VINKEM LABS LIMITED

INNOVATION & EXCELLANCE ARE OUR PASSION

Accessible & Affordable Care for Cancer Patients in the World

COMPANY PROFILE

- **Vinkem Labs Limited, --Established in the year 1994 for the Research and manufacturer Oncology API molecules out of Vinca Rosea Leaves – a dry land traditional herb cultivated by small and marginal farmers and exported to west for the last 3 decades.**

- **Vinkem's scientific & Technical expertise in manufacturing "difficult to make" niche Oncology products have made it a partner of choice for its customers.**

- **Vinkem is a pioneer in manufacturing Vinorelbine Tartrate by isolation of its intermediates from Vinca and with state-of-art technology. Vinflunine is the latest addition to their oncology basket.**

PROMOTER'S PROFILE

- The promoter, Mr. M. PERUMAL a technocrat having 35 years specialized experience in the field of Natural product isolation, semisynthetic, synthetic molecule Chemistry and Pharma world.
- Varied experience in multi-functional fields - R&D, API Production, Formulation development, Aseptic Filling, Quality Control.
- Pioneer and the only manufacturer of Vinblastine, Vincristine, Vinorelbine , Vinflunine & Vindesine, Cyclophosphamide, Ifosfamide in India.
- Member on the board of studies at Madras University and SIET College for curriculum in Chemistry.
- Developed in-house technical know-how for very large number of oncology and high value low volume molecules Viz. Cyclophosphamide, Ifosfamide, Topotecan, Irinotecan, Docetaxel, Paclitaxel, Oxaliplatin, Carboplatin, Cisplatin, Zoledronic acid, Gemcitabine, Pemetrexed, Reserpine, Colchicine, Thiocolchicine, Coleus forskholin, Solanesol, Co-enzyme Q10, Buprenorphine, Dibekacin, Bortezomib Bendamustine etc.
- Participant of various International Pharma meets, trade shows, US FDA workshops and Indian Delegation.

VINKEM

1994

Birth of Vinkem

R&D, API plant Establishment work 1996-97

1998 – 2007

Manufacture of Oncology API

R&D got DSIR approval

2003 - Debt Free

2007 – 2012

25 MUS$ Fresh Investment on USFDA Compliable Dedicated Oncology

a. API Facility. (WHO-GMP in 2007)

b. Aseptic Filling Liquid and Lyophilized Oncology Injectable

2012 Jan – Commercial Operation.

Injectable facility got WHO-GMP in 2014.

A world class dedicated oncology API and Injectable facility with unique molecules and 1 Billion US$ business potential facility is fully Ready.

Mission Statement

- To utilise Innovation for the benefit of global cancer patients
- To develop a value driven organization with high level of trust, transparency & integrity.
- Establish state of the art facilities to suit the needs of our customers and provide services from concept to commercialization
- Consistently strive to achieve high level of customer satisfaction by means of innovative technologies, systems, processes and people
- To effectively utilize innovative methods to drive the costs down, ensuring that end users who are cancer patients are benefitted
- To develop a value driven organization with high level of trust, transparency and integrity
- To Commit ourselves to society by being conscious about environment and safety

Vission

- To be the most preferred partner of choice for customers and industries through innovation, quality and competitive pricing.
- To nurture a skilled and motivated team of employees to address the needs of medical fraternity and end user
- To provide cost effective treatment for patients and reduce their disease burden.
- To be guided by our values of trust, transparency, integrity and social consciousness.

FACILITIES

R&D Lab

Approved by

Department of Science & Technology, India.

API

USFDA

Compliable

Injectables

USFDA

Compliable

Injectable Facility

- State of the Art cGMP Facility, compliable to all Regulatory requirements : USFDA, EMA, PMDA and other regulatory bodies.
- Bosch Germany Filler with RABS Technology
- Integrated Vial Washing & Depyrogenation Tunnel
- Fill volumes from 2.0 to 50 ml with IPC
- Lyophilizer with 7.5 M3.
- Equipment & Instruments are SCADA 21 CFR Compliant.
- Facility access using Sciemen's Bio-metric control and BMS.
- Environmental monitoring using continuous SMA and PMS Systems.
- Global Marketing Sales
- Contract Manufacturing available.


