

**HETERO**

*Research is Development*

[www.heteroeurope.com](http://www.heteroeurope.com)



## WE MAKE THE CHEMISTRY WORK

We are HETERO, a research-based, global pharmaceutical company that develops, manufactures and markets Active Pharmaceutical Ingredients (APIs), Intermediate Chemicals and Finished Dosage Forms.

### HOW DO WE MAKE THE CHEMISTRY WORK?

**WE HAVE BREADTH AND DEPTH.** The strength of our R&D is showcased in a rich portfolio and pipeline of products ranging from conventional generic drugs through to specialized therapeutic areas including oncology and anti-HIV.

**WE ARE COST EFFECTIVE.** By leveraging the competitiveness of Indian manufacture alongside full vertical integration of our services we have established processes to develop high quality, affordable drugs.

**WE ARE LOCAL.** Our HETERO EUROPE headquarters in Barcelona provide us with close proximity to the whole of Europe, allowing us to maximise the strength and productivity of our client relationships.

**WE CARE.** As a privately owned company we have always maintained a strong sense of social responsibility and awareness. We work to high standards and worldwide regulatory approvals, and continue to use our strong chemical and scientific background to discover new or improved drugs in areas like HIV, HCV and diabetes.



## THE CHEMISTRY OF BEING WORLD CLASS

At Hetero we are continually scaling new heights and achieving greater milestones. Our success is the result of concerted efforts across the whole organisation to perform world class, industry leading work.

### A TRADITION OF EXCELLENCE

Since our establishment in 1993, our core values have centred around a commitment to consistently and excellently deliver and make easily available affordable drugs of the highest quality.

High standards and adherence to worldwide regulatory guidelines have always been part of the HETERO tradition. Our 18 manufacturing facilities comply with cGMP and global standards for infrastructure and systems, the majority of these being approved by internationally recognised regulatory authorities such as USFDA, WHO, TGA (Australia), ANVISA (Brazil), and several European agencies.



### A COMPETITIVE, FULL SERVICE OFFERING

As one of the leading international suppliers we currently hold a comprehensive portfolio of over 200 products from a wide range of therapeutic categories. Our model of vertical integration cost-effectively joins the areas of discovery research, process chemistry, active pharmaceutical ingredients (API) manufacturing, formulation development, finished dosage forms manufacturing, supply and commercialisation.

All stages are carried out at our state-of-the-art facilities in India and released in Europe, meaning we can profit from the combination of European proximity and Indian manufacturing competitiveness. Furthermore, from the European headquarters in Barcelona we offer partners the possibility of:

- licensing eCTD-dossiers
- full regulatory support with European submissions-national, MRP or DCP
- supply of the finished dosage forms

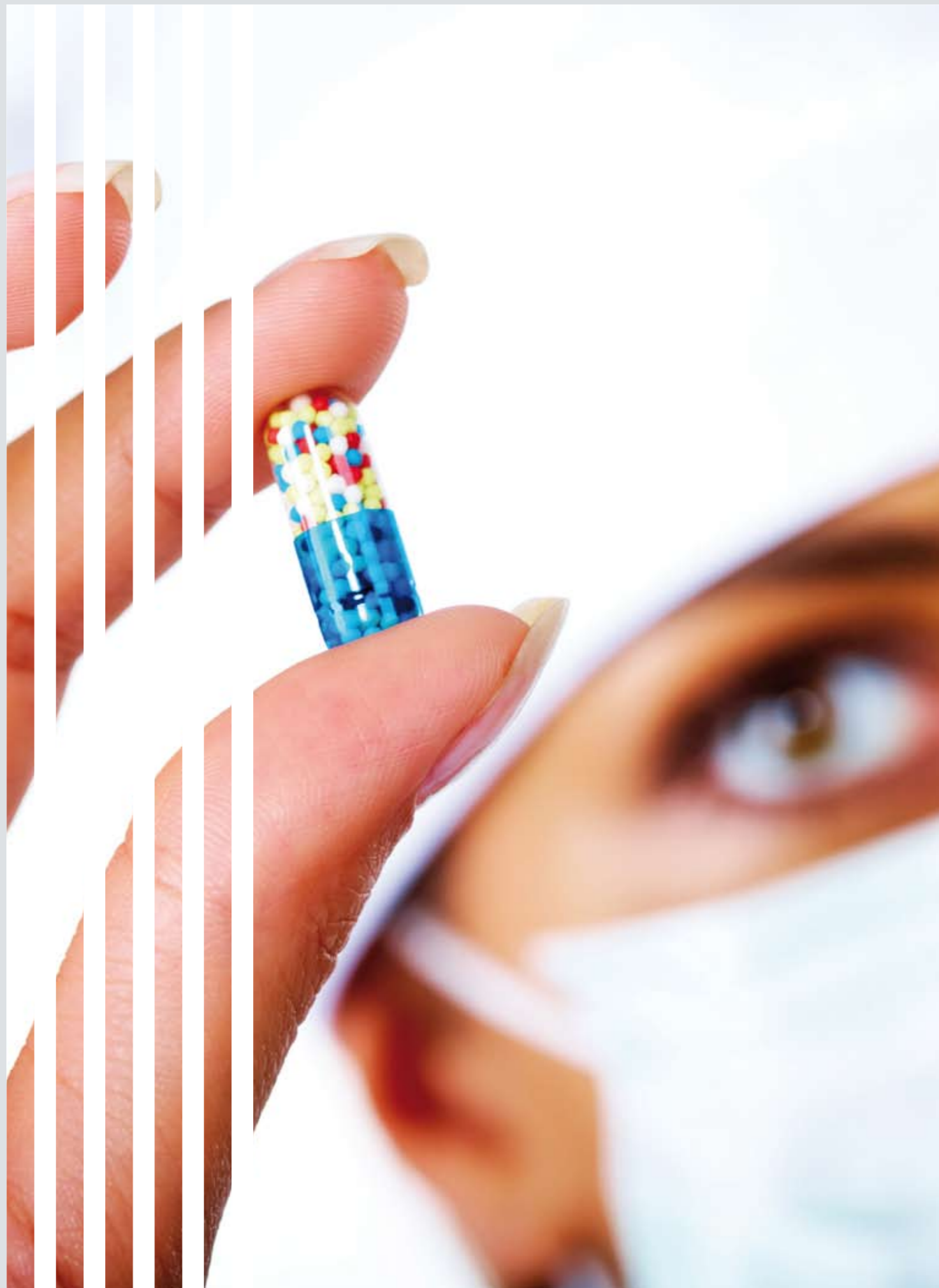
Truly a “full service package”. As a result our products are successful and profitable, helping to ensure both HETERO’s and our partner’s success and future survival in the marketplace.

