



**Costcon Healthcare LLP**

*Innovations for a better life*

# INTRODUCTION

*Established with an objective to provide a world class products and services to pharma industry globally by partnering with innovative technology driven companies with a highly skilled team*

# OUR GROUP COMPANIES

- PR Pharma Source Pvt Ltd
- Spark Alchemy Pvt Ltd
- Imex Overseas
- Costcon Healthcare LLP

Group turn over of approx. USD 20 Million



# Sourcing Partner

We are associated with manufacturers in India, offering various pharmaceutical Products for Domestic & International Pharmaceutical Companies

- APIs
- Advanced Intermediates
- Speciality Chemicals
- Pellets
- Finished Formulations
- Medical Devices

## **Other Value Added Services**

- Registration of foreign Companies, their APIs and Finished dosage forms in India
- Project management for formulation Business for non - regulated / regulated markets
- In - Sourcing / Out - Sourcing of technologies

# API Development

- ✓ Process Research, Development & Optimization
- ✓ Custom Synthesis from Milligram to Kilogram
- ✓ Scale-up of Existing Processes
- ✓ Large-Scale Synthesis & cGMP Commercial Manufacturing

# Analytical Development

- ✓ Analytical method development and validation
- ✓ Process validation
- ✓ Batch release
- ✓ Characterization of solid state properties, (e.g. particle size)
- ✓ Identification of impurities
- ✓ Preparation of Analytical Reference Standards
- ✓ Conduction of stability studies

# Regulatory Affairs Management/ cGMP Support Service

End to end regulatory services for US, EU, Canada, India , Latin America , Asia , Middle East and other emerging markets :

- ✓ 505(b)(2) NDA , IND, ANDA , MAA filings.
- ✓ Electronic CTD filings regulatory outsourcing services.
- ✓ Coordinating Pre-IND Meetings and Scientific Advisory meetings
- ✓ Responding Regulatory queries / deficiencies.
- ✓ Conducting Due Diligence Audits , Base Line GMP audits , Comprehensive systems audits , Risk based audits
- ✓ GMP training and support in development of good quality systems and good documentation practices.
- ✓ 21 CFR part 11 compliance management
- ✓ Compilation of Dossiers
- ✓ Preparation of regulatory responses
- ✓ Post approval regulatory changes

# Contract Research And Manufacturing Services (CRAMS)

- Contract process Research from milligram to multi grams level in a stipulated timeline.
- Scaling up the process from gram to kilo and pilot plant.
- Guiding the process for commercial production at customers approved manufacturing facilities.
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- FTE model (full time equivalent), for fixed tenure, on a mutually agreed target compound/processes.
- Analytical method development and validation.
- Supply of Impurity standards.
- Polymorph evaluation.
- Salt screening.



# Types of Reactions Handled

- Friedel Crafts Alkylation/Acylation
- Halogenation Reaction (Bromination/Iodinazation/Iodinazation)
- Nitration/Sulfonation
- Rearrangement Reaction
- Reductive Amination/Alkylation
- High/Low Pressure Catalytic Hydrogenation
- Swern Oxidation
- Multi Step Synthesis
- Heck reaction
- Grignard Reactions
- High Temperature Condensation (+250 degree Celcius)
- Mitsunobu reaction
- Sonogashira coupling
- Lithium/Sodium Hydride
- Ozonolysis
- Asymmetric Synthesis
- Oximation/Alkylation
- Suzuki Coupling
- Wittig Reaction
- Optical Resolution

# Working Standards & Impurities

Our synthetic and analytical team work in close coordination to develop process for Synthesis and characterization of impurities by various spectrometric techniques.

## Phytochemicals

Our team of phytochemical section is isolation of key ingredients through various technologies including flash column technology

# Our Association

## **We are associated with –**

- UK MHRA approved manufacturing site for General Tablets, Capsules, & liquid injectables
- US FDA & EU GMP manufacturing site for APIs
- Renowned effervescent tablets manufacturing site in India and Europe for Pharmaceuticals & Nutraceuticals
- Topical spray manufacturing company
- State of the Art Pharmaceutical Dosage form Development Center
- Filter Validation studies for Liquid injectables
- Manufacturer of Impurities and working standards
- Clinical trial Center, Medical Writing & Paper Publication Centre

# Professional Team

We have experienced and talented scientific professionals with excellent track record in the pharmaceutical industry under global regulatory environment.

These Professionals comes from various disciplines such as Research, IP, Manufacturing, Quality, Regulatory Affairs, Business development and Marketing .

# Our Core Team

	Industry Experience
❖ Mr. Paresh Bagadia (Inter CA)	25+ yrs
❖ Mr. Maullik Patel (M.Pharm.; MBA)	15+yrs
❖ Mr Pundrikaksh Dubey (B.Sc Industrial Chemistry, MBA)	8+yrs

We look forward for your valuable support for our new venture.

# THANK YOU

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