crore for the project. It has appointed Hindustan Latex Ltd. (HLL) as consultant, jointly with international GMP experts. NINE Pharmaplan, has come out with designs for civil works and equipment installation. Now that approval for construction has been received, HLL will plunge into field work soon," he said. "The new lab will increase the installed capacity to produce 30 million doses (m) from the present 8 m. This will increase diphtheria-pertussis-tetanus (DPT) vaccine production capacity to 60 m from 40 m and tetanus (TT) to 55 m from 30 m. DT will continue to be 15 m," he revealed. "Our present mandate is to supply 38 m DT before September. We have already supplied 10 m. We will fulfill the task on time," added Dr. Sekar.

4. Lancet
5. New England Journal of Medicine
6. New Scientist
7. Vaccines

List of Indian Journals Purchased:

1. MIMS.
2. Antiseptic
3. Chemical Product Finder
4. CIMS
5. Herald of Health
6. Indian Journal of Biotechnology
7. Indian Practitioner
8. Pharma Review
9. Tamil Computer
10. Sarita Magazine (Hindi)
11. India Today (Hindi) Magazine
12. Indian Journal of Veterinary Medicine

Details regarding Amount Spent:

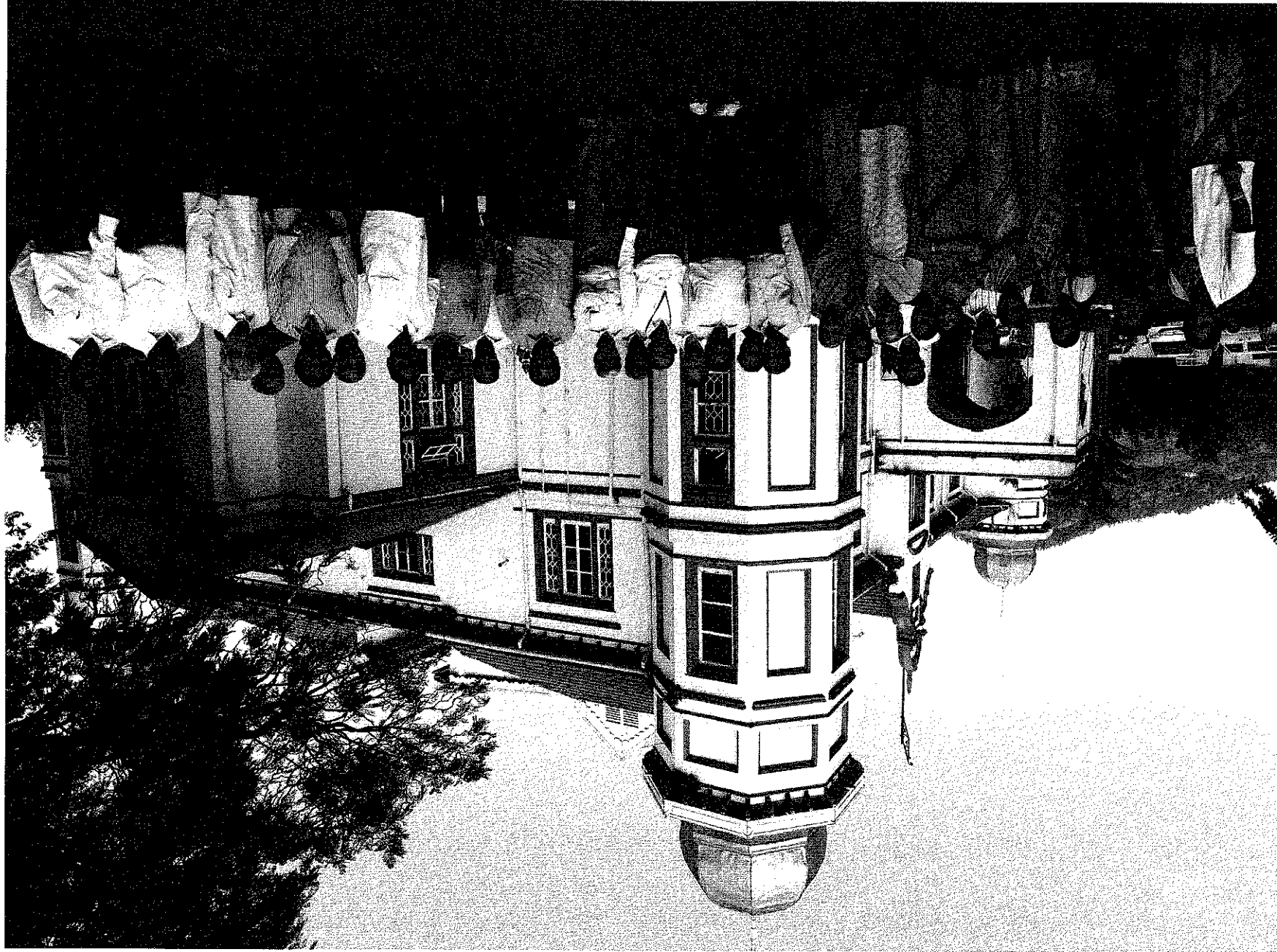
Amount spent on purchase of books (01-04-2013 to 31-03-2014)	: ₹ 1,62,931/-
Amount spent on renewal of foreign and Indian journals	: ₹ 8,52,511/-
Total	: ₹ 10,15,442/-

