

CUSTOM RESEARCH AND MANUFACTURING SERVICES

C.R.A.M.S.



- Collaborative
- Customised
- Complete
- Secure
- Timely

Surya Advanced Research & Development Centre

Corporate Overview

- Established in India in 1992, SPL has rapidly emerged as a premier integrated pharmaceutical company
- Listed on National Stock Exchange and Bombay Stock Exchange
- Sales turn-over US\$ 350 million
- Strong team of 6000 professionals
- State-of-the-art R&D Centre, recognized by DSIR, Govt. of India
- World-class competence for Gram-to-Kilo-to-Multi Ton synthesis
- cGMP pilot plant facility under approval
- Nine manufacturing sites
- Quality Certifications: Trading House Certificate , ISO 22000-2005, ISO 9001:2000
- Mint manufacturing facility registered with US FDA
- Global business experience: clients in 90 countries

Salient Features of Custom Research and Synthesis Services

- 17 years of experience in broad range complex chemistry reactions
- Globally recognized for semi-synthetic Penicillins & Cephalosporins
- Strong R&D, Engineering and Manufacturing capabilities across the scale of operations
- Track record of multi-step synthesis to Pharma industry
- Sound understanding of global regulatory requirements
- Professional dedication to product quality
- High Health, Safety and Environmental standards
- Dedication to confidentiality obligations and IPR protection
- Robust business process and project management capability
- Assured achievement of milestones and deliverables
- Partnering with R&D Industry, Pharma/Biotech and Specialty/Cosmetic chemical companies
- Highly qualified and experienced team for CRAMS.

Categories of Services & Product-line

- All plants ISO 9001 and ISO 22000 certified
- cGMP Compliance for all APIs and Dosage form plants
- G KFDA approved API Plant
- R&D Centre recognized by DSIR
- Strong R&D, Engineering and Manufacturing capabilities across the scale of operations
- USFDA registered for mint products
- COS By EDQM for many products
- Star Kosher Certificate
- Halal Certificate

Categories of Services & Product-line

- Chemistry / Analytical services for Gram-to-Kilo-to-Multi Ton synthesis
- Full Time Equivalent (FTE) Research & Manufacturing Services
- Active Pharmaceutical Ingredients, APIs
- Intermediates for drug synthesis
- Finished Drug Formulations
- Mint/ Menthol derivatives
- Herbal Products

State-of-the-Art Research & Development Centres

S.No.	Facility	Numbers
1	Process Chemistry Laboratory	5
2	Impurity Profile Laboratory	1
3	Analytical Wet Laboratory	2
4	Analytical Instrumentation Laboratory	6
5	Formulation Development Laboratory	2
6	Stability Laboratory	1
7	Kilo Laboratory	1
8	Regulatory office	1
9	IPR Cell	1
10	Library	1
11	Stores (8°C/ RT)	3
12	Conference room, Meeting & Training room	4
13	Offices, Server Room and Utilities	



- Two state-of-the-art research facilities spread over 75,000 sq.ft. with latest instrument and equipments
- 70 scientist with relevant experience: 55 post graduates and 15 with doctorates
- Well accessible library facility with Scifinder, STN, Beilsten
- 30 fume hoods and walking hoods

Fully equipped well designed analytical lab with all latest advanced equipments :

Sr. No.	Analytical Equipment	Make
1	HPLC	Waters, Shimadzu
2	HPLC with PDA Detector	Waters, Shimadzu
3	Preparative HPLC	Waters
4	GC	Shimadzu
5	GC with Head space	Perkin Elmer
6	FTIR	Perkin Elmer
7	UV Spectrophotometer	Shimadzu
8	Lyophiliser	Vertise
9	Auto Titrator	Metler
10	KF Apparatus	Metler
11	Purified Water System	Milipore
12	Digital Polarimeter	Rudolph
13	pH Meter	Metler
14	LCMS MS	Applied Bio Science
15	XRD	PAN Analytica
16	NMR 400MHz	Brooker
17	GCMS	Agilent
18	Preperative HPLC	Waters
19	Particle size analyzer	Malvern



