



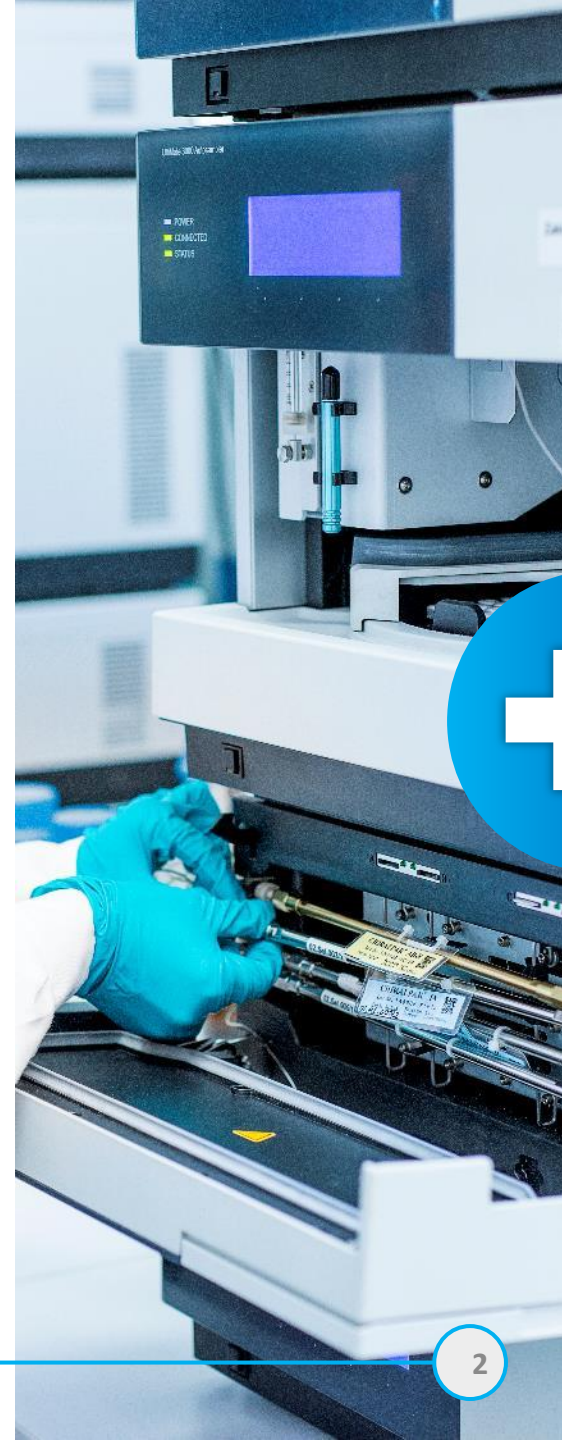
ANALYTICAL SUPPORT



Cell and Molecular Biology Laboratory

Scope of services

- ✓ Pharmacodynamic *in vitro* studies
- ✓ Signal transduction analysis
- ✓ Binding studies and affinity characterization
- ✓ Biomarkers analysis *in vitro* and *in vivo*
- ✓ Cytotoxicity and proliferation studies
- ✓ Development and validation of biochemical methods
- ✓ Development and validation of cell-based assays
- ✓ Genotoxicity studies
- ✓ Enzymatic activity testing



Selvita



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Custom assay development service: biochemical and cell-based

