

# Virupaksha Group of Companies



**Virupaksha Organics**

**Virupaksha Labs**



**Vector Bio Sciences**

## About the Company

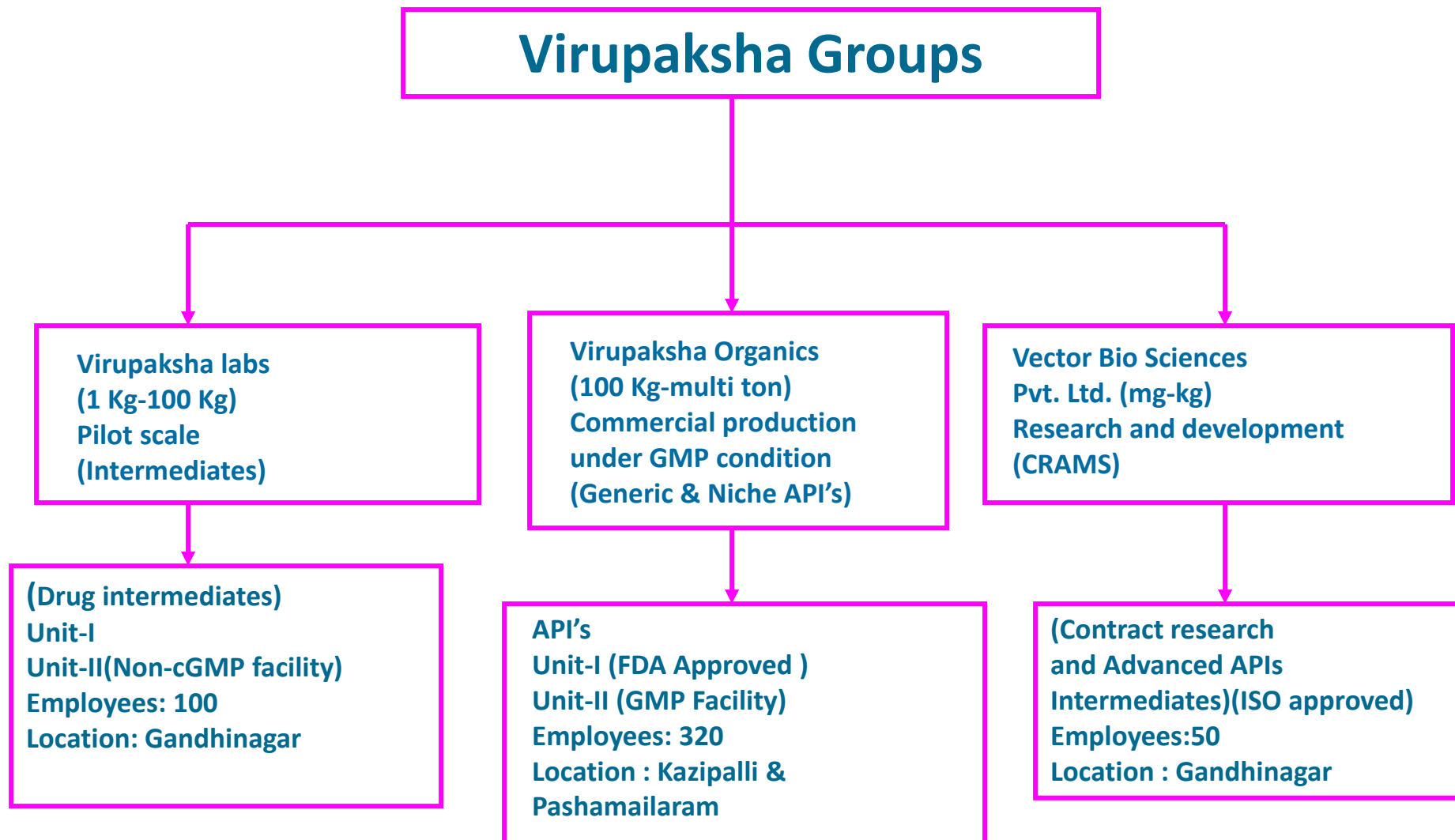
- Virupaksha Group Established in 2003
- Limited Company
- Currently making a revenue of 35 Million USD
- Recently acquired 100 acres land to built Virupaksha Campus

