



Dishman Carbogen Amcis™



OUR
SYNERGY
BRINGS LIFE TO
YOUR
SCIENCE

COMPANY PROFILE





R&D centre at Bavla, India

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SUPPORTING THE PHARMACEUTICAL AND BIOPHARMACEUTICAL INDUSTRIES

We have been supporting the pharmaceutical and biopharmaceutical industries with drug development for over 30 years, assisting our clients in developing and bringing new drugs to market while improving the lives of their patients across the world.

OUR VISION

Our objective is to help our customers create a better world as the partner of choice to develop and manufacture complex and challenging substances, highly potent active ingredients, and breaking new ground with innovative vitamin, healthcare, and industrial products.

OUR FOCUS: CLIENT SATISFACTION

Dishman Carbogen Amcis Ltd focuses on the reduction of operational risk in chemical development and commercial manufacturing by:

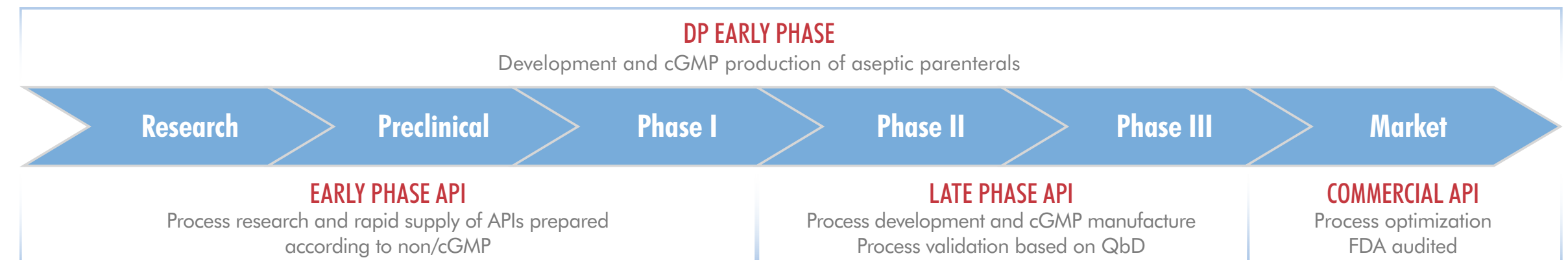
- Minimising the time associated with drug development
- Decreasing the risks associated with drug development
- Providing long-term and value-added contract manufacturing solutions



- Dishman Carbogen Amcis Ltd is a global outsourcing partner for the pharmaceutical industry offering a portfolio of development, scale-up and manufacturing services. Dishman Carbogen Amcis Ltd improves its customers businesses by providing a range of development and manufacturing solutions at locations in India.

Our commitment is to deliver high added value solutions with technical excellence and to be a reliable partner to our customers, protecting their interests as if they were our own.

CONTRACT RESEARCH & MANUFACTURING SERVICES



DISHMAN CARBOGEN AMCIS GROUP

Dishman Carbogen Amcis Ltd owns CARBOGEN AMCIS and form together the Dishman Carbogen Amcis Group.

BUSINESS UNIT	MANUFACTURING LOCATIONS	BUSINESS FOCUS
Dishman Carbogen Amcis Ltd Contract Research & Manufacturing Services (CRAMS)	India	High-value contract services. Process development, process optimization, manufacture for late stage clinical and commercial supply.
CARBOGEN AMCIS	Switzerland, France, United Kingdom, China, The Netherlands, India	High quality process research and development. API supply to support clinical trial requirements. Niche scale commercial manufacture. Highly Potent API supply.
Dishman Carbogen Amcis Ltd APIs	India	High quality supply of generic Active Pharmaceutical Ingredients (API) for the pharmaceutical industries.
Dishman Carbogen Amcis Ltd Special Chemicals Solutions	India	World leading manufacture of Phase Transfer Catalysts. High quality supply of intermediates, fine chemicals, and products for the pharmaceutical, cosmetic and related industries.
Dishman Carbogen Amcis Ltd Vitamin D & Analogues	The Netherlands	Vitamin D2, Vitamin D3 and Vitamin D analogues, related products for pharmaceutical, cosmetic and related markets.
Dishman Carbogen Amcis Ltd Soft Gels Formulations	India	Sophisticated infrastructure which enables the production of various novel dosage formulations in soft gelatin capsules, such as Therapeutic, Nutraceutical and OTC.

