

# The Company

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## About Nortec Chemical

### Largest manufacturer of Active Pharmaceutical Ingredients (IFAS) in Latin America

Nortec Química is the largest manufacturer of Active Pharmaceutical Ingredients (APIs) in Latin America and started its determined activities to guarantee quality medicines with (APIs) developed in Brazil. For this, the company combined the knowledge of the main National Research Centers with the experience of the Brazilian Chemical and Petrochemical Industry.

Nortec Química is of great importance in the Brazilian pharmaceutical scenario and in the Unified Health System (SUS), producing APIs for branded, generic and similar drugs and drugs for neglected diseases.

After 40 years, Nortec Química accounts for the development and manufacture of more than 50 APIs, all using proprietary technology. This achievement is also due to a team of excellence, with more than 50% of employees having higher education, many of whom are academically supported by the company. The company has a product supply and development portfolio aimed at more than 250 Pharmaceutical Laboratories in Brazil and the world and has become recognized for its quality with successive Awards for Excellence in the Supply of APIs.

Nortec Química's commitment is to people's health and, therefore, it develops research for Neglected Diseases, as defined by the World Health Organization (WHO). Nortec Química is the only producer of Benzidazole in the world and the largest producer of Antiretrovirals in the West.

The relevance of Nortec Química on the world stage remains with the increase in production capacity completed in 2017 and in the performance in Research & Development with the project to install the Plant for High Potency Drugs, contributing with technological solutions to improve well-being, of people's lives and health.

## Nortec 40 years

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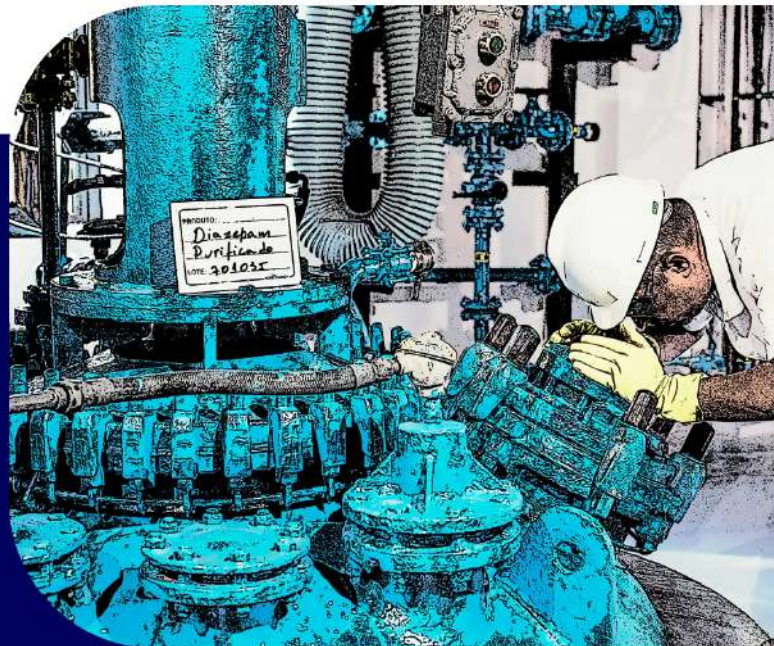


#### Cutting-edge Industrial Technology

We have great importance in the Brazilian pharmaceutical scenario and in the world scenario.

#### International Recognition

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# Research And Development

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## Scientific knowledge is in the DNA of Nortec Química.


Research & Development activities represent an important foundation in Nortec Química's business strategy. The more than 50 APIs currently produced are all developed with proprietary technology in Brazil between Nortec Química and Research Centers of Excellence in the country. This Company – University cooperation model has been one of the pillars for the company's growth, allowing Nortec Química to achieve excellence in the development of Industrial Technologies and API production processes (Active Pharmaceutical Ingredients).

## Specialized Team

In the research and development sector, we have a team of chemists, pharmacists, masters and doctors, who are responsible for the development of New Molecular Entities (NMEs)

## Partnerships

The company maintains sustainable relationships around the world, generating partnerships and alliances to support the development of new APIs and technologies, including formal agreements with Government Agencies, Institutes of Science and Technology (ICTs) and Official Laboratories.



# Production

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## Fully Compliant Constructed Area

With 38,000m<sup>2</sup> of total area, Nortec Química has 12,962m<sup>2</sup> of built area fully in compliance with the most demanding regulations of regulatory agencies.

## Expansion of the Industrial Park

To support the growth and development of APIs, Nortec Química expanded its industrial park, inaugurating in 2017 two new units with an engineering project of Italian origin and with the highest technology of equipment, such as dryers and high-performance centrifuges and German technology, qualified areas and even a pilot plant for the development of new molecules.

## Respecting the Requirements of ANVISA

The plants were also designed for future ANVISA requirements related to area classification, in accordance with NBR 1644. Currently, Nortec Química has 116m<sup>2</sup> of reactors spread over 5 multipurpose units, with a production capacity of 340 tons IFA/year.



# Quality

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## Meeting the most rigorous Brazilian and International standards

With Certification in Good Manufacturing Practices (cBPF) granted by ANVISA since 2002 and by the Food and Drug Administration (FDA) since 2016, Nortec Química is proud to have facilities and documentation system that meet the most rigorous Brazilian and international standards. The more than 50 Active Pharmaceutical Ingredients manufactured by Nortec Química have a complete DMF (Drug Master File), registered with the various Regulatory Agencies around the world and are being updated to the CTD (Common Technical Document) format. In 2019, Nortec Química started the process of obtaining the CEP (Certificate of Suitability to the monographs of the European Pharmacopoeia) for its APIs, starting with Prilocaine.

## Team in Constant Development

The Nortec Chemicals team is constantly developing and updating new regulatory trends. The quality of its APIs is guaranteed through the development and validation of analytical methodologies, including official compendia, such as the American Pharmacopoeia and the European Pharmacopoeia, analysis of critical process parameters, control of the attributes of starting materials, raw materials and finished products.

## High Tech Equipment

Stability studies are carried out in accordance with current legislation, serving other climate zones, as required by our customers. The company also has high-tech equipment, with chromatographs managed by software that meet the requirements of the FDA CRF21 part 11 standard.



# Sustainability

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## In line with regulatory standards and the environment

Nortec Química has an Effluent Treatment Station that reproduces the natural treatment cycle, in an area of high efficiency, being able to avoid the environmental impact with the use of defined processes and times, in accordance with the strictest regulatory standards and with the environment. In a technological partnership with COPPETEC/UFRJ, since the 1980s, Nortec Química has been developing a project of excellence for the effluent treatment process of the entire company.

## sustainable excellence project

Based on the Experimental Studies carried out with COPPETEC/UFRJ, it was concluded that Nortec Química's effluent is organic, biodegradable and liable to biological degradation. As a consequence, the treatment system and the engineering project of the ETE were defined, contemplating its various stages: anoxic, aerobic, physical-chemical separation and obtaining the stabilized biomass.

## Commitment to the environment

Waste that is not treated at the company itself is sent to competent companies accredited by the environmental agency. The company's commitment to the environment and its environmental requirements are part of the Operation License (LO) issued by the State Environmental Institute of the State of Rio de Janeiro.

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