ANALYTICAL & BIOANALYTICAL SERVICES

CERTIFIED MANAGEMENT SYSTEMS
CERTIQUALITY
UNI EN ISO 9001:2015
UNI EN ISO 14001:2015
UNI EN ISO 45001:2023
IQNET RECOGNIZED CERTIFICATION
CERTIQUALITY IS MEMBER OF CISQ FEDERATION

CERTIFIED MANAGEMENT SYSTEM
CERTIQUALITY
UNI CEI EN ISO 50001:2018
IQNET RECOGNIZED CERTIFICATION
CERTIQUALITY IS MEMBER OF CISQ FEDERATION

PLATINUM Top 1%
ecovadis
Sustainability Rating
OCT 2025

CHIMAN srl

ABOUT OUR COMPANY

CHEMISTRY & PHYSICS ANALYTICAL LAB

Chiman is a Contract Research Organization focused on improving the world's health.
We do this by providing a portfolio of analytical and bioanalytical services that help clients transform scientific discoveries into new medicines.
Chiman has a strong commitment to quality in all aspects of our service. We aim to continuously improve our service and customer satisfaction by customer care first in everything we do.
Our core values support our commitment to meeting quality standards and accreditation.

REFERENCE

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OUR MISSION

Our mission is to provide customized high-quality services to pharmaceutical companies.
Our priority is to support the client's needs and the project's requirements.
Our key asset is flexibility: we don't only work to make the client's vision our vision, we become partners in their projects.

OUR VISION

We work hard to be our clients' preferred analytical laboratory.
We focus on analytical chemistry, biochemistry and medical devices, with an expertise in the respiratory therapeutic area.

CERTIFICATION

Ministero della Salute

Agenzia Italiana del Farmaco
AIFA

FDA Establishment Registration for Testing Laboratories

FEI NUMBER: 3015176596

GOOD MANUFACTURING PRACTICES (GMP)

AIFA (Italian Medicines Agency) has authorized CHIMAN to perform analytical controls on medicinal products and investigational medicinal products (GMP) since July 2006.

ISO CERTIFICATION

Chiman S.r.l. is a third-party laboratory, founded in 1991, specializing in performing chemical and chemical-physical analyses for the pharmaceutical sector, performing analytical activities on clients' proprietary products and/or samples according to protocols established/approved by them and performing analyses relevant for GMP purposes or for exploratory R&D purposes.
Chiman has 30 years of experience in pharmaceutical development and testing.
This is achieved by providing a portfolio of analytical and bioanalytical services that help customers transform scientific discoveries into new medicines.
Chiman has a strong commitment to Environmental Protection, Worker Health and Safety, Energy Efficiency and Environmental Sustainability in all aspects of its service delivery, aiming to continuously improve service, customer satisfaction and the achievement and maintenance of high quality standards in the various areas of interest.
Our mission is to provide high-quality customized services to pharmaceutical companies with a view to increasing the sustainability of their processes.
Our key asset is flexibility: not only do we work to make the customer's vision our vision, but we aspire to become a partner in their projects.
We focus on analytical chemistry, biochemistry and medical devices, with expertise in both raw materials and conventional finished products as well as significant experience in the respiratory therapeutic area, combining analytical leadership, innovative technology and scientific expertise in the field to provide a state-of-the-art service for both customers and patients.

We perform a wide range of services, including:

- analysis of inhalation preparations
- conventional formulations
- generic drugs
- development studies
- biological analyses
- stability and preservation tests
- identification of impurities/degradation products
- analysis for batch release for retail sale on the market
- analyses for batch release for clinical studies

ISO CERTIFICATION

Chiman S.r.l. has been authorized by AIFA to perform chemical-physical controls on medicinal products for human use since July 2006 and on experimental medicinal products since December 2008.

Chiman is authorized by AIFA to carry out chemical (F1) and chemical-physical (F2) controls on medicinal products for human use and on investigational medicinal products for clinical trials pursuant to Legislative Decree of 24 April 2006, No. 219 as amended.

Chiman is FDA registered (FEI Number: 3015176596).

'Chiman aims to make a concrete contribution to the health and improvement of people's quality of life while respecting its Workers and the Environment also through energy efficiency'.