### WORLDWIDE, FIRST-CLASS FACILITIES

At HETERO we employ over 6000 people across the globe. By applying our full-scale marketing resources across this network we are able to market our products directly or through partners to more than 100 countries worldwide.

Our commitment and investment into manufacturing facilities and capabilities is always increasing. Proof of this can be seen in our recent inauguration of one of India’s largest finished dosage manufacturing facilities. Featuring a total unit area of 75 acres and with two manufacturing plants, this facility offers an annual production capacity of 18 billion tablets and capsules. It has a dedicated oncology facility with a production capacity of 200 million tablets and capsules, 15 million liquid injectable vials, and 15 million lyophilised injectables.

Furthermore, this world-class facility meets the cGMP and regulatory requirements and boasts an integrated quality management system. All quality control instruments are 21-CFR compliant and the production facility features state-of-the-art equipment such as walk-in type stability chambers, a Honeywell Integrated building management system, a VirTis Lyophilizer and a BOSCH Liquid Filling Machine.



## THE CHEMISTRY OF COMPLETE SOLUTIONS

We believe it is our full-engagement with every step of the process that makes HETERO such a strong business partner. Our unique vertical integration approach means we can offer clients a competitive and complete solution, whatever their business needs.

### ACTIVE PHARMACEUTICAL INGREDIENTS (API)

As one of the largest leading manufacturers and suppliers of active pharmaceutical ingredients (APIs) and intermediate chemicals, HETERO's manufacturing infrastructure is one of the best, fully equipped with state-of-the-art facilities designed to meet global standards and cGMPs.

To cater to the ever-increasing requirements of the worldwide pharmaceutical market, 11 API manufacturing facilities are in operation in order to produce and supply more than 200 APIs to different countries. Six of the API facilities are approved by USFDA, TGA, EU and WHO, making HETERO a trusted supplier in a wide range of therapeutic categories and the largest supplier of a complete range of antiretroviral products.

### DOSSIER DEVELOPMENT AND REGULATORY SUPPORT

Our experienced European and Indian teams work in close collaboration in order to develop eCTD dossiers of the highest quality, ensuring easy and smooth submissions across Europe by HETERO or its partners. Our European team based in Barcelona submits applications for registration and assists our partners with European submissions, through national, multiple recognition, or decentralised procedures. Our aim is to develop, compile and submit more than 20 dossiers annually, leveraging HETERO's vast portfolio from other markets across the globe.



## FINISHED DOSAGE FORMS

HETERO has first-class facilities for manufacturing a wide range of finished dosage forms. As a leading, innovation-driven corporation, our growing portfolio of pharmaceutical products meets some of the world's most urgent medical needs. Today, our global product portfolio includes 200 products in major therapeutic areas, namely:

- Cardiovascular Disease
- Central Nervous System
- Dermatology
- Diabetes
- Gastroenterology
- Infectious Diseases Including HIV/AIDS
- Oncology
- Pain Management

From this portfolio, HETERO EUROPE will offer more than 50 products to our European partners, and we expect to add a significant number of new products each year.