## OUR VISION

*“To become a one-stop destination for global companies that require chemistry services starting from lead generation till commercial production (mg to multi ton)”*

# Company Location and Services

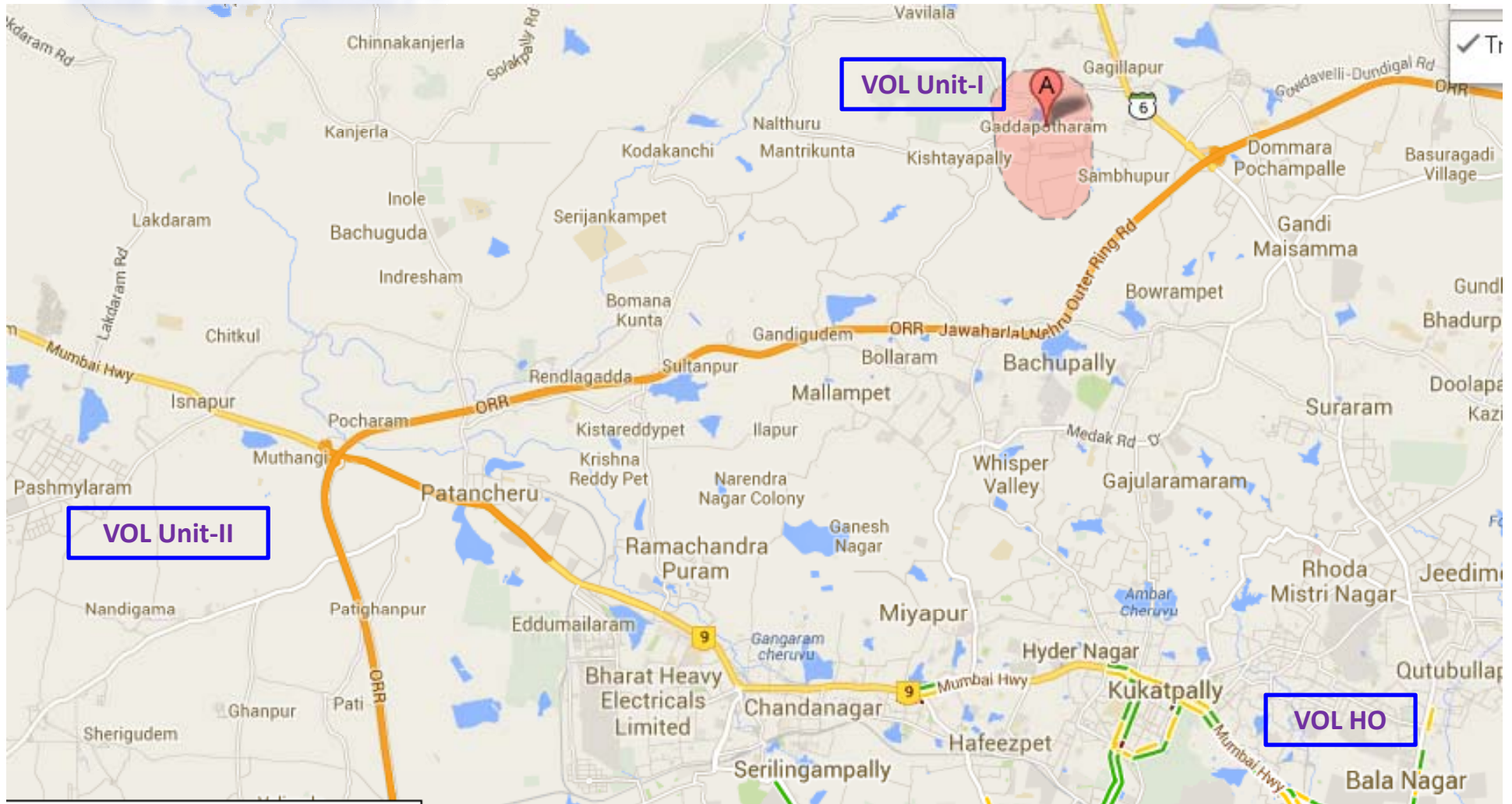
## Virupaksha Groups





# VIRUPAKSHA ORGANICS LIMITED

Site information :