Academic Activities:

In addition to the usual library activities the industrial visit from different colleges and universities were entertained to the students to enrich their scientific knowledge and to create awareness in vaccine production and immunization procedures etc. From April 2012 to March 2013, 91 batches of students have visited the Institute.

During the period April 2013 to March 2014, 12 students for project, 25 students for training were enrolled.

The library is having internet connection to utilize the E-Journal service to the maximum. Project certificates and attendance certificates were prepared and made all the arrangements to issue the same to the students through library.



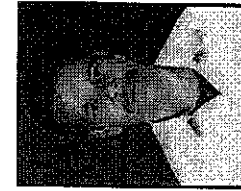
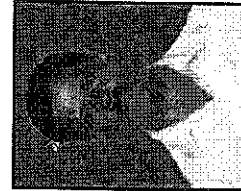
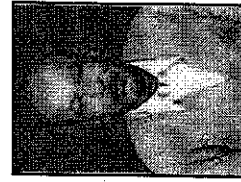
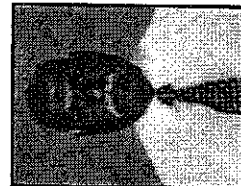
DETAILS OF THE PROMOTION MADE DURING APRIL 2013 TO MARCH 2014

Sl. No.	Name	Designation	Promoted to	Date
1.	Shri S. Basavaraj	Maintenance Technician	Supervisor	01.05.2013
2.	Shri M.E. Sridharan	Maintenance Assistant	Maintenance Technician	01.05.2013
3.	Shri B. Bastin	Laboratory Assistant	Laboratory Technician	01.07.2013
4.	Shri S. Lingan	Multi Tasking Staff	Laboratory Assistant	01.07.2013
5.	Shri K. Devaraj	Laboratory Technician	Technical Assistant	11.07.2013
6.	Shri R. Raja	Laboratory Assistant	Laboratory Technician	11.07.2013
7.	Shri C. Vadivelu	Multi Tasking Staff	Laboratory Assistant	11.07.2013
8.	Shri M. Bellan	Technical Assistant	Sr. Technical Assistant	28.08.2013
9.	Shri N. Ragupathi	Laboratory Technician	Technical Assistant	28.08.2013
10.	Shri C. Selvaraj	Laboratory Assistant	Laboratory Technician	28.08.2013
11.	Shri B.B. Sundaram	Multi Tasking Staff	Laboratory Assistant	28.08.2013

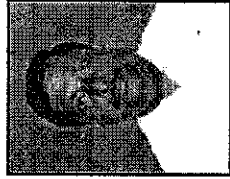
To strive to seek to find and not to yield

DETAILS OF THE STAFF SUPERANNATED/OPTED VRS DURING THE PERIOD FROM APRIL 2013 TO MARCH 2014

1. Shri M. Natarajan Supervisor Served From 01.09.1980 to 30.04.2013	2. Shri G. Mudalagiri Laboratory Technician Served From 02.06.1980 to 30.06.2013	3. Shri R. Gunasekaran Laboratory Assistant Served From 01.01.1985 to 03.10.2013	4. Shri K. Nagarajan Assistant Technical Officer Served From 04.01.1979 to 31.01.2014
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DETAILS OF THE STAFF DECEASED DURING THE PERIOD FROM APRIL 2013 TO MARCH 2014



1. Shri N. Govindaraj
Technical Assistant
Served From
02.02.1981 to 01.07.2013



2. Shri A. Devasagayam
Sr. Technical Assistant
Served From
25.11.1981 to 31.07.2013

VISIT OF DIGNITARIES DURING THE PERIOD

- Shri Keshav Desiraju, Secretary to Govt. of India & Chairman of the Governing Body of Pasteur Institute visited the proposed land for the viral vaccine manufacturing at Govt. of India Press, Coimbatore on 30.12.2013 and visited this Institute on 31.12.2013 to assess the progress on the civil construction of the Green field GMP project for DPT vaccine production and also inspected the existing manufacturing facility.

