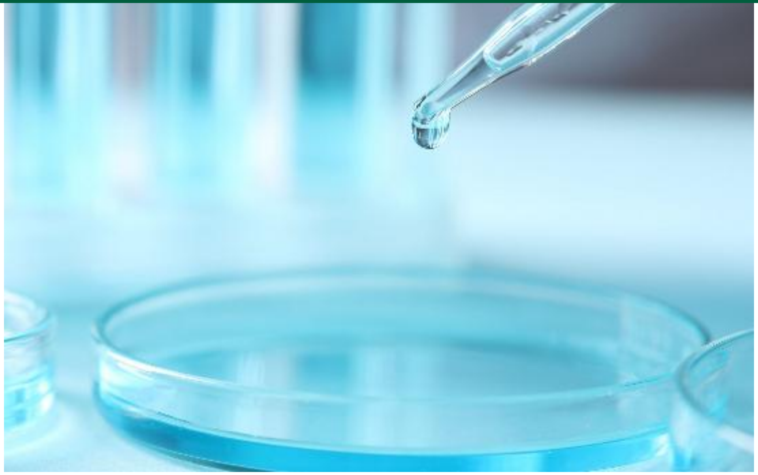
Method Development & Validation

Tailored Services



- **Method development** to specific customer needs, from raw materials to finished products, ensuring precise and reliable methods and release

- **Method validation** covering all critical parameters, adhering to ICH guidelines or according to customer's specifications to ensure method reliability across diverse applications

- **Optimization of existing methods** enhancing the performance of supplied methods to ensure better reliability, efficiency, sensibility and specificity

QC Release & Raw Materials

Partner for Routine Testing

- **Quality Controlled Release Analyses** of pharmaceuticals and raw materials to ensure compliance and readiness for market release

- **Quality controlled** release testing of Euphoriant (narcotic) substances class B, C, D and E

- **Analytical testing** in compliance with cGMP requirements and regulations such as ICH, EP and other official guidelines

Microbiological Services

Strong Microbiological Expertise

- **Suitability test**

- **Microbiological examination of non-sterile products:**
    - Total Yeast and Mould Count (TYMC)
    - Total Aerobic Microbial Count (TAMC)
    - Escherichia Coli
    - Salmonella
    - Staphylococcus Aureus

Stability Studies

Testing throughout Shelf Life

- **Temperature and humidity-** controlled chambers, monitored 24/7 with validated online alert platform system

- **ICH Compliant** stability studies at test conditions:
  - 25 °C/60% RH
  - 40 °C /75% RH

Analytical Techniques (EP)

Gas Chromatography 2.2.28

- Residual Solvents e.g. Methanol, Ethanol and Acetone

Liquid Chromatography 2.2.29

- Identification
- Assay and Related Substances on Sample Types:
  - Tablets and Powder
  - Oil and Extracts
  - Suppositories and Hard Fat Formulations

Spectrophotometry Absorption

- FT-IR (2.2.24)
- Ultraviolet and Visible (2.2.25)

Elemental Impurities and Others

- Elemental Impurities (2.4.20) via AAS (2.2.23)
  - Magnesium (2.4.6)
  - Iron (2.4.9)
  - Calcium (2.4.3)
- Disintegration of Tablets and Capsules (2.9.1)
- Dissolution Test for Solid Dosage Forms (2.9.3)

Analytical Techniques (EP)

General Pharmacopoeia Methods and Chemistry

- Potentiometric (2.2.20) and Voltametric (2.2.65) Titration
- pH Measurement (2.2.3)
- Loss on Drying (2.2.32)
- Sulphated Ash (2.4.14)

- Appearance of Solution (2.2.1) Clear and (2.2.2, Method II) Colourless
- Melting Point (2.2.14 Capillary Method)
- Determination of Water by Karl Fischer
- Capillary Viscosity (2.2.9)
- Thin Layer Chromatography (2.2.27)
- Optical Rotation (2.2.7)
- Conductivity (2.2.38)
- Optical Rotation (2.2.7)

- Other Electro-Chemical Testing and Reactions e.g.
  - Chlorides (2.4.4)
  - Sulfates (2.4.13)