

Analytical Research & Development

*End-to-end analytical testing
& regulatory-ready solutions.*



21 CFR Part 11 Compliance with GxP System



ANALYTICAL EXPERTISE



Method Development, Validation/Verification & Method Transfer



Finished Product & Raw Material Testing as per Pharmacopoeia & In-house methods (USP/EP/JP/BP)



Chemistry, Manufacturing & Controls (CMC) Analytical Services



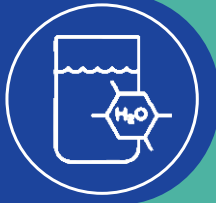
Stability Storage & Testing as per ICH Guidelines



FTIR/UV Spectrometers Related Testing



Elemental Impurity Analysis (ICH Q3D)



Residual Solvents Analysis by GC



Related Substances & Organic-Inorganic Impurities Analysis



Working Standard & Reference Standard Qualifications



Testing of Psychotropic Drugs & Controlled Substance

KEY INSTRUMENTATION & SYSTEMS

- ❖ **ICP-OES / MS** - Perkin Elmer Optima 8000 / Agilent 7800
- ❖ **HPLC / UPLC** - Waters Alliance e2695 / 2489 (ARC) / Acquity H class
- ❖ **GC / GC HS** - Perkin Elmer Clarus 580 & Agilent 7980A & HS 7694E
- ❖ **LC MS** - Waters Acquity SQD2
- ❖ **NMR** - Bruker Avance Core 400 MHz
- ❖ **Stability Chambers** - Newtronic