OTHER ACTIVITIES DURING THE PERIOD

NATIONAL WORKSHOP ON "ASSESSING RABIES FREE STATUS OF NILGIRIS DISTRICT, TAMILNADU" ORGANIZED BY THE DIRECTOR OF PUBLIC HEALTH AND PREVENTIVE MEDICINE, DIRECTORATE OF PUBLIC HEALTH AND PREVENTIVE MEDICINE, CHENNAI ON 31ST AUGUST, 2013 AT PASTEUR INSTITUTE OF INDIA, COONOR

With prevailing situation of rabies in Nilgiris district a National Workshop on arriving at guidelines to prepare Nilgiris district for declaring as 'Rabies free district' was organized on 30.08.2013 at Pasteur Institute of India (PII), Coonoor to assess the situation of rabies in Nilgiris district and prepare guidelines for taking forward the rabies situation in the district so as to facilitate to declare rabies free district in future.

This workshop was organized by Department of Public Health and Preventive Medicine, Govt. of Tamilnadu with technical support of PII, Coonoor. The workshop was organized by the District Collector, Nilgiris District. She has expressed her keen interest in arriving at feasible guidelines and to take forward for declaration of district as rabies free. The workshop was chaired by Dr. M.K. Sudarshan, President, Rabies in Asia Foundation, Bangalore and co-chaired by Dr. Mala Chhabra, Joint Director, NCDC, New Delhi. Experts in the field of Rabies presented different topics of concerned as follows.

- Dr. G. Sampath, Association for the Prevention and Control of Rabies in India (APCRI) – "Rabies in India"
- Dr. M.K. Sudharshan, KIMS, Bangalore – "WHO consultation on declaring Rabies-free area"
- Director of Public Health and Preventive Medicine, Govt. of Tamilnadu – "Prevention of Rabies in Tamilnadu"
- Director, PII, Coonoor – "Report on Animal bite cases and suspected rabies cases reported to PII, Coonoor"



5. Dr. Ilona, Worldwide Veterinary Services – “Report on dog rabies vaccination/ABC programme in Nilgiris”
6. Animal Husbandry Department, Nilgiris/State AHD – “Report on Animal Rabies”
7. Dr. Ashwanth Narayana, KIMS, Bangalore – “Preparation of an area for declaring rabies free”

Around 30 participants consisting of the experts, the stakeholders of rabies control and prevention in Nilgiris and officers from the Department of Public Health and Preventive Medicine, Officers from Animal Welfare Board of India, Department of Animal Husbandry and NGOs attended the workshop.

The inputs offered by experts were widely discussed followed by recommendations were formed by the Committee where District Collector as chairperson with members from different agencies in the District and the state. Terms of references arrived at are as follows:

- Advisory
- Monitoring and Evaluation
- Strengthening of Intersectoral co-ordination
- Social Mobilization and IEC

It was decided that the committee shall meet periodically every quarter and as and when required.

Actions to be taken both at the human and animal fronts were identified. On the whole the meeting was fruitful and facilitated the formation of a well laid down guidelines to take the situation of rabies in Nilgiris to declare Nilgiris as rabies free in future.

WORLD RABIES DAY:

- World Rabies Day was celebrated at Pasteur Institute of India, Coonoor on 28th September, 2013, in commemoration of Death anniversary of Louis Pasteur. Dr. D. Gururaj, Joint Director, Central Silk Board, Coonoor flagged off the rally. The rally started from PII, Coonoor and reached Coonoor bus stand. Officers and staff and college students have participated in the rally. In the rally, placards carrying the messages on prevention of rabies among human and animals were displayed, Hand bills were distributed. Earlier in the day, hand bills in English and Tamil were distributed along with the newspapers locally. These activities were covered by local media and newspaper.
- In commemoration of the World Rabies Day which falls on 28th September every year, this Institute had organized an inter school quiz competition on ‘Vaccine Preventable Diseases’ on 7th November, 2013 at 10.30 a.m. at the Stanes A.I. Higher Secondary School Auditorium, Coonoor. About 60 schools in Nilgiris District, both private and government schools, were invited to participate in the quiz competition among which 9 teams from 9 schools have participated. The quiz competition was inaugurated by Mr. Glenn Croning, Principal, Stanes AI HSS, Coonoor. Initially screening of 9 teams were held and 6 teams with 2 students each had been selected for the main quiz competition. The main aim of the quiz competition was to create awareness on diseases that can be prevented by vaccination among school children and to the general public through them.
- I - Prize was awarded to Ms. M. Sasmita and Ms. A. Shahanaz of the Stanes AI Higher Secondary School, Coonoor.



