

Technologies for Commercialization

2011

Compiled and Edited by

Dr Sadhana Srivastava

Dr K. Satyanarayana

*Intellectual Property Rights Unit
Indian Council of Medical Research
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New Delhi*



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Foreword

Major thrust and focus of the Indian Council of Medical Research (ICMR), New Delhi, is to work towards improving the health of the Indian people. The Council has 30 Research Institutes/Centres and six Regional Medical Research Centres engaged in full time in this task through research and development on communicable diseases, non-communicable diseases, reproductive health and nutrition and environmental and occupational health *etc.* using both conventional and cutting edge technologies. The Council also has a strong extramural research support system to researchers and clinicians engaged in all areas of biomedical research within the mandate of the Council working in Medical Colleges and other institutes in India. The Council currently is in its *Centenary Year* having been established in 1911.



In its long and distinguished history, the ICMR has significantly contributed towards promoting better health for the Indian public through the development, evaluation and delivery of various public health technologies. Until recently the thrust and focus of the Council has been more towards understanding and controlling of infections like tuberculosis, diarrhoeal diseases, leprosy, malaria, filariasis, leishmaniasis, viral diseases like Japanese encephalitis, dengue *etc.* which is being gradually expanded to adequately cover non-communicable diseases, reproductive health, socio-behavioural and health systems research and other topical issues. The Council has also played a key role in assisting the Government of India during disease epidemics, like bird flu or those with unknown etiology, wherever they occur, through laboratory support by providing diagnostics. Focused R&D for the generation of new drugs, diagnostics, vaccines, devices and other tools of public health significance did not receive adequate attention until recently. The post-TRIPS era and the new product-patent regime have thrown up new challenges for the country especially in the health sector as the affordability of health products is under serious threat. There is a serious need to give strong impetus and urgency for the creation of indigenous products and processes. To that end there is now a paradigm shift in the ICMR and the Department of Health Research through the initiation of a strong and vibrant Translational

Research Programme. Several leads have been identified and some efforts on towards conversion of these leads into products and processes for public good. In brief, my vision for the Council in the near future would be bring in the much needed increased synergy between focused laboratory research targeted to product development through strong and vibrant partnerships with the Indian industry to quickly bring products for public health use. Needless to say, while research focused on implementation will remain a priority, cutting edge basic research that adds new knowledge will continue to be encouraged. All the systems and procedures for the identification, protection, preservation and exploitation of the IP generated with Council's support, have long been in place; the IPR Unit of the ICMR Headquarters which will continue to provide a single-window support for ICMR sponsored research from concept to commercialization.

This revised and updated third edition of the document "Commercialization of ICMR Technologies" catalogues the technologies generated by the ICMR both by our intramural scientists working in various Council's institutes and researchers from medical colleges, universities and other institutes through extramural support. Some technologies have already been transferred to the industry and many are awaiting commercialization. I earnestly urge the Indian industry and emerging global leaders to partner with ICMR to work towards our common endeavour of providing affordable health care to the Indian people through indigenous products and processes.



Vishwa Mohan Katoch
Director-General
Indian Council of Medical Research &
Secretary
Department of Health Research
Government of India
New Delhi

National Institute of Virology (NIV), Pune

Japanese Encephalitis Vaccine

Product/Process: Chimeric peptide vaccine candidate against Japanese Encephalitis virus.

Application/Uses: Japanese encephalitis virus is endemic in many areas of India. Chimeric peptide sequences can be incorporated in the future vaccines.

Salient Technical Features: Using combination of bioinformatic tools and immunological studies, peptide sequences inducing neutralizing antibodies and T helper activity in mice were identified. Chimeric peptides incorporating both these epitopes showed induction of immunity against JE virus and partial protection from lethal challenge in mouse model.

Scale of Development: The project was a collaborative effort between National Institute of Virology, Pune, and Bioinformatics Centre, University of Pune, with funding from Department of Biotechnology, New Delhi. It is developed up to laboratory scale.

Status of Commercialization: Four international patents were filed in USA (Application no. 10/250,468), Korea and Japan and Philippines and one national phase application was filed in India based on PCT application (Application no. PCT/INO2/0003). Negotiation are in progress with Hyderabad based Company M/s Bharat Biotech India Ltd. for commercializing this technology.

Diagnostic for Japanese Encephalitis, Dengue and West Nile Viruses

Product/Process: MAC ELISA kit for the diagnosis of Japanese Encephalitis (JE), Dengue (DEN) and West Nile (WN) viruses.

Application/Uses: It is used for diagnosis of JE, WN and DEN viral infections, which are of great public health importance. They are highly sensitive (96%) and specific.

Salient Technical Features: The technique is based on micro plate IgM ELISA which detects virus specific IgM antibody. The probe incorporated in current MAC ELISA is useful for detection of infection of three flaviviruses (JE/WN/DEN).

Flaviviruses have several common antigenic determinants and classical tests like haemagglutination inhibition (HI) and complement fixation (CF) showed significant cross reaction thereby giving ambiguous diagnosis but ELISA test does not require any pretreatment of the sample.



Scale of Development: Kits are regularly supplied to research institutes in India and to the WHO.

Status of Commercialization: The technology has been transferred to Zydus Cadila, Mumbai.

Diagnostic for Hepatitis A

Product/Process: Diagnostic kit for detection of IgM anti-hepatitis A (HAV) and total antibodies to HAV.

Application/Uses: It is useful for detection of IgM anti-HAV antibodies for diagnosis of recent and past infections of hepatitis A, and in seroepidemiological studies and viral hepatitis surveillance. It is also used for detection of HAV specific antigen.

Salient Technical Features: This is the first indigenously developed hepatitis A diagnostic kit. The technology utilizes tissue culture grown HAV that provides a steady source of relatively clean preparation of virus (HAV) free from bacterial or other viral contaminants. The indigenous production of the following major components has been achieved:

- Rabbit IgG against human IgM

- Anti-HAV IgG from serum of HAV infected human/rhesus monkey
- HAV antigen
- HRP based immunoconjugate linked to purified anti-HAV IgG. The reagents of the kits are stable for 6 months.

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: The technology has been transferred to Bharat Biotech International Ltd., Hyderabad.

Vaccine for Hepatitis A

Product/Process: Vaccine candidate against hepatitis A.

Application/Uses: MRC-5/VERO cell culture adapted Indian isolate of hepatitis A for the preparation of hepatitis A vaccine. The indigenous vaccine preparation can be useful to high risk groups such as:

- Children from high socio-economic status
- Young food handlers
- Sibling of hepatitis A patients
- HBV/HCV carrier children.

Salient Technical Features: A strain of hepatitis A virus was isolated from fecal sample of a patient. The isolation and adaptation of virus was carried out in BGMK cell line. The adapted strain of HAV was designated as NIVIN 97. The strain was further adapted to VERO cell line. It showed strong positive reactions in ELISA tests employed for detection of anti-HAV antibodies. Additionally, immune microscopy was performed at different passage levels and full virus particles detected.

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: An agreement has been signed between National Institute of Virology, Pune (ICMR) and Bharat Biotech International Ltd. (BBIL), Hyderabad, for the transfer of MRC- 5/VERO cell culture adapted from Indian isolate of hepatitis A virus for the preparation of hepatitis A vaccine.

Kyasanur Forest Disease Vaccine

Product/Process: Kyasanur Forest Disease (KFD) vaccine.

Application/ Uses: This vaccine has been primarily used in health care system for KFD restricted to the state of Karnataka, India.

Salient Technical Features: An inactivated vaccine is prepared using KFD virus in chick embryo culture (CEC). Clinical trials for this were conducted by NIV, Pune.

Scale of development: The technology has been developed at laboratory scale and production would be done at Virus Diagnostic Laboratory (VDL), Shimoga, Karnataka.

Status of Commercialization: The technology has been transferred to VDL, Shimoga for production for Karnataka Government. The NIV also maintained instruments and logistic support to VDL, Shimoga up to 1998. Currently, vaccine production is carried out at Karnataka Govt. owned autonomous Veterinary Vaccine Production Unit at Hebbal. Safety of the vaccine is being tested at VDL, Shimoga.

Diagnostic for Rotavirus

Product/Process: Diagnostic kit for rotavirus.

Application/Uses: It is used for detection of rotavirus from the fecal samples of diarrhoea patients.

Salient Technical Features: The rapid ELISA test was developed at NIV, Pune. It is easy to perform, has high sensitivity and specificity and is cost effective as large number of fecal samples could be tested using indigenously developed reagents. This can essentially avoid unnecessary use of antibiotics in diarrhoea patients. This kit is also useful during surveillance studies to obtain data on disease burden.

Scale of Development: It has been developed up to laboratory scale.

Status of Commercialization: An Indian patent (no. 187163) was granted. Negotiation for technology transfer with BBIL, Hyderabad is on.

Rotaviral Diarrhoea Treatment

Product/Process: Immune goat colostrum against rotavirus.

Application/ Uses: Hyperimmune goat colostrum is useful in inducing passive immunity against rotaviruses among children. It is effective in reducing the duration and severity of childhood diarrhoea due to rotavirus. It also serves as an enriched food for babies.

Salient Technical Features: Anti-rotavirus antibody titers as assessed by ELISA and neutralization test are significantly high in hyper immune goat colostrum. Spray dried powder of hyperimmune goat colostrum retain anti-rotavirus antibodies which can be suitably used as baby food supplement.

Scale of Development: It has been developed up to laboratory scale.

Status of Commercialization: An US patent entitled "The preparation of immune goat colostrum against rotavirus" (Application no. 10/100.165) has been filed.

Mosquito Repellent Device

Product/Process: Insect repellent device.

Application/Uses: It is used as mosquito repellent where no electricity is available, particularly in rural areas.

Salient Technical Feature: This device comprises of holding arrangements provided with a plurality of connecting means which is made of metals. A curved metal plate of 2-5 cm of diameter has been held by these connecting means. Heating source is placed at a distance of 1.0 to 10 cm from the metal plate.

Scale of Development: It has been developed up to laboratory scale.

Status of Commercialization: An Indian patent has been granted. (Patent no. 195269).

Vector Control Research Centre (VCRC), Puducherry

Biocontrol Agents of Mosquitoes

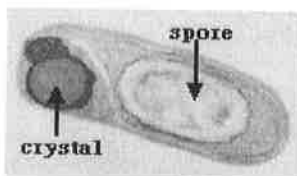
Bacillus thuringiensis var. *israelensis*

PRODUCT/PROCESS: Water Dispersible Powder (WDP), Slow Release Granules (SRG) and Aqueous Suspension (AS) formulations from *Bacillus thuringiensis* var. *israelensis* and process thereof.



APPLICATION/USES: These products are effective against the immature stages of mosquitoes transmitting malaria, filariasis and dengue viz., *Anopheles*, *Culex* and *Aedes* mosquitoes. The AS formulation was found to be effective in clean water bodies breeding Anophelines at an application dosage of 0.5 ml/m² for 2 weeks and in polluted water bodies breeding Culicines at an application dosage of 1 ml/m² for 1 week. The WDP (40%) formulation at 2.5 – 5 kg/ha for clear and 5 – 15 kg/ha for polluted habitats was found to have residual activity for about a week against *Culex quinquefasciatus*. The SRF formulation at 10 kg/ha was found to have a residual activity for 3 months in disused wells, while the same at 15 kg/ha showed residual activity for 1 month in polluted habitats against *Cx. quinquefasciatus*.

SALIENT TECHNICAL FEATURES: *Bacillus thuringiensis* var. *israelensis* (VCRC B17), a naturally occurring bacterial pathogen of mosquito larvae was isolated from the paddy field soil of Puducherry. It is a rod shaped bacterium producing parasporal bodies (crystals) along with the spores. The endotoxin of the parasporal body is responsible for the mosquito larvicidal activity.



SCALE OF DEVELOPMENT: The technology has been developed up to pilot scale and assigned to National Research Development Corporation (NRDC) for commercialization.

STATUS OF COMMERCIALIZATION: The process technology of Aqueous Suspension (AS) formulation has been licensed to the following commercial firms:

- (i) Tuticorin Alkali Chemicals, Chennai
- (ii) Revathi Agrifood Industries Pvt. Ltd., Chennai and
- (iii) R.K. Biotech Product Private Ltd., Chennai.
- (iv) Bacto Power India Pvt Ltd., Coimbatore
- (v) Coromandal Biotech Industries (India) Limited, Hyderabad
- (vi) Neelagriva Biosciences Pvt. Ltd., Vidyarangapuram, Mysore

- (vii) Amit Biotech, Kolkata
- (viii) Kilpest India Ltd, Bhopal
- (ix) Biotech International, New Delhi
- (x) Fine Trap, Yavatmal

An Indian Process Patent (no. 192 055) has been granted and a product patent application (No. 650/DEL/2003) has also been filed.