❖ 35 Kms from the Hyderabad city & 75 Kms from Hyderabad Airport



# VIRUPAKSHA ORGANICS LIMITED

## Site information

### Area of the factory :

Total area : 17742 sq. meters

Build up : 4090 sq. meters

### Manufacturing blocks :

03 Production blocks & 04 Pharma blocks

### Facility operation Hours :

Facility operates in 3 shifts A,B,C and General shift

Business hours 9:00 to 17:30 Hours

# Our Products

## Generic API's

FLUCONAZOLE  
FEXOFENADIN HCL  
TRAMADOL HCL  
ES-CITALOPRAM OXALATE

INH/USP/EP  
USP/EP  
EP/BP  
INH/USP

ANTI-FUNGAL  
ANTI-HISTAMINIC  
ANALGESICS  
ANTI-DEPRESSANT

## Niche API's

Sofosbuvir  
Ledipasvir  
Daclatasvir  
Efinaconazole  
Obeticholic acid

All the above products are not available in the patent covered areas Responsibility with respect to third parties patent rights in specific country lies exclusively with the buyer.



## Approvals & Certification

Regulatory authority	Certification	Date
ISO 9001-2008	Accreditation	14.01.2013
Schedule "M" GMP	Certification	27.07.2013
WHO - GMP	Certification	22.06.2012
Certificate of Suitability for Fexofenadine Hydrochloride	Revision	10.04.2013
Japanese Accreditation for Fluconazole	Accreditation	14.05.2010
COFEPRIS GMP	Certification	07.05.2013
MFDS, Korea for Tramadol HCl Fluconazole	Certification	16.05.2013 10.02.2014
US FDA for Fexofenadine HCl	Accreditation	23.12.2013

# Reaction Capabilities

- Grignard Reactions
- Phosgenation
- Reduction
- Oxidation
- Sulfonation
- Friedel - Crafts Reaction
- Condensation
- Bromination
- Chlorination
- Methylation
- Nitration
- Esterification
- Hydrogenation







# VIRUPAKSHA ORGANICS LIMITED

## OUR INFRASTRUCTURE

- ❖ ISO 9001 – 2008 & WHO-GMP APPROVED COMPANY
- ❖ THE FINISHED PRODUCT AREA IS EQUIPPED WITH AIR HANDLING SYSTEM OF CLASS 100000 AIR SUPPLY WITH HEPA FILTERS.
- ❖ PROPERLY DESIGNED EFFLUENT TREATMENT FACILITIES AND EFFECTIVE WASTE MANAGEMENT SYSTEMS.
- ❖ QUALITY CONTROL LABORATORY WITH SOPHISTICATED INSTRUMENTS.
- ❖ MICRO BIOLOGICAL LABORATORY.
- ❖ QUALITY ASSURANCE DEPARTMENT.
- ❖ IN PROCESS DEVELOPMENT LABORATORY.
- ❖ PILOT PLANT (PB-03) - AS PER CGMP GUIDELINES IS UNDER REFURBISHMENT



# VIRUPAKSHA ORGANICS LIMITED

- ❖ WARE HOUSE DESIGNED AS PER cGMP WITH STORAGE FACILITY FOR FOR SOLIDS AND TANK YARD FOR THE SOLVENTS.
- ❖ MODERN IN PROCESS DEVELOPMENT FACILITIES WITH ATTACHED PILOT PLANT (PB-03) WITH CAPACITIES FROM 1 KG TO 200 KGS
- ❖ CUSTOM SYNTHESIS AND CONTRACT RESEARCH FACILITIES



