NUVISAN

SPECIAL SOLUTIONS

API Manufacturing

API Research, Development and Manufacture Services

From Milligrams to Kilograms

For the pharmaceutical, veterinary or cosmetic industry, NUVISAN offers a wide array of chemistry services from the early phase, with the research and development of robust and economical routes for the synthesis of APIs, up to manufacturing.

Our chemists have experience in route scouting and in developing scalable, innovative, sustainable, safe and robust processes up to GMP manufacturing for toxicological studies and clinical phase IIa. Working alongside our chemists, analysts and pharmaceutical development experts provide services all along the value chain including highly reliable method development and validation, impurity identification, quality control, solid state studies and stability studies.

For your API project, our chemistry and analytical teams are based in Sophia-Antipolis (FR). With their unique know-how and state-of-the-art equipment, they are able to develop reliable synthetic routes while offering a deep knowledge of the characterization of your drug substance.

Our API R&D services at glance

18 chemists seamlessly working on our GMP certified sites

Strong expertise in route scouting, process development, solid state studies

Ability to develop and manufacture API, from mg to kg

+200 m^2 GMP facilities with dedicated rooms for highly potent API

Best-in-class equipment including 266 L Reactor Capacity for GMP API manufacturing

DE-RISK YOUR DRUG DEVELOPMENT PROJECT

For the development of your drug substance, our Chemistry and Analytical specialists work hand in hand to design and optimize an effective and scalable synthetic route from small scale to kilo-lab production under GMP standards and up to technology transfer.

Consistent studies and optimizations performed all along the drug substance development stages, consolidate insights, generate reliable data and thus maximize your chances to be successfully and in a timely manner on the market.

+150 projects initiated in 24 months

ROUTE DESIGN

- Route scouting
- Elimination of toxic & hazardous reagents
- Reaction troubleshooting
- Early polymorph screening
- Identification of impurities
- Yield maximization
- API characterization
- Fast development of analytical methods for intermediates and final API release

PROCESS DEVELOPMENT

- Demo batch production
- Highly potent API process development
- Identification of impurities
- Early polymorph screening
- Design of experiments (DoE)
- Development of analytical methods for intermediates and final API release
- Synthesis of impurities, reference compounds and metabolites
- Early and late stage process optimization

OUR SERVICES IN DETAIL

SCALE-UP AND GMP MANUFACTURING

- Identification of impurities - ICh Q3A/C/D-M7
- Manufacture of GMP batch up to 10kg
- Highly potent API GMP manufacturing until HHB5 (OEL >0.1 µg/m3)
- Validation of analytical methods for starting materials, intermediates and API
- Toxicology safety assessments
  - Chemical risk assessment (OEL and OHB classification, MSDS)
  - *In silico* safety assessment (QSAR prediction, ICh M7) and AMES test (screening and GLP) monitoring
- Seamless tech transfer package

INTEGRATED ANALYTICAL SERVICES

- Analytical Method development and validation
- Synthesis and purification of analytical standards
- Impurity isolation at gram scale and identification
- Salt screening, e-polymorph screening, solubility curves
- Solid phase identification by XRPD (GMP)

PROJECT MANAGEMENT

A single Project Manager is assigned to the Client as a key contact, responsible for the project coordination with the analyst and to liaise with the Client and conduct regular project meetings.

Highlights

Process Research, development and GMP manufacturing

Handling High Potency API (HPAPI) under GMP standards

GMP XRPD measurements

STATE-OF-THE-ART LABORATORY

CHEMISTRY

- Reaction vessels (up to 100-L)
- Fume hoods
- Double jacketed Reactor 10L-20L BuchiGlass (-78°C +140 °C)
- Hydrogenation station, 5L up to 30 Bars Top industries
- Flow reactor, Vapourtec
- Flow reactor hydrogenator H-Cube midi, up to 100bars ThalesNano
- Double jacketed Reactors Optimix, 16L-2*25L-2*100L De Dietrich (-40 °C-140 °C)

ANALYTICAL DEVELOPMENT

- NMR 400 MHz, H, C, N, F, P, B multiprobe Bruker
- XRPD D2Phazer, Bruker
- Crystal 16, Avantium
- DSC 4000, Perkin Elmer
- Easy max calorimeter, Mettler Toledo
- UPLC acquity, Waters
- UPLC Agilent, 1290
- HPLC preparative, Waters/Gilson
- SFC preparative
- UPC2, waters
- Microwave initiator, Biotage
- Microscope Zeiss
- Karl Fischer, Gas Chromatography, MetrOhm
- GC Clarus 580, Perkin Elmer
- 2 HRMS (Q-Exactive & Xevo)
- Thermo Scientific ICP-OES platform

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).

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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?

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