Bacillus sphaericus

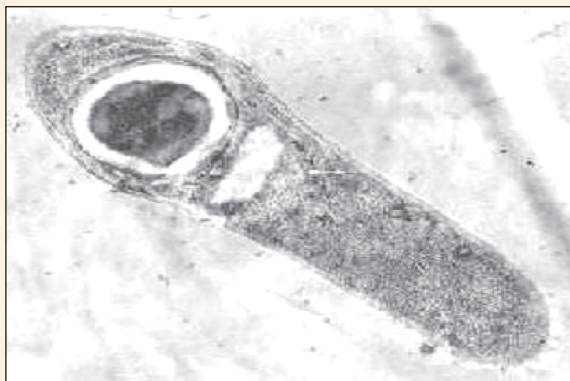
Product/Process: Slow release and wettable powder formulation from *Bacillus sphaericus*.

Application/Uses: The formulation is used for controlling immature stages of mosquitoes in polluted and non-polluted water.

Salient Technical Features: This is a mosquito pathogenic bacterial agent isolated from soil samples collected from paddy field near Puducherry. It is rod shaped bacterium which forms spores at terminal position. This isolates (Accession No. VCRC B42) has been given 5 star ranking by International Bacterial Biopesticide Reference Centre, Pasteur Institute, Paris. Water Dispersible Powder (WDP) at 10 kg/ha controls the immature mosquito for a week in polluted and non-polluted water. Slow Release Formulations (SPHERIFIX) has residual activity for over 2 months. For maximum effect, application of the bacterial pesticide should be done taking into consideration the surface area of the breeding habitat, type of habitat and mosquitoes species present.

Scale of Development: The technology has been developed up to pilot scale and production of this biocontrol agent has been assigned to NRDC for commercialization.

Status of Commercialization: An Indian patent has been filed for the process of SPHERIFIX—a mosquito larvicide from *B. sphaericus*.



Microbial pupicide

Product/Process: B 426 - A bacterial metabolite from *Pseudomonas fluorescens* showing pupicidal activity.

Application/Uses: This bacterial metabolite in simulated field conditions caused significant mortality of *Culex quinquefasciatus* pupae and suppression of adult emergence.

Salient Technical Features: The formulation eliminates 100% of larvae, pupae within 24 h after application and maintains >80% reduction in the pupal density for 10 days.



Scale of Development: The technology has been developed up to pilot scale.

Status of Commercialization: An Indian patent (no. 192872) has been granted. Technology has been assigned to NRDC, New Delhi, for commercialization.

Microbial Oviposition Attractant

Product/Process: *Trichoderma viride* showing oviposition attractancy.

Application/Uses: This new formulation containing fungal metabolite is used to attract *Cx. quinquefasciatus* females for oviposition at 10 ppm.

Salient Technical Features: It is a process for the production of mosquito oviposition attractant useful for surveillance and control of mosquitoes. The formulation showed remarkable attractancy to gravid females with an oviposition active index of +0.52.

Scale of Development: Technology has been developed up to pilot scale.

Status of Commercialization: An Indian Patent (no. 199635) was granted in 2006. This technology has been assigned NRDC, New Delhi, for commercialization.

Insect Repellent

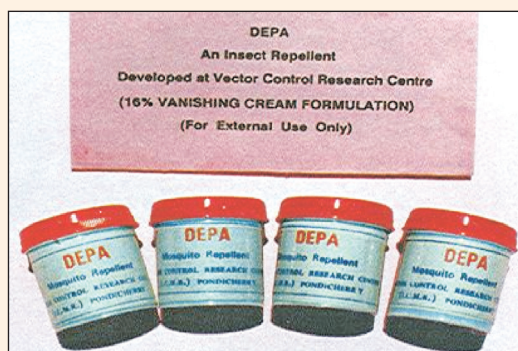
Product/Process: Three different formulations for DEPA (N,N-Diethyl phenyl acetamide), a synthetic amide.

Application /Uses: DEPA has been used as chemical control agent for personal protection against haematophagous arthropods. The repellent has been formulated as antiseptic cream, polymer based liquid and liposphere lotion.

Salient Technical Features: DEPA is effective in protecting individuals from blood-sucking arthropods, mosquitoes, land leeches, and sand flies and black flies. DEPA gives protection for 6.75 h against mosquitoes, 7.0 h against black flies, 6.0 h against land leeches at 0.5 mg/cm² and 6.5 h against sand flies at 0.2 mg/cm².

Scale of Development: Technology has been developed at laboratory scale.

Status of Commercialization: The technology has been transferred to Defence Research and Development Establishment, Gwalior for commercial exploitation.



Insect Growth Regulator (IGR)

Product/Process: DPE-28-a Controlled Release Formulation (CRF) of an IGR.

Application/Uses: Formulations of DPE (Diphenyl ethers) were found effective in controlling the immature stage of *Cx. quinquefasciatus* for two weeks at the application rate controlling to 0.1 mg/l.

Salient Technical Features: DPE-28 is a fine yellow powder and used for the preparation of CRF with sodium carboxymethylcellulose slurry and insolubilization with aluminum ion. DPE-28 is diphenyl ether with one of the phenyl group bearing tertiary butyl group at 2 and 6 positions and other phenyl group bearing chlorine at position 1 and nitro groups at position



1 and 4. DPE-28 was found to be effective in inhibiting growth of immature stages of *Cx. quinquefasciatus* within EI_{50} value (concentration to inhibit the adult emergence in the treated population by 50%) of 2.2×10^{-3} mg/ml.

Scale of Development: The technology has been developed up to laboratory scale.

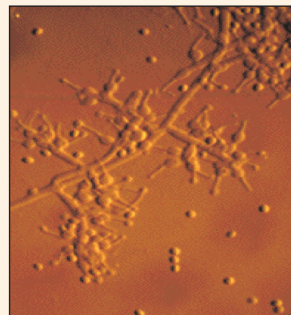
Status of Commercialization: An Indian patent (no. 191820) has been granted for the process of the production controlled agent of DPE-28. The technology for the development of controlled released formulation of DPE - 28 has been assigned to NRDC, New Delhi. NRDC has transferred this technology to M/s Sree Ramcides Chemicals Pvt. Ltd. (SRCPL), Chennai.

Immuno-suppressive Fungal Metabolite - Cyclosporine

Process/Process: A process for the preparation of Cyclosporine from the fungus *Tolypocladium*.

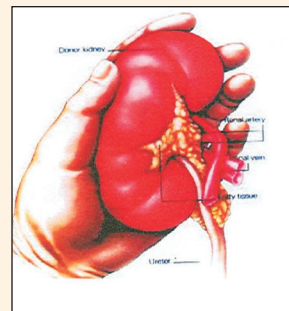
Application/Uses: It is used as an immunosuppressive drug while transplanting the organ. It is administered for the prevention of organ rejection in transplantation surgery.

Salient Technical Features: During the course of searching of microbial agents for mosquitocidal properties, a fungus *Tolypocladium* was obtained which also produces cyclosporine A. A laboratory scale process for the production of cyclosporine A and a HPLC method for the identification of cyclosporine A, B and C isomerism fermentation samples were developed.



Scale of Development: The technology has been developed up to laboratory scale for production of cyclosporine A.

Status of Commercialization: An Indian Patent (no. 182916); European Patent EP-725-076-EP-300674, Canadian patent (2,142,240) and US Patent no. 5,656,459 have been granted on this technology. The technology has been transferred to M/s Nixcil Pharmaceuticals & Specialities, Lucknow, through NRDC, New Delhi.

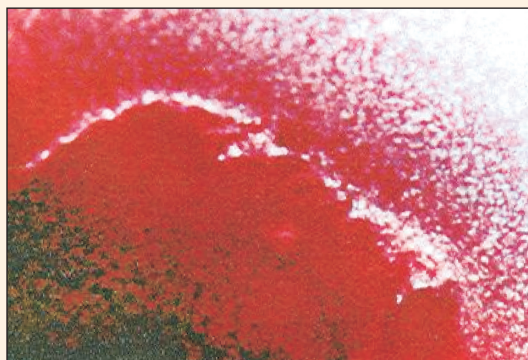


Thrombolytic Enzyme - Thrombinase

Product/Process: Thrombinase- a novel thrombolytic enzyme derived from a strain of *Bacillus sphaericus*.

Application /Uses: This product has enormous use for the treatment of the cerebral thrombosis stroke, myocardial infarction, deep vein thrombosis and in the prevention of post-surgical adhesion.

Salient Technical Features: This product is not a plasminogen activator, but it acts specifically on fibrin clots. Toxicological data have been generated through animal experimentation. The product has been cleared by Drug Controller General of India (DCGI) for Phase I clinical trials.



Scale of Development: A pilot scale production process for thrombinase from the culture broth of *B. sphaericus* is developed.

Status of Commercialization: Both the US and Indian patents have been obtained (Indian Patent no. 196869 and US Patent no. 5,434,059). The technology has been transferred to M/s Maladi Research Centre, Chennai, through NRDC, New Delhi.

Macrofilaricidal Composition of Naphthalene Dione Derivatives

Plumbago rosea/indica

Product/Process: The lead molecule 5-hydroxy-2-methyl-1,4-naphthalenedione has been identified from *Plumbago indica/rosea*, an indigenous medicinal plant.

Application/Uses: A composition comprising of one or more derivative of 5-hydroxy-2-methyl-1, 4-naphthalenedione may give rise to a potential macrofilaricide for treatment/prevention of filariasis.

Salient Technical Features: *Plumbago indica/rosea* (Family: Plumbaginaceae) is a perennial shrub found throughout India. The methanolic extract of roots of this plant when tested at 0.05 mg/ml *in vitro* against *Setaria digitata*, a filarial parasite of cattle, resulted in 100% immobilization at an incubation period of 30 min. The macrofilaricidal activity was further confirmed by MTT reduction assay. The novel composition comprising of one or more derivatives of this molecule may result in a potential macrofilaricide.



Scale of Development: The technology has been developed up to the laboratory scale.

Status of Commercialization: An Indian Patent Application no. 1083/DEL/2003 has been filed.

Trachyspermum ammi

Product/Process: The lead molecule, a monoterpene with phenolic properties has been identified from *Trachyspermum ammi*, an indigenous medicinal plant.

Application/Uses: A composition comprising of one or more derivatives of monoterpene with phenolic properties is likely to yield a potential macrofilaricide.

Salient Technical Features: *Trachyspermum ammi* (Family: Apiaceae) is a perennial shrub found throughout India. The methanolic extract of the fruits of this plant yielded a monoterpene with phenolic properties, which when tested *in vitro* against adult worms of *Setaria digitata*, the filarial parasite of cattle, resulted in more than 80% immobilization of the worms at an incubation period of 2h and the activity was confirmed by MTT reduction assay. The novel composition comprising of one or more derivatives of this molecule may result in a potential macrofilaricide.



Scale of Development: The technology has been developed at the laboratory scale.

Status of Commercialization: An Indian Patent Application no. 1082/DEL/2003 has been filed.

Bird Feather Based Biopesticide

Process/Process: A process for attracting and killing mosquitoes from bacterial culture filtrates using bird feather.

Application/Uses: At laboratory scale level, the inventions more specifically claim the utility of an inexpensive biological waste product from poultry industries (bird feathers).

Salient Technical Features: The invention describes an economical process for producing bio-insecticide. It also describes the production of *Bacillus sphaericus* and *B. thuringiensis* serovar *israelensis* based biopesticides utilizing cheap and locally available biological waste material through simple fermentation technology. Potential mosquitocidal toxins are also identified from new fermentation medium. The crystal toxins are optimized at various levels of feather based fermentation medium. Extraction of crystal toxins and testing the toxic effect of these toxins against mosquito larvae is also done.

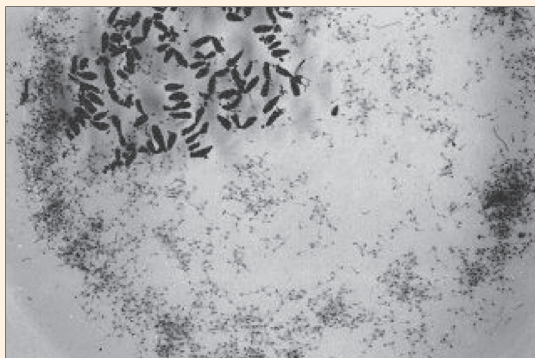
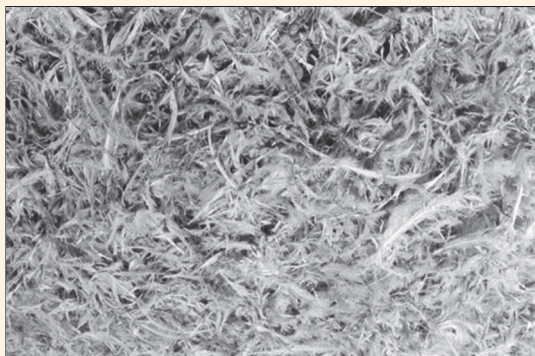
Scale of Development: The technology has been developed at laboratory scale.

Status of Commercialization: An Indian patent (Application no. 319/DEL/2005) has been filed on this technology.

Biocidal Composition for Mosquitoes

Product/Process: The invention relates to a biocidal composition which can be used to attract gravid mosquitoes to lay their eggs and subsequently kill the larvae emerged from these eggs.