BOSCH

Finish Dosage Products (injectable)

- Carboplatin
- Cisplatin
- Cyclophosphamide (Lyo)
- Ifosfamide (Lyo)
- Daunorubicin
- Docetaxel
- Doxorubicin
- Epirubicin
- Etoposide
- Gemcitabine (Lyo)
- Irinotecan
- Oxaliplatin
- Paclitaxel
- Pemetrexed (lyo)
- Topotecan
- Vinblastine
- Vincristine
- Vinorelbine
- Vindesine (Lyo)
- Vinflunine
- Zoledronic Acid

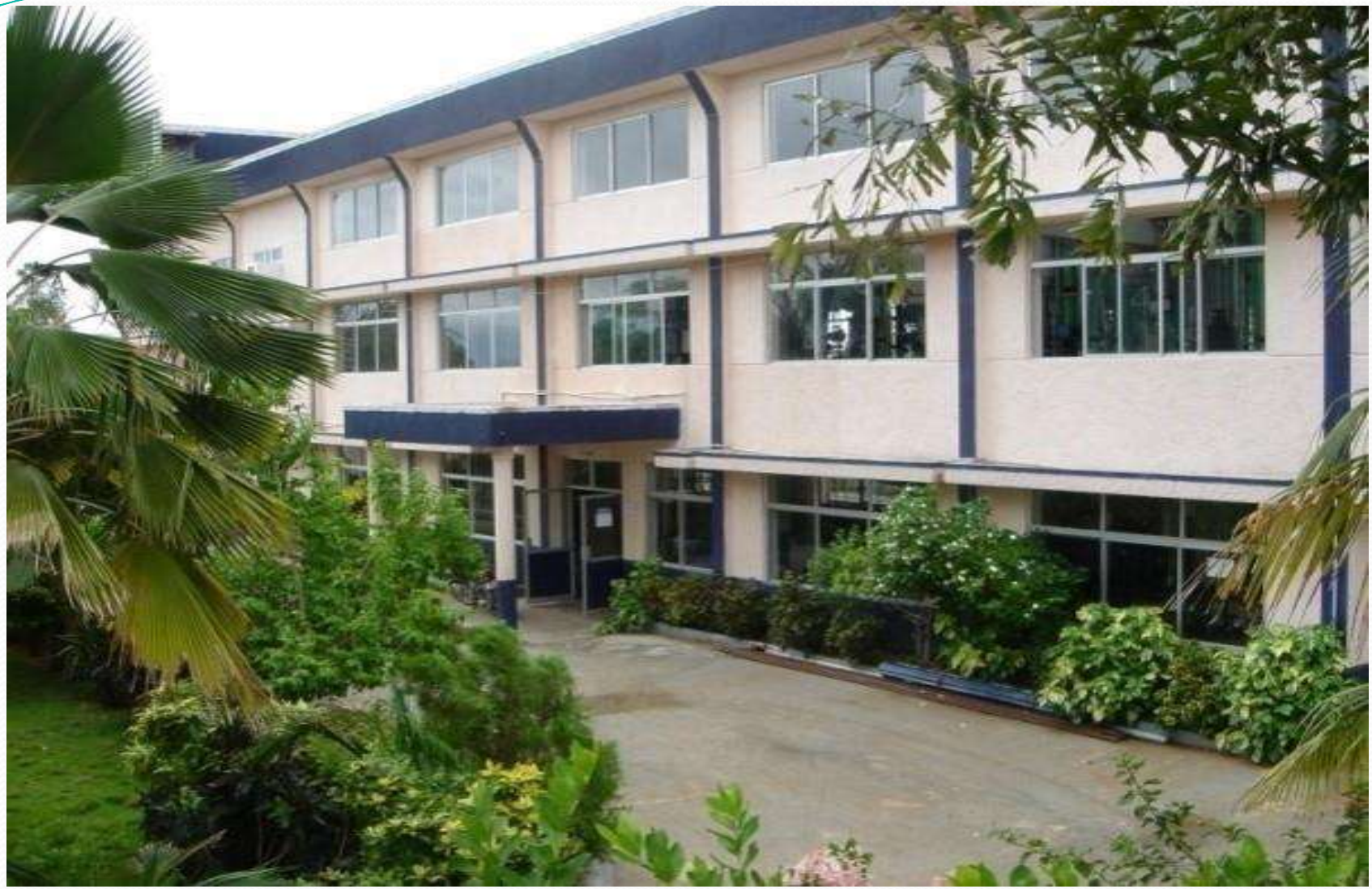
Products – API's

- Vinblastine sulfate
- Vincristine sulfate
- Vindesine sulfate
- Vinorelbine tartrate
- Vinflunine tartrate
- Cyclophosphamide
- Ifosfamide
- Carboplatin
- Oxaliplatin
- Cisplatin
- Docetaxel
- Paclitaxel
- Irinotecan
- Topotecan
- Bortezomib
- Bendamustine
- Zoledronic acid