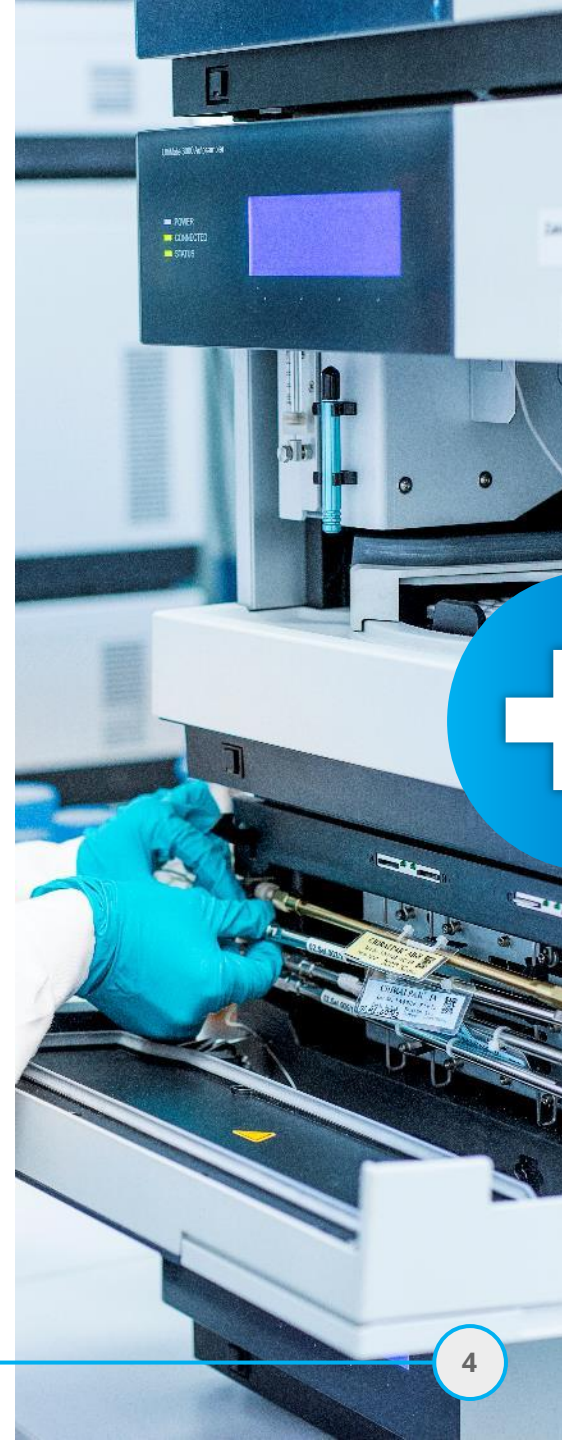
- ✓ **Various detection modes**
absorbance, fluorescence intensity, fluorescence polarization, time-resolved fluorescence (TRF) – LANCE and DELFIA technologies, LanthaScreen, luminescence measurements, AlphaLISA, AlphaScreen, AlphaPlex technologies, SPR, FACS
- ✓ **Wide range of available cellular models**
case-by-case selection of suitable cellular model/s to investigate the biological mechanism of interest (e.g. cancer cell panels of a specific type and/or with common mutation patterns), in-house production and validation of recombinant cell lines as (if required)
- ✓ **Multi-factor design of assay development experiments**
statistical parameters analysis to support a reliable and robust assay for routine use



Analytical Laboratory

Scope of services

- ✓ Development of new drugs - ADME and PK studies
- ✓ Development of bioanalytical methods
- ✓ Analytical method development and validation
- ✓ Stability and release testing
- ✓ Impurity synthesis and identification
- ✓ Support in CMC projects

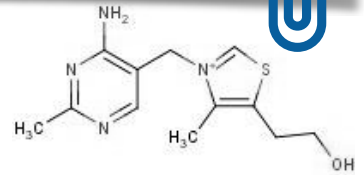
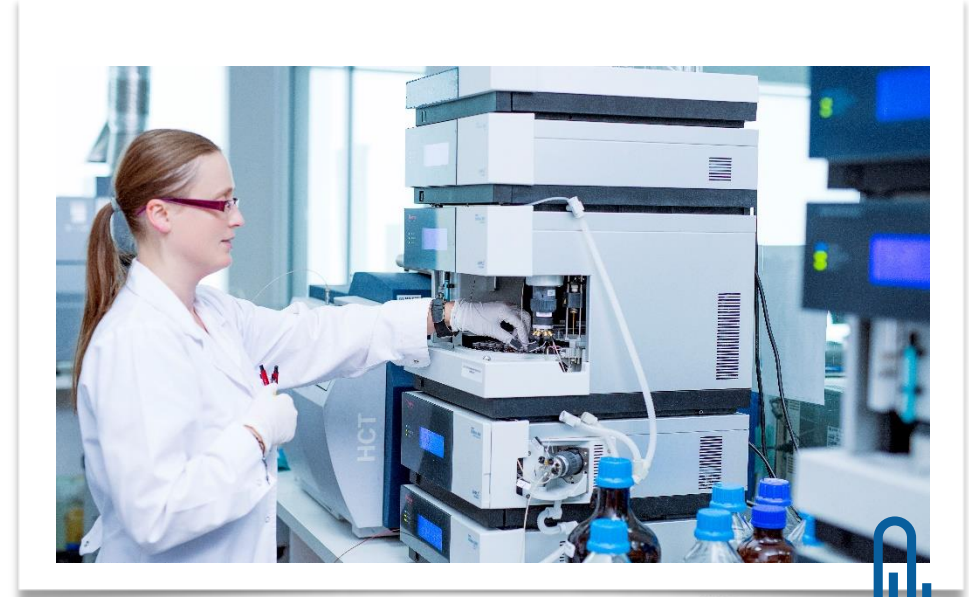