Application /Uses: Identification of novel mosquitocidal toxins that differ in structure and mode of action produced by *B. sphaericus* (Bs) and *B. thuringiensis*



sub *sp. israelensis* (*Bti*) may be of great interest. The invention is the first to show that the extracellular insecticidal toxins (exotoxins) of Bs and Bti produced from bird feather culture filtrates can attract the disease causing female mosquitoes for laying their eggs. Further, the freshly emerged mosquito larvae on the surface of the water medium died immediately thus controlling the mosquito larvae to emerge further into the environment.

Salient Technical Features: The novelty of this invention lies with the culture filtrates derived from bird feathers. This biological material serves as an excellent source for efficient production of biopesticides at a cost effective manner to control mosquito larvae by harvesting the bacterial cells and crystal toxins.

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian Patent (Application no. 358/DEL/2006) has been filed.

Diagnostic kit for Filariasis

Product/Process: A process for detecting larvae of filarial parasite *Wucheraria bancrofti*, in the mosquito vector, *Culex quinquefasciatus*.

Application/Uses: It is used in endemic areas for detection of infectivity of vector mosquito and in monitoring control operations.

Salient Technical Features:

- It is a kit comprising a set of primers.
- It detects L3 larval stage of *W.bancrofti*.
- In this process a novel *W.bancrofti* L3 specific probe is employed in reverse transcription PCR.

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian Patent (Application no. 2793/DEL/2006) has been filed.

Biocontrol agent for vector mosquitoes

Product/Process: A microbe based product effective against larvae, pupae and adult stages of mosquito.

Application/Uses: It is used as vaporizing mat or liquid vaporizer or aerosol to kill all stages of mosquitoes.

Salient Technical Features:

- This product is a cyclic lipopeptide of soil microbe - VCRC B471.
- B471 is a gram positive spore forming bacterium.
- It has unique adulticidal activity.

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian Patent (Application no. 544/DEL/2008) has been filed.

Bioinsecticide from industrial wastes

Product/Process: A microbial fermentation process comprising ghee sediment waste for the growth of mosquitocidal bacteria (Bs and Bti).

Application/Uses: It produces potential biolarvicide used in mosquito eradication.

Salient Technical Features:

- The present invention provides culture media utilizing bio-organic wastes, to produce biopesticides (*Bacillus sphaericus* and *B. thuringiensis* serovar *isrealensis*).
- The culture media supports high growth rate of bacteria and subsequently high toxin production.
- The invention provides a culture media that is very easy to process and economical compared to the conventional media.

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian Patent (Application no. 1106/DEL/2007) has been filed.



National Institute of Cholera and Enteric Diseases (NICED), Kolkata

Cholera Vaccine

Product/Process: Oral recombinant live strain VA1.3.

Application/Uses: *Vibrio cholerae* O1 biotype E1 Tor serotype Inaba strain genetically tailored to develop a novel non-reactogenic oral recombinant live oral cholera vaccine strain and named VA1.3.

Salient Technical Features: Initial attempts were made by parenteral administration of antigens like killed bacteria, LPS and toxoid. However, these were discontinued in clinical practice due to unacceptable side effects as well as inefficient protection. Since induction of immunity by the oral injection of live attenuated candidate cholera vaccine strains closely mimics infection derived immunity, this approach received great emphasis. Among the live oral vaccine strain, CVD103 HgR developed in the Centre for Vaccine Development, USA, is the most successful one. However, vaccine strain CVD103 HgR is only effective against classical type of cholera. Present cholera situation in India as well as in other parts of world is caused by E1 Tor *V. cholerae*, where CVD103 HgR is not found to be effective in providing protection. Therefore, it is important to develop a vaccine that will be effective against cholera caused by E1 Tor as well as classical strains.

Scale of Development: Vaccine trials are being conducted in Society for Applied Sciences (SAS), Kolkata, and Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIM), Lucknow, in collaboration with NICED, Kolkata. Volunteers, who were fed with inoculum dose of 5.0×10^9 CFU did not shed the vaccine strain. The vaccine strain was non-reactogenic even at high doses. Sera samples were collected on 0, 15, 90 and 180 days from the vaccines and are being assayed.

Status of Commercialization: An US patent has been granted for the candidate vaccine strain (US Patent no. 6,106,843).

Holey/Lacey Carbon Films for Electron Microscopy

Product/Process: A new method for the preparation of holey/lacey support film for electron microscopy.

Application/Uses: In electron microscopy, there is a tremendous requirement for holey/lacey plastic, carbon, carbon reinforced plastic and other polymer films. The requirement has increased manifold with the advent of cryoelectron microscopy. Holey films are also used for checking astigmatism, resolution and stability of the electron microscope. There is, thus, requirement for a method of preparing holey/lacey films, which is simple and reproducible. The aim of the present invention was to develop such a method for preparing holey/lacey films.

Salient Technical Features: Methods generally used in the preparation of holey/lacey films has some drawbacks and/or cumbersome. In this study, a new method for the preparation of holey/lacey supports film for electron microscopy has been invented. Additional reinforcement can be done with a thin layer of carbon, if needed.

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian Patent (Application no. 2844/DEL/2005) has been filed.

A novel *Salmonella typhi* protein as a subunit vaccine

Process/Product: A novel Protein of *Salmonella typhi* as a probable subunit vaccine

Application/Uses: A novel recombinant protein of *S. typhi* may elicit T cell-dependent response conferring specific protection by inducing cell- mediate immune response and is expected to provide long term immunological memory.

Salient technical feature: Being a recombinant protein, the newly developed vaccine may be significantly cheaper and more effective in conferring long term protection than the existing ones. In addition, toxicity would be much less compared to a live attenuated or whole cell killed vaccine. The protein of invention may be used to develop a Vi polysaccharide conjugate vaccine.

Scale of development: The technology has been developed up to laboratory scale.

Status of commercialization: An Indian patent Application no 506/DEL/2010 has been filed.

National Institute of Malaria Research (NIMR), Delhi

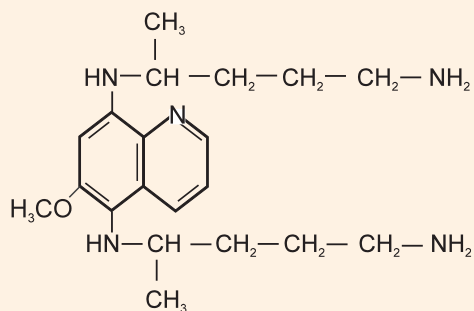
Formulation for Malarial Treatment

Product/Process: New drug formulation for malaria.

Application/Uses: This new formulation is used for treatment of malaria as gametocidal and schizontocidal drug.

Salient Technical Features:

Primaquine has been conventionally employed for relapsing *Plasmodium vivax* malaria and for gametocidal action in *P. falciparum* malaria for a long time. However, the drug is toxic particularly in patients deficient in glucose-6-phosphate dehydrogenase (G6PD). The present drug formulation helps treat malaria without any side effects.



Scale of Development: This treatment has been developed up to laboratory scale. The drug formula has been tested for *in vivo* study infected mice/hamster before and after treatment with the new drug. This observation was further assessed by feeding *A. stephensis* mosquitoes on *P. voelli* infected mice/hamster before and after treatment. Complete loss of infectivity in mice after treatment has been noticed.

Status of Commercialization: An Indian patent (no. 189970) has been granted.

Herbal Composition for Mosquito Control

Product/Process: Composition containing *Solanum nigrum* extract.

Application/Uses: This herbal composition is used as larvicidal agent for controlling mosquitoes.

Salient Technical Features: This composition which comprises fruit extract of *Solanum nigrum* in hexane solvent was found to be 13 fold more efficacious than aqueous extract.

Scale of Development: The technology has been developed up to laboratory scale. A patent (No. 2344279) has been granted by Indian Patent Office.

Status of Commercialization: Technology commercialization is being explored.

A Plant Based Insecticide for Mosquito

Product/Process: The invention relates to insecticide isolated from plant *Valeriana jatamansi* against major vectors of malaria, filaria and dengue.

Application/Uses: The fraction isolated from plant possesses very good adulticidal activities against common vectors of malaria, filaria and dengue viz. *Anopheles stephensis*, *Anopheles culcifacies*, *Aedes aegypti* and *Culex quinquefasciatus*. These fractions also possess larvicidal activity.



Salient Technical Features: *Valeriana jatamansi* is a common plant distributed in mountains and Himalayas from Kashmir to Bhutan and has been used for its calming, relaxing and emotionally balancing influences. A purified fraction of this plant possesses good insecticidal properties against mosquitoes. Adulticidal activity of this plant against major vectors of dengue, malaria and filaria has been demonstrated determined by WHO method on impregnated papers of two fractions (MRCHAR/03/05/S and MRCHAR/03/05/C).

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian Patent (Application no. 3234/DEL/2005) has been filed.

Immunodiagnostic reagent

Product/Process/ Process: Hybridoma cell line producing antibody against *Plasmodium vivax*.

Application/Uses: This monoclonal antibody is specific for *P.vivax* and is useful for detection of *P.vivax* antigen in patient's blood.

Salient technical feature:

- It is based on immunodiagnostic antibody probe for detection of *P.vivax* antigen.
- The monoclonal antibody is unique.

- The fusion of spleen cells takes place with mouse myeloma cells.
- After fusion, the cell was cultured and then cloned.

Level/Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian patent (Application no. 1606/DEL/2008) has been filed.

A botanical formulation for mosquito control

Product/Process: A new plant based insecticide for the control of Malaria, Filarial and Dengue.

Application/Uses: The plant is used as insecticide and exhibit very good adulticidal activity against *Anopheles culicifacies*, *A. fluviatilis*, *Aedes aegypti*, and *Culex quinquefasciatus*.

Salient technical features:

- The fraction code MRCHR 04/04/S was isolated from *Lantana camara* is utilized.
- The yield of the fraction is 0.4%.
- The isolated fraction showed good adulticidal activity and may be stored at low temperature.



Level/Scale of Development:

The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian patent (Application no. 2405/DEL/2007) has been filed.

National JALMA Institute for Leprosy & Other Mycobacterial Diseases (NJIL&OMD), Agra

Drug target / Vaccine for Mycobacterial disease

Product/Process: A process for expression of virulence factors of *Mycobacterium leprae*.

Application / Uses: It is used for the differential expression of virulent genes of *Mycobacterium leprae* during the disease spectrum in the host.

Salient Technical Features:

- A DNA chip is used for identification of virulence in *Mycobacterium*.
- The expression of virulence factor is determined through functional genomic approaches.

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian Patent (Application no. 2012/DEL/2007) has been filed.

A Novel primer to identify the Mycobacteria

Product/Process: A Process for identification of pathogenic *Mycobacteria*.

Application / Uses: It is used to differentiate pathogenic mycobacterial isolates at species level.

Salient Technical Features:

- These novel primers identifies pathogenic *Mycobacteria* by gene amplification analysis.
- Fragements generated from amplicons by this assay are bigger which can be easily separated and analyzed.
- It is cost effective, rapid method to differentiate mycobacterial isolates at species level.

Scale of Development: The technology has been developed at laboratory scale.

Status of Commercialization: An Indian Patent (No. 242073) has been granted and assigned to NRDC, New Delhi for commercialization.

Therapeutic / Diagnostic targets for Tuberculosis

Product/Process: Process for identification of efflux pumps proteins of *Mycobacterium tuberculosis*.

Application / Uses: It is useful for detection of efflux mediated MDR in *M. tuberculosis*.

Salient Technical Features:

- It is a reliable method for the detection of efflux mediated multidrug resistance in *M. tuberculosis*.
- These novel drug efflux pumps as potential therapeutic / diagnostic targets.

Scale of Development: The technology has been developed up to laboratory scale.

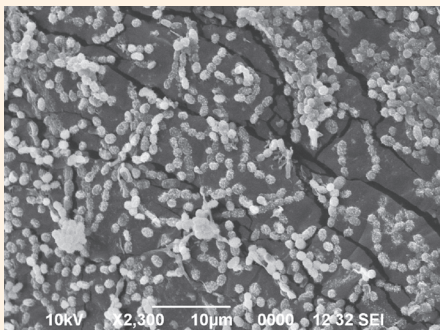
Status of Commercialization: Two Indian Patents (Application no. 884/DEL/2007 & 2071/DEL/2007) have been filed.

Tuberculosis Research Centre (TRC), Chennai

Product/Process: An antibacterial and antiviral compound.

Application /Uses: Since the discovery of streptomycin from *Streptomyces griseus*, actinomycetes derived antibiotics are in use for the treatment of tuberculosis. The compound is also useful against other bacterial pathogens. The invention is to provide a compound which is effective against bacterial and viral pathogens and a process of preparing the compound. It is to provide a novel strain of Actinomycetes which produces the chemical compound having activity against bacterial and viral pathogens.

Salient technical features:



1. The compound of the invention is effective against drug sensitive, multiple drug resistant and extensive drug resistant strains of *Mycobacterium tuberculosis*. It is effective against latent bacilli also.
2. The compound of the invention is also effective against other bacterial pathogens.
3. The compound of the invention is effective against Human Immuno Deficiency Virus (HIV).
4. The process of producing the compound of the invention is a simple process and does not require complex laboratory set-up. Therefore, the process of production of compound is economically viable.