To strive to seek to find and not to yield

- II - Prize was awarded to Mr. Methew Mathew Alani Junior and Mr. M. Pradeep of The Laidlaw Memorial School and Junior College, Ketti.
- III - Prize was awarded to Mr. Aakash Nandakumar and Mr. S. Kishore of St. Josephs' Boy's A.I. Higher Secondary School, Coonoor.
- Consolation Prize was awarded to Ms. A. Abishaya and Ms. R. Srividhya of St. Josephs' Convent A.I. Girls Higher Secondary School, Coonoor.
- The winners were awarded cash prize of Rs.6000/- each with a shield and certificate for the first place, Rs.4000/- each with a shield and certificate for the second place and Rs.3000/- each with a shield and certificate for the third place. A cash award of Rs.1500/- each with a shield and certificate were also given as consolation prize.
- The cash prizes were sponsored by Bank of Baroda and were distributed by Mr. Chinnasamy, Asst. General Manager of Bank of Baroda, Coonoor. The certificates were distributed by the Principal of Stanes A.I. Higher Secondary School, Coonoor to the winners and to all the other participants too.
- The audience were the students of the Stanes Anglo-Indian Higher Secondary School, Coonoor and open questions were also addressed to the audience and those who answered correctly were awarded. The quiz masters were Dr. (Mrs) Jeeva Kalaiselvan, Sr. Research Officer and Mr S. Jagannathan, Assistant Research Officer of the Institute. Dr. N. Sivananda, Assistant Research Officer of the Institute was the quiz master of ceremony. The programme was co-ordinated by Dr. B. Sekar, Director of Pasteur Institute of India, Coonoor.

- Prior to the quiz competition, this Institute had also conducted Essay Writing Competition among the school students of Nilgiris District on 22-10-2013. 44 students had participated from 22 schools among which Ms. R. Aishwarya of St. Josephs Convent AI GHSS, Coonoor won I prize of Rs.3000/- and Ms. M. Kousalya of St. Ann's Girls Hr. Sec. School, Aruvankadu won II prize of Rs.2000/- Ms. A. Alexia of Govt. High School, Kattabettu and Ms. Hazel J. Karen of St. Ann's Girls Hr. Secondary School, Aruvankadu shared III prize of Rs.1500/- each. Two consolation prizes of Rs.750/- were also awarded to Ms. T.Shan Amrutha of St. Josephs Convent AI GHSS, Coonoor and Mr. A. Vignesh of Govt. High School, Konavakkari. Certificates were also distributed to all the other participants too.

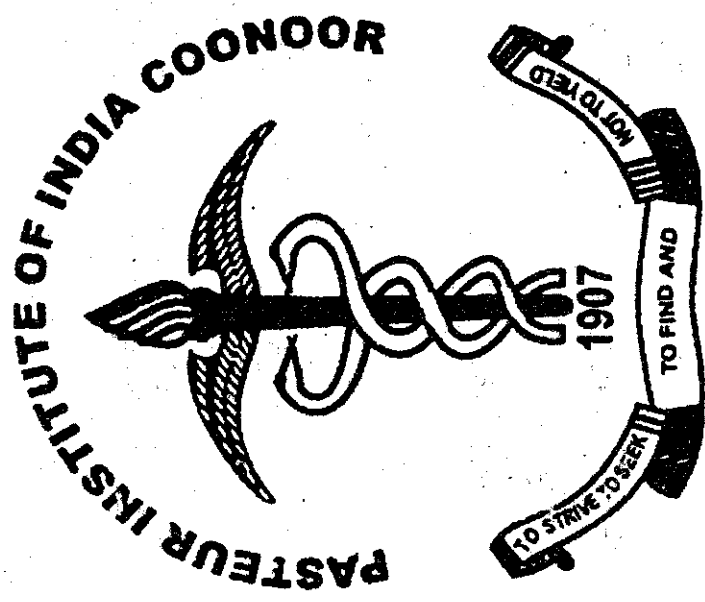
- On the whole the two competitions held in commemoration of World Rabies Day enriched the students with sound educational information on the importance of the vaccine and the disease that can be prevented by vaccination.

CONCLUSION

The civil construction for our new GMP project was initiated this year as a first step for new GMP project for manufacturing DPT group of vaccine. Concurrently DPT vaccine production in existing facility was continued and we supplied 188.19 lakh doses of DPT vaccine to the UIP in the reporting year. The whole team of this Institute is committed to bring the glory of this Institute back.