Fundamental points of this policy are:

- the commitment to guarantee the availability of the information and resources necessary to achieve the objectives and targets set in terms of the Environment, Workers' Health and Safety as well as Energy Efficiency and environmental sustainability of activities;
- the commitment to comply with all the mandatory regulations applicable to the activities of Chiman s.r.l. concerning the Environment, Workers' Health and Safety and Energy use;
- the commitment to 'maintaining the level of Effectiveness' of the Quality Management System, of the Environment, Health, Safety and Energy Integrated Management System, of what is defined in the respective Policies and the related Objectives with a view to 'Continuous Improvement
- the commitment to periodically review the Quality Management System, the Environment, Health, Safety and Energy Integrated Management System, the related Policies and Objectives with a view to 'Continuous Improvement';
- the commitment to periodically review the Quality Management System, the Environment, Health, Safety and Energy Integrated Management System, the related Policies and Objectives with a view to 'Continuous Improvement';
- the commitment to the protection of the Environment, to the prevention of pollution and to increasing environmental sustainability;

ISO CERTIFICATION

- the commitment to provide safe and healthy working conditions for the prevention of accidents and occupational diseases, eliminating risks to Workers' Health and Safety and, where not possible, reducing them through appropriate prevention and protection measures;
- the commitment to involve Workers and their representatives through specific consultation and participation activities;
- support the procurement of energy-efficient products and services that have an impact on energy performance, while keeping the level of quality as high as possible;
- support design activities that consider improving energy performance;
- the commitment to identify, recognize, pursue and satisfy the needs of 'Interested Parties' at a Local, Regional, National, European and Global level;
- the commitment to promote, pursue and periodically verify the satisfaction of Customers who use Chiman's Services;
- the active participation in the continuous improvement of the quality of the Services by all the Personnel involved, including external suppliers and collaborators;
- the creation of an internal climate marked by collaboration and optimization of the capabilities and satisfaction of all Collaborators;
- attention to Environmental, Energy and Safety issues in the workplace.
- the attention and active participation in the increase of the 'Italian Product' image in Europe and worldwide;
- attention to Ethical and Social components in all operational phases, namely
    - in relations with production and employment realities;
    - in relations with the 'market';
    - in the traceability and utilization of Skills and Research itself for emancipatory and social purposes;
    - in respecting multi-ethnicity and religious and areligious pluralism as essential values for socio-cultural growth;
    - in the employment of social issues through the pursuit of objectives for the development of employment opportunities.

CODE OF ETHICS AND SOCIAL RESPONSABILITY

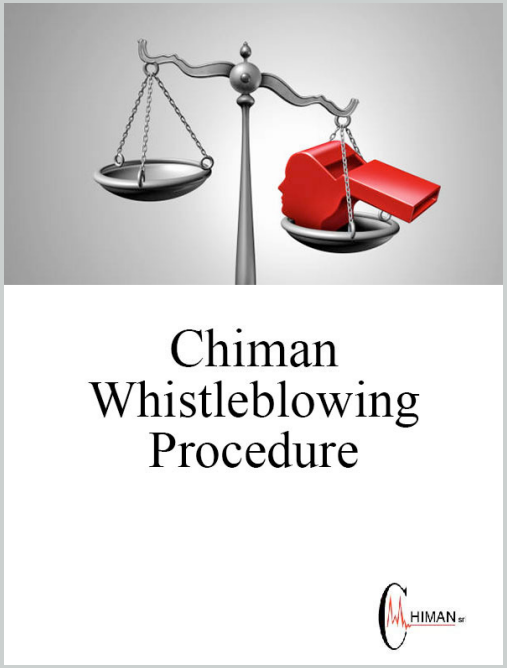
Codice Etico
di Chiman Srl

Codice di
Condotta
Chiman Srl

Modello di
Organizzazione,
Gestione e
Controllo

Download these documents at: https://www.chiman.it/code-of-ethics-and-social-responsability/

WHISTLEBLOWING



Whistleblowing introduction

Whistleblowing is the reporting of an offense, risk, or dangerous situation by a person who, in the course of their duties, becomes aware of an offense, risk, or dangerous situation that could cause harm to the company they work for, as well as to customers, colleagues, citizens, and any other category of individuals.