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- Assay/identity (HPLC, GC, potentiometric titration)
- Identity (MS, NMR, classical methods)
- Impurity profiling and Identification
- Stress studies and degradation profiles
- Stability testing - shelf-life determination, storage and handling requirements
- Cleaning validation
- Residual solvents determination
- Dissolution profiles – pharmaceutical equivalence
- Metal analysis using AAS, ICP techniques
- Microbial purity testing
- Excipient determination - reverse engineering
- CMC projects – analytical method establishment and validation, analytical support of synthesis and formulation stability testing, release analysis
- ADME (solubility, liofilicity, metabolic and plasma stability, metabolite profiling, permeability, plasma protein binding, cytochrome P450 inhibition)
- Study of physicochemical properties (KF, osmolality, logD, pKa, DSC, melting/freezing point, IR, NMR, PSD, SEM-EDS, XRPD)
- Genotoxicity testing of impurities (*performed by the Cell & Molecular Laboratory*)



ANALYTICAL SUPPORT FOR CHEMISTRY, MANUFACTURING AND CONTROLS (CMC) PURPOSE

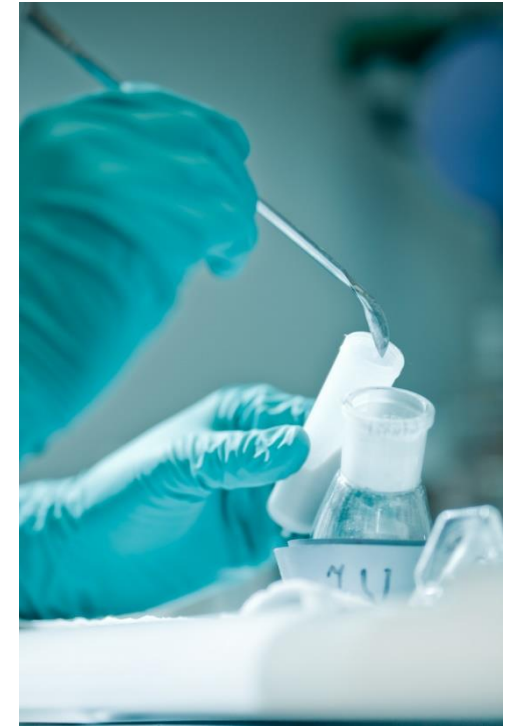
- ✓ **Analytical method development and pre-validation:**
assay, identity, purity, stress tests, residual solvents,
techniques: H(U)PLC-DAD/UV/CAD/ELSD/MS, GC(HS)-FID/MS
 - Impurity identification
 - In-process manufacturing/formulation support
- ✓ **Analytical method validation/verification**
 - Characterization and qualification of reference standard
 - Stability testing (for demo batches and GMP batches)
 - GMP lot release testing or
 - Analytical method transfer



STABILITY TESTING

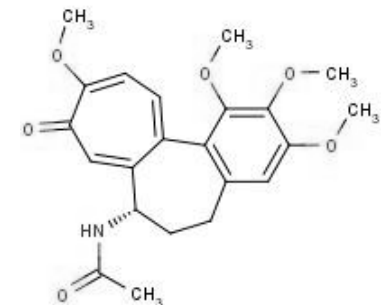
STORAGE AND ANALYSES, FOR FORMULATIONS, DRUG SUBSTANCE AND DRUG PRODUCT

- Long-term stability testing (including refrigerator, freezer and below -20°C)
- Intermediate stability testing
- Accelerated stability testing
- Forced degradation study
- Photo stability testing
- Other (freeze/thaw, in-use stability, open-pot stability)



RELEASE AND SHELF-LIFE EVALUATION OF RAW MATERIALS, DRUG SUBSTANCES AND DRUG PRODUCTS FOR SPECIFICATION COMPLIANCE

- Appearance
- Identification by HPLC-DAD, UV, HPLC-CAD, GC-FID-HS, LC/MS , IR
- Uniformity of mass
- Loss on drying
- Hardness
- Disintegration time
- Dissolution
- Assay by HPLC-DAD, UV, HPLC-CAD, GC-FID-HS, LC/MS
- Related Substances: identified and unidentified impurities by HPLC-DAD, UV, HPLC-CAD, GC-FID-HS, LC/MS
- Microbiology (microbial purity limits, bacteria, fungi, E.coli)
- Analysis by ICP-OES, ICP-MS - catalyst residues
- Analysis by AAS - metal content