Surya Technology Platforms

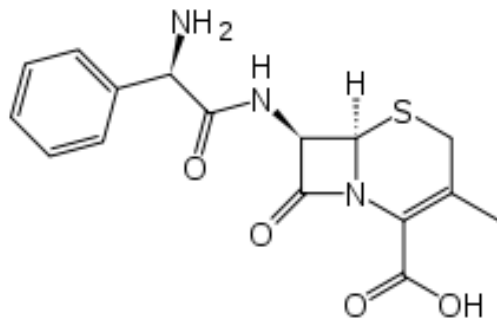
Some examples:

- Friedal Craft Alkylation: Sertraline
- Hydrogenation: Intermediate 7-ANC
- Grignard Reaction: Menthyl Chloride
- Ozonolysis: 7-ACCA
- Finkelstein Reaction : Cefixime
- Fisher – Indole Synthesis :Sumatriptan
- Swern Oxidation: Cefditoren Pivoxil
- Halogenation : Flomoxef
- Acylation: Cefuroxime Acid
- Lewis Acid Catalysed Condensation: Intermediate of Ceftizole
- Vilsmeier – Haack Reaction (Reagent Preparation)
- Metal Hydride reductions: Cefditoren
- NaBH₄ Reduction : Intermediate of 7-ANCA
- Oximation: Side chain of Cilastatin
- Oxidation: Intermediate of 7-ACCA
- Reductive Methylation: Sumatriptan
- Silylation: Intermediate Imipenem
- Epoxide Formation: Fluconazole
- Wittig Reaction: Cefixime

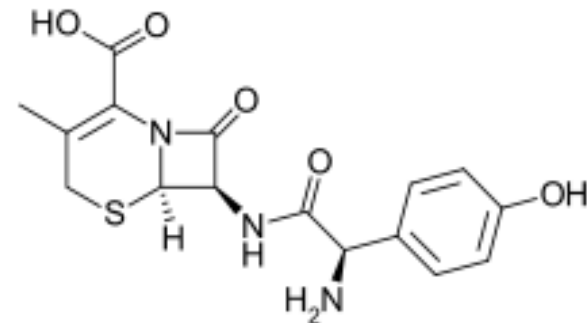
Our Expertise:

Process Chemistry

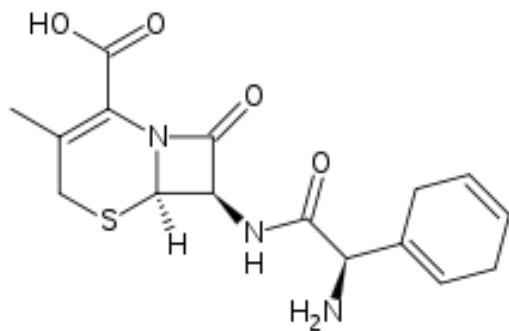
Cephalosporins



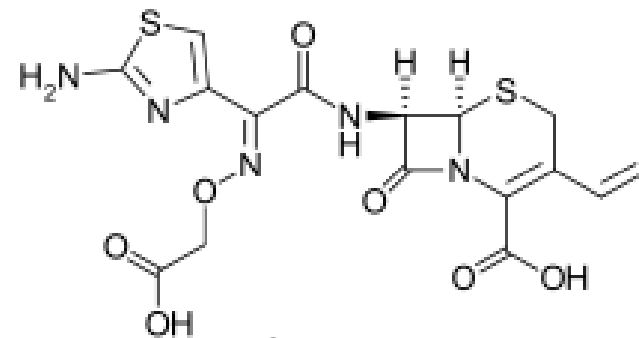
Cefalexin



Cefadroxil

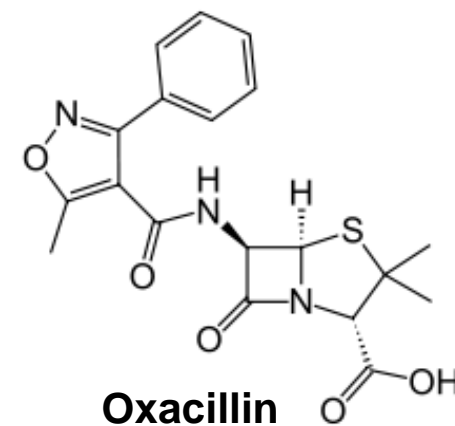
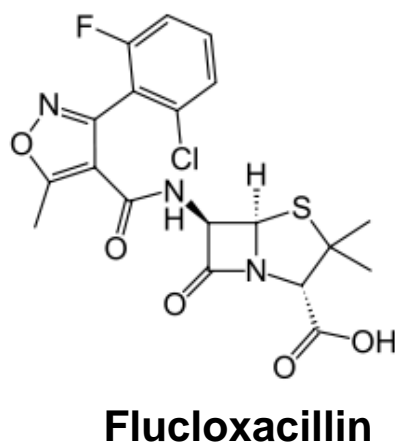
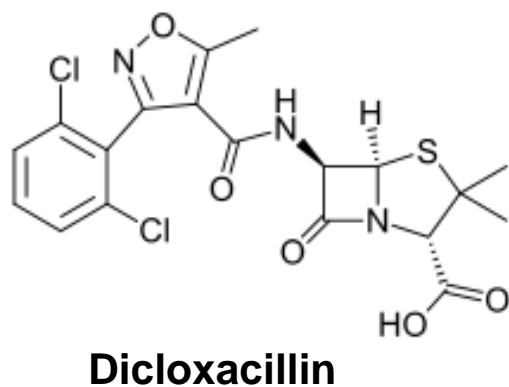
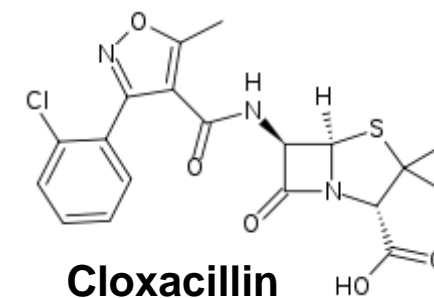
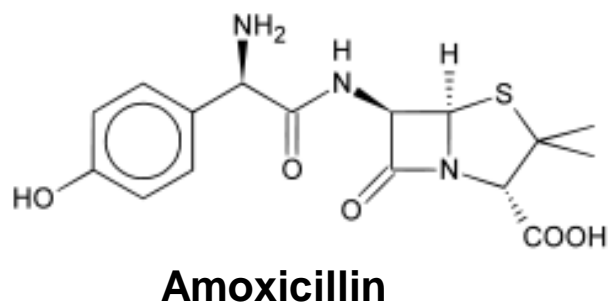
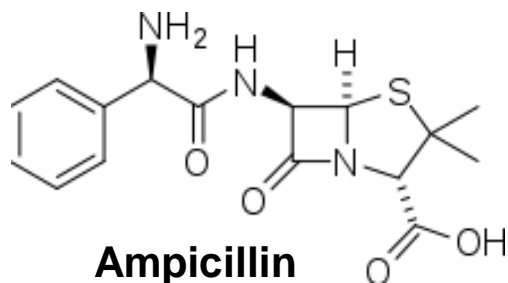