**PASTEUR INSTITUTE OF INDIA
COONOR 643 103, NILGIRIS
TAMILNADU**



SCIENTIFIC REPORT

2013-14

RESEARCH ARTICLES PUBLICATION IN JOURNALS

Epizootiology, treatment and control of tropical rat-mite infestation in a breeding colony of Swiss mice under temperate climate of Nilgiris Hill - India

A.J. Nath, K.N. Venkataramana, R. Folster-Holst, W. Beck

Animal Science Reporter. 2013; 7(3): 114-120.

Abstract:

Ectoparasites are cause of concern to laboratory mice colonies maintained for research, as they cause severe annoyance to the host, affecting colony production, besides transmitting zoonotic diseases. Tropical rat-mite (*Ornithonyssus bacoti*) is an obligate, blood-feeding parasite with an extensive host range, but common in wild rodents. There are ample records regarding the existence of this parasite in rodent breeding colonies in many countries in the world. This paper describes the epizootiology, treatment and control of rat-mite infestation in a breeding mice colony at Pasteur Institute in Nilgiris Hill in India. Incidentally, it is the first report on the epizootiology of this parasite in a temperate climate in India. This mite was discovered following the complaints received from the personnel working in the mice colony about the development of insect-bite like lesions on the skin, along with intense itching. The mice were also found to be infested with mites. The infested mice were hyperactive, as evidenced by their grooming activities. The mites were also present in the cages and racks. The mites were identified as *Ornithonyssus bacoti* on the basis of morphological characteristics, magnified under a simple microscope. The mice in the colony were dipped in a solution of Butox vet® (Deltamethrin, 12.5% suspension, Intervet, Mumbai, India). The animals completely recovered after a single treatment, and did not show any side effect during the observation period of six months. The treated animals did not express any short term or long term side effects, including toxic effect. There was no untoward skin reaction, abnormality in behavior, and colony production. The mites started disappearing from the cages and the racks after a single treatment of Butox vet® spray, and were observed in abundance in a sluggish state in the environment, e.g., floor and walls of the shelter room. There was no recurrence of the parasite in animal cages and shelter during the observation period of six months. It is concluded that Butox vet® was an effective and safe acaricide in the eradication of tropical rat mites from the rodents as well as its environment.

Large scale recovery of tetanus toxin and toxoid from fermentation broth by microporous tangential flow filtration.

Chellamani Muniandi, Kavarratty Raju Mani, Rathinasamy Subashkumar

International Journal for Biotechnology and Molecular Biology Research. (2013) Vol. 4 No. 2: 28-37.

Abstract:

The commercial production of purified tetanus toxoid mainly depends on the effective separation of the bacterial toxin and toxoid from large volumes of fermentation broth of *Clostridium tetani* (Harvard 49205) vaccine strain. Tangential flow or cross-flow filtration system was used as rapid drive in the processing of immunobiological assays of tetanus toxin. Tetanus toxoid was prepared by detoxifying the culture filtrates of *C. tetani* and further purified by ultrafiltration, salt fractionation and adsorption onto aluminium phosphate. Present study deals with the separation of tetanus toxins using a microporous membrane (0.22µm) and concentration of tetanus toxoids using an ultrafiltration membrane (30kDa, NMWL-pore size) with operational variables like average trans-membrane pressure (ATP), cross flow rate, flux. Under the best conditions, >96% recovery was achieved. Additionally, potency control of 10 batches of tetanus toxoid, prepared from



the filtered toxins/toxoids lots by microporous tangential flow filtration system, was evaluated by *in vitro* passive haemagglutination (PHA) assay and the result obtained in the *in vitro* PHA were compared with *in vivo* toxin neutralization (TN) test. An excellent correlation between *in vitro* test and *in vivo* TN test was observed by Spearman's correlation coefficient. It reveals that the process development in which employing available equipment and the *in vitro* PHA is a promising alternative to the toxic TN test in the potency assay of tetanus vaccine.

Standardization of process for increased production of pure and potent tetanus toxin.

Chellamani Muniandi, Premkumar Lakshmanan, Kavaratty Raju Mani, Subashkumar Rathinasamy

Journal of Microbiology and Infectious Diseases. 2013; 3(3):133-139. DOI: 10.5799/ahinjs.02.2013.03.0096.

Abstract:

When stationary pot culture was replaced by submerged cultivation of *Clostridium tetani*, an anaerobic organism, in a fermentor using a vibromixer and optimum supply of sterile air to the headspace of the fermentor to flush out the accumulated gases, a significant increase in the tetanus toxin yield in a short time cultivation (about 5 to 6 days against 8 days) was noticed. It was found that under optimal conditions of temperature, vibromixing, surface aeration, and an alkaline pH favored toxin release. Furthermore, to enhance the production volume, fermentor culture is more suitable. The tetanus toxin was produced with good Limes flocculation (Lf) titre and high antigenic purity. Under optimal conditions, the papain digest broth was successfully substituted in place of NZ Case for the production of pure and potent tetanus toxin.