DISHMAN CARBOGEN AMCIS LTD OFFERS INNOVATION, SECURITY OF SUPPLY & VALUE FOR MONEY

QUALITY

- USFDA inspected facilities
- All sites operate to the highest international standard of quality, safety and environmental control
- Complete API regulatory support including substantial experience in generating DMFs and ECOS

CUSTOMER SERVICE

- We have local representation, and support in all major markets
- Rigorous project management procedures delivered by dedicated project management personnel
- Openness throughout the customer relationship
- Communication and reporting tailored to match customer specific requirements

RISK MANAGEMENT

- Strong, tenured leadership at corporate and local levels
- Multiple site, multiple country locations
- Strong IP protection policies
- Global supply chain and logistics support

PARTNERSHIP

- Single partner for R&D, process development and commercial production
- Offering the best of the New World as a centre for commerce
- Offering flexible, innovative terms for partnership
- An ongoing commitment to add services and expertise valued by our pharmaceutical customers



PROCESS R&D

Dishman Carbogen Amcis Ltd offers Process R&D with a specialization in developing processes that are truly scalable through to commercialization, be this through process research, process development or optimization. We have 200 staff operating in continuous three shifts, 6 day R&D operations in state of the art dedicated R&D centres. Our promise is safe, efficient scale-up and problem solving delivering robust, economic processes.

Dishman Carbogen Amcis Ltd enforces strict IP protection policies. We protect our customers' interests as if they were our own.

ANALYTICAL SERVICES

Analytical services support both process control and material characterization for R&D and manufacturing operations, from initial raw material release through to the release of the final APIs. The range of our equipment is necessarily extensive, mirroring that which one would find within an integrated pharmaceutical company.

PILOT, FULL SCALE & COMMERCIAL SUPPLY

We offer an extensive range of segregated, purpose built, kilo and pilot scale facilities for cGMP production of API. These facilities are an integral part of our R&D centres to facilitate maximum interaction and ensure seamless process transfer from laboratory to plant.

At commercial scale, we offer a vast range of dedicated and multipurpose facilities for the cGMP production of APIs and intermediates.

- 12 multi-purpose and dedicated production facilities
- Comprehensive range of skills and capabilities encompassing all routine chemistries and a wide range of sophisticated, modern technologies
- USFDA inspected facilities
- Multiple site, multiple country locations, all operating to the highest international standards of quality, safety and environmental control
- >1125m³ of reactor capacity
- An ongoing commitment to add services and expertise valued by our customers.

- Dishman Carbogen Amcis Ltd contract research and manufacturing services are the very core of our business. We offer a portfolio of services from process R&D, through kilo and pilot supply to full scale and commercial manufacture from purpose built and dedicated facilities.

By offering technical and manufacturing excellence in multiple locations around the globe, Dishman Carbogen Amcis Group is THE global outsourcing partner for the pharmaceutical industry, providing innovative development to value-for-money, long-term commercial supply.



HIGHLY POTENT API SUPPLY



- Dishman Carbogen Amcis Group offers unparalleled capability in scale-up development and commercial manufacture for highly potent compounds. These highly potent services are offered under the CARBOGEN AMCIS business.

The Dishman Carbogen Amcis Group provides state-of-the-art containment services. All facilities operate to current Good Manufacturing Practice (cGMP) and can produce material for preclinical testing, clinical trials and commercial use. Our manufacturing sites are regularly inspected by the US Food and Drug Administration (FDA) and local regulatory bodies.