5. The compound of the invention is a natural product. Also, the compound is produced by naturally occurring novel marine microorganism. Therefore, the compound itself or the process of producing the same are eco-friendly and does not pose any threat to environment.
6. The compound is a brominated, yellow pigmented molecule with a simple structure. The compound is novel based on published, patented and chemical database search.
7. The compound shows very poor cytotoxic activity. Therefore, the compound can be effectively used to manufacture pharmaceutical formulations against bacterial and viral pathogens.

Status of Commercialization: An Indian patent (provisional application no. 247/DEL/2011) has been filed. Accession number MTCC 5597 has been provided to the novel marine *Streptomyces* sp. by IMTECH, Chandigarh.

Diagnosis of pathogenic *Mycobacterium tuberculosis*

Product/Process: A non-hazardous and simple technique for the detection of acid-fast bacilli in sputum.

Application/Uses: It is used to sterilize and stain the sputum in its container before making a smear and is cost effective.

Salient Technical Features:

- Simple staining procedure to employ without heating of carbol-fuchsin.
- Pathogenic *Mycobacteria* is stained in the sample in the container before making a smear.
- Preparation of smear is non-hazardous.
- The reagent costs less as the quantity used for staining is 3-4 times less.
- Sputum sample can be transported from remote health facilities to microscopy centres.

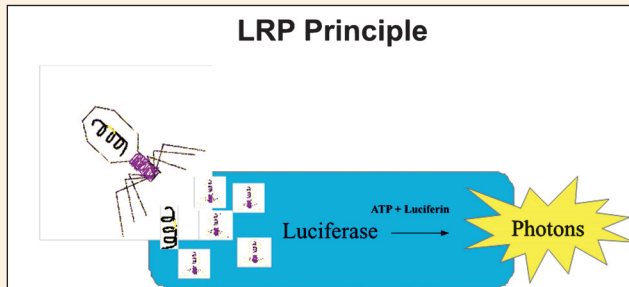
Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian Patent (Application no. 630/DEL/2008) has been filed.

Assay for detection of tubercle bacilli

Process/Product: A luciferase reporter phage assay for detection of tubercle bacilli.

Application/Uses: This technique is more rapid, specific and sensitive. The assay of the invention is a promising technique to diagnose actively growing as well as latent tubercle bacilli present in sputum samples. It is a very simple technique which is economically viable as well.



Salient technical feature: The invention provides a kit for detection of tubercle bacilli in manual. The kit may comprise combination of different phages depending upon its utility a sample. The kit comprises of a set of reporter phages along with an instruction and applicability for the type of sample.

Scale of Development: The technology has been developed up to laboratory scale.

Status of commercialization: An Indian patent Application no 2530/DEL/2010 has been filed.

Regional Medical Research Centre (RMRC), Port Blair

Diagnostic for Leptospirosis

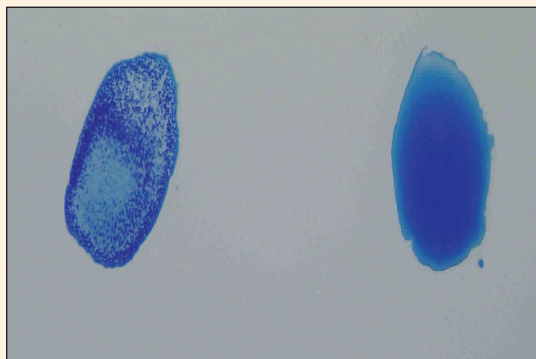
Product/Process: Latex agglutination test for the diagnosis of leptospirosis.

Application/Uses: This test is used to diagnose the leptospirosis, endemic in Andaman & Nicobar Islands, Kerala & Tamil Nadu.

Salient Technical Features: A latex agglutination test has been developed by using an antigen for diagnosis of leptospirosis. Laboratory based evaluation of the indices of validity of the test was carried out. Field evaluation for its indices of validity, predictive values, reproducibility and cost effectiveness to incorporate the test into the screening system for surveillance against leptospirosis and for diagnosis of disease in epidemic situations has to be done in the field.

Scale of Development: Technology has been developed up to laboratory scale.

Status of Commercialization: Technology commercialization is being explored.



Regional Medical Research Centre (RMRC), Dibrugarh, Assam

ELISA Technique for Sero-diagnostic for human paragonimiasis

Process/Process: Sero-diagnosis of human paragonimiasis.

Application/Uses: This diagnostic process is especially used in cases of overlapping clinical manifestations and as similarities between X-ray pictures in pulmonary paragonimiasis and pulmonary tuberculosis create diagnostic confusion, in areas where both diseases co-exist.

Salient Technical Features: No commercial kit is available for sero-diagnosis of human paragonimiasis. This is the first indigenously developed ELISA based technique with 100% sensitivity, specificity, efficiency, positive and negative predictive value for screening human population for paragonimiasis in India. It is the first indigenously developed excretory-secretory (ES) antigen based IgG ELISA system that can be effectively used for screening large populations for human paragonimiasis in India.

Scale of Development: Technology is developed up to laboratory scale.

Status of Commercialization: Technology commercialization is being explored.

A herbal anti-plasmodial agent

Product/Process: It is used for the treatment of Malaria.

Application / Uses: An antiplasmodial / antimalarial agent obtained from the roots of the plant *Brucea mollis* Wall. *Ex kurz.*

Salient Technical Features:

- It is a highly active extract from the roots of the plant *Brucea mollis* Wall. *Ex kurz.*
- It has antiplasmodial / antimalarial activity.

- It is biodegradable, ecofriendly, economic and commercially viable.

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian Patent (Application no. 31/DEL/2008) has been filed.

National Institute for Research in Reproductive Health (NIRRH), Mumbai

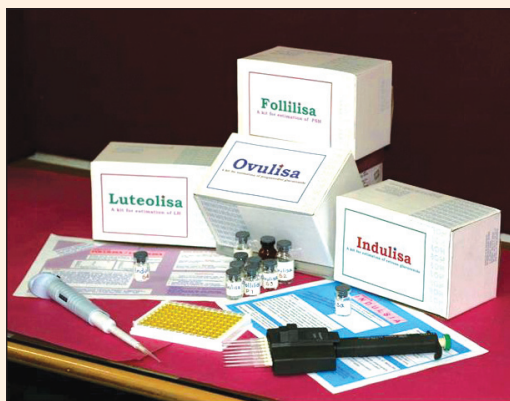
Fertility Assessment Kits

Product/Process: Fertility assessment kits and their assays-

- Indulsa - a kit for estimation of estrone glucuronide in urine (E_1G) by ELISA.
- Corpulisa - a kit for estimation of pregnanediol glucuronide (PdG) in urine.
- Luteolisa - a kit for estimation of leutinizing hormone (LH) in urine by ELISA.
- Follilisa - a kit for estimation of follicle stimulating hormone (FSH) in urine by ELISA.

Application/Uses:

- Indulsa - E_1G assay is used in conjunction with either ovarian ultrasonography and / or cervical mucus score in:**
 - Monitoring induction of ovulation therapy.
 - For timing the retrieval of pre-ovulatory oocyte *in vitro* fertilization and Assisted Reproductive Technology (ART) programmes.
- Corpulisa - PdG assays is used for:**
 - Detection for occurrence of ovulation.
 - Assessment for corpus luteum function.
- Luteolisa - LH assay is used in conjunction with FSH and / or sex steroids hormone in-**
 - Investigation in delayed and precocious puberty.
 - In determining the cause of subfertility such as gonadal failure, polycystic ovarian disease and evaluation of hypothalamic pituitary gonadal axis.



- d. **Follilisa** - FSH assay is used for estimation of FSH in urine. It is used in conjunction with LH assay for the above disorders.

Salient Technical Features:

- a. **Indulsa** - The ovarian follicular development can be properly assessed by serial ultrasonographic scanning of ovarian follicle and serum 17β oestradiol measurements. Assessment by oestradiol assay requires collection of a series of blood samples at an appropriate time during the menstrual cycle. Collection of a series of blood sample is stressful and causes discomfort to patients. It has been reported that the pattern of excretion of E_1G , principal metabolite of oestradiol in urine, closely resembles that of its parent oestradiol 17β in circulation. Therefore, estimation of E_1G in urine is more advantageous as sampling is non-invasive.
- b. **Corpulisa** - The plasma progesterone concentration rises rapidly following ovulation and raised level of progesterone during luteal phase as an indicator of occurrence of ovulation. After achieving ovulation, a properly functional corpus luteum is used for implantation of ovum. Pregnan diol glucuronide is the principal metabolite of progesterone in urine and the levels of which reflect those of progesterone in circulation.
- c. **Follilisa** - FSH and LH are intimately involved in the control of the growth and reproduction activities of the gonadal tissue which synthesizes and secretes male and female sex hormones. The level of FSH and LH are controlled by the sex hormones negative feedback relationship. FS promotes the proliferation of follicular cells, development of the graafian follicle and maturation of the ovary and appear to act with LH to stimulate testosterone production.
- d. **Luteolisa** - Leutinsing hormone (LH) is produced in both men and women from the anterior pituitary gland in response to gonadotropin releasing hormone (GnRH) which is released by the hypothalamus. LH is responsible for cyclical ovarian changes during the female menstrual cycle, including maturation of graafian follicle, ovulation and steroid production. LH in conjugation with FSH is required for maturation of spermatozoa in the seminiferous tubules and has the primary function of stimulating the interstitial cells to produce testosterone.

Scale of Development:

(a) The technology has been developed as follows -

- (i) Bulk quantities of well-characterized and high titre antisera (about 60-70 ml for each analyte) have been raised.

- (ii) Methods for preparation for enzyme analyte conjugation have been standardized.
- (iii) Presentation of antisera coated plates, enzyme labeled analytes, standard analytes, QC pools and substrate color indicator solution to suit kit format have been identified and their stability at defined conditions for defined period of time achieved.
- (iv) Presentation of individual reagents in the kit format is achieved.

Therefore, products can be up-graded to any scale.

(b) Technique used for mass production of antigen/antibody and outline of the processes involved are:

- (i) Raising of polyclonal antisera to analyte by immunizing rabbits.
- (ii) Purification and characterization of antisera.
- (iii) Preparation of enzyme labeled analyte: Mix-anhydride reaction in case of E₁G and PdG conjugations. One-step glutaraldehyde method for protein hormones.
- (iv) Selection of appropriate dilutions of labels and antisera.
- (v) Stability studies of reagents and other components of the kits.
- (vi) Selection of appropriate containers and packaging materials.

(c) Annual production of the kit: Approximate 1000 kits can be produced per annum.

Status of Commercialization: The technology is in process of being transferred to M/s HLL Health Care, Thiruvanthapuram.

Pregnancy Detection Kit - Pregstrip

Product/Process: Pregstrip - Pregnancy detection test based on excretion of human chorionic gonadotropin (hCG) in urine.

Application/Uses: Pregstrip is a dipstick ELISA test for pregnancy detection. Pregnancy detection is very simple and convenient due to the concentrated coating of high affinity antibodies on the nitrocellulose membrane pad for precise detection. Its sensitivity, specificity, and accuracy is 99.2%, 99.6% and 99.84% respectively, and detects pregnancy just after period is missed. Easily interpretable results can be achieved by colour differentiation.

Salient Technical Features: At present, the card tests available for pregnancy detection are not manufactured in India. hCG is glycoprotein hormone secreted

by the developing placenta in doubling quantities shortly after fertilization. The appearance and rapid rise in concentration of hCG in the maternal serum and urine, makes it an excellent marker for detection of pregnancy. The test utilizes β specific antibodies to hCG, immobilized on nitrocellulose membrane (0.45 μ) attached to plastic strip. These tests are based on immunochromatographic principle and are sensitive (20 mIU/ml). However, in India reasonably sensitive (50 mIU/ml) and simple tests are required as most Indian women approach clinicians in 1-2 weeks after missing periods. Keeping in view the needs of Indian women, the pregstrip is user-friendly, rapid and more sensitive. It can strengthen MTP programme of our country. Presently pregnancy detection kits are based on imported technologies and there is a great scope of detection test based on indigenous technology.

Scale of Development:

1. The technology has been developed up to laboratory scale (500 strips).
2. Methods of preparation of enzyme analyte concentration have been standardized.
3. Presentation of strips in dried format, enzyme label, control and substrate color indicator solution in kit format have been identified and stability at defined conditions for defined period of time have been achieved. Therefore, product can be upgraded to any scale.

Status of Commercialization: Technology commercialization is being explored.

Iron Deficiency Detection - Ferritinest

Product/Process: Ferritinest—a kit for the measurement of ferritin in serum to detect iron deficiency.

Application/Uses: Ferritinest provides a reliable immunoassay with minimum detection of limit 1.7 ng/ml. The antibody developed is specific and shows negligible cross reactivity with other serum component such as human serum albumin, alpha foetoprotein, haemoglobin, transferrin and ferric chloride. The test is cost effective, more sensitive and stable at refrigerator temperature. It is regularly required for screening general population, blood donors and patients undergoing renal dialysis.