Poster presented in the Association of Prevention and Control of Rabies in India conference held on 6th and 7th July, 2013 at Pune.

STATUS OF ANIMALS INVOLVED IN CASES REPORTED TO PII, COONOOR FOR POST EXPOSURE PROPHYLAXIS

Dr Sibani Barman, K.N. Venkataramana and Dr. B. Sekar

ABSTRACT

Pasteur Institute of India is a referral centre for diagnosis of rabies and treatment of animal bites. Since 2003-2004 no case of rabies reported to our center from Nilgiris district although cases of rabies patients were reported from other district of Tamilnadu. With this back ground we planned to examine the status of animals involved in human bite cases reported to this Institute during last five years, 2008-2013 in terms of types of animal involved, survival status and vaccination history. During last five years (2008-2013) totally 9551 animal bite cases reported to OPD, PIIIC. Out of which 2392 from Nilgiris and 7159 from other district of TamilNadu. Out of 2392 reported from Nilgiris, 2065 (86.3%) cases were due to dog bite, pet dog 1607 (67.2%), Stray dogs 458 (19.5%) and 327 (13.4%) cases are from bites of other animals. Out of the pet dogs alive were 1573 (65.7%), Killed/Died 34 (2.4%), Vaccinated dogs 222 (9.28%) out of stray dogs alive were 224 (9.36%), Killed/died were 41 (1.7%) and missing were 193 (8%) dogs. Total animal bites reported from other districts of TamilNadu were 7159, Dog bites were 6758 (94.4%) and other animals were 401 (5.6%), Pet dogs 2567 (35.86%), Stray dogs 4191 (58.54%), Among dog bites alive were 2228 (32.12%), killed/died 339 (4.74%), vaccinated 216 (3.02%). Out of stray dogs from other district of TamilNadu alive were 712 (9.95%), died 2316 (32.35%), missing 1163 (16.25%) dogs. In Nilgiris district dog bites due to pet dogs (67.2%) were more than stray dogs (19.5%) whereas in other districts the dog bites due to stray dogs (58.54%) were more than pet dogs (35.86%). Among pet dogs those alive were more in Nilgiris district



(65.7%) than other districts (32.12%). Vaccinated among pet dogs were more in Nilgiris (9.28%) than in other district (3.02%). All these data suggest that the magnitude of rabies problem among dogs in Nilgiris district is low which may be contributing to the observation that no human rabies case reported from 2003-04 onwards from Nilgiris district.

Poster presented in the Association of Prevention and Control of Rabies in India conference held on 6th and 7th July, 2013 at Pune.

STUDY ON ANAMNESTIC RESPONSE AFTER BOOSTER DOSES OF TISSUE CULTURE ANTIRABIES VACCINE BY INTRA-DERMAL ROUTE OF ADMINISTRATION

C Palaniappan, N. Sivananda, G Chandramohan and Dr. B. Sekar

It is known that after primary vaccination with TCARV the protective antibody level (>0.5 IU/ml) appears between 10th and 14th day after the 1st dose of vaccination. However the information of the time interval and the titre of protective antibody appearance in pre-immunized individuals after the booster dose are not widely reported in booster vaccination by intra-dermal route. Hence we conducted a study to find out the time interval and the titre of antibody appearance after the booster dose. We have included individuals having Virus Neutralizing Antibody (VNA) titre ranging from 0 to 4.0 IU/ml in the study. Two booster TCARV on 0 and 3rd day were administered intra-dermal route. Blood samples were collected on these samples to estimate the VNA titre. The results of the study reveals that the minimum protective level (0.5 IU/ml) of rabies neutralizing antibody develops in 91.66% cases among pre-immunized individuals on third day after rabies booster vaccination and 100% cases develops on seventh day after booster vaccination by intra-dermal route of vaccination. Our earlier study conducted on individuals receives primary rabies vaccination without history of any previous rabies vaccination the 100% sero conversion appears only on 14th day from first rabies injection.

