#### ACHARYA GROUP The Chemistry Specialists



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### ACHARYA GROUP The Chemistry Specialists

- Estd : 1975
- Founder : Dr. S. P. Acharya
- Today has five manufacturing sites
- Employees ~300
- Activities :
  - Product Manufacturing and Sale
  - Contract Research
  - Custom Manufacturing

### ACHARYA GROUP The Chemistry Specialists



- acharya chemicals
  - Ambernath

Ambernath



HERBERT BROWN Pharmaceutical & Research Laboratories 1975

1984

API and Advanced Intermediate Site (GMP)

Research & Small Volume API (GMP) and Intermediate Site



- Shirdi Chemicals Pvt. Ltd.
  Pawane, Navi Mumbai
  Dr. Acharya Laboratories Pvt. Ltd.
  2002 Intermediate & Specialty Chemicals Sites (ISO9001)

### Infrastructure



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### **Manufacturing facilities**

Five independent manufacturing facilities - 150 TPM 25 Glass Lined total volume of 100,000 litres 30 SS Reactors with total volume of 100,000 litres

- Glass Lined Reactors from 50 litres
  to 10000 litres
- SS316 reactors from 100 litres up to 15000 litres
- High Pressure Reactor 45 kg/cm<sup>2</sup>
- Centrifuges
- AGNF (3KL to 12KL) SS, Hastelloy
- Leaf/Membrane/Sparkler Filters
- Pulverisor/Multi Mills/ Microniser

- Blender and sifter
- Driers : RVD, FBD, VTD
- DM Water Plant
- Steam / Thermic Fluid Boiler
- Chilling Plants
- Licensed Underground Solvent Tank Farm
- Power Generators
- MEE/RO for ETP

#### **Manufacturing facilities**

#### Shirdi Chemicals - ISO 9001:2000 Certified









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#### Manufacturing facilities Acharya Chemicals – WHO-GMP / US-FDA Approved





Intermediate - Reaction Area

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#### Manufacturing facilities Acharya Chemicals – WHO-GMP / US-FDA Approved





#### API Crystalisation – Centrifuging Section



#### Manufacturing facilities Acharya Chemicals – WHO-GMP / US-FDA Approved



**API Drying** 



**Central Corridor** 



**API Pulverising** 







### Manufacturing Facilities Summary

- Herbert Brown Phar. & Res. Labs.
  - Low Volume campaigns
- Capacity available at Ambernath
  - 20 M.T. per month taken on campaign basis
- Asvik Pharma, Dombivli
  - 20 M.T. capacity per month
- Shirdi Chemicals, New Mumbai
  - 50 100 MT capacity per month
- Dr. Acharya Labs., Ambernath
  - High volume manufacturing

### **R&D Facilities**



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# **R&D facility**

- Synthetic lab.
  - Three labs with hoods
  - Medium Pressure Prep. Liquid Chromatography
  - Nano filtration systems for purification
  - High Pressure facility 5L @ 350 bar 250 C
  - Fractional Distillation System under high vacuum
  - Solvent dehydration system
- Strength : 20



Synthesis Lab



Nano filteration System



Prep. HPLC System



# **R&D Facilities**

- LC-MS Single Quad with Multiple Sources
- Gas Chromatography
- Head Space Sampler for OVI
- HPLCs with UV-Vis and PDA Detector
- UV-VIS Spectrophotometers
- FT-IR with solid sample accessory for polymers
- Coulometer KF with Oven sampler for low moisture determination
- microVISC Portable Viscometer
- Microscopy Biovis PSA 2000
- Environment Chambers for Stability Studies
- Mettler Balance, Karl Fisher Titration Units etc.



Analytical Development Lab. with HPLC-PDAs



## **Business Model**

Product Development and Sale

Contracts – Exclusive Supply



## **Product Development and Sale**



### Products APIs

- Benzyl Nicotinate #
- Methyl Nicotinate #
- Metronidazole Benzoate #
- Valbenazine Tosylate

\* under development # DMF available

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## **Products**

#### Intermediates & other building blocks

- Caronic Anhydride
- Myosmine
- 1,2,5-Trimethylpiperidine-4-One
- 2-Aminobenzonitrile
- 2-Amino-5-chlorobenzophenone