Chiman, sensitive to ethical and proper business conduct issues, has implemented internal reporting systems to allow those identified by law to report violations of national or European Union regulations that harm the public interest or the integrity of public administration or private entities, of which they have become aware in a public or private work context, including violations of the Code of Ethics or the Organization, Management, and Control Model pursuant to Legislative Decree 231/01.

Contesto di riferimento

Legislative Decree no. 24/2023 (the “Whistleblowing Law”), implementing EU Directive 2019/1937, governs the protection regime for individuals who report unlawful conduct committed in violation of European and national provisions, provided that it is based on proven grounds and is detrimental to the public interest or the integrity of the entity.

In light of Chiman’s corporate structure, which averages less than 50 employees and has successfully adopted and implemented Model 231, the whistleblowing legislation applies only to reports concerning unlawful conduct relevant to the provisions of Legislative Decree 231/2001 or violations of Model 231.

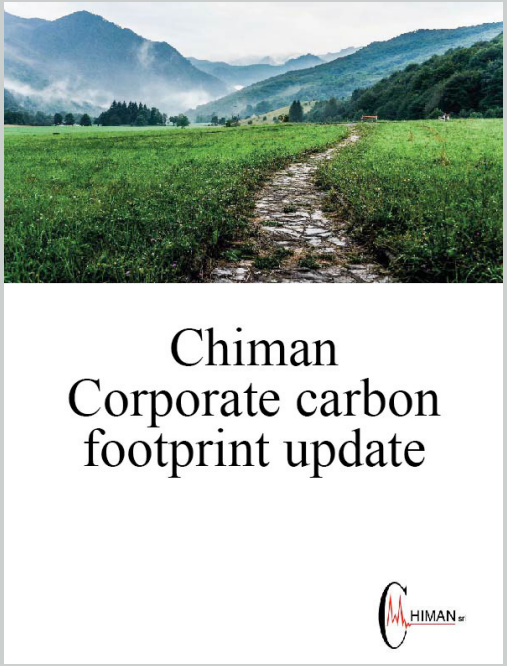
Such reports may be made only through the internal channel, established with the specific procedure referred to, in compliance with all the requirements, protections, and guarantees provided and imposed by the legislation.

Therefore, other types of reports, even if provided by law, will not be considered, nor will additional reporting channels be considered, as they are not specifically applicable to Chiman.

Whistleblowing Procedure

For more information and details or to submit a report visit:
https://www.chiman.it/WHISTLEBLOWING/

SUSTAINABILITY



Sustainability is one of the core values for Chiman. With this in mind, we decided to act to reduce our environmental impacts.

We are proud to announce our commitment to the Science Based Targets initiative (SBTi), aligning our operations and strategies with the global effort to combat climate change through science-driven goals.

Our Journey to Decarbonization

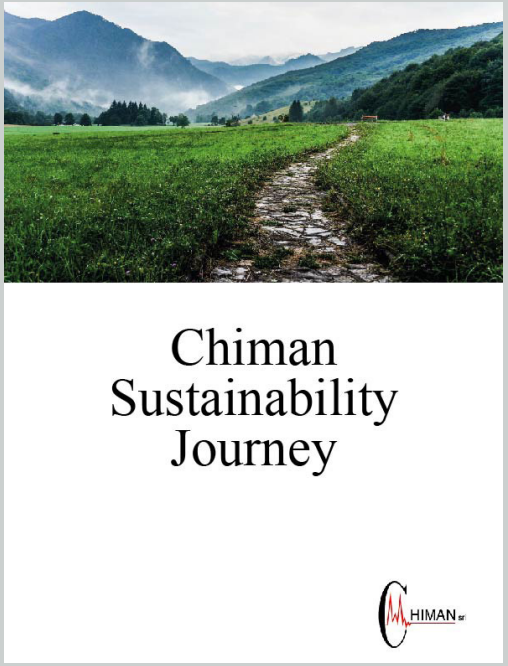
Understanding our impact was the first step towards meaningful change. With this in mind, in 2023 we started by measuring our 2022 carbon footprint, to identify key areas where we have the majority of our carbon emissions. We calculated our emissions according to the GHG Protocol standard, in order to have an overview of both our direct and indirect carbon emissions.