OTHER PROJECTS CARRIED OUT IN THE REPORTING PERIOD

A COMPARATIVE ANALYSIS OF INDIGENOUSLY PREPARED RABIES IMMUNOGLOBULIN CONJUGATE WITH DIRECT LABELLED EQUINE RABIES IMMUNOGLOBULIN CONJUGATE FOR RABIES DIAGNOSIS

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The FITC Rabies Immunoglobulin conjugate plays a vital role in the diagnosis of Rabies disease in humans and animals. In the present study the FITC Rabies Immunoglobulin conjugate indigenously prepared at Pasteur Institute of India and is compared with commercially available equine rabies immunoglobulin tagged with FITC dye, the resultant rabies conjugate prepared was used for the rabies diagnosis. Rabies polyclonal antibody was produced in guinea pigs and the serum obtained was purified by ammonium sulphate purification method and the purified immunoglobulin was tagged with FITC by conjugation method. A comparative analysis was done on commercially available purified equine rabies immunoglobulin tagging with FITC with indigenously prepared Rabies Immunoglobulin conjugate and the better result obtained from indigenously prepared conjugate.



STUDY ON QUALITY CONTROL TESTING AND COMPARATIVE QUANTIFICATION OF PROTEIN CONTENT OF DIPHTHERIA AND TETANUS TOXOID ESTIMATION BY KJELDHAL METHOD AND LOWRY'S METHOD

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Diphtheria-Tetanus-Pertussis (DTP) group of vaccines consist of purified Diphtheria toxoid, Tetanus toxoid and heat inactivated Bordetella pertussis organisms. The estimation of protein nitrogen content in the toxoid samples prior to formulation with adjuvant is one of the important quality control tests. The antigenic purity of the BPDT and BPTT depends on the amount of protein nitrogen present in the samples. With the given quantity of Lf/ml, the antigenic purity is better with low protein nitrogen content and vice-versa. In the present study the protein concentration of BPDT and BPTT is determined by the Kjeldhal method and Lowry's method. The protein content of 12 batches of purified toxoid samples obtained by these two methods is almost identical. The antigenic purity of the purified toxoid is expressed as ratio of the toxoid concentration (Lf/ml) to protein nitrogen concentration. The purified Diphtheria and Tetanus toxoid shall pass the test if it contains no fewer than 1500 and 1000 Lf/mg of protein nitrogen respectively. In general Kjeldhal method is more time consuming process and it takes several hours to determine the protein content of the BPDT and BPTT samples. Lowry's methods of protein estimation is simple, economical and time saving process and this method may be used as an alternative method for protein estimation in purified toxoid samples.

EFFECT OF SYNTHETIC MEDIUM FOR TETANUS TOXIN PRODUCTION

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ABSTRACT

Tetanus is an infectious disease caused by highly toxigenic strain of Clostridium tetani. The toxin is highly potent and blocks inhibitory neurotransmitters in the central nervous system and causes muscular stiffness and spasms typical of generalized tetanus. According to WHO report about 29000 deaths occurred between 2000-2003 in India mainly due to neonatal tetanus. An antigenic substance, is used to provide immunity.

The regular production medium namely Mueller and Miller contains meat infusion as one of the important gradient which is of animal origin. In this current study soy protein, a vegetable base, used to supplement meat based one. Glucose was used as carbon source based on the earlier work of profrio.z... et.al., in 1997. A study was attempted to standardize the optional concentration of soy protein based infusion in the place of meat infusion in the basal M.M. medium for the cultivation of the tetanus vaccine strain. The cultivation was done in the beakers by varying the concentration of the soy protein. Soy peptone in the concentration of 20% and 80% and infusion in the concentration range of 20%, 40% and 80% yielded good toxin. The toxin samples were subjected to various analysis like SDS PAGE, Lf test, MLD and MTV. The results are comparable with the conventional medium. This work needs some more trials to come to a logical conclusion.



STUDIES ON OPTIMAL PURIFICATION OF HEAT LABILE TOXIN (HLT) IN BORDETELLA PERTUSSIS FOR AN APPROACH TO CELLULAR VACCINE

Name of the student: S. Pandiyarajan, M.Sc., Microbiology, J.J. College of Arts and Science, Ms. T. Umadevi, M.Sc., Biochemistry, PSG College of Arts and Science

Supervisors: Dr: K.C. Shivanandappa, Asstt. Research Officer

Abstract:

B. pertussis produces more than eight virulence factors such as PT, ACT, FHA, etc., including endotoxin and heat labile toxin (HLT). Each virulence factor has their own role of immunogenicity and biological property of final pertussis vaccine. In this regard, this project study is revealed the assessment of detoxification, immunobiological and biochemical properties of HLT which is one among the eight virulence factors.

HLT toxin is purified and estimated by gel filtration chromatography subsequently with DEAE ion exchange. The biochemical analysis of HLT by SDS-PAGE of purified HLT gives an apparent molecule mass of 140 KDa and similarly the crude fraction shown different molecular bands ranging from 40KDa this result indicates that apart from HLD (140kDa) the pertussis vaccine also contains other virulence factors having different molecular weight.