# VIRUPAKSHA ORGANICS LIMITED

## The production facilities include

- ❖ Glass lined reactors – 18 No's (0.6 KL – 5KL) - Total capacity - ~ 40.0 KL.
- ❖ SS 316 reactors – 36 No's (0.25 KL – 6KL) - Total capacity - ~ 90.0 KL.
- ❖ Equipment for production isolation and filtration systems like SS316 centrifuges(36" & 48" size), Leaf filters and micron filters.
- ❖ Drying facilities like Tray dryers & Fluid bed dryers.
- ❖ The utilities include
  - ❖ Boiler - 1.5 T/hr. at 10 Kg/cm<sup>2</sup> - 1 No.  
- 2,00,000 K.Cal/hr. - 1 No.
  - ❖ Vacuum pump - 1 TOR - 7 No's.  
- 2 TOR – 6 No's. & 3 TOR – 2 No's
  - ❖ DM water - Through RO Water system – 4kL/hr with conductivity of 2.1 µS/cm
  - ❖ Cooling tower - 725 TR - 5 No's.
  - ❖ Chilling plant - 300 TR at -15°C - 1 No.  
- 200 TR at -10°C – 1 No.
  - ❖ Compressed air system - 1 No.
- ❖ In the manufacturing area all the fittings, fixtures & electrical installations are flame proof.
- ❖ 720 sqm area ware house provision has been made for storage facilities for solvents, acids & alkalis as well as raw materials, packing materials and finished goods
- ❖ 380 KV generator set as an alternate stand by arrangement for power.



# VIRUPAKSHA ORGANICS LIMITED

## Safety, Health and Environment Management System

- ❖ Safe work procedures
- ❖ Safety committee meetings
- ❖ Emergency alarm
- ❖ Emergency safety response team
- ❖ Fire hydrant system
- ❖ Onsite emergency plan
- ❖ Mock drills
- ❖ Safety trainings
- ❖ First aid training program
- ❖ Periodic medical checkup
- ❖ Scrubbers for vent emission
- ❖ Effluent treatment facility with zero discharge

## Analytical Testing Facility(QC)

HPLC	-	WATERS – e 2695 Alliance
HPLC	-	WATERS – Auto-sampler 2707
HPLC	-	SHIMADZU – LC2010 AHT GRADIENT
HPLC	-	SHIMADZU – LC - SPD-10AVP
GC	-	SHIMADZU – GC - GC-17A
GC	-	SHIMADZU – GC - GC-17A
Head space GC	-	AGILENT 7694 series
UV Spectrophotometer	-	SHIMADZU-UV-1800
FT IR Spectrophotometer	-	PERKIN ELMER
Potential meter	-	LASCO-MVT
Digital Balance	-	ESSAE - 220E
Analytical Balance	-	DENVER – TB215DDE
Digital melting point apparatus	-	POLMON – MP- 96
Karl – fisher apparatus	-	POLMON - MI-453
Milli Q Water System	-	DIRECT – 8
Tap Density Tester	-	ETD – 1020

## Analytical Testing Facility (Microbiology)

- |                        |   |                         |
|------------------------|---|-------------------------|
| ▪ BI Incubator         | - | Biotechnics             |
| ▪ Vertical Autoclave   | - | Smart lab tech          |
| ▪ Vertical Autoclave   | - | Biotechnics             |
| ▪ Laminar Air Flow     | - | MH Enterprises          |
| ▪ Hot Air Oven         | - | Smart lab tech          |
| ▪ Refrigerator         | - | Whirlpool               |
| ▪ Dynamic Passbox      | - | Fumex                   |
| ▪ Weighing Balance     | - | Essae                   |
| ▪ pH Meter             | - | Global                  |
| ▪ Binocular Microscope | - | Optica                  |
| ▪ Colony counter       | - | Smart LabTech           |
| ▪ Fumigator            | - | Remi                    |
| ▪ Vacuum Pump          | - | Millipore               |
| ▪ BOD Incubator        | - | Smart lab tech (2 No's) |