Salient Technical Features: The system comprises of one polyclonal antiferritin antibody coated on microtitre well and another polyclonal anti ferritin antibody from a different source, which is conjugated to the enzyme horse radish peroxidase. The concentration of ferritin is directly proportional to the colour intensity of the test.

Scale of Development: The present technology is developed up to laboratory scale only and can be upgraded to industrial scale.

Status of Commercialization: Technology commercialization is being explored.

Biochemical Marker for Osteoporosis

Product/Process: Osteocalcin is a biochemical marker for diagnosis of osteoporosis and assessment of bone pathophysiology.

Application/Uses: Weakening of bone is an age related phenomenon and more so in geriatric population. Early diagnosis by using osteocalcine can reduce the incidence of future risk of fracture.

Salient Technical Features: Osteocalcine is a low molecular weight peptide and is secreted by osteoblasts. The synthesis of osteocalcine increases with enhancement in demineralization of bone. Elevated level of osteocalcine in serum and its appearance in the circulation is an early and acceptable indicator of bone pathology. Since it is cost effective, more sensitive and stable at refrigerator temperature, it is regularly required for screening general population and renal dialysis patient and therefore, has commercial potential.

Scale of Development: Pilot experiments are completed in which osteocalcine isolated was checked for purity through SDS-PAGE. Immunoreactivity of this preparation was also studied through a standard ELISA using DSL kits.

Status of Commercialization: Technology commercialization is being explored.

Biochemical Marker for Reproductive Tract Infections

Product/Process: Elastase (hydrolase) enzyme is used as a biochemical marker for reproductive tract infection (RTIs) including sexually transmitted infection (STIs).

Application/Uses: Elastase one of the proteins released during the inflammation due to the infection is used as biochemical marker for RTIs.

Salient Technical Features: Inflammation leads at the time of RTIs /STIs which liberates different types of proteins including elastase. A simple colorimetric assay was standardized to measure elastase in different biological samples like semen, urine, blood and cervical samples. The sensitivity and specificity of the assay is 87% and 98%, respectively.

Scale of Development: Technique is standardized and available in the laboratory for screening of RTIs and STIs.

Status of Commercialization: No indigenous technique is commercially available in India.

Nisin Peptide - A Contraceptive

Product/Process: A novel composition useful as a contraceptive comprising nisin peptide.

Application/Uses: It is used as non-vaccine preventive measure for RTIs/HIV infection and possess spermicidal properties.

Salient Technical Features: This composition comprising a therapeutically effective amount of biologically sufficient to cause spermicidal activity together with non-toxic vehicle. The vehicle used in the composition is saline and compound may be formulated as a lotion or a solution or any other form available for topical administration.

Scale of Development: Technique is developed up to laboratory scale. An Indian patent (no. 218373) has been granted.

Status of Commercialization: Technology commercialization is being explored.

Isolation of Pluripotent, Very Small Embryonic-like Stem Cells (VSELs) from Cord Blood and Bone Marrow

Product/Process: Superior and simple method to isolate VSELs without the use of Flow Cytometry.

Application/Uses: It is used to isolate VSELs from bone marrow and cord blood or other tissues

Silent technical feature: It is a simpler approach to isolate VSELs from bone marrow or cord blood without the use of sophisticated and expensive Flow Cytometry approach that employs the use of cell-specific markers to isolate VSELs. It is simple method and can be easily conducted even in an ordinary lab set up. It will reduce processing cost which is a major issue if we aim to reach the masses. It isolates VSELs without labeling them with antibodies for flow sorting. It minimizes the lab manipulations.

Stability/Cost: It is a cheaper and more practical method as it does not involve the use of sophisticated instrument like a Flow Cytometer

Scale of development: The technology has been developed up to laboratory scale.

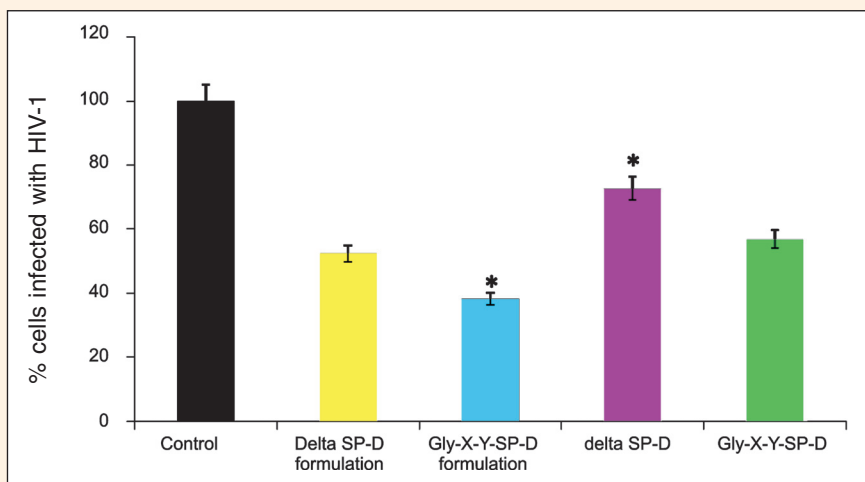
Status of commercialization: Technology commercialization is being explored.

Recombinant SP-D protein against HIV

Process/Product: Formulation of the lung surfactant protein SP-D against sexually transmitted infections including HIV

Application/Uses: Formulation with recombinant human lung surfactant protein SP-D effectively works against sexually transmitted infections including HIV.

Salient technical feature: The identification of SP-D in the human female reproductive tract has now opened up a new line of research on its therapeutic application in reproductive tract infections. It provides a recombinant SP-D directed against sexually transmitted infections including HIV.



Scale of development: It is developed up to laboratory scale.

Status of commercialization: An Indian patent Application no 1685/DEL/2009 has been filed.

National Institute of Nutrition (NIN), Hyderabad

Kit for Estimation of Haemoglobin

Process/Process: Estimation of haemoglobin without using a pipette.

Application/Uses: Nutritional anemia is a public health problem in the world. In India, the prevalence of anemia is very high in the vulnerable segments of the population *viz.* women and children. Estimation of hemoglobin in field setting is carried out by accurately delivering a measured amount of blood of 20 microliter using calibrated pipette from a finger prick sample. The present technology eliminates the use of the above delivery procedure.

Salient Technical Features: A special type of filter paper with the ability to spread blood uniformly from a finger prick sample is used. The sample is air-dried after which a known area of blood spot is punched out for estimations using a standardized steel paper punch. The area punched out contains blood equivalent to 20 microliter of blood. It is comparable to conventional technique using calibrated pipette.



Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: Technology commercialization is being explored.

Diagnostic Kit for Serum Ferritin

Product/Process: Indigenous diagnostic kit for serum ferritin.

Application/Uses: This kit is used for the measurement of serum ferritin which is considered to be an accurate and convenient method to estimate body iron.

Salient Technical Features: Ferritin is a high molecular weight iron storage protein. It is chiefly found in liver, bone marrow and spleen and is induced by iron. The circulating form of ferritin depends upon its release from tissue and reflects the altered status of body iron. Thus, measurement of serum ferritin is

considered to be an accurate and convenient method for assessing total body iron store. Ferritin from standards or samples is allowed to react with human liver ferritin antiserum coated micro titer plates. The ferritin bound to the antiserum is measured by adding an enzyme labeled ferritin antiserum. The unreacted reagents are washed with buffer to provide specific reaction. Finally, an enzyme substrate is added to get a colour which is measured in an ELISA reader. The cut off values for serum ferritin to be indicative of iron depletion is less than 12 µg/L. A value more than the cut off and below 300 µg/L is generally suggestive for iron adequacy. Values more than 500 µg/L suggest iron excess. Thus, ferritin measurement in population can be a useful indicator to define the cause and the stage of anemia. It is comparable to the foreign IRMA kit.

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: Technology commercialization is being explored.

Fortified Common Salt for Prevention of Deficiency Disorders

Product/Process: Common salt fortified with iodine or/ and iron.

Application/Uses: To improve micronutrients status of population to prevent deficiency disorders due to iodine or / and iron. The fortified salt can also be used for cattle.

Salient Technical Features: Iodine and iron deficiencies are widely present in the country. The micronutrients can be conveniently delivered through common salt. NIN has developed a simple and inexpensive technology to fortify common salt with iodine or/and iron: (i) powdering of crystal salt to uniform size in a crusher (ii) mixing powdered salt with iodine or/and iron chemicals in the right proportion along with appropriate stabilizers for nutrient retention, in a blender for a specified time (iii) packaging of the fortified salt. Dry mixing technology and uniform distribution of the micro-nutrients are the salient features of the present technology. Single Fortified Salt (SFS) technology is in production state. Approximately Rs. 3 lakh investment is sufficient for producing 2000 kg/day.

Scale of Development: The technology is at the level of industrial scale.

Status of Commercialization: Technology has been transferred to six Indian companies.

Salt Testing Kit

Product/Process: Rapid testing kit for iodine/iron in edible salt.

Application/Uses: To estimate quickly iodine/iron content of fortified salt under field conditions.

Salient Technical Features: Salt is fortified with micronutrients such as iodine and iron. It is often necessary to know their contents to ensure that the consumers get the quality product. This can be assured if a rapid test is available for use under field condition. Very few such rapid kits are available in the market. The present kit consists of (i) two reagent solutions (one for iodine and one for iron) in 10 ml capacity plastic dropper bottle; and (ii) standard colour gradation chart for iodine (0, 7, 15, and 30 ppm) and iron (0, 500, 850, and 1000 ppm). To a pinch of salt placed in a white background, a drop of the reagent solution is added and a colour produced is at the consumer level are > 15ppm iodine and > 850 ppm iron. One reagent bottle lasts for 100-200 tests. The testing can be done by any person.



Scale of Development: The technology has been developed up to pilot scale.

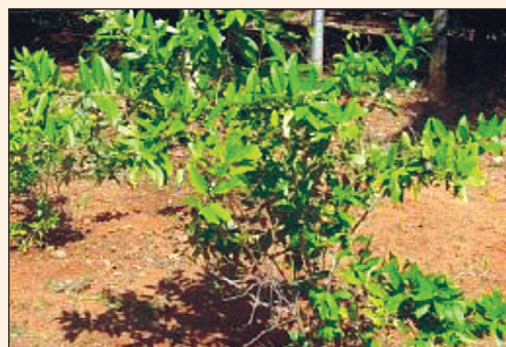
Status of Commercialization: Technology commercialization is being explored.

Herbal Leaf Powder for Tibial Dyschondroplasia in Poultry

Product/Process: Herbal leaf powder for poultry.

Application/Uses: This new formulation is used as source of nutritional manipulation in the feed of poultry to improve the bone strength and egg shell thickness. In broilers, it increases bone weight, density, strength and body weight on one hand and reduces the bone disease tibial dyschondroplasia on the other.

Salient Technical Features: Leg weakness is the major problem in fast growing broilers. Tibial dyschondroplasia femoral degeneration which is common in broilers may be controlled by nutritional manipulation. A continuing concern of the poultry industry is the



high incidence (12%) of egg loss in the laying house due to poor egg shell quality. Calcium homeostasis is a key factor in egg shell formation. It has been noticed that leg weakness in broilers and egg shell thickness in layers were significantly increased with supplementations of 1, 25(OH)2D3. *Cestrum diurnum* has been identified as a cheap, natural and rich source of 1, 25(OH)2D3.

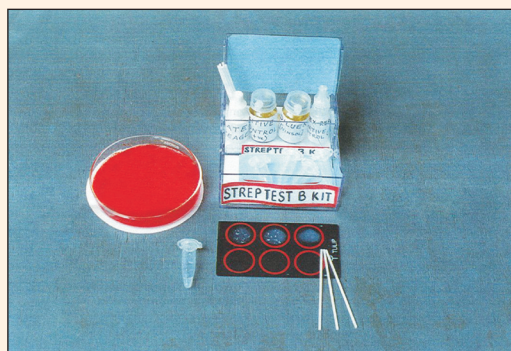
Scale of Development: This technology has been developed up to laboratory scale.

Status of Commercialization: Technology commercialization is being explored.

Immunodiagnostic Kit For *Streptococcus agalactae*

Product/Process: Latex agglutination kit for *Streptococcus agalactae*.

Application/Uses: It is used for the detection of sub-clinical infections in laboratory animals. It is applicable in veterinary medicine, bovine streptococcal mastitis and dairy farms. It is also applied to monitor the infection in throat, UTI, neonatal septicemia and septic abortions.



Salient Technical Features: The developed immunodiagnostic kits for *Streptococcus agalactae* (Group B) were checked for cross reactivity with a number of bacterial pathogen viz. *Streptococcus A, C, D, S. pneumoniae, S. aureus, Corynebacterium diphtheria, E. coli, Salmonella typhimurium* and *Proteus vulgaris*.

Scale of Development: This technology has been developed up to laboratory scale.

Status of Commercialization: Technology commercialization is being explored.

Institute of Cytology & Preventive Oncology (ICPO), Noida

Product/Process: A device for visualizing the pre-cancerous and cancer lesions of uterine cervix and oral cavity

Application/Uses: Useful instrument for the detection of pre-cancerous and cancer lesions of uterine cervix and oral cavity in low resource settings.