Building on this data, we drafted a first decarbonization plan, tailored to our specific operational needs and sustainability goals.
Afterwards, we decided to join the widely recognized Science Based Targets initiative.

Why Science Based Targets?

The Science Based Targets initiative (SBTi) is a collaboration between the Carbon Disclosure Project (CDP), the United Nations Global Compact, World Resources Institute (WRI), and the World Wide Fund for Nature (WWF). The initiative aims to encourage companies and organizations worldwide to set greenhouse gas (GHG) emission reduction targets in line with the level of decarbonization that the latest climate science suggests is necessary to keep global temperature increase below catastrophic levels and reach net-zero by 2050 at latest.

SUSTAINABILITY



Our decision to commit to the SBTi comes from our dedication to set robust and ambitious sustainability targets. The SBTi provides a clear and effective framework to reduce greenhouse gas emissions, guiding us in the implementation of our decarbonization plan. By setting science-based targets, we ensure our strategies are aligned with the latest climate science necessary to meet the goals of the Paris Agreement.

In line with SBTi rules, Chiman:

• Set target for Scope 1 and 2, committing to reduce their GHG emissions 42% by 2030 from a 2022 base year;

• Committed to measure and reduce our scope 3 emissions.

We just started our journey, but we already measured our 2022 (base year) and, since then, we have been measuring and updating annually complete carbon footprints, including Scope 1, 2 and 3 emissions to show our progress towards decarbonization.

More information can be found in the Sustainability Journey document available at:
https://www.chiman.it/sustainability/
and on the Science Based Targets initiative website, searching for “Chiman” in the “Companies taking action” list.

SERVICES

CHIMAN FOR PHARMACEUTICAL

Chiman is a small private Contract Research Organization with more than 30 years of experience in pharmaceutical development and controls.
Chiman Lab combines analytical leadership, ground-breaking technology and scientific expertise in the field to provide leading edge outcomes for customers and patients alike.
We are a top choice provider amongst private labs across the country.
We serve pharmaceutical groups and perform a large range of services, including:

- Analyses of drug for inhalation
- Conventional formulations
- Generics
- Early development studies
- Bioanalyses
- Stability testing and storage
- Identification of impurities/degradation products
- Analyses for batch release for market retail
- Analyses for batch release for clinical studies

MAIN SERVICES

RAW MATERIALS, NATURAL EXTRACTS, INTERMEDIATES AND FINISHED PRODUCTS PHYSICAL-CHEMICAL ANALYSES

- Analytical method development for human/veterinary medicinal, chemical, natural and nutraceutical products
- Stability indicating trials of chromatographic methods
- Validation of analytical methods according to ICH guidelines
- Quantitative and qualitative determination of active ingredients (API), related substances, residual solvents, contaminants, preservatives and dyes (by chromatographic, spectroscopic)
- Phisycal testing and characterization
    - Inhaler testing (by DUSA, USCA, ACI, NGI, MSLI and TSI apparatus for pressurized, dry powder inhalers and aerosol devices and by SPRAY VIEW® for the study of force/angle of delivery and shape/size of the particles delivered)
    - Cleaning validation (analytical procedure development and validation)
    - Indentifications (identification of impurities/degradation products)

MAIN SERVICES

STABILITY STUDIES

- Stability storage in compliance with ich guidelines (main available conditions: 5°C, 25°C/60%RH, 30°C/65%RH, 40°C/75%RH, for semipermeable and permeable containers, temperature cycling and photostability)

BIOANALYTICS

- Analytical method development (mainly by HPLC-MS-MS)

- Method validation (according to FDA/EMA guidelines)

NITROSAMINES

CHIMAN ON THE FRONT LINE IN GENOTOXIC IMPURITIES EVALUATION AND DETERMINATION

N-Nitrosamines Contamination

N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA), both classified as probable human carcinogens, were not identified as impurities of Sartan APIs and the same problem was found in Ranitidine HCl drug product.
Sodium azide, Zin Chloride in presence of Dimethyl formamide giving quenching with sodium nitrite transformed it in nitrous acid. Nitrous acid fast reacting with secondary amines gives N – Nitrosamines, classified as human carcinogens.