# Vector Bio Sciences Pvt. Ltd.

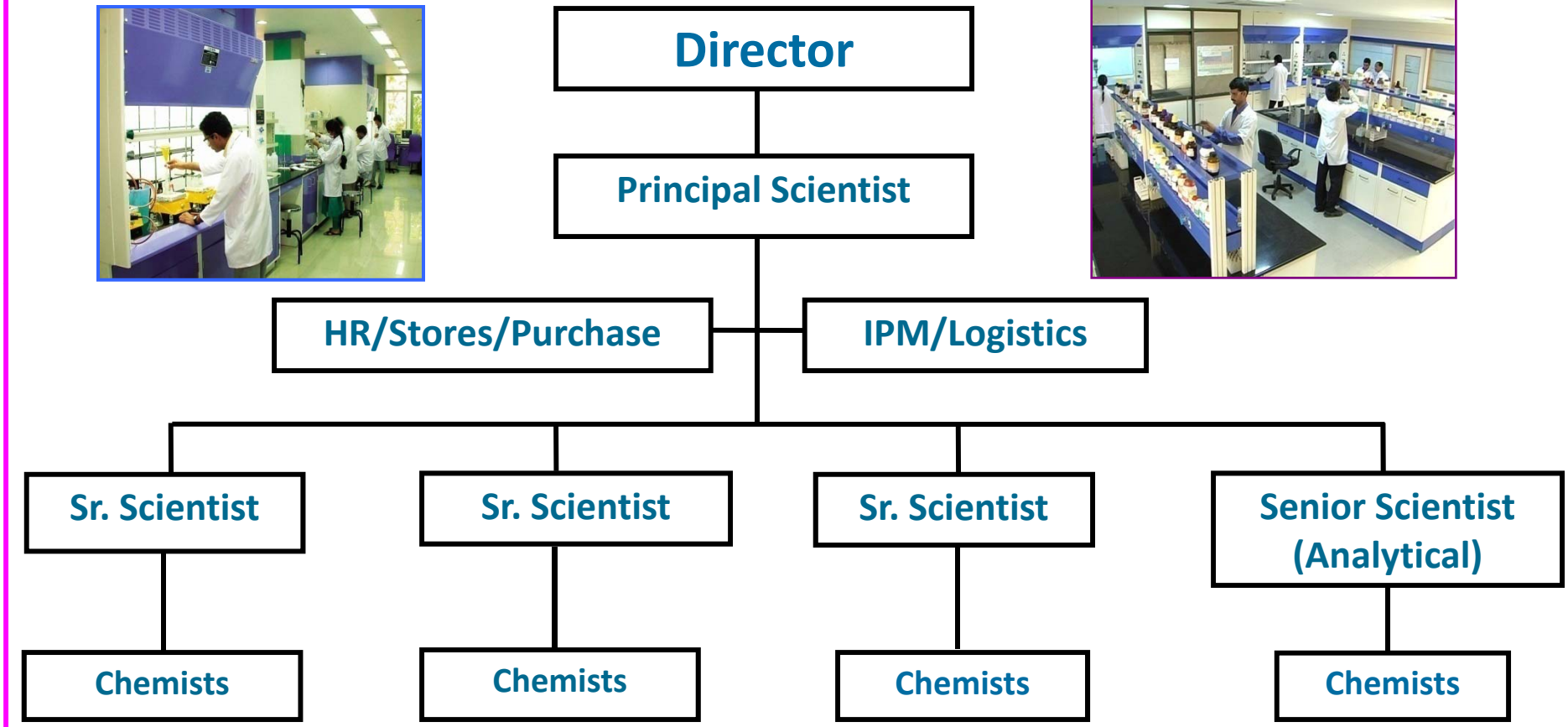
- **Vector Bio Sciences Pvt Ltd Established in 2007**
- **It is a R&D division of Virupaksha Group of companies**
- **Vector Bio Sciences Pvt Ltd certified by ISO 9001:2008 and DSIR.**
- **Developing advanced intermediates for new and clinical API's.**