1. AV Magnivisualizer is a low cost illumination device for visualizing the cervix which can be used, where there is no cytology and colposcopy facilities are available.
2. This device can also be used for the screening of early cancer and cancer lesions of oral cavity.

Salient technical feature: This unique device has following features:-

1. This device can be used where electricity is a problem, because it can be operated on 12 volt rechargeable battery
2. White light of AV Magnivisualizer has colour temperature of 5500⁰K – 6000⁰K with full visible spectrum of light.
3. It was designed to improve the sensitivity of visual inspection. Ordinary torch light may mask many of the features of the lesions (e.g. colour, contour



margins etc.). That may result missing some of the lesions or may interfere with identifying biopsy site.

4. Interchangeable magnifying lenses (1+, 2+ and 4+ dioptre) are provided for different magnification. We recommend 1+ and 4+ dioptre combination to be used
5. Handy grip is provided having switch under the right hand thumb so that it can be operated easily.
6. It is light weight (less than 500 grams, excluding battery) and can be easily carried anywhere.
7. AC adapter cum charger having dual use is provided.

Status of Commercialization: An Indian patent has been filed (Application no. 121/DEL/2010) and transferred to a Delhi based company M/s Smart Sciences for Commercialization.

Human Papilloma Virus Testing Method

Process/Process: Dry paper smear method for rapid testing of human papilloma virus (HPV).

Application/Uses: Paper smear can be employed for collection of almost all types of cytologic specimens for molecular analysis such as blood, cervical scrape/smear, fine needle aspirates, ascitic fluid, urine, sputum, amniotic fluid, semen, biopsy imprints and all cultured specimens. The samples can be stored in dry form at room temperature for 10-12 years.

Salient Technical Features: The HPV has been identified as a pathogen associated with the development of the cancer of uterine cervix. Up to 98% cervical cancer cases are found to be positive with HPV. Among 100 types of HPV identified, about 20 types were associated with cervical cancer. The major 'high risk' types are HPV 16 & HPV 18 type and infection of these 'high risk' HPVs leads to a high rate of progression of dysplastic lesions to invasive cancer. Conventionally, the test used for identification of cervical abnormalities (HPV) is Pap test, generally employed for diagnosis of cytomorphological changes in early cervical lesions. But Pap test is not fully reliable. Dry paper smear method is simple, rapid, safe and most convenient for collection, storage and transport of cervical scrapes/ smears and biopsies at room temperature and allow detection of HPV DNA or other gene sequences by a simple PCR method.

Scale of Development: This method has been developed up to laboratory scale.

Status of Commercialization: Technology commercialization is being explored.

Desert Medicine Research Centre (DMRC), Jodhpur

Calotropin, a New Bio Larvicide against vector of dengue

Product/Process: A compound Calotropin useful as an effective vector control agent for dengue.

Application/ Uses: This is first plant extracted larvicidal compound against mosquito vectors of dengue fever and hemorrhagic fever.

Salient technical feature:

- The latex of desert shrub *Calotropis* gives efficacy of killing larvae at a certain concentration.
- It also shows ovicidal action against eggs of *Aedes aegypti*.

Level / scale of development: The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian patent (Application no. 389/DEL/2008) has been filed.

Institute of Pathology (IOP), New Delhi

Detection of Kala-azar and Post Kala-azar Dermal Leishmaniasis

Product/Process: Method for detection of kala-azar and post kala azar dermal leishmaniasis (PKDL).

Application/Uses: The test provides a diagnosis of Kala-azar and PKDL with 96% sensitivity.

Salient Technical Features: PCR assay has been developed to amplify kinetoplast DNA(kDNA) of *Leishmania donovani*. With Indian strain and isolates of *L. donovani*, the assay was sensitive enough to detect kDNA in an amount equivalent to single parasite or less. The minicircles of k DNA have been used as a target for selective amplification of parasite DNA. The identification of conserved sequence elements represents within the kDNA of a given species of *Leishmania* would allow the species specific identification of parasites in clinical samples.

Scale of Development: This method has been developed up to laboratory scale.

Status of Commercialization: Technology is being commercialized.

Monoclonal Antibody for *Chlamydia trachomatis*

Product/Process: Sero var specific monoclonal antibody for *Chlamydia trachomatis*.

Application/Uses: It is used for the diagnosis of *C. trachomatis* infection.

Salient Technical Features: *Chlamydia trachomatis* is a human mucosomal pathogen, which causes three forms of disease, trachoma, genital infection and lymphogranuloma venerum. It is divided into 15 serovar A, B, Ba, C, D, E, F, G, H, I, J, K, L₁, L₂ and L₃ and amongst them D to K are common causes of genital infection throughout the world. To know the prevalent serovar of *C. trachomatis* in female genital tract, genotyping was done using PCR followed by restriction fragment length polymorphism (PCR-RFLP). Predominance of serovar D was found in female genital tract. To develop the indigenous diagnostic assay for *C. trachomatis*, a serovar D specific monoclonal antibody has been developed

using hybridoma technology from an Indian patient's isolate. This developed anti-chlamydial clone can be used for detection of *C. trachomatis* infection.

Scale of Development: This method has been developed up to laboratory scale.

Status of Commercialization: A patent (No.246263) has been granted by Indian Patent office. Technology is being commercialized.

Dot-blot assay for *C. trachomatis* infection

Product/Process: Oligonucleotide primers for amplification and cloning of chlamydial heat shock protein 60 (cHSP60) genes.

Application/Uses: A process for amplifying cHSP60 gene by polymerase chain reaction (PCR).

Salient Technical Features:

- Dot-blot assay for prognosis of severe sequelae to *C. trachomatis* infection using chlamydial heat shock protein 60.
- Sequelae like infertility and ectopic pregnancy in women.
- A pair of oligonucleotide primers for amplifying cHSP60 gene from *C. trachomatis*.
- Amplification is performed by PCR.

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian Patent (Application no. 1861/DEL/2008) has been filed.

Cervical Epithelial Cell Line

Product/Process: Primary Epithelial Cells from Cervical lavage

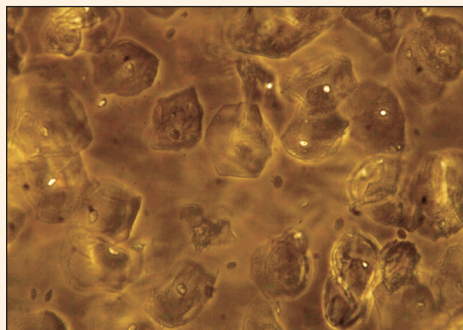
Application /Uses:

- The presently available *in vivo* models, such as tissue explant system or the human tissue xenograft model is widely used to study the impact of microbe cytotoxicity on the vaginal epithelial structure, however, these model system are limited in scale either by tissue sample size or by availability.
- The *in vivo* models such as the transformed cell lines HeLa adenocarcinoma cells, the most commonly used cell line derived from human female lower genital tract mucosa are ideal for long- scale studies because of their relatively longer replicative lifespan before senescence.

- However, the studies that can give insight on how these pathogens modulate the host response and to test feasibility of drugs within a region would be of great importance hence cells of primary human origin are required. These can also be used as model system for various bioassays and vaccine or drugs development.

Salient technical feature:

- 1 A patent application has been filed.
- 2 A derivation of cells from this procedure involves no surgical procedure and is less time consuming.
- 3 The cells would help in understanding the host response associated with the epithelial cells in the female genital tract.



Status of Commercialization: An Indian patent (Provisional Application no 44/DEL/2010) has been filed.

Institute of Immunohematology (IIH), Mumbai

Monoclonal Antibody Development of Foetal Haemoglobin

Product/Process: Development of monoclonal antibody to foetal haemoglobin.

Application/Uses: Murine monoclonal antibody is used accurately to quantitate the cells at low and high values of HbF. This antibody is also used for isolation of foetal cells from the maternal blood by flow cytometry for non-invasive prenatal diagnosis.

Salient Technical Features: Foetal haemoglobin (HbF) forms a predominant component after 8 weeks of gestation. It is increased to a variable extent in several hereditary disorders like β -thalassemia, hereditary persistence of foetal haemoglobin (HPFH), sickle cell anemia, besides acquired hematological disorders like megaloblastic anemia, leukemia, aplastic anemia *etc.* Conventionally, estimation of foetal Hb is usually done by alkali denaturation method. This method is not accurate at low and high values of HbF. Hence, a murine monoclonal antibody has been developed against foetal hemoglobin by cell culture methods which can accurately quantitate the number of F cells in the above conditions. This antibody will also be useful for isolation of foetal cells from the maternal blood by flow cytometry for non-invasive prenatal diagnosis. Such an antibody to foetal Hb is not yet commercially available. This antibody is highly specific as confirmed by immunoblot analysis and also by flow cytometry using mixtures of adult and cord cells in different proportions.

Scale of Development: This technology at present is at laboratory scale. The clones secreting this antibody are well preserved in liquid nitrogen and hence one can get unlimited supply of culture supernatant having the same specificity and sensitivity over a long period of time.

Status of Commercialization: An Indian patent has been filed (Application no. 869/MUM/2001). The technology is being commercialized.

Diagnostic kit for detection of β -Thalassemia Syndromes (RDB KIT)

Product/Process: A Process for the preparation of a diagnostic kit for detection of β -Thalassemia syndromes.

Application/Uses: The kit uses the principle of PCR and reverse dot blot hybridization for detection of common Indian β -Thalassemia Syndromes.

Silent technical features: The kit provides an easy and economical method for detection of six common Indian β -Thalassemia mutations along with two abnormal hemoglobins, HbS and HbE in a single PCR and hybridization step with great accuracy, without using radioactive isotopes and hazardous reagents. This covers about 85 to 90 % of the mutations seen in Indians.

Scale of development: The technology has been developed up to industry scale.

Status of commercialization: An Indian Patent has been granted. (Patent no 194149). The technology has been transferred to M/s Imgenex India Pvt. Ltd., Bhubaneswar, Orissa, India.

Regional Occupational Health Centre (ROHC), Kolkata

Transportation Device

Product/Process: Redesigned model of cycle rickshaw.

Application/Uses: Redesigned model of cycle rickshaw reduces the occupational health problems of cycle rickshaw pullers. The redesigned model is based on “ergonomic principle”. It is a cheap mode of transportation device, extensively used in India and many other South-East Asian Countries.

Salient Technical Features: ROHC developed three models of cycle rickshaw namely, Parthav, Sarathi and Parthasarathi. The model Parthasarathi is considered the best model from both aesthetic and technical point of view. Changes have been made in both the structural and functional configuration which include changes in structure and weight of vehicle, driving mechanism, brake system, hood including drivers hood, passengers seat unit, luggage space and boarding height.

Scale of Development: The technology has been developed up to the laboratory scale.

Status of Commercialization: An Indian Patent (Appl. no. 1643/DEL/2005) and Design application (Class 12-11) has been filed. Technology is being commercialized.



Indian Council of Medical Research (ICMR), New Delhi

Solar powered baby warmer

Product/Process: Solar powered baby incubator and solar powered baby warmer

Application/Uses: The invention is to provide an infant care unit for maintaining the desired temperature of the baby which can run on solar energy as an alternative source of power. It is mobile and/or portable.

Silent technical feature: The invention can be used in newborn corners, sick newborn unit in the sub centre, primary health centre, Community health centre and district hospitals in our country, bedside the home based care of the newborn.

Scale of development: The technology has been developed up to laboratory scale.

Status of commercialization: An Indian patent Application no 2247/DEL/2010 has been filed.

Solar powered portable incubator

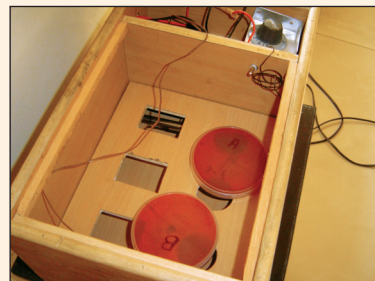
Process/Product: A system for culturing the biological Sample.

Application/Uses: A portable device or apparatus which is useful for culturing biological samples such as blood, urine and other body fluids for microorganisms. The incubator maintains optimal temperature, humidity and other conditions needed for culturing human samples.

Salient technical feature: It is not entirely dependent on electricity but can also function on solar energy hence can be used in rural areas where there is frequent power shortage. It is cheap and economically more viable as the system can be manufactured with material such wood, thermocol.

Scale of development: The technology has been developed up to laboratory scale

Status of commercialization: An Indian patent Application no 1901/DEL/2010 has been filed.



EXTRAMURAL RESEARCH

Promoters of *Mycobacterium tuberculosis*. All India Institute of Medical Sciences (AIIMS), New Delhi

Product/Process: Hypoxia responsive promoters of *Mycobacterium tuberculosis*.

Application/Uses: The study demonstrates the utility of *M. smegmatis* as a surrogate host to study hypoxia responsive promoters of *M. tuberculosis*. The study provides a whole cell assay to monitor *M. tuberculosis* promoter activity and would find use in the screening of compounds that inhibit these promoters.

