ANALYTICAL & BIOANALYTICAL SERVICES

CHIMAN srl

ABOUT OUR COMPANY

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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

Alberto Sfulcini
General Manager and Qualified Person
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Fabio Mizzi
Quality Control Manager
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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.

SERVICES

CHIMAN FOR PHARMACEUTICAL

Chiman is a small private Contract Research Organization with more than 25 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)
- PHYSICAL TESTING AND CHARACTERIZATION (by dissolution test, disintegration test, viscosity, density)
- INHALER TESTING (by DUSA, USCA, ACI, NGI, MSLI and TSI apparatus for pressurized, dry powder inhalers and aerosol devices)
- CLEANING VALIDATION (analytical procedure development and validation)
- INDENTIFICATIONS (identification of impurities/degradation products)

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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)
- SAMPLE ANALYSIS SUPPORTING:
  - PHARMACOKINETIC
  - METABOLISM
  - BIOEQUIVALENCE
  - RESIDUE STUDIES

CORE BUSINESS

RESPIRATORY

Chiman has more than 20 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 EQUIPEMENTS

PHYSICAL/CHEMICAL TESTING

- DISSOLUTION
- DISINTEGRATION
- VISCOSIMETER
- POTENTIOMETRIC TITRATOR
- KARL FISCHER
- COULOMETER
- DENSIMETER

CHROMATOGRAPHY

- UPLC-MS-MS
  (triple quadruple)
- HPLC
  (UV-Vis, DAD),
  each system equipped with
  autosampler (also refrigerated)
  and column heater
- TLC
- Chromatografic software in
  compliance with
  21 CFR PART 11

INHALERS TESTING

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

SPECTROSCOPY

- UV-Vis
- AA

CERTIFICATIONS

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.

CLINICAL TRIALS

CHIMAN has been admitted to clinical trials of medicinal products according to Italian D.M. 19 March 1998 since August 2007
(AUSL of Piacenza issued the qualification on 03 August 2007, prot. N. 42567).

AIFA (Italian Medicines Agency) on 17 April 2008 (communication N. AIFA.II/40983/P/i.5.i.m/O) has recorded CHIMAN admission to perform laboratory analyses for Phase I / Bioequivalence / Bioavailability Studies from clinical trials of medicinal products on healthy volunteers (according to Italian D.M. 19 March 1998).

Ministero della Salute

Agenzia Italiana del Farmaco
AIFA

ISO CERTIFICATIONS

ON GOING

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