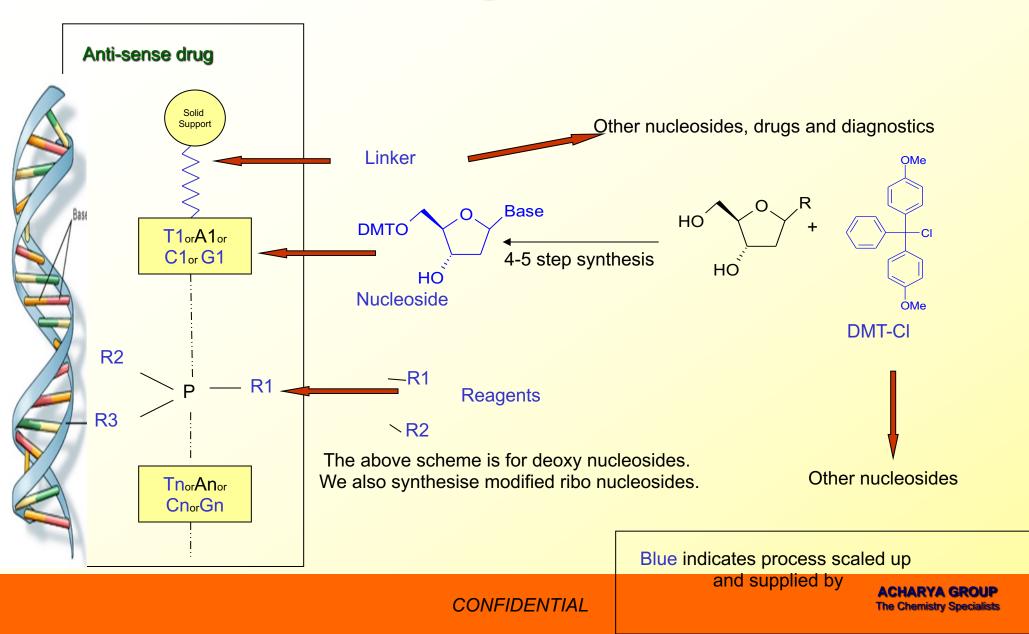


### **Products** Nucleoside Related

- Bis(phenylacetyl) disulfide [PADS]
- Protected Nucleosides
- Linkers with Solid Support
- Amidites

The above products will be offered subject to permission from patent holder and access rights for the respective technologies to the buyer.

### **Materials for Oligonucleotides**



## **Contract – Exclusive Supply**

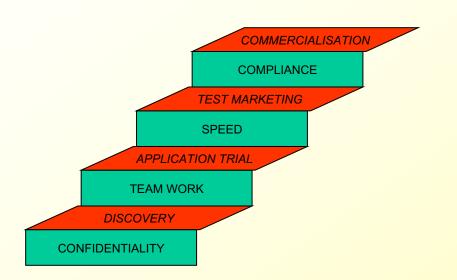


### Business Model Contracts – Exclusive Supply

- Sector
  - Pharma
  - Specialty Chemicals
  - Agro Intermediates
- Type
  - Contract Research
  - Custom Synthesis
  - Contract Manufacturing

### **Contract Research & Custom Synthesis**

- Team of Specialists
- High End Instrumentation from world reputed brands like Agilent, Shimadzu etc



- Pilot Plant
  - 50 L to 1000 L Scale SS and Glass Reactors
  - Centrifuges
  - FBD and Vacuum Tray Drying
  - Liquid N2 Handling capability
  - Column Chromatography system
  - Lyophilizer

### **Project Management**

- Project Infrastructure Speed
  - e.g. Agro Intermediate technology development to project implementation in 4 months
- In-licensed API project with Polymorph and filed US DMF
- Aided in Life Cycle Assessment of Projects

#### Project Management High Pressure Reactor Project



Plant batch starts on 2<sup>nd</sup> June

9/Ma

30/Apr

21/May

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# **CMC Partner**

#### **Project Phase**

- Discovery Preclinical P1/2/3
- Launch
- Commercial Production

#### **Key Services**

- Technology In-transfer
- Process Development
  - Feasibility
  - Viability
  - Scalability
- Supply Chain
- Stability
- Regulatory