Through our four finished dosage manufacturing facilities and dedicated oncology facility we offer a range of products including sterile dosage forms, pre-filled syringes, solid and liquid oral dosage forms, ointments, soft gelatine capsules and inhalers.

## CUSTOM RESEARCH AND MANUFACTURING SERVICES (CRAMS)

At HETERO we have initiated a customer-centric division for delivering Custom Research and Manufacturing Services (CRAMS) to large, mid-sized and emerging biotech and pharmaceutical entities globally.

Our plan is to partner with these companies, cultivating opportunities to research, manufacture, and develop compounds across the entire drug life cycle. The CRAMS division will deliver fully consolidated or customised manufacturing solutions for APIs, intermediate chemicals, pre-formulations and formulations across each stage of the pharmaceutical life cycle. As a result we will be able to provide premium solutions for product life cycle management including life cycle extensions and line extensions.

## RESEARCH & DEVELOPMENT

R&D forms the foundation of our philosophy to develop cost-effective, high quality and safe medicines to society. HETERO Research Foundation is one of the most innovative, productive, and respected scientific research organizations, and is recognised by the Government of India's Department of Science & Technology.

The Foundation has a team of over 400 dedicated scientists working in three areas of research: Process, Analytical and Discovery. The R&D centre conforms to international standards and has advanced equipment to carry out both basic and applied work.

- **Process R&D:** The Foundation has developed processes for over 200 molecules for markets across the globe. The R&D team is actively involved in process development, scaling-up and technology transfer and works alongside the manufacturing teams throughout the life-cycle of the product. At HETERO we have always ensured that the processes adopted for the products are cost-effective, safe to handle, and bring optimum advantages in terms of yield and quality.
- **Analytical R&D:** The Foundation's analytical research is equipped to conduct complete physical and chemical characterizations of API's and NCE's. Furthermore, the team is well versed with regulatory filings and has vast experience with documentation procedures. The infrastructure includes advanced instruments like LC-MS-MS, GC-MS, NMR, Powder XRD as well as several HPLC systems.
- **Discovery R&D:** We started our drug discovery research by focusing on developing NCE's in selected therapeutic areas. Scientists at our Drug Discovery Division are working on research projects in HIV, HCV and diabetes. Our business strategy is to outlicense early-stage discovery molecules and to explore early-stage collaborations as a way of maximising the potential of our research projects.

## BIOTECHNOLOGY

One of our current areas of focus is the development and manufacture of bio-generics for domestic and international markets. With several biosimilars at various development stages and some products in oncology and nephrology nearly on the market, here at HETERO we are truly set for the future.

## THE CHEMISTRY SHARED WITH SOCIETY AND OUR PEOPLE

As a socially responsible organisation, at HETERO we recognise and value the obligations we have towards society as a whole. We constantly strive to use our expertise to transform or improve the lives of the less privileged, whilst at the same time ensuring that our work methods and policies benefit our employees as well as the external environment.



### DEVELOPING SOCIETIES

HETERO undertakes a number of initiatives in less privileged countries, including the adaptation of rural villages to encourage more rapid development. We assist in setting up schools in areas with no or limited access to education facilities and help students who show academic promise reach their goals through financial assistance. There is also sponsorship available for athletes from various educational institutions so they can participate in both national and international high-level sports events.

In socially backward areas HETERO conducts periodical medical camps at various locations to provide timely medical assistance to those in need. We have liberally donated medicines to the Government of India, and also to various hospitals and non-profit organisations such as the Clinton Health Access Initiative (CHAI) to whom we provide antiretroviral and antiviral drugs.

### ENVIRONMENTAL AWARENESS

Global pollution is a growing problem but with modern manufacturing techniques it is possible to make better use of scarce resources and limit the environmental burden. For the sake of future generations, HETERO has assumed its responsibilities by enhancing our environmental awareness, optimising our entire production including the critical areas of power management, waste treatment and water supply management.

### SAFETY AND WELLBEING IN THE WORKPLACE

The safety of each individual in the workplace is a top priority for HETERO, clearly demonstrated by the stringent safety standards enforced in all of our manufacturing facilities. In order to eliminate the risk of accidents or exposure to potentially harmful substances we have a number of processes in place, for example the compulsory use of clean-air suits and the provision of additional protection for female employees.

For a company that prides itself on employing top-skilled staff, the workplace environment is also of crucial importance. HETERO provides its employees with benefits such as an attractive workplace in green surroundings, complimentary healthy meal plans and a health care scheme that contributes to their daily wellbeing and motivation.

## THE CHEMISTRY OF REALISING DREAMS

At HETERO our aim is simple - to maintain our position as one of the world's leading suppliers of high-quality, easily accessible and affordable drugs.

The global need for cost-effective medicinal products is greater than ever. In working towards our aim we take pride in being one of the manufacturers truly making a difference. We will make the chemistry work.





## HETERO EUROPE S.L.

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