Salient Technical Features: The environment within granulomas is believed to be hypoxic. *Tubercle bacilli* within this environment are thought to be in a non-replicative persistent state. The current anti-tubercular drug target actively replicating bacilli and therefore persistent bacteria are refractory to the conversational anti-tubercular drugs. Hypoxic or anaerobic conditions and nutrient limitation trigger non-replicative persistence of *M. tuberculosis*. Up-regulation of dev R- dev S under hypoxia suggests the essentiality of this system in the adaptation of *M. tuberculosis* to hypoxic conditions. *M. tuberculosis* being a slow growing pathogen is relatively difficult to handle and hence *M. tuberculosis* a fast growing non-pathogenic species of the same genus, is often used to study these physiological aspects of *M. tuberculosis* that are common to both species. By the use of *M. tuberculosis* model, hypoxia responsive gene activity can be studied and evaluated for the efficacy of candidate compounds in blocking hypoxia - modulated gene expression.

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian Patent has been granted (no. 211217).

Antitubercular Drug Targets from *Mycobacterium tuberculosis*, Delhi University, South Campus, New Delhi

Product/Process: The invention relates to identification of the role of protein tyrosine phosphates (MptpA and MptpB) in the pathogenesis of *Mycobacterium tuberculosis*.

Application/Uses: These secretory proteins represent attractive targets for the development of new anti-tubercular drugs for short-term therapy against tuberculosis.

Salient Technical Features: The invention provides a method for demonstration of the role of MptpA and MptpB in the pathogenesis of *M. tuberculosis*. The mutant strain lacking tyrosine phosphatases associated with either MptpA or MptpB was employed to understand the role of these proteins in the survival of *M. tuberculosis* in murine macrophages and in the ability of the mutants to cause disease in guinea pigs. These mutant strains were constructed by homologous recombination and showed impaired ability to survive in guinea pigs.

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian patent (Application no. 882/DEL/2003) has been filed. A PCT application (Application no. PCT/IN04/00203) has also been filed with countries U.S., Europe, Brazil, Japan and Singapore as national phase applications.

Fractionation of *Adhatoda vasica* leaves. Entomology Research Institute, Chennai

Process/Product: A process for isolation of fraction from *Adhatoda vasica* leaves for antimycobacterial activity.

Application/ Uses: Extracted fraction of *Adhatoda vasica* leaves useful in antimicrobial activity with no side effects. It can be used in medical and pharmaceutical application.

Scale of development: The plant based invention from *Adhatoda vasica* leaves with antimicrobial activity has been generated through ICMR funded project. The invention relates with antimycobacterial activity against tuberculosis. It is developed up to laboratory scale.

Salient technical feature: The novel compounds vasicine acetate and 2-Acetyl benzyl amine work as antimicrobial and are not harmful for human beings. They show good anti-tubercular properties against *M.tuberculosis* and their effect is comparable with standard drugs for curing tuberculosis.

Status of Commercialization: An Indian patent Application no 1025/DEL/2010 has been filed.

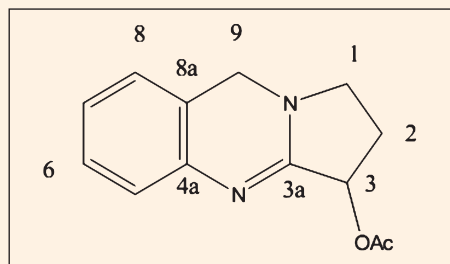


Fig.1. Vasicine acetate

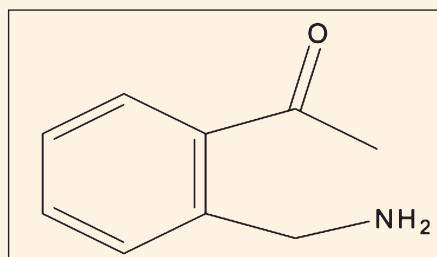


Fig.2. 2-Acetyl benzylamine

Styrene Maleic Anhydride - a male contraceptive. Indian Institute of Technology (IIT), New Delhi

Product/Process: RISUG (Reversible Inhibition of Sperm Under Guidance).

Application/Uses: It is a copolymer compound - Styrene Maleic anhydride (SMA) used as male contraceptive.

Salient Technical Features: The original compound of RISUG is a co-polymer of maleic anhydride and styrene and used as male contraceptive. When it comes in contact of body fluids, the acid maleic anhydride is hydrolyzed and the carboxyl group exerts a pH lowering effect, which is limited to the immediate vicinity of the polymer. The polymer generates electrical charge, which alter normal negative charge of sperm head, resulting in defects on sperm membranes. Because of these defects, sperm enzyme leaches out from the acrosome and sperm loses its fertilizing ability.

Scale of Development: The technology has been developed at laboratory and pilot scale. Phase I and Phase II clinical trials have completed and restricted Phase III clinical trial is underway.

Status of Commercialization: An US patent (no. 5488075) has been granted on this product. Commercialization of this product is being explored.

Process of preparing male contraceptive. Indian Institute of Technology (IIT), New Delhi

Product/Process: Process of preparing injectable copolymer - Styrene Maleic anhydride (SMA).

Application/Uses: This injectable co-polymer used as male contraceptive.

Salient Technical Features: The process comprises of co-polymerizing styrene and maleic anhydride monomer to a polymer having molecular weight ratio of 1:1 subjecting the polymerized product (co-polymer) to the step of irradiation, precipitating solid co-polymer and subjecting the same to the step of washing for the removal of traces of monomers and homopolymers.

Scale of Development: The technology has been developed at both laboratory and pilot scales. Phase I and Phase II clinical trials and restricted Phase III clinical trials are going on.

Status of Commercialization: Two Indian patents (no. 179093 & 183196) have been granted on the process of preparing SMA. Commercialization of this product is being explored.

Fluoride containing Dental Varnish. Sri Ram Institute for Industrial Research, New Delhi

Product/Process: Duraphet - fluoride containing indigenous dental varnish.

Application/Uses: It is used for caries prophylaxis, which permanently bound on the enamel surface and used in treatment of hypersensitive necks of teeth.

Salient Technical Features: Fluoride content in the indigenous varnish ranged from 20510 to 21000 ppm. After post evaluation intervals of 1 week, considerable amount of fluoride leached out. In spite of leaching out of unstable forms of fluoride, the amount retain was statistically significant. This fluoride is relatively permanently bound on surface and responsible for the caries preventive effect of the varnish.

Scale of Development: The technology has been developed up to laboratory and pilot scale at Sri Ram Institute, New Delhi.

Status of Commercialization: A patent has been applied by NRDC, New Delhi. Technology has been transferred to M/s ICPA Health Product, Mumbai.

Anti-neoplastic compound and process for its preparation. University of Kolkata, Kolkata

Product/Process: An anti-neoplastic compound and process for its preparation.

Application/Uses: The invention provides a novel anti-neoplastic compound and obtained from the skin extract of the Indian snake head fish, *Channa striatus*, locally known as shol fish. It also provides a process for the isolation of a novel anti-neoplastic agent useful for therapeutic application in neoplasia and as a biomedical research probe/tool.

Salient Technical Features: A novel and potent anti-neoplastic compound has been purified from the skin extract of Indian common murrel *Channa striatus* by thin layer chromatography followed by two step silica gel column chromatography. The anti-neoplastic compound is devoid of hemorrhagic, hemolytic and defibrinogenating activity. This novel anti-neoplastic compound had no toxic effects on liver and kidney tissues. It possesses haematinic effects and showed potent anti-neoplastic effect in animal (*in vivo*) and human carcinoma cell line studies (*in vitro*).

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: An Indian patent (Application no. 832/DEL/2003) has been granted. Technology is being commercialized.

Anti-diabetic Drug - Vijyasar. Regional Research Laboratory (RRL), Jammu

Product/Process: Vijyasar - an Ayurvedic drug obtained from *Pterocarpus marsupium*.

Application/Uses: It is used in the treatment of newly diagnosed or untreated non-insulin dependent diabetes mellitus (NIDDM).

Salient Technical Features: The therapeutic option in the treatment of NIDDM includes dietary modification. Oral hypoglycaemic effects have been attributed to various active principles in Vijayasar. An active principle epicatechin isolated from the heartwood of the *P. marsupium* was found to have protective and restrictive effect in alloxan-induced diabetic rats. Other active principles are three phenolic constituents viz. marsupin, pterosupin and pterostilbene, which have been shown to significantly reduce the blood glucose level in hyperglycemia. Well conducted clinical trials have been made to see the effect of Vijayasar in NIDDM patients.

Scale of Development: The technology has been developed up to laboratory and pilot scale.

Status of Commercialization: Two Indian patents (no. 192163 and 194292) have been granted. Technology commercialization is being explored.

Herbal Therapeutic Product from *Eugenia jambolana*. University College of Medical Sciences (UCMS), New Delhi

Product/Process: Process for the preparation of an herbal therapeutic product extracted from the pulp of a species *Eugenia jambolana*.

Application/Uses: The product is effective against controlling diabetes mellitus.

Salient Technical Features: The present invention relates to a herbal therapeutic product for controlling diabetes mellitus comprising of at least one hypoglycemic compound extracted from the pulp of fruit *Eugenia jambolana*. The process comprises cleaning and drying the fruit of *Eugenia* to remove extraneous material. De-seeding the fruit and soaking the said de-seeded fruit in water under controlled cooled conditions overnight to retain the activity of hypoglycemic compound.

Scale of Development: The technology has been developed up to laboratory scale.

Status of Commercialization: Three patents have been granted (US Patent no. 6,428,825 and two Indian patents no. 216784 & 188759).

Resistance Modifying Agent against Multidrug Resistance. Chittaranjan National Cancer Institute (CNCI), Kolkata

Product/Process: Non-toxic Resistance Modifying Agent (RMA) against multi-drug resistance.

Application/Uses: Application of non-toxic RMA sensitizes drug resistance cell to anti-cancer drugs and overcome the problem of multidrug resistance (MDR).

Salient Technical Features: The development of this product is based on transition metal and organic moiety (ligand). Three transitional metal complexes of same ligand have been prepared and exhibit resistance modifying properties. By the application of RMAs along with anticancer drug (doxorubicin), the life span of mice increased tremendously. The study was performed in mouse model with drug resistance *Ehrlich ascites* carcinoma cells and drug resistance-lewis lung carcinoma cells. The metal complexes are novel and characterized by detailed spectroscopic studies.

Scale of Development: The technology has been developed up to laboratory and pilot scale.

Status of Commercialization: A patent (Application no. 1210/DEL/2004) has been filed at Indian Patent Office, New Delhi. Technology commercialization is being explored.

New phosphor based UVB phototherapy lamp. Baba Ramdeo Kamla Nehru Engineering College, Nagpur

Product/Process: A process to prepare rare earth activated phosphor compounds.

Application / Uses: The present invention relates to new, narrow UVB emitting phosphors for indigenous production of narrow UVB phototherapy lamps.

Salient Technical Features:

- Rare earth activated phosphor compound are prepared in a single step.
- These phosphors are produced from indigenously available raw materials.
- The process of preparation of these phosphors is cost effective.



Scale of Development: The technology has been developed up to laboratory scale.

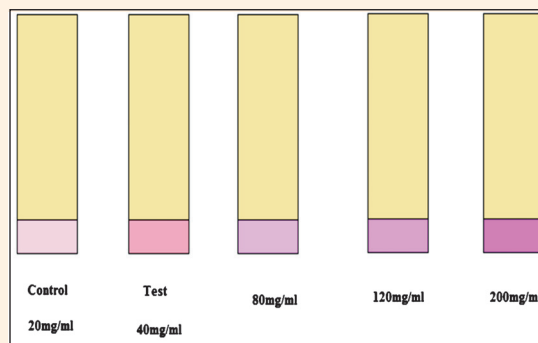
Status of Commercialization: An Indian Patent (Application no. 2665/DEL/2006) has been filed.

Disposable strip for detection of urinary oxalate. Maharshi Dayanand University Rohtak

Process/Product: Disposable strip for semi-quantitative analysis of urinary Oxalate with the help of chromogen o-toluidene.

Application/Uses: This strip can be used by the patient at his/her bedside without the help of a laboratory and skilled person to diagnose primary/secondary hyperoxaluria.

Salient technical feature: This invention is more fruitful as most of prior art describing quantitative oxalate determination has one or more limitations such as requirement of laboratory, skilled person for analysis and time consuming process, therefore it is not possible for the patient to test the urine at his/her bedside. It is of great ease and provides instant and reliable result within 30 seconds. It is cheap and economically available to the purchasing public.



Scale of development: It is developed up to laboratory scale.

Status of commercialization: An Indian patent Application no 2989/DEL/2010 has been filed.

Disposable strip for detection of urinary oxalate

Process/Product: Disposable strip for semi-quantitative analysis of urinary Oxalate with the help of chromogen o-dianisidine.

Application/Uses: This strip can be used by the patient at his/her bedside without the help of a laboratory and skilled person to diagnose primary/secondary hyperoxaluria.