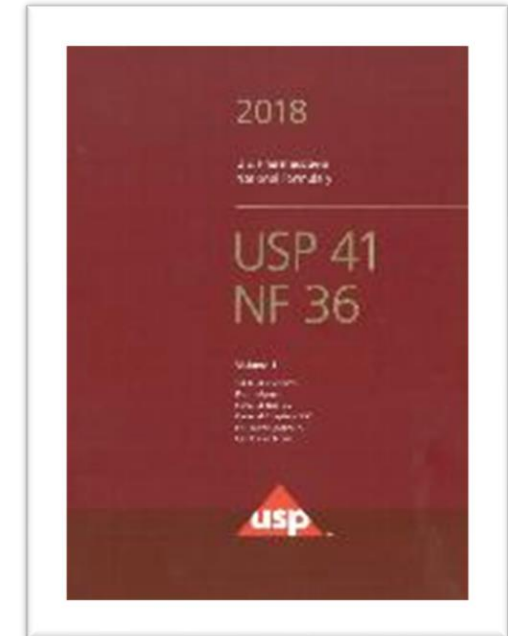
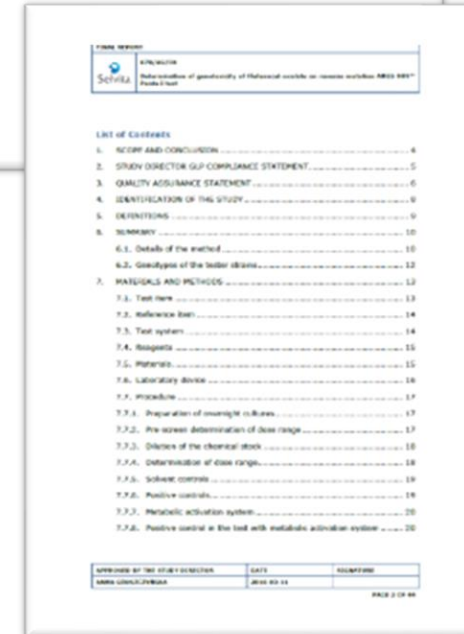
METHOD DEVELOPMENT, VERIFICATION, VALIDATION AND TRANSFER



- ✓ For small and big (biosimilar) molecules
- ✓ According to the requirements of the respective guidance
 - ICH Topic Q2 (R1) Validation of Analytical Procedures: Text and Methodology, CPMP/ICH/381/95
 - U.S. Department of Health and Human Services, Food and Drug Administration: Guidance for Industry, Analytical Procedures and Methods Validation for Drugs and Biologics, July 2015
 - Committee for Medicinal Products for Human Use (CHMP): Guideline on bioanalytical method validation, 21 July 2011, EMEA/CHMP/EWP/192217/2009
 - U.S. Department of Health and Human Services, Food and Drug Administration: Guidance for Industry, Bioanalytical Method Validation, May 2018

- ✓ According to the general pharmacopoeial requirements (methods and monographs); customer's methods and specifications; internal procedures
 - Verification of analytical methods
 - Optimization and development of analytical methods
 - Pre-validation
 - Validation
 - Transfer

- Report on analytical method development
- Report on pharmacopoeial analysis
- Report on analyses for specification compliance (stability, release)
- Certificate of Analysis
- Parts of the Common Technical Document
- Analytical method – Standard Operating Procedure
 - Validation protocol and report
 - Transfer protocol and report
 - Raw/integrated/calculated data



Equipment (GLP/GMP)

- GC(HS)/FID (Agilent)
- GC(HS)/FID (Shimadzu)
- GC/FID/MS (Agilent) - ESI/quadrupole
- GC(HS)/MS (Shimadzu) - ESI/quadrupole
- UHPLC/HPLC/MS (Bruker) - ESI/APCI/ion trap
- UHPLC/MS (Thermo Fisher Scientific) - ESI/APCI/TSQ
- UHPLC/MS (Thermo Fisher Scientific) - H-ESI/APCI Q/Orbitrap
- UHPLC/MS (Shimadzu) - ESI/APCI/QQQ
- UHPLC/MS (Agilent) - ESI/APCI/QQQ
- HPLC-VWD (Dionex/Thermo Scientific)
- UHPLC-DAD (Agilent)
- HPLC-DAD (Dionex/Thermo Scientific)
- HPLC/VWD/Corona (Dionex/Thermo Scientific) Detector (CAD)
- HPLC/PDA (Dionex/Thermo Scientific)
- HPLC/DAD/ELSD (Dionex/Thermo Scientific, Agilent)
- HPLC/VWD/RI (Dionex/Thermo Scientific)
- HPLC/UV/FLD (Dionex/Thermo Scientific)
- HPLC/DAD (Dionex/Thermo Scientific) - non-aqueous conditions
- IC (Dionex/Thermo Scientific)
- Capillary electrophoresis CESI 8000 Plus (Sciex)
- Isoelectric focusing electrophoresis (IEF), iCE3 (bio-technique)
- Spectrophotometer UV-VIS (Shimadzu, Agilent)
- Dissolution analysis SR8+ (Hanson Research)
- ICP-MS (Agilent), ICP-OES (Shimadzu), AAS (Thermo Fisher Scientific)
- FTIR (Thermo Fisher Scientific), NIR (Thermo Fisher Scientific)
- KF (Metrohm, Crison)
- Osmometer
- Particle analyser
- Disintegration DISI (Hanson Research), hardness (ERWEKA), friability (ERWEKA)
- Stability chambers (Mettler)





THANK YOU FOR ATTENTION!

Get in touch with us: sales@selvita.com



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