Chiman has invested in a UPLC – Orbitrap Q Exactive Classic, to be able to detect those impurities at the lowest regulatory level set.

Other API's and Drug Products are under investigation by the European Medicine Agency and FDA, in order to increase safety and quality of the Medicinal Products potentially contaminated by those impurities.

NITROSAMINES

Chiman services

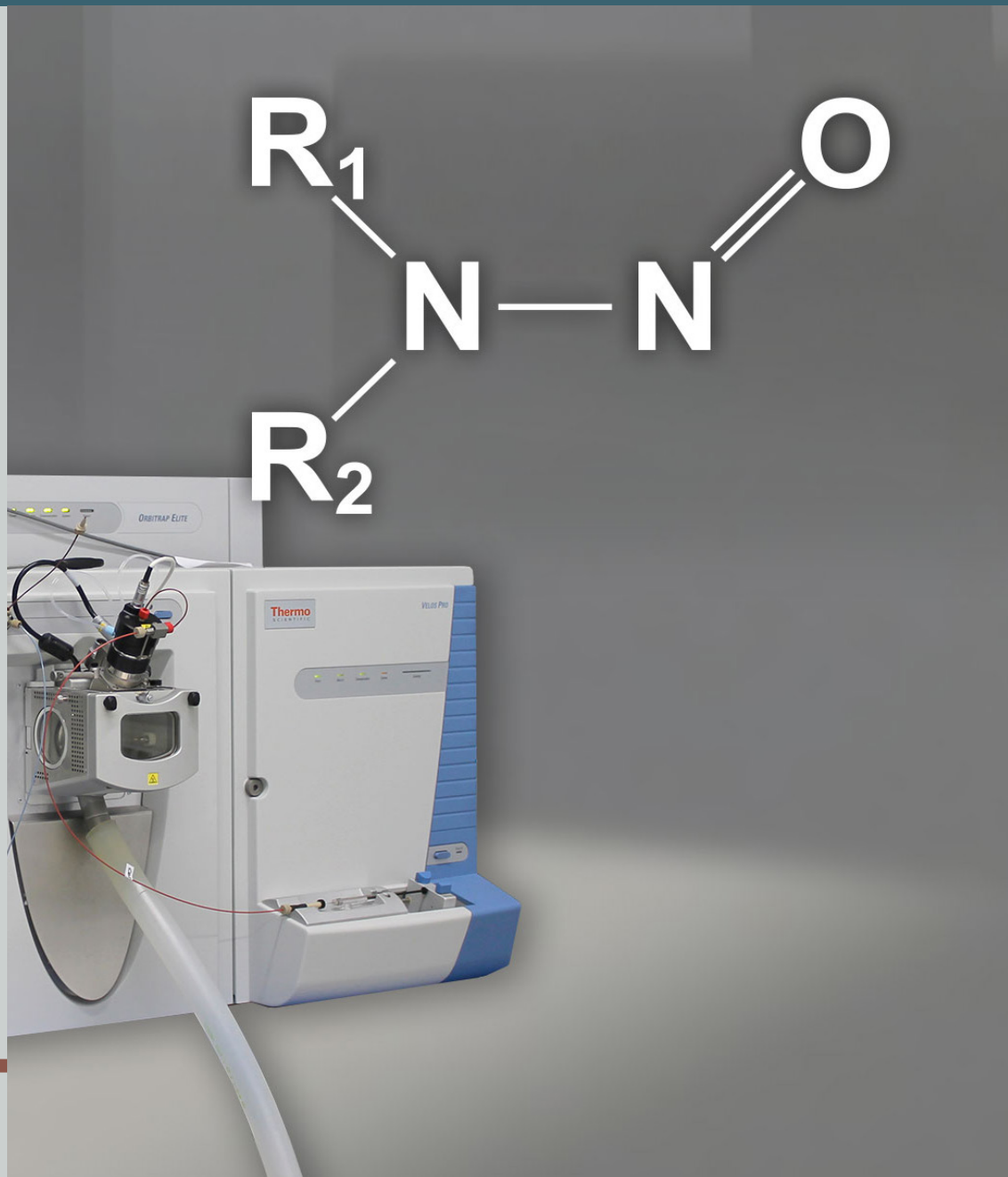
Chiman Laboratory following evidence of the risk assessment is able to develop methodologies and analytical testing plans in order to sustains risk-based considerations. Chiman quality assurance approach is based on state-of-the-art analytical equipment, completely in accordance with CFR21 requirements.

