

Dishman Carbogen Amcis^{LTD}

OUR SYNERGY BRINGS LIFE TO YOUR SCIENCE

COMPANY PROFILE





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OUR MISSION

Dishman Carbogen Amcis Group continually invests in the global pharmaceutical industry, ensuring the company's business can provide pharmaceutical customers with high-value, high-quality products and services today and in the future.

- Our focus is to add value to the global pharmaceutical industry by serving as a reliable partner
- Our business is successful only when our customers are successful

OUR FOCUS: CLIENT SATISFACTION

Reduce operational risk in chemical development and commercial manufacturing by:

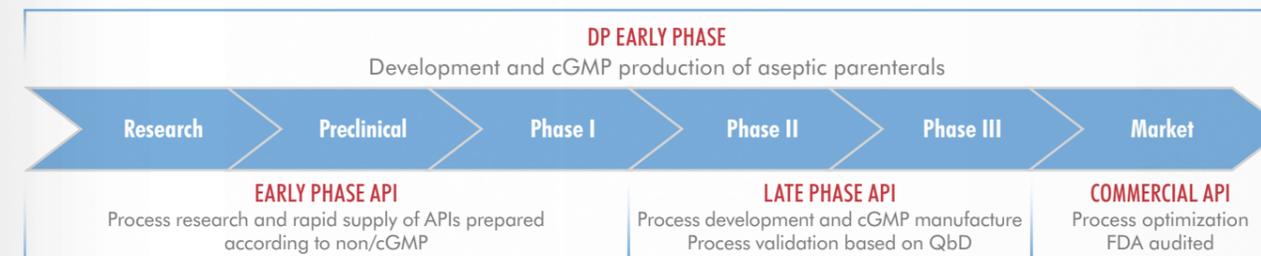
- Reducing the time associated with drug development
- Reducing the risk associated with drug development
- Providing long-term and value-added contract manufacturing solutions



- 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 Niche 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	India	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 Care	India	Next generation innovative antiseptic and disinfectant formulations.

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.

WHY IS DISHMAN CARBOGEN AMCIS LTD THE PARTNER FOR YOU?

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

- 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.





- 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 250 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 8,000 L
Riom 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.

SOPS, UOPS, DOCUMENT SYSTEMS, TRAINING

LEVEL 4: Personal Protective Equipment and Occupational Health Monitoring

LEVEL 3: Room and Associated Environment

LEVEL 2: Containment

LEVEL 1: Process System





- 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.

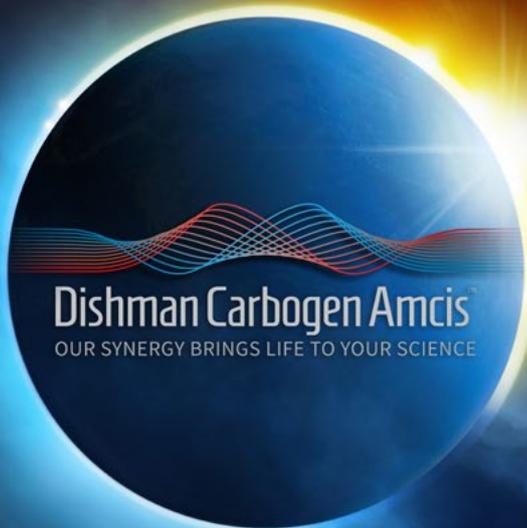
CASE STUDY 2: Customer dedicated facilities

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.



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Dishman Carbogen Amcis Ltd is a global, dynamic group of companies offering a continuum of services to the pharmaceutical industry. We are a global outsourcing partner for pharmaceutical companies, offering a portfolio of products and development, scale-up and manufacturing services. Dishman (word) and Dishman Carbogen Amcis Group (word) are trademarks owned or licensed by Dishman Carbogen Amcis Limited and all rights are reserved.

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