### **Reaction Capabilities**

Reaction	Lab.Scale	Pilot Scale	Plant Scale	Reaction	Lab.Scale	Pilot Scale	Plant Scale
Acetal Formation			Х	Epoxidation	Х		
Acid Chloride Formation			Х	Esterification		Х	Х
Acylation		x	x	Friedel-Crafts Reaction	x	x	x
Alkylation of Phenols			Х	Grignard Reaction	Х	Х	Х
Amidation			x	High Pressure Reaction	x	x	x
Amination		Х	Х	Hydrogenation	Х	X	
Arbusov	Х	X	Х	Hydrolysis	Х	X	X
Beckmann Rearrangement	Х	Х		Michael Addition		Х	
Bromination			x	n-ButylLithium Reactions		x	x
Catalytic Reduction using LiAIH4 and NaBH	Х	х	х	Nitration			Х
Chiral Reactions	Х	Х		O-Glycosidation	Х		
Chiral Chemistry (Induced resolution)	х	x		Oxidation Reaction		x	x
Chlorination of Phenols & Aromatic Acid Anhydrides			х	Oximation	x	х	х
Chlorosulfonation	х	x		Protection and Deprotection of Carbohydrates	x	x	x
Condensation			Х	Reduction			Х
Cryo Reactions	Х	x		Sandmeyer Reaction			x
Decarboxylation	Х	Х		Silylation	Х	Х	
Dehydration of Amides to Nitriles	Х	x	х	Substituted Piperidones	х	х	Х
Diazocoupling ( ring cyclisation )	Х	х	х	Transesterification			Х
Diazotisation	Х	x	x	Vilsmeier Haack Reaction	x	X	x
Dieckmann Reaction	Х	x		Wolff Kishner Reduction	х		

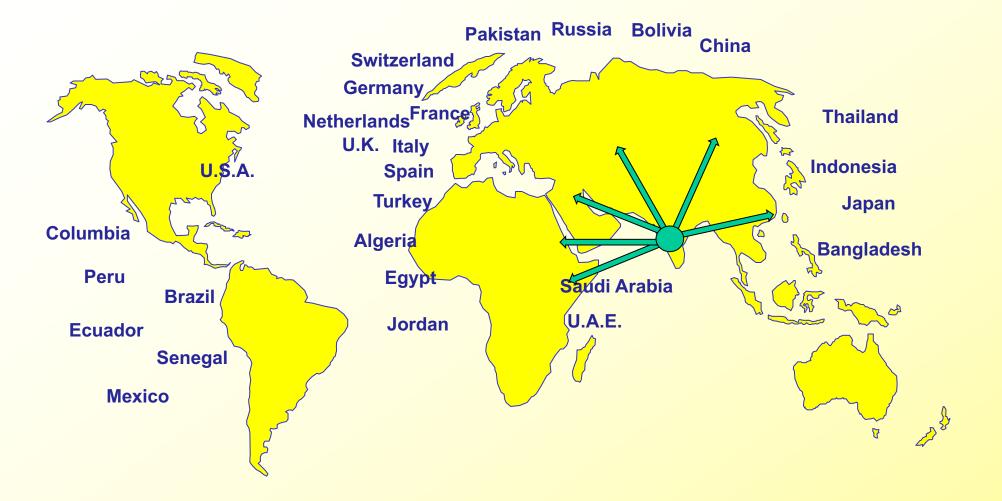
## Unique Production Scale Technical Capabilities

- High Pressure Reactor @45 kg/cm2 in 3500 Litres volume
- Preparative HPLC Flow rate @ 4 litres/min
- Nano-filtration system for product purification based on molecular weight
- Class 100,000 powder processing area in API plant
- Carbohydrate Chemistry : Nucleic Acid Chemistry and its related agents
- Capabilities of handling pyrophoric reagents on plant scale e.g. n-Butyllithium, Diethylzinc, Triethylaluminium(TEAL), LAH etc

### Core High Volume Capabilities (Multi 100 T Capabilities)

- High Pressure Reaction upto 640 psi
  - Ammonolysis (using Ammonia gas tonners)
  - Hydrogenation
- Low melting solids handling capability
  - Phenol/Cresol/Xylenol based reactions with bulk storage and handling of materials
- Fractional Distillation under vacuum
- Grignard Reaction
- Diazotisation and other functional groups introduction
- Dehydration of amides to form nitriles
- Acid Chloride formation using SOCl<sub>2</sub> / POCl<sub>3</sub>

### Exports (90% of Total Sales)



# **Key Drivers for Partnership**

- Partner Compatibility
- Adaptability
- Right sized
  - Advantages of Instrumentation, Systems and Thought Process of Large Companies
  - Flexibility, Quick Implementation, Decision Making, Confidentiality, Loyalty
- Business Model Exclusive Supply