All containment facilities are designed based on a containment concept utilizing barrier isolation technology and Rapid Transfer Ports (RTPs) as well as a strict zone concept with pressure cascades, airlocks and access controls. This allows the safe handling of highly potent compounds including cytotoxics.

We offer services starting from laboratory scale for process research and development purposes, up to large-scale manufacturing on 630 L in Switzerland, on 1,600 L scale in Bavla, India and on 8,000 L scale in Shanghai, China. These facilities offer containment down to category 4 (down to $0.05 \mu\text{g}/\text{m}^3$) in Switzerland and India and down to category 3 in China (down to $1 \mu\text{g}/\text{m}^3$).

To support the Active Pharmaceutical Ingredient (API) development process through all stages, a variety of high-containment analytical purification and milling capabilities complement the chemistry service portfolio.

HIGHLY POTENT API FOR (PRE)CLINICAL TRIALS & COMMERCIAL USE

Switzerland	Up to Category 4 OEL down to $0.05 \mu\text{g}/\text{m}^3$	Laboratories Up to 30 L
	Up to Category 4 OEL down to $0.05 \mu\text{g}/\text{m}^3$	Conjugation Laboratories Up to 20 L
	Up to Category 4 OEL down to $0.05 \mu\text{g}/\text{m}^3$	Large-Scale Manufacturing Facility up to 850 L
	Up to Category 3 OEL down to $1 \mu\text{g}/\text{m}^3$	Pilot Plant Manufacturing Facility up to 1,600 L
Bavla India	Up to Category 4 OEL down to $0.05 \mu\text{g}/\text{m}^3$	Large-Scale Manufacturing Facility up to 1,600 L
Shanghai China	Up to Category 3 OEL down to $1 \mu\text{g}/\text{m}^3$	Large-Scale Manufacturing Facility up to 6,300 L
Saint-Beauzire France	Up to Category 4+ OEL down to $0.05 \mu\text{g}/\text{m}^3$	Aseptic Filling up to 5,000 vials

NB: Containment is ensured through rigid barrier isolation systems and flexible segregation of key equipment. Results are validated by containment testing performed according to ISPE's SMEPAC-guideline.
* Result of surrogate containment testing: $0.01 \mu\text{g}/\text{m}^3$