Silent technical feature: This invention is more fruitful as most of prior art describing quantitative oxalate determination has one or more limitations such as requirement of laboratory, skilled person for analysis and time consuming process, therefore it is not possible for the patient to test the urine at his/her

bedside. It is of great ease and provides instant and reliable result within 45 seconds. It is cheap and economically available to the purchasing public.

Scale of development: It is developed up to laboratory scale.

Status of Commercialization: An Indian patent Application no 2990/DEL/2010 has been filed.

**A rapid invitro method for screening low density lipoprotein subfraction.
All India Institute of Medical Sciences, New Delhi**

Process/Product: A rapid invitro method for high through put screening of small dense low density lipoproteins (sd LDL) by 3% Polyacrylamide Slab Gel Electrophoresis (PASGE).

Application/Uses: It provides a redesigned, gel electrophoresis having changes incorporated into the percentage of gel concentration, number of gel beds (dual) and number of wells. The dual slab gel electrophoresis setup comprises of an Upper buffer chamber and lower buffer chamber, glass plates, clamps, combs & wells and dual assembly. The apparatus is constructed with Acrylic sheet to make the setup resistant to traditional buffers.

Salient technical feature: This method is simple, rapid, uses native polyacrylamide slab gel electrophoresis for screening large number of samples for LDL subfractions.

The invention is to provide a simple screening technique for low density lipoprotein subfractions. It is a rapid technique and a technique in which more number of samples for screening LDL are loaded or processed making it suitable for screening large number of samples for small, dense low density lipoproteins (sd LDL).

Status of commercialization: An Indian patent Application no 2551/DEL/2008 has been filed.

Annexure

List of ICMR Patents

<i>Sl. No.</i>	<i>Year of filing</i>	<i>Country</i>	<i>Title of the patent</i>	<i>Institute</i>
1	1989	India	A process for the preparation of an injectable copolymer for use as a contraceptive by male	IIT, Delhi
2	1991	India	A process for the production of Thrombinase, a blood clot dissolving enzyme from <i>Bacillus</i> sp.	VCRC, Puducherry
3	1993	USA	A process for the production of Thrombinase, a blood clot dissolving enzyme from <i>Bacillus</i> sp.	VCRC, Puducherry
4	1994	USA	Contraceptive for use by a male	IIT, Delhi
5	1994	India	A process for the preparation of Cyclosporin A	VCRC, Puducherry
6	1994	Canada	A process for the preparation of Cyclosporin A, an immunosuppressant from <i>Tolypocladium</i> sp.	VCRC, Puducherry
7	1994	USA	Process for the preparation of Cyclosporin a <i>tolypocladium</i> sp.	VCRC, Puducherry
8	1994	India	Slow release and wettable powder formulation from <i>Bacillus sphaericus</i>	VCRC, Puducherry
9	1994	India	A process for the preparation of a contraceptive for use by a male	IIT, Delhi

<i>Sl. No.</i>	<i>Year of filing</i>	<i>Country</i>	<i>Title of the patent</i>	<i>Institute</i>
10	1995	India	Mechanical mosquito sampler	DMRC, Jodhpur
11	1995	India	Kshaarsootra-medicated thread-Improved indigenous machine for production of coated threads	RRL, Jammu
12	1996	Europe	A process for the preparation of Cyclosporin A	VCRC, Puducherry
13	1998	India	A new tissue schizontocidal and gametocytocidal drug in the treatment of malaria	MRC, New Delhi
14	1999	USA	Oral recombinant cholera vaccine	NICED, Kolkata; CSIR, New Delhi and DBT
15	1999	India	ELISA diagnosis for rotavirus	NIV, Pune
16	1999	India	A process for isolation of <i>Pterocarpus marsupium</i>	RRL, Jammu
17	1999	India	A process for preparation of a mixture of hypoglycemic compounds	UCMS, New Delhi
18	1999	India	Mosquito larvicidal preparation of <i>B. thuringiensis</i> var <i>israelensis</i>	VCRC, Puducherry
19	2000	India	Standard antidiabetic formulation of plant origin	RRL, Jammu
20	2000	India	An herbal therapeutic product	UCMS, New Delhi
21	2001	India	Monoclonal antibodies to foetal haemoglobin	IIH, Mumbai
22	2001	India	Insect repellent device	NIV, Pune
23	2001	India	Chimeric T-helper - B Cell peptide vaccine against <i>Japanese Encephalitis</i> virus	NIV, Pune
24	2001	India	A process for the production of mosquito oviposition attractant	VCRC, Puducherry

<i>Sl. No.</i>	<i>Year of filing</i>	<i>Country</i>	<i>Title of the patent</i>	<i>Institute</i>
25	2001	India	A process for the production of mosquitocidal compound	VCRC, Puducherry
26	2001	India	Mosquito larvicidal preparation of <i>Bacillus thuringiensis</i> var <i>israelensis</i> - Process patent	VCRC, Puducherry
27	2001	India	Diagnostic kit for detection of β -thalassemia syndromes	NIH, Mumbai
28	2002	USA	Species - specific PCR assay for detection of <i>Leishmania donovani</i> in clinical samples of Kala - azar and post- Kala azar dermal leishmaniasis	IOP, New Delhi
29	2002	USA	The preparation in immune goat colostrums against rotavirus	NIV, Pune
30	2002	USA	Process for the preparation of an herbal therapeutic product extracted from the pulp of species <i>Eugenia jambolana</i>	UCMS, New Delhi
31	2003	India	A simple and fast process for evaluating promoter activity of persistent <i>M.tuberculosis</i> in hypoxic conditions using <i>M.smegmatic</i> as a surrogate host	AIIMS, New Delhi
32	2003	India	A novel cobalt complex useful for reversal of resistance and the preparation thereof	CNCI, Kolkata
33	2003	USA	A cytological specimen loaded filter paper and an efficient method of using the same for dry collection, transportation and storage to screen for infection using PCR.	ICPO, New Delhi
34	2003	India	Monoclonal antibody from <i>Chlymadia trachomatis</i>	IOP, New Delhi

<i>Sl. No.</i>	<i>Year of filing</i>	<i>Country</i>	<i>Title of the patent</i>	<i>Institute</i>
35	2003	USA	Chimeric T-helper - B Cell peptide vaccine against Japanese encephalitis virus	NIV, Pune
36	2003	Philippines	Chimeric T-helper - B Cell peptide vaccine against Japanese encephalitis virus	NIV, Pune
37	2003	Japan	Chimeric T-helper - B Cell peptide vaccine against Japanese encephalitis virus	NIV, Pune
38	2003	Korea	Chimeric T-helper - B Cell peptide vaccine against Japanese encephalitis virus	NIV, Pune
39	2003	India	A herbal anti-diabetic compound and the process thereof.	UCMS, New Delhi
40	2003	India	A process for the isolation of novel anti-neoplastic compound useful for pharmacological purposes	UCST, Kolkata
41	2003	India	Tyrosine phosphatases of <i>Mycobacterium tuberculosis</i> as potential targets for developing antitubercular drugs	University of Delhi South Campus and TRC, Chennai
42	2003	India	Nephthaquinone analogue against macrofilaricidal activity	VCRC, Puducherry
43	2003	India	Macrofilaricidal activity of the fruit extract of <i>Trachyspermum ammi</i> against adult filarial worm	VCRC, Puducherry
44	2003	India	Mosquito larvicidal preparation of <i>Bacillus thuringiensis</i> var <i>israelensis</i> - Product patent	VCRC, Puducherry
45	2004	India	Larvicidal properties of leaf extract of <i>Solanum nigrum</i> Linn.	NIMR (MRC), New Delhi
46	2004	India	Nisin peptide for spermicidal/ contraceptive properties.	NIRRH, Mumbai

<i>Sl. No.</i>	<i>Year of filing</i>	<i>Country</i>	<i>Title of the patent</i>	<i>Institute</i>
47	2005	India	New plant (<i>Vallarina jatamanasi</i>) based insecticide for mosquito control	NIMR (MRC), New Delhi
48	2005	India	Preparation of Holey/Lacey carbon films using a novel method	NICED, Kolkata
49	2005	India	Transportation device	ROHC, Kolkata
50	2005	Europe	Mutants of <i>Mycobacterium</i> and process thereof	University of Delhi South Campus and TRC, Chennai
51	2005	Singapore	Mutants of <i>Mycobacterium</i> and process thereof	University of Delhi South Campus and TRC, Chennai
52	2005	US	Mutants of <i>Mycobacterium</i> and process thereof	University of Delhi South Campus and TRC, Chennai
53	2005	Japan	Mutants of <i>Mycobacterium</i> and process thereof	University of Delhi South Campus and TRC, Chennai
54	2005	Brazil	Mutants of <i>Mycobacterium</i> and process thereof	University of Delhi South Campus and TRC, Chennai
55	2005	India	Microbial fermentation process using bird feather for the production of biopesticides	VCRC, Puducherry
56	2006	India	Expression of virulence factors of <i>M. leprae</i> in human host during infection by functional genomic approaches	NJIL&OMD, Agra
57	2006	India	Novel primers for a PCR-RFLP assay for identification of pathogenic mycobacteria	NJIL&OMD, Agra and DBT, New Delhi
58	2006	India	Rare earth activated phosphor compounds and the process of preparation thereof	RKNEC, Nagpur
59	2006	India	Biocidal composition and preparation thereof	VCRC, Puducherry

<i>Sl. No.</i>	<i>Year of filing</i>	<i>Country</i>	<i>Title of the patent</i>	<i>Institute</i>
60	2006	India	A process for diagnosis of infective (L3) stage larvae of <i>Wuchereria bancrofti</i> in vector mosquito <i>Culex quinquefasciatus</i>	VCRC, Puducherry
61	2007	India	A new botanical formulation for mosquito control	NIMR (MRC), New Delhi
62	2007	India	Probes and primers for identification of mycobacterial protein useful as potential drug targets	NJIL&OMD, Agra
63	2007	India	A set of oligonucleotide probes, primers and DNA chip	NJIL&OMD, Agra and DBT, New Delhi
64	2008	India	Calotropin, a new biolarvicide against vector of Dengue	DMRC, Jodhpur
65	2008	India	Development of Dot Blot assay for prognosis of sequelae to <i>Chlamydia trachomatis</i> infection in women using chlamydial heat shock protein 60	IOP, New Delhi
66	2008	India	Immunodiagnostic reagent as an antibody probe from detection of <i>Plasmodium vivax</i> antigen	NIMR(MRC), New Delhi
67	2008	India	Highly active extract(s) from the roots of the plant <i>Brucea mollis</i> for in vitro antiplasmodial/antimalarial activity.	RMRC, Dibrugarh
68	2008	India	Pot staining of sputum for detection of acid fast bacilli	TRC, Chennai
69	2008	India	A cyclic lipopeptide of <i>Bacillus subtilis</i> ssp. <i>subtilis</i> (VCRC B471) with potential to kill mosquito stages	VCRC, Puducherry
70	2008	India	New bacterial culture media for the production of mosquito pathogenic Bacilli using industrial wastes	VCRC, Puducherry

<i>Sl. No.</i>	<i>Year of filing</i>	<i>Country</i>	<i>Title of the patent</i>	<i>Institute</i>
71	2008	India	Composition useful for identification of microorganism of interest	TRC, Chennai
72	2008	India	IA rapid 3% polyacrylamide slab gel electrophoresis method for high through put screening of LDL phenotype	AIIMS, Delhi
73	2009	India	Active principles of <i>Cl. Collinus</i> extract are proton transport inhibitors	CMC, Vellore, Tamil Nadu
74	2009	India	A novel method of culturing human epidermis for autologous grafting in burns	IOP, Delhi
75	2009	India	Formulation of the lung surfactant protein SP-D against sexually transmitted infections including HIV	NIRRH, Mumbai
76	2010	India	A luciferases reporter phase assay for detection of tubercle bacilli	TRC, Chennai
77	2010	India	A process for isolation of fraction from <i>Adhatoda vasica</i> leaves that exhibit antimycobacterial activity	ERI, Chennai
78	2010	India	Disposable strip for semi-quantitative analysis of urinary oxalate	MDU, Rohtak, Haryana
79	2010	India	Disposable strip for semi-quantitative analysis of urinary oxalate	MDU, Rohtak, Haryana
80	2010	India	A system for storing, maintating and culturing the biological sample (Solar Powered Portable Culture Incubator)	ICMR, New Delhi
81	2010	India	A novel protein of <i>Salmonella typhi</i> as a probable subunit vaccilne	NICED, Kolkata

<i>Sl. No.</i>	<i>Year of filing</i>	<i>Country</i>	<i>Title of the patent</i>	<i>Institute</i>
82	2010	India	Solar powered baby warmer	ICMR, New Delhi
83	2010	India	A novel mutation detection assay for Sabin oral poliovirus vaccine	ERC, Mumbai
84	2010	India	A device for visualizing the pre-cancerous and cancer lesions of uterine cervix and oral cavity	ICPO, Noida
85	2010	India	Development of primary cervical epithelial cell line	IOP, Delhi
86	2011	India	An antibacterial and antiviral compound	TRC, Chennai
87	2011	India	Superior and simple method to isolate VSELs without the use of Flow Cytometry	NIRRH, Mumbai