NUVISAN

SPECIAL SOLUTIONS

Pharmaceutical Analytical Solutions

Pharmaceutical Analytical Solutions for your Drug Development

From Discovery to Clinic

To effectively support your drug development project, NUVISAN offers a wide array of analytical solutions from early discovery, with the development of new chemical entities to early phase clinical trials through to formulation development.

Based on an analytical continuum, our testing experts provide solutions all along the value chain including method development, validation, quality control, stability studies of the main physicochemical and microbiological testing for innovative and generic products.

With operations performed at 3 sites in Neu-Ulm (DE), Waltrop (DE) and Sophia-Antipolis (FR), our team, with their unique know-how and state-of-the-art equipment, is able to offer a deep knowledge of the characterization and performance of your product all the way to manufacturing, commercialization and Life Cycle Management.

Our pharmaceutical analytical expertise at a glance

80 analytical experts seamlessly working across our 3 GMP certified sites

Ability to test API and finished products (solid, semi-solid and liquid forms), biosimilars and biologicals

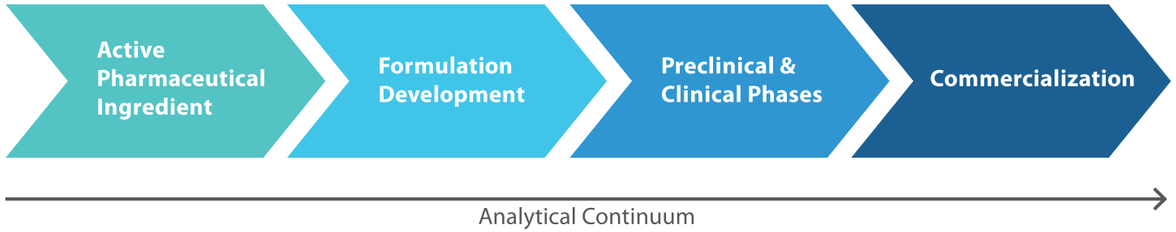
+5.000 m^2 GMP facilities with dedicated rooms for highly potent products.

Best-in-class equipment including:
70 Liquid Chromatographs
(HPLC I UPLC), LCMS and LIMS

ANALYTICAL CONTINUUM AT **NUVISAN**

To choose the best formulation for your drug product, our formulation and chemistry specialists work hand in hand to gain a thorough knowledge of the Active Pharmaceutical Ingredient (API) behaviour and its interactions with excipients. In the meantime, our analytical team performs consistent studies all along the drug development stages to consolidate their insights, to generate reliable data and thus maximize the chances to be successfully and quickly on the market.

Based on the stage of your project, a tailor-made analytical package is defined to maximize knowledge and data for resulting in fit-for-purpose analytical methods.



Highlights

Structural elucidation and solid form characterization

In Vitro Release Test (IVRT)

Container Closer Integrity Testing (blue dye, high voltage leakage detection and oxygen and carbon dioxide headspace gas analyser).

+230m^3 chambers for stability testing including conditions recommended in the ICH guidance.

API METHOD DEVELOPMENT & VALIDATION

- Method development
- Method validation and transfer
- QC testing: In Process control, drug substance
- ICH stability studies & storage
- Cleaning verification
- Structural elucidation of impurities
- Forced degradation studies
- Solid form characterization
- Non sterile microbiological testing

FORMULATION DEVELOPMENT

- Compatibility studies
- Pre-formulation studies
- Preliminary stability during formulation development
- Microstructure characterization and performance

(PRE)-CLINICAL STUDIES & COMMERCIALIZATION

- Analytical support to manufacturing process development, scale up and Quality by Design approach
- Batch release
- Pre- and post study analysis
- Commercial batch release
- QP release
- Structural elucidation for unknown impurities

PROJECT MANAGEMENT

A single project manager is assigned to the client as a key contact, responsible for project coordination with all technical experts and to liaise with the client through conduct of regular project meetings.

NUVISAN

YOUR SCIENTIFIC CRO PARTNER

NUVISAN is a fully integrated CRO/CDMO offering all solutions from drug discovery to Proof of Concept in patients including: target identification, high throughput screening, compound profiling, pre-clinical DMPK, toxicology, API synthesis, formulation development, pharmaceutical analysis, and clinical trials in healthy volunteers and patient populations.

With capabilities distributed over 5 locations in Europe and with more than 40 years of experience, we deliver high-quality solutions certified by various accreditations and inspections (e.g. BfArM, EMA, FDA, ANVISA, ANSES, AAALAC, GLP, GMP).

40

A trusted scientific partner
With a 40-year track record of customer satisfaction

A wide range of expertise
A unique, comprehensive and integrated offer from target identification to clinical trials

A data-focused expert
Our top priority is to ensure accurate, reliable, and consistent data quality

A flexible service provider
Fast turnaround ability and strong responsiveness to change

Enquire now

Whether you need support in specific areas only, or need a more comprehensive offer, NUVISAN can tailor a solution to fit your specific requirements.

Any questions or need further information?

Call: +49 731 9840-0
Mail: hello@nuvisan.com
Web: www.nuvisan.com

Follow NUVISAN on Linkedin

NUVISAN GmbH | Wegenerstrasse 13 | 89231 Neu-Ulm | Germany