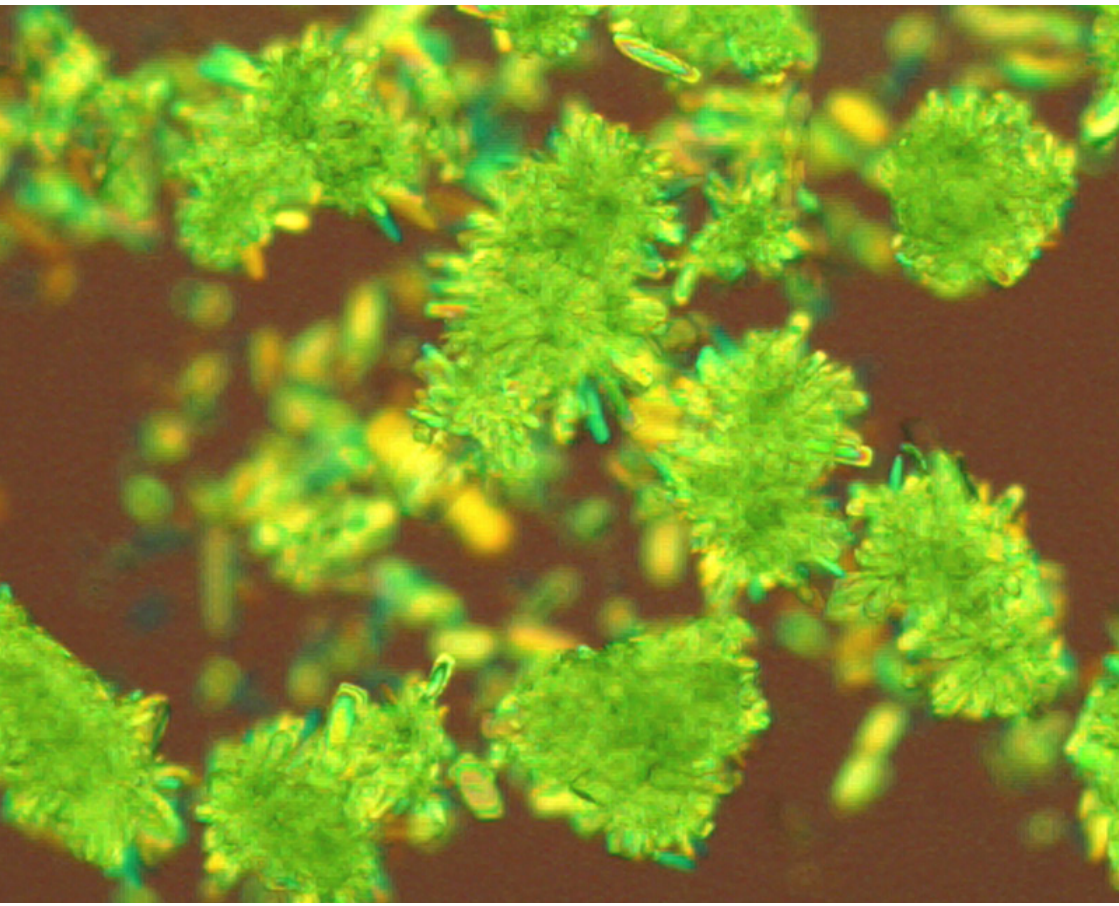
NUVISAN



DRUG DEVELOPMENT

Chemical Development

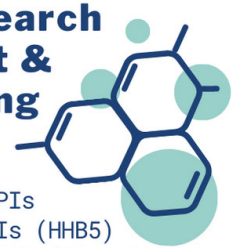
www.nuvisan.com

CHEMICAL DEVELOPMENT

+150 **PROJECTS INITIATED SINCE 2021**

in the pharmaceutical, veterinary & cosmetic industry

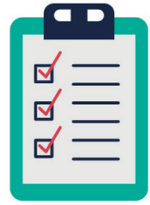
Process Research Development & Manufacturing up to 10 kg



- Intermediate & APIs
- Highly Potent APIs (HHB5)
- Isotope-labeled API (2H, 13C)

Certifications

GMP **ANSM**



Integrated solutions with **analytical development, validation and QC**

- **1.000 m² non GMP & GMP** facility
- **266L** total reactors capacity

STATE-OF-THE-ART EQUIPMENT

NMR, XRPD, HRMS, UPLC, SFC,
De Dietrich glass lined reactors

Identification & structural elucidation of impurities

Solid state studies: polymorph & salt screening

NUVISAN

Bridging the gap between CRO & CMO

Process development starts from lab-scale process evaluation through safety and scalability analysis, process optimization, purification development, and solid state analyses. Nuvisan`s scientific team has extensive knowledge in the development of chemical processes, with a strong focus on solid phase characterization and impurity profiling. Our scientists and lab professionals cover a full range of chemical development and preclinical chemistry solutions for the early-phase supply of drug substances. As our client you benefit from our expertise at all points of the chemical development of your API, from early project de-risking to late stage route scouting. We offer:

- Fully equipped state-of-the-art laboratories for a fast and efficient route evaluation, selection & scale-up for all kind of chemistries
- 20 highly experienced chemists accustomed to focus on robustness, effectiveness, high-throughput, purity profile, scalability & safety of complex & multi-step chemical processes
- API manufacture from route scouting up to phase IIa
- Infrastructure optimized to support process development from mg to kg
- GMP compliance
- Tox & GMP batches manufacture up to 10 kg
- HPAPI up to OEL 0.1 µg/m3

PROCESS RESEARCH & DEVELOPMENT

SOLID PHASE INVESTIGATIONS

GMP BATCH MANUFACTURING

IMPURITIES IDENTIFI-CATION & ASSESSMENT

API Scale-up from mg to kg

Process Research & Development

Our state of the art laboratories are fully equipped for a fast and efficient route evaluation, selection, and scale-up for all kinds of chemistries.

- Process development and kg batch manufacturing performed at the same site to ensure preclinical supplies to be delivered at the appropriate time, speed, and reduced costs of your clinical supplies
- Production of batches from 1 to 10 kg of your intermediate or API in our Kilo Lab with control of impurities to ensure preclinical studies

GMP Batch Manufacturing

Advance your candidate from preclinical through phase I/IIa clinical studies by scaling up in NUVISAN'S GMP Kilo Lab.

- Starting material definition
- Analytical method validation
- CoA with specifications
- PGI assessments
- Informal and full ICH stability studies
- Our batch records and technical package enable straightforward transfer to a CMO to produce larger batches of your API

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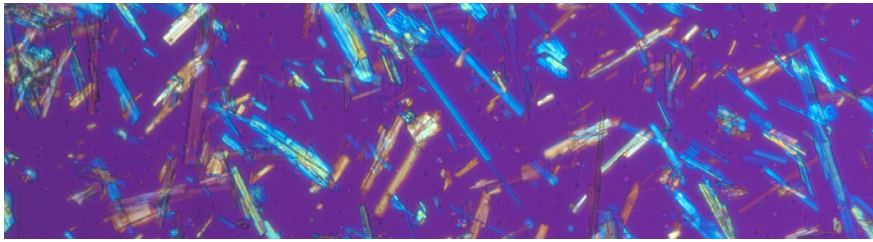


Solid Phase Investigations

Our highly experienced scientists can readily help you in selecting and controlling the solid state of your API.

- Solid state investigations of small organic molecules to identify new solid forms such as polymorphs, salts, co-crystals, or amorphous forms
- Deep understanding of the solid state of your intermediates or API

Impurities Identification & Assessment

Impurity identification and structural elucidation of impurities represents a frequent and often challenging task in process development.

- Isolation, identification, synthesis & assessment of unknown impurities present at levels higher than allowed by ICH legislation (0.1 %)
- Analysis of degradation pathways
- Identification of potential ingredient interactions facilitating the examination of your dossier by regulatory agencies

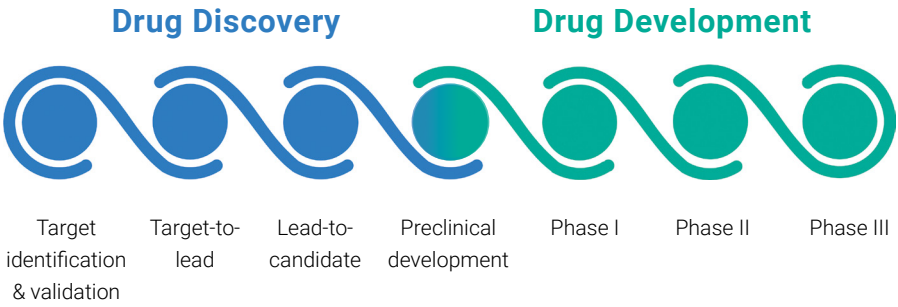
NUVISAN

The Science CRO - From Target to Patient

The NUVISAN group is a contract research and development and manufacturing organization (CRO/CDMO) with six sites in Germany and France as well as local experts situated in Latin America.

We offer unique, high-quality, and tailored integrated solutions along the drug discovery and development value chain to our biotech startup, pharma, non-profit, and venture capital clients – from target identification to the patient.

Thanks to more than 40 years of experience and about 1,000 employees (incl. > 70 % industry experienced scientists and lab professionals), we know how to discover, develop, and bring the next generation medicines to market. At the same time, our scientists understand that every project is different. With a flexible and innovative approach and transparent communication, our teams are passionate about closely collaborating with you to adapt to your individual needs.



Contact us

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