The antiserum raised against purified HLT (in guinea pig) showed that good antigen antibody reaction in agglutination test which performed after antiserum separation. From this project study it is concluded that the HLT is one of the major virulence factor and which play an important role inducing immunogenicity, biochemical activity in pertussis vaccine. Therefore, it was further expelled its ability to form haemorrhagic necrosis in animals examined. In this report, this findings which indicates that the purification of HLT toxin it may help in the production of antiserum against HLT for the diagnostic purpose and also these findings are more interest and helpful for further investigation in immunological studies of B. pertussis. This is the preliminary approach to the development of acellular pertussis vaccine it needed further research.

DIPHTHERIA TOXIN PREPARATION AND DETOXIFICATION BY FORMALDEHYDE AND GLUTARALDEHYDE

Name of the student: C. Prakash, M.Sc., Biotechnology, Thiruvalluvar University

Supervisors: Mrs. Shanthi Mani, Research Officer, Mrs. Chandra Charles, Asstt. Research Officer

A SINGLE STEP COLUMN CHROMATOGRAPHY PURIFICATION OF VERO CELL DERIVED RABIES VACCINE

Name of the student: B. Lavanya, M.Sc., Biotechnology, Muthayammal College of Arts and Science

Ms. S. Farisa Banu, M.Sc., Microbiology, PSG College of Arts and Science

Supervisors: Dr. A. Premkumar, Research Officer

ADSORPTION STUDIES ON TOXOIDS

Name of the student: Ms. Lena, M.Sc., Medical Biochemistry, Karunya University

Supervisors: Shri B. Annamalai, Asstt. Research Officer



Conference/Ministry/Training/Guest Lecture Attended/presented by Staff member

S.No	Name	Designation	Subject	Place/ Organization	Date	Particulars
1	Shri C. Palaniappan Dr. A. Premkumar Dr. Samyak Sahu	Sr. Research Officer Research Officer Medical Officer	National Symposium	NIMHANS, Bangalore	24.03.2013 to 26.03.2013	National Symposium on Recent advances in Rabies
2	Dr. B. Sekar Dr. (Mrs) Sibani Barman Shri C. Palaniappan Dr. A. Premkumar Dr. Samyak Sahu	Director Sr. Medical Officer Sr. Research Officer Research Officer Medical Officer	National Conference	Pune	06.07.2013 & 07.07.2013	15 th National Conference of APCRICON
3	Mrs. Shanthi Mani Shri R. Mohan Dr. K.C. Shivanandappa Mrs. T. Lalitha Shri B. Annamalai Shri J. Kamaldeen	Research Officer Research Officer Asst. Res. Officer Asst. Res. Officer Asst. Res. Officer Maintenance Officer	Observation	CRI, Kasauli	20.11.2013 to 22.11.2013	Observation of GMP infrastructure
4	Shri B. Sundaran	Assistant Director	Workshop	WHO-SEARO, New Delhi	30.10.2013 to 02.11.2013	2 nd Workshop to brief manufacturers on vaccine prequalification
5	Shri B. Sundaran	Assistant Director	Guest Lecture	Cordite Factory, Arivankadu	29.11.2013	Guest Lecture on "Quality"
6	Shri B. Sundaran	Assistant Director	Workshop	New Delhi	18.12.2013	Workshop organized by CDSCO on "Review of Periodic Safety Update Report/Post Marketing Surveillance Data and Pharmacovigilance Planning of Marketed Products"
7	Dr. K.C. Shivanandappa Shri S. Jagannathan	Asst. Res. Officer Asst. Res. Officer	National Seminar	Coimbatore	08.01.2014	National Seminar on "Prospectino for todays world"
8	Dr. N. Sivananda	Asst. Res. Officer	Guest Lecture	Bannari Amman Institute of Technology, Sathyamangalam	06.01.2014	"Microbial Production on vaccines"
9	Dr. Samyak Sahu	Medical Officer	National Hindi Conference	AIIMS, New Delhi	12.02.2014 & 13.02.2014	3 rd National Hindi Conference
10	Shri C. Palaniappan	Sr. Research Officer	Workshop	CDSCO, New Delhi	12.02.2014	"Review of Stability Data submitted for Market Authorization" for vaccines
11	Shri B. Sundaran	Assistant Director	Workshop	CDSCO (South Zone), Chennai	07.03.2014 & 08.03.2014	Harmonization of effective recall and Good Distribution Practices (GDP)
12	Dr. B. Sekar	Director	International Conference	Bangalore	23.02.2014 & 24.02.2014	Commonwealth Veterinary Association's Asian Regional Meeting and International Conference

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