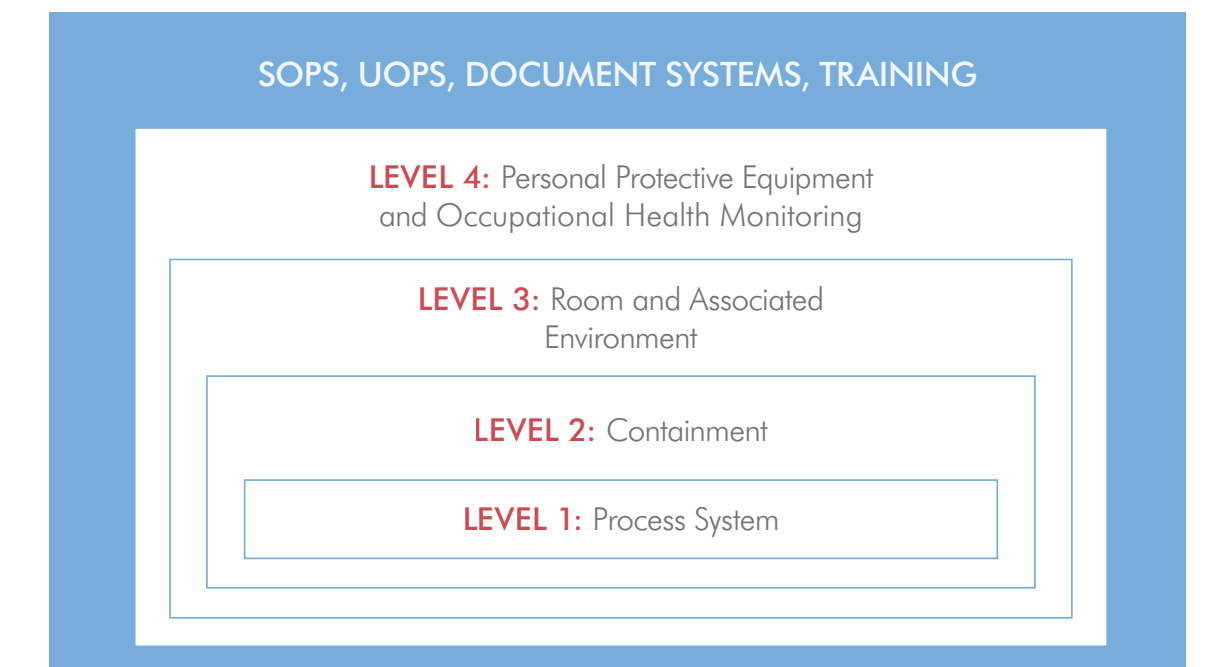
SAFETY & PRODUCT QUALITY

We are fully committed to managing the risks associated with handling and producing highly potent and/or toxic materials. Safety and quality considerations encompass our staff, customers and patients using the materials we produce, as well as the environment and our neighbors.

We are dedicated to maintaining and improving safety, environmental and health standards above and beyond the standard legal requirements. This remains the responsibility of both our management and individual employees. All processes follow our "protection cascade" of four increasing levels of containment technology systems and procedures, ensuring that worker safety and product quality are never compromised.

PROTECTION CASCADE

Our rigorous system of Standard Operating Procedures (SOPs) and Unit Operation Procedures (UOPs), supplemented by extensive worker training, enhances safe working processes and awareness of potent compound safety at all Dishman Carbogen Amcis Group's production sites.





- Dishman Carbogen Amcis Group is a global, multi-site, multi-location organization, offering our customers the opportunity to obtain a comprehensive range of chemical and manufacturing solutions from one single supplier.

This extends from rapid Active Pharmaceutical Ingredients (APIs) supply for preclinical and clinical use (through CARBOGEN AMCIS) to large-scale manufacture of intermediates and APIs. An efficient technology transfer process is the key for a successful transfer either from the customer to Dishman Carbogen Amcis Ltd or among the Dishman Carbogen Amcis Group sites.

TECHNOLOGY TRANSFER PROCESS

Complex, multi-step processes under both current Good Manufacturing Practice (cGMP) and non-GMP have been successfully transferred. For transfer outside of Switzerland, a specialist team follows an established three-stage procedure:

- 1 INITIATION:** the scope and goals are agreed upon by all parties – preparation of technology transfer master plan, definition of responsibilities, as well as preparation and transfer of technical information package;
- 2 PILOTING:** the process is trialed in the lab and in small production runs and extensively reviewed – compliance with regulatory and quality standards; and
- 3 SIGN-OFF:** the mutually agreed process is accepted by all parties – production against established batch instructions. A crucial element in successfully transferring technology processes across linguistic and cultural barriers is frequent communication involving our experienced personnel.

Clear definitions of the responsibilities of the technology transfer team members during the transfer process minimize the time and effort needed for this critical step in the successful scale-up of intermediates or APIs.

Dishman Carbogen Amcis Ltd can also offer technology transfer for our own processes which will enable our customers to produce their APIs with our technologies.



CASE STUDY 1: Cost Advantages and Continuous Local Management

The first three steps from a registered process, previously run in Switzerland on 1,600 L scale, were successfully transferred to operations in India within a timeframe of five months. The intermediate of an API which goes generic in a few years required us to provide larger quantities of intermediates at lower costs. The process is now being performed on a scale up to 4,000 L with the intermediate being sent to Switzerland for further conversion to the final API. This approach offers the maximum flexibility in handling the cost and quantity demands of the product in development and commercialization life cycles. The customer benefits from cost advantage and continuous local project management.