Cefradine

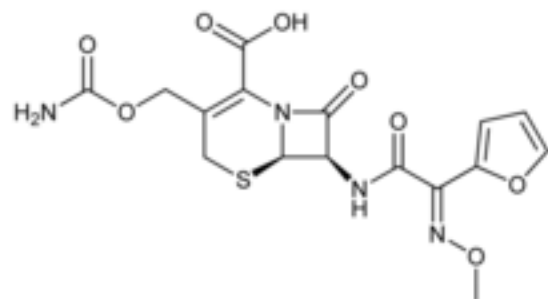


Cefixime

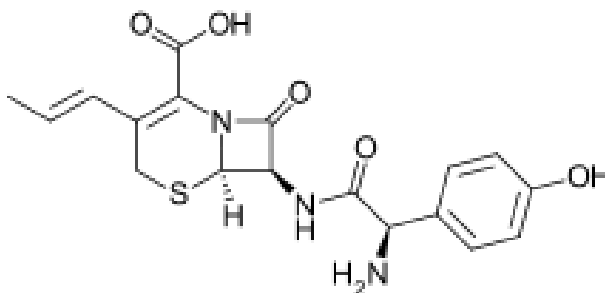
Betalactams



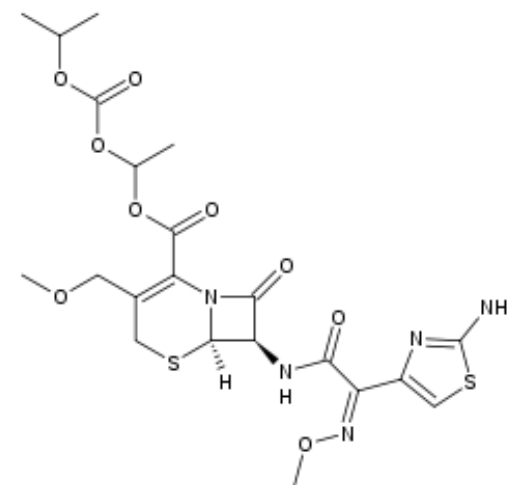
Cephalosporins



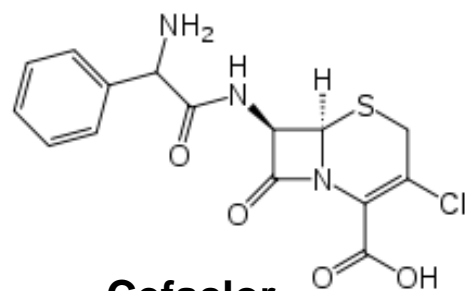
Cefuroxime



Cefprozil

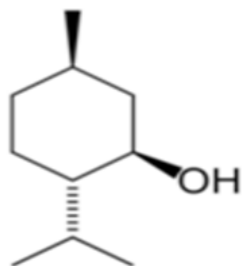


Cefpodoxime Proxetil

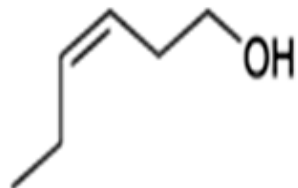


Cefaclor

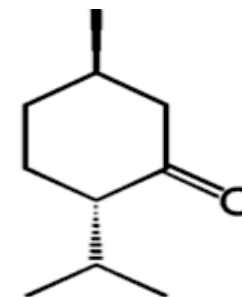
Mint Products



Menthol

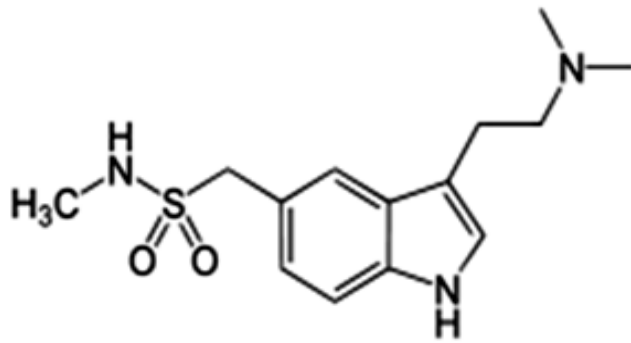


Cis-3-Hexenol

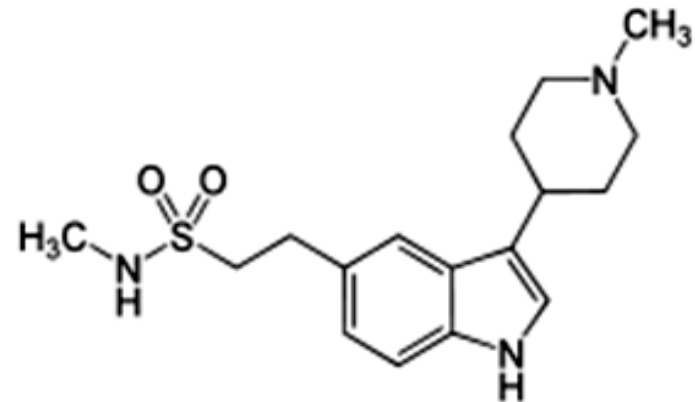


Menthone

Antimigraine Products

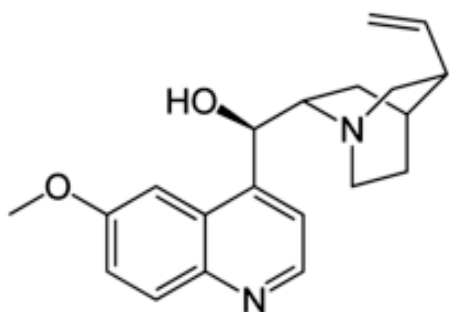


Sumatriptan

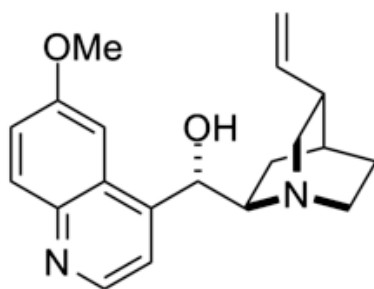


Naratriptan

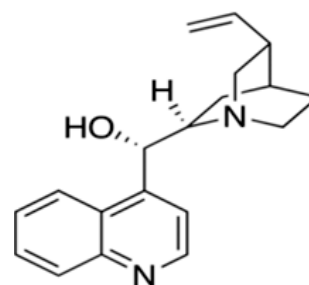
Cinchona Alkaloids



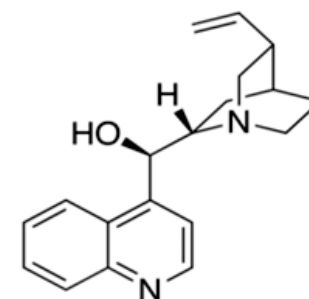
Quinine



Quinidine

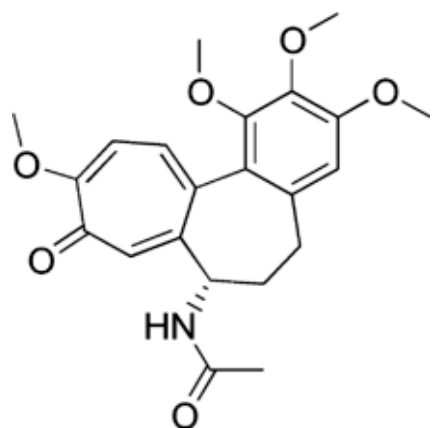


Cinchonine

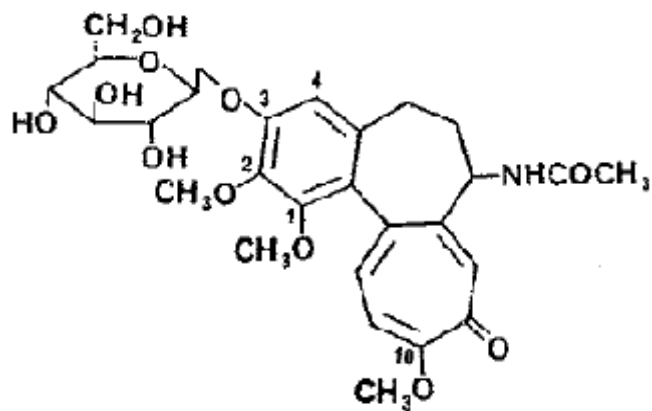


Cinchonidine

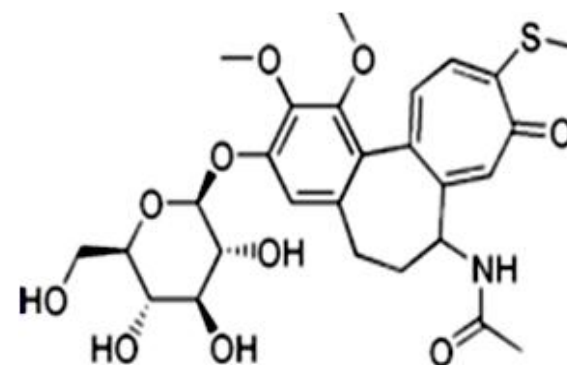
Colchicine Alkaloids



Colchicine

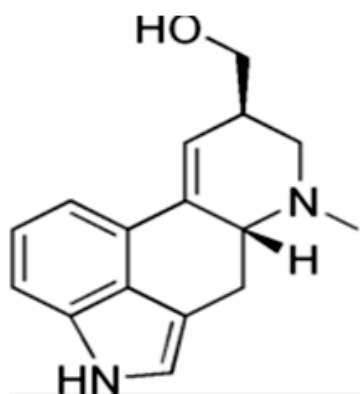


Colchicoside

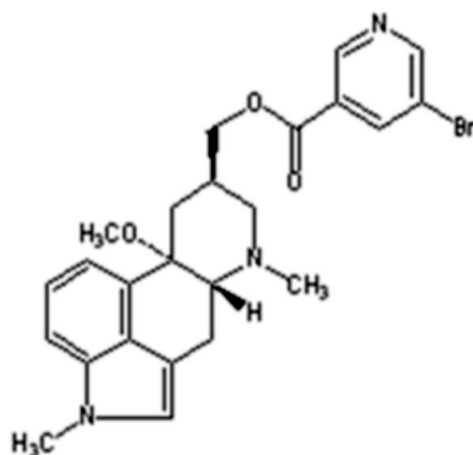


Thiocolchicoside

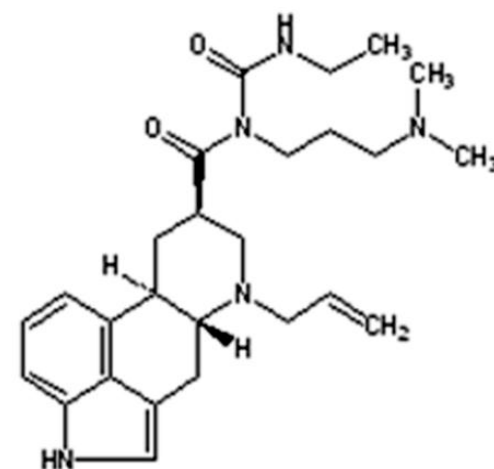
Ergot Alkaloids



Lysergol



Nicergoline



Cabergoline

For more compounds, please refer to www.suryapharma.com

Custom Research & Manufacturing Services (CRAMS) CM&C

Intermediates & APIs – Drug Substance

- **Custom Research & Development Services** - Offering route design, process development services for Intermediate and APIs. Also offering analytical protocol development support to offer a complete dossier that can be scaled to any multiple. (FTE as well as on Fee for services basis)
- **Scale-up Services** -Offers fast and efficient scale-up manufacturing services (from few 100s of grams to few 100s of kilograms) for pre clinical and early clinical phase projects (from customer's process or the developed process for customers)
- **Custom Manufacturing Services** - seamless scale-up and commercial manufacturing of intermediates and APIs (from few 100s of kilograms to multi tons scale)

Custom Research & Manufacturing Services (CRAMS) CM&C

Formulation Development – Drug Product:

- Study of pre-formulation information of active substances
- Prototype formulation development based on physico chemical properties & stability of drug substances
.Screening stability of prototype formulation & identification of lead formulation
- Optimization of lead formulation & process parameters
- Custom manufacturing of commercial quantities for Solid Dosage Forms, Dry Syrups, Oral Liquid Formulations, Topical Formulations (Ointments, Creams, Gels and Lotions)

Medicinal Chemistry Services on FTE basis also

- Building Blocks, Scaffolds, Intermediate compounds for generating analogues
- Reference compounds for in- vitro assays and in-vivo animal model studies
- Custom synthesis of lead compounds in grams
- Pharmacophore based focused libraries generated for a particular target

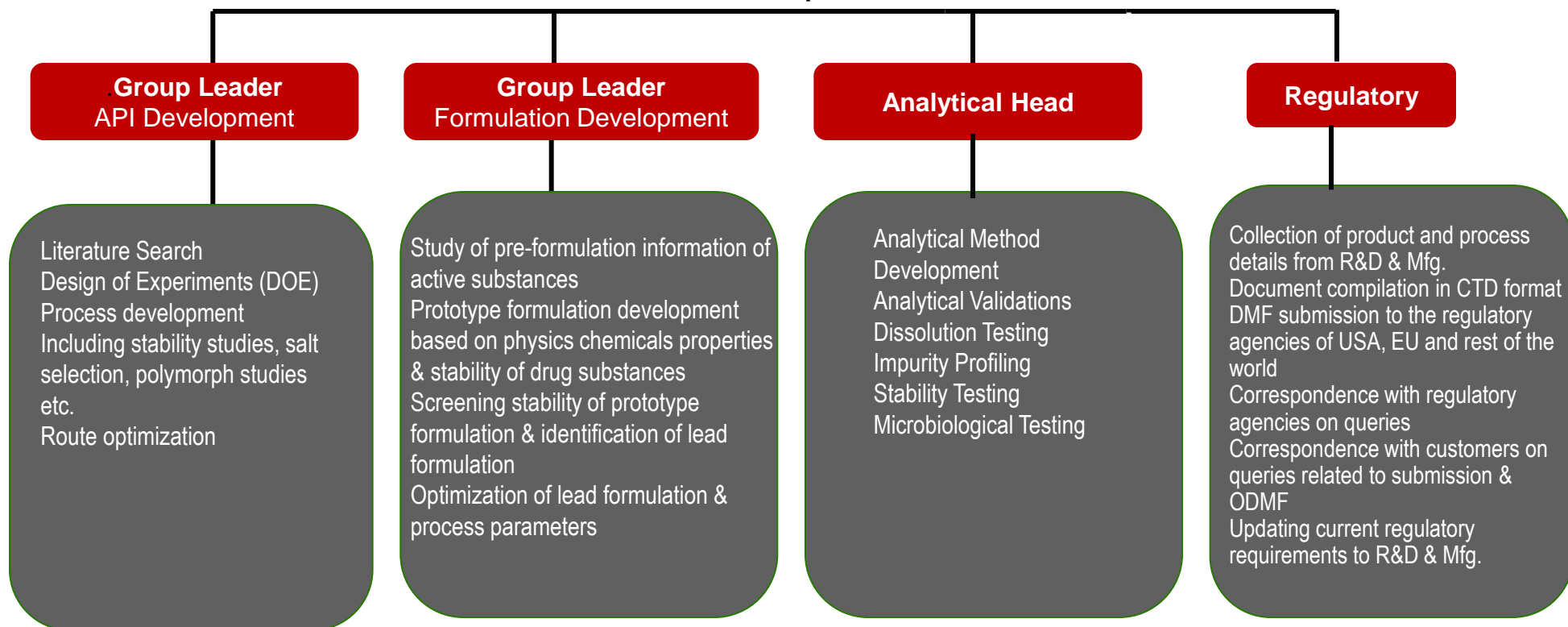
Isolation and Purification at medchem scale

- Isolation of impurities of active pharmaceutical ingredients from mg to gram level.
- Isolation and purification of new chemical entities and their impurities using Preparative HPLC from mg to gram level.
- Isolation and purification of degradation impurities by Preparative HPLC.
- Isolation and purification of raw materials, intermediates and APIs for standard preparations

CM&C Service Support

Surya understands the drug development process and can provide complete CM&C support

CM&C Team & Responsibilities



Surya Services Model

Custom Research on long term FTE basis

- Customer deploys group of FTEs for long term basis and gives projects to them regularly.
- Regular reporting is done in a prescribed format
- Regular interaction of tele/video conferencing between scientists of both sides
- Customer is updated on the status from time to time and his feedback is sought
- On each project completion, a dossier along with a sample is sent to the customer.

Custom Research – Molecule basis (Fee for product)

- Customer gives the project and we offer him the timeline and cost for developing the product
- On completion of project a dossier along with a sample is sent to the customer.

Scale-up of clinical quantities

- Regular RFPs through e-room & e-mail. We offer through e-room and get individual orders against our price and timeline.
- In most cases, customer gives process and in some cases the he asks us to do process modification/development on a fixed time and cost basis.

Custom manufacturing of commercial quantities – For launched products

- In most cases, customer gives the process and in some cases we do the process optimization/development

Pilot Plant Facility

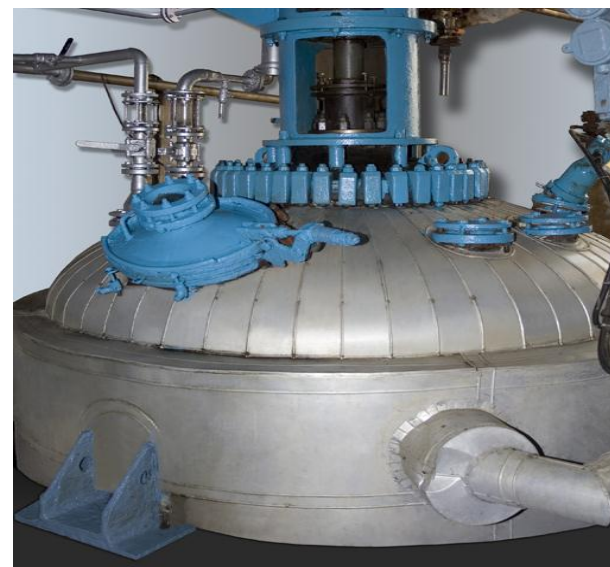
- **Location: Panchkula (North India)**
- **Reactors : 22 (50-5000Ltrs.)**
- **Volume : 29000 Ltrs**
- **MSGL :**

Commercial Manufacturing Plants

Location: Banur

Banur commercial plants with five multipurpose blocks have >85 reactor for various capacities and MOC with total volume >275KL. Out of this, 22 MSGL Reactors start from 0.6KL to 8KL capacity)

S. No.	Block /Area	No. of Reactors	Total Capacity
1	Module-1	26	106 KL
2	Module-1A	24	64.8 KL
3	Module-2	19	62.8 KL
4	Ozonation block	6	26 KL
5	Hydrogenation block	11	16.225 KL



Commercial Manufacturing Plants

Location : Jammu

Jammu Plant, a state-of-the-art strictly cGMP compliant facility has >36 (9 MSGL , 27KL) reactor for API facility with total ~100kl capacity

S. No.	Block /Area	No. of Reactors	Total Capacity in KL
1	Plant 1	05	10.6
2	Plant 2	04	8.6
3	Plant 3	12	31.3
4	Plant 4	Dosage form block	----
5	Plant 5	15	46



Surya's Strict IPR Compliance Assurance

- Sharing information on Need-to-Know basis during project implementation
- Restricted access and efficient data archiving / retrieval system
- Stringent systems for Quality, Confidentiality and Data Security
- Ensuring products and processes being developed are non- infringing
- Protecting any IPR generated through patent filing (Own as well as of customers)
- Flexible IPR ownership business model with our customers for services business

THANK YOU



Surya Advanced Research & Development Centre
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