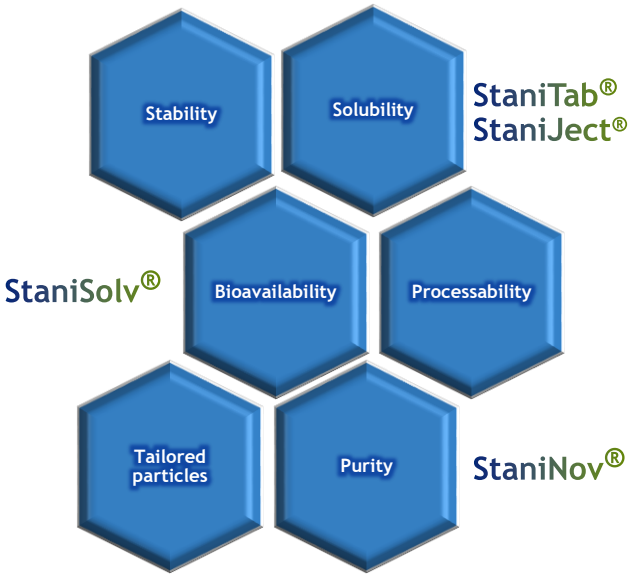
StaniPharm
Solutions for Tailored Active Nano-Ingredients

YOUR PARTNER FOR CHALLENGING HEALTH PRODUCTS

From product development to GMP manufacturing of clinical trial materials

Our technology platform takes advantages of the unique properties of near-critical and supercritical fluids, such as carbon dioxide, to efficiently solve your development and manufacturing challenges.



Some challenges our supercritical fluid technology platform has solved for our customers

- ✓ StaniNov®
  - Purification of a medical copolymer: removal of reactive monomers (e.g. acrylate), synthesis impurities, low Mw polymers and organic solvents
  - Supercritical fluid drying of a medical device
  - Fractionation of a medical copolymer: manufacturing of narrow Mw fractions
  - Extraction of leachables in a medical device
  - Cleaning of precision medical parts or textiles: removal of oils, waxes, lubricants
  - Fractionation of glycolipids and sphingolipids, lecithin deoiling
  - Deoiling of a sensitive raw material prior to proteins isolation (immunotherapy product)
  - Removal of high boiling point organic solvents (NMP, DMSO)
  - Extraction of residual solvent in injectable drug-loaded polyester microspheres

- ✓ StaniSolv®
  - Tailored particles for inhaled therapy
  - Cost efficient desolvation of a sensitive solvate form, polymorph screening
  - Drug impregnation of a porous excipient
  - Solid dispersion microparticles

- ✓ StaniTab®/StaniJect®
  - Bioavailability enhancement of poorly soluble drugs: manufacturing of crystalline drug nanoparticles
  - Development of a stable injectable drug suspension

Our Facilities & Services

Analytical Development & Quality Control

Our analytical development and quality control facilities are equipped to support the development and manufacturing of non-GMP and GMP products.

HPLC, GPC, GC, particle size, DSC, KF, FTIR, *in vitro* dissolution, handling of high potent APIs…

Product Development

Our facilities include a wide range of supercritical fluid processing units to develop your product from laboratory scale feasibility trials to pilot non-GMP batches.

Small scale units are operated in dedicated development laboratories, some of them being suitable for the processing of highly potent compounds. These flexible units are designed to work with minimal API amount and make it possible to meet very short deadlines.

Pilot scale units are operated in one of our clean rooms dedicated to the development and manufacturing of preclinical materials.

GMP Manufacturing

Manufacturing of clinical trial material is carried out in compliance with GMP Part II “Active Substances as Starting Materials”.

Our clean rooms include Class 5 areas for critical downstream and upstream operations.

The GMP manufacturing area is designed for the operation of particle design and purification processes pertaining to our supercritical fluid technology platform. On a project basis, other manufacturing techniques are available to provide our customers with products which require complementary processing steps: mixing, milling, vacuum drying, freeze-drying…

Our Values

- ✓ A flexible approach focused on our customer specific needs
- ✓ Passion for problem-solving science
- ✓ Operating with transparency with frequent communication, interactions and follow-up
- ✓ Fast project start-up, on time and on budget delivery
- ✓ Strict confidentiality
- ✓ Delivering high-quality results and products using commercially viable technical solutions

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