API Facility

- Dedicated Oncology Facility - cGMP/USFDA standards
- Extraction of Natural products (5 Mt/day) from plant material.
- Isolation and Semi-synthesis of API from plant extracts
- Synthesis difficult to make high value low volume products.
- DMFs for the Products in CTD format are ready to file
- Expertise in handling hazardous reaction involving triisobutyl aluminium, Super acid, HF, Hydrogenation, Fluorination, highly active metals like K, cryogenic reaction, molecular distillation, Isolation technology using commercial Preparatory HPLC, high pressure reactions etc.

Precious metal complexes synthesis, hazardous phosphorus molecules synthesis



GROWTH DRIVERS FOR THE COMPANY

US FDA, EU EMEA Approval

Global Sales

Finish Dosage **INJECTABLE**

USFDA Std.

Oncology API Manufacture

USFDA Std.

R&D Technology Development

CURRENT STATUS

API Facility

- Facility established and operated as per USFDA norms,
- Validation Batches taken few molecules and DMF are in place.
- The API product out of this supplied to Injectable facility.
- Documents to be filed with USFDA/ EMA are ready.
- **Work to be done before Filing:**

a. Required Manpower for QC/QA to be recruited
b. Facility / equipment to be re-validated
c. All the documents to be updated.

Current Status – Injectable facility

Facility is fully ready for Regulated, Semi-Regulated and Domestic market

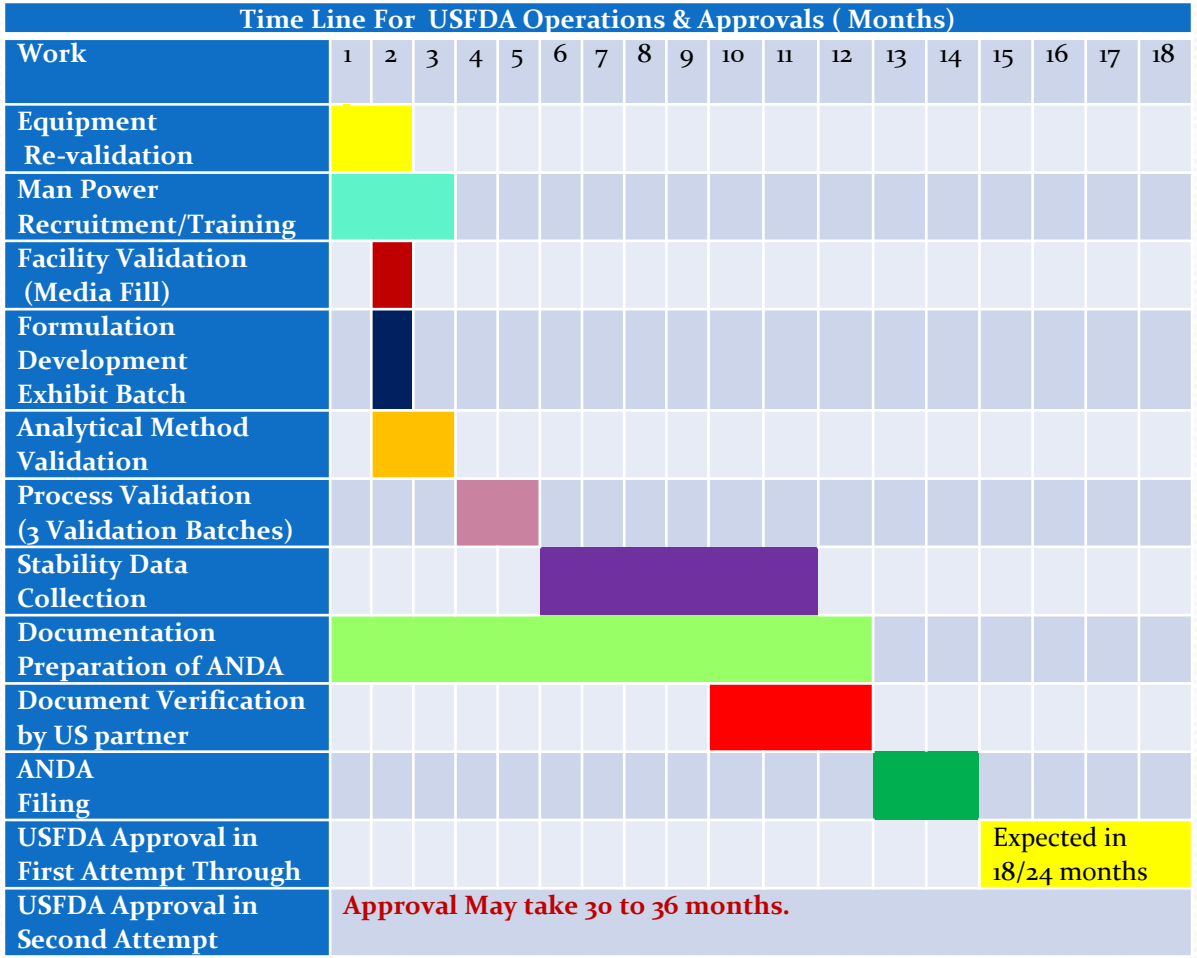
- The Facility was operated as qualified as per cGMP and validated by USFDA Aseptic Fill Finish Expert from PDA.
- 21 Molecules 46 product manufactured out of this facility.
- WHO- GMP Certification got in April 2013.
- Documents of SOP/STP are in place
- Oncology product in liquid and lyophilized form ANDA can be filed in 12 month time.
- Capacity:

Vial Size Fill volume	Line Speed Vials/minute	Lyophilized vials Max Batch size	Liquid Vials Max Batch size
2 ml	120	Nil	100,000
10 ml	100	12,000	100,000
30 ml	60	8,000	50,000
50 ml	25	3,800	20,000

US FDA and EU Approvals and Marketing

- Facility created for USFDA and EMA market purposes with installation of world top rank equipment to give 100% perfection and satisfaction for the regulatory authorities.
- Facility meets latest cGMP requirements of 100% SAL, Contineous monitoring of Active and Inactive particles, Zero error in operations, SCADA, 21 CFR compliant full traceability. Very few to find such a facility in the world and they have been used only for NDA approved high value products.
- Number of Aseptic Filling Oncology facility is very limited in the world and there is great shortfall in supply in USA. More number of old USFDA approved injectable facility keep on getting more citation and struggling to meet the current 100% SAL and Particle monitoring conditions.
- More than dozen International buyers visited the facility to check the fitness of the facility for USFDA. Singed CDA and Business Agreement negotiations are in progress.

USFDA Approval Plan



Unique Project with High Business Potential

- 20 years-Technology driven strong focus on R&D and innovation.
- Dedicated Oncology facility with world top ranking high end plant & Machinery to suit current USFDA requirements .
- Project Implementation, training of personnel, validation of equipment and facility validation by medial fill – all done by USFDA / PDA approved Subject Matter Expert.
- Wide range of oncology injectable with in-house API source – Competitive Benchmarking with MNC -Affordable cost and advantage
- Pioneer in India & innovator to isolate all the 5 vinca alkaloids . Only two approved source for Cyclophosphamide High tech product – Combining with Ifosfamide the business potential can be around 1 Billion US$
- Good prospects to sell APIs and Formulations in regulated markets post USFDA/ EDQUM approval.
- Launch of Vinflunine, Abirateron and few more new molecules (after Patent expiry); Nano particle – Liposomal cytotoxic molecule API and Formulation manufacture are in very advanced stage.
- Ready infrastructure available to accommodate two more injectable filling line.
- Oral Soli dosage (Soft gel/capsule/tablet) facility for cytotoxic molecules facility is in active plan. This will makes VINKEM -A COMPLETE ONCO PRODUCT SOURCE. Vinorelbine tartrate – oral dosage can be manufactured at 1/10 of the current 380$

VINKEM'S COMMITTMENT

- **BE SURE**
- **WE SERVE**


Thank You!