




# CHEMICAL SYNTHESIS AND DRUG FORM DEVELOPMENT SUPPORT

A collage of four images in a hexagonal grid: a close-up of a glass vial, a beaker with blue liquid and bubbles, a scientist in a lab coat using a pipette, and a pile of yellow powder on a surface.

**Selvita Contract Chemistry Department** specializes in planning and optimization of synthetic routes of organic substances, prediction of metabolic paths and substance toxicology profiles, pre-formulation activities, formulation development, process optimization and scale-up. We also perform complex analyses of physicochemical characteristics of the synthesized substances and patent-literature search. Our clients can rely on the experience of our world-class specialists, as well as on their commitment and flexibility to fulfill the clients' needs and requirements. Project management excellence, supply chain management and high quality of service, certified with ISO 9001:2000, and fulfilling, where appropriate, the requirements of quality systems like GLP, GMP and 21 CFR Part 11, make Selvita the partner of choice for pharmaceutical companies.

## Experience and operating excellence in contract synthesis

We specialize in the synthesis of compounds of complex structures, often with chiral characteristics and high purity (98–99%). We take on difficult syntheses, time-consuming and multistep processes, under increased pressure. Our offer includes:

*design of a synthesis route for chosen substrates, optimization of synthesis paths to avoid undesired dangerous and toxic substances, modification of the existing technological processes in order to increase efficiency of the key steps or optimize costs, analysis of by-products (identification of impurities, finding the best way to utilize waste), custom synthesis in mg to kg scale (also intermediates, reference compounds), scaling-up and optimization of synthesis processes, elaboration of purification methods with the use of preparative flash chromatography*

Participating in research and development at the synthesis stage and providing analytical solutions, we can help the client to reduce the time and costs of development through:

*proposition of several alternative methods for the synthesis of a compound, reliable estimation of possible yields of each particular step, synthesis cost-estimation for a compound*

## CONSULTING SERVICES

- *patent-literature research, including literature reviews with regard to a substance, substance classes and technologies*
- *studies concerning potential metabolic pathways and toxicology profile of a substance, based on analyses conducted with the use of modern LHASA and Molecular Networks software packages*

## ANALYTICAL SUPPORT OF SYNTHESIS FOR QUALITY ASSURANCE OF PRODUCTS

Selvita also specializes in the field of physicochemical analysis and may provide a complex chemical characteristics of the synthesized substances. We are experienced in providing solutions for problems connected with the solid form of chemical compounds, like:

*characterisation and control of polymorphic forms, development of a process to obtain a specific polymorphic form, stability study and impurity profile of the active pharmaceutical ingredient (API), hygroscopicity and solubility studies*

## EQUIPMENT

The research is conducted with the use of state-of-the-art equipment, among which the most important are:

*Analytical HPLC systems + UV, DAD and CAD Corona (Dionex, Agilent), LC/MS systems (Dionex/Bruker Daltonics, Agilent), semi-preparative chromatographic systems + UV detection (INTERCHIM), X-ray diffractometer (Rigaku), UV-VIS spectrophotometers (Shimadzu), dissolution apparatus (Hanson Research), analytical balances (Denver Instruments), dryers (Binder), lyophilizers (Christ), evaporators, magnetic & mechanic stirrers (IKA, Heidolph), glass reactors, including jacketed 20L glass reactor (Radleys), large scale rotary evaporators (Büchi), high pressure vessels (ChemGlass Inc.)*

## DRUG FORM DEVELOPMENT SUPPORT

Thanks to our experience in the area of drug form research, we can support you during pre-formulation studies and formulation development, through:

- *API Suppliers' qualification*
- *research and description of substance pharmacokinetic and physicochemical properties*
- *choice of excipients and packaging materials leading to a stable formulation – compatibility study*
- *dissolution research at the product development stage*
- *development of a discriminative dissolution method leading to bioequivalent formulations*
- *performing dissolution profiles in three standard media (low/medium/high pH) for drug products + analytical method validation*
- *verification of pharmacopoeial analytical methods, their validation and transfer (especially HPLC, UV/Vis, LC-MS and GC-MS)*
- *impurity profile characterization*
- *residual solvents analysis*
- *cleaning validation*
- *pharmaceutical development registration documentation preparation (CTD, ICH)*

## OUR ASSETS AND BENEFITS FOR CLIENTS

Selvita employees have a long-term experience in research and development centers in both academia and pharmaceutical sector. We continuously improve our competencies and invest in the equipment and laboratory space. In order, to meet our clients' needs, we put stress on timelines and the quality of the projects carried out, at the same time offering competitive terms for project realization. Selvita offers the real potential to shorten and optimize costs of chemical synthesis and drug formulation processes what makes us an ideal partner for organizations looking for optimal solutions and professional support of synthetic, formulation and analytical issues.