# CRAMS Business

- Business with innovator & generic API companies
- Filed two patents for Antiretroviral API's (HCV)
- Non-Infringing process support for first to file (P IV)
- Process development and Optimization
- Analytical method development and validation
- Synthesis of complex APIs
- Complete regulatory and documentation support.
- Cost competitiveness.
- FDA approved facility for commercial production.
- IP owned by customer



# Organization Chart



# Equipments

- HPLC with PDA detector
- GC
- FT- IR
- LC-MS
- 300 MHz NMR access from nearby facility
- 1L – 10L rotavaps
- Microwave synthesizer
- 96 well parallel synthesizer
- 12 and 6 carousel stations
- 250mL -2L Parr hydrogenation apparatus
- Autoclave – 5L capacity with 1000 psi pressure



# Literature Support

- Reaxys access
- Access to Central Government Institute Libraries in Hyderabad for CA and other journals
- Online Patents access
- Online journal access for ACS and Elsevier journals

# Reaction capabilities

- Grignard & Wittig reactions, protection & deprotection reactions
- Handling air sensitive reagents like n-BuLi, t-BuLi, LDA, LHMDS, KH and NaH
- Pd based chemistry & various condensation reactions
- Handling of Boronic acids and phosphate esters
- Handling of phosgene, cyanide reactions, Brominations, Nitrations
- Chiral synthesis using chiral reagents or chiral catalysts
- Liquid ammonia reactions and sealed tube reactions
- Autoclave (5 L) and Hydrogenations (250 ml – 1 L parr apparatus) under high-pressure up to 1000psi.

# List of Products:

S.No	Compound Name	CAS.No	Therapeutic category
1	Apixaban Intermediates		Anti Coagulant
2	Canagliflozin Intermediates		Anti Diabetic
3	Dapagliflozin Intermediates		Anti Diabetic
4	Dex pramipexole/Pramipexole Intermediates		Anti Parkinsonian
5	Darunavir Intermediates		Anti HIV
6	Dolutegravir Intermediates		Anti HIV
7	Efinaconazole Intermediates		Anti fungal
8	Linagliptin Intermediates		Anti Diabetic
9	Luliconazole Intermediates	187164-19-8	Anti Fungal
10	Lurasidone Intermediates		Anti Psychotic
11	Perampanel Intermediates		Anti Epileptic
12	Pralatrexate Intermediates		Anti Cancer
13	Ravuconazole Intermediates		Anti Fungal

# List of Products:

15	Sofosbuvir Intermediates		Anti HIV
16	Ticagrelor Intermediates		Anti Depressant
17	Vilazodone Intermediates		Anti Depressant
18	Daclatasvir intermediates		Anti-HIV
19	Ledipasvir intermediates		Anti-HIV
20	Obeticholic acid intermediates		

# Project Management

- SOPs for various stages of project execution
- Reactions are monitored by TLC AND HPLC technique
- All the intermediates and final compounds are characterized by IR,  $^1\text{H-NMR}$ , Mass or LC-MS and HPLC
- Purifications carried out using gradient column or flash column chromatography
- Transparent communication process
- Secure e-mails, teleconferences and meetings
- Weekly reports and Final report – standard or customised formats
- Lab note books shipped to the client

# Policies

- All Intellectual Property (IP) owned by Client
- Scientists enforce strict confidentiality
- CDA signed with each employee
- Details of the project known to the respective Project Managers only
- Experiments are recorded by chemists in dedicated Lab books
- Project Codes used for Chemical Procurement, Spectral data requisitions and sample shipments



# Commitment

## We are committed to provide

- Quality products
- Manufacturing at GMP facility
- Complete documentation with Regulatory support
- Development process with GMPs
- Delivery in estimated time frame
- Protecting client's IP

THANK YOU