Analytical Methodologies

Following FDA methodologies like FY19-107-DPA-S_LC-MS Method for Detection of Six Nitroso Impurities in angiotensin II receptor blocker Drugs_051619, Chiman can provide UHPLC-ESI-APCI-MS/MS analysis of N-Nitrosamines in API's and Drug Products by using official methods or customized methods on Client's needs.

All the methods will be validated according to ICH Guidelines, before their use.

All the regulatory Agencies investigation up-grades will be integrated in Chiman methodologies.



CORE BUSINESS

RESPIRATORY

Chiman has more than 30 years of experience in drug development and analytical testing of drug for inhalation. (Pressurized metered dose inhalers, dry powder for inhalation and drug for nebulization)

Main services are:

- Analytical assistance to drug development (Early development and Phase I)
- Formal Development Studies according to ICH and FDA guidelines
- ICH stability studies
- Process validation
- In-vitro bioequivalence
- Inhalation performances characterization

MAIN EQUIPMENTS

PHYSICAL/CHEMICAL TESTING

- POTENTIOMETRIC TITRATOR
- KARL FISCHER
- COULOMETER

SPECTROSCOPY

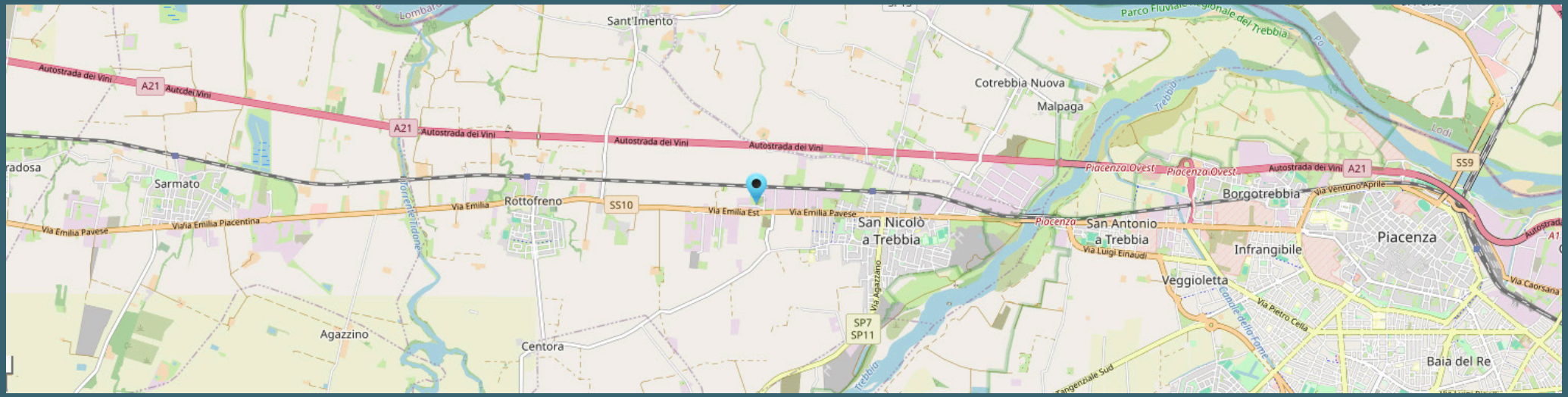
- UV-Vis
- AA

CHROMATOGRAPHY

- GC-FID
- UPLC-MS-MS
  (Orbitrap, single quadrupole, triple quadruple)
- HPLC (UV, DAD, CAD)
  each system equipped with autosampler (also refrigerated) and column heater
- TLC
- Chromatographic software in compliance with 21 CFR PART 11

INHALERS TESTING

- SPRAY VIEW®
- NEXT GENERATION IMPACTORS
- ANDERSEN CASCADE IMPACTOR
- MULTI STAGE LIQUID IMPINGER
- DOSE UNIT SAMPLING
- TWIN STAGE IMPINGER
- FAST SCREANING IMPACTOR
- BREATH SIMULATOR



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