CASE STUDY 2: Customer dedicated facilities

A large, multinational pharmaceutical company required significant cost of goods reduction to deliver a market leading drug product. Dishman Carbogen Amcis Ltd optimized the process and built a dedicated facility for the API production. Dishman Carbogen Amcis Ltd further reduced costs by developing its own more cost-effective routes for the three key starting materials. An overall cost reduction of more than 50% was achieved. Routine commercial manufacture is now ongoing at the Bavla site, offering the customer significant cost advantages and a simplified and secure supply chain.

CASE STUDY 3: Commercialization from a Laboratory Process within 12 months

A European Specialty Pharmaceutical company approached Dishman Carbogen Amcis Ltd for the contract manufacture of a late life cycle API. The client had a non-infringing laboratory scale process for the API which needed optimization and scale up to commercial production.

The process was transferred and then optimized at an R&D level. This was followed by pilot scale validation batches and then 10mT commercial production within 9 months of initiating technology transfer.

During the commercial production, alternative, more cost effective supply solutions were found for key starting materials and these were incorporated into production post validation. An agreed regulatory programme was completed and Dishman Carbogen Amcis Ltd provided the client with a full technical dossier to enable regulatory filings. As a consequence of the success of this program, the client has transferred a further 3 projects into the Dishman Carbogen Amcis Group.

WHY IS DISHMAN CARBOGEN AMCIS LTD THE PARTNER FOR YOU?



- The mission of Dishman Carbogen Amcis Ltd and its fundamental purpose is to offer support and assistance to people across the world suffering from illness and disease, striving to ensure that this is completed efficiently, comprehensively, and effectively. To do so, we aspire to continually improve and innovate to provide the highest standards of quality, reliability, and timeliness; these standards are underpinned by a wide range of capabilities in an ever-diversifying environment and range of localities to meet clients' needs.

CUSTOMER SERVICE

- A relationship driven business model that invests in pharmaceutical companies rather than competes with them
- Transparency through open, responsive customer service and project management
- A continuum of services offered under flexible and innovative terms

SECURITY OF SUPPLY

- Technical and manufacturing excellence in multiple sites worldwide, allowing us to leverage the best in cost and quality controls
- We protect our customers interests as if they were our own
- Strong, tenured leadership at corporate and local levels

ADDING VALUE

- Commitment to deliver excellent economical and technical services
- Offering the best of the New World as a centre for commerce
- Innovative development to competitive, long term commercial supply

CORPORATE SOCIAL RESPONSIBILITY

We believe in making prosperity scalable through our social actions around education and healthcare. We remain committed to empowering communities and bringing meaningful positive change in their lives for an equitable and inclusive growth.

EDUCATION

We deeply understand that the advancement of our society and the progress of its members are inherently intertwined with education. Therefore, we consider it our duty to facilitate access to high-quality education and learning resources, particularly in areas and for individuals who have been unable to seize the opportunities available through mainstream channels.

HEALTHCARE

Our profound dedication lies in the pursuit of extending accessible and top-notch healthcare to all strata of society. Aligned with this objective, we have been actively involved in supporting hospitals and foundations to provide free medical aid to those in need. Through collaborative efforts, we have facilitated the implementation of a program enabling cost-free medical services, specifically paediatric heart surgeries, to young patients in need. Our partnerships reflect our continued support for healthcare initiatives, as we collectively strive to ensure comprehensive health services for the well-being of the community.



QUATERNARY AMMONIUM SALTS EXPLAINED

Quaternary Ammonium Salts (Quats) are a crucial part of organic chemistry processes across many major industries. But do you know exactly what Quats are, how and where they are used, and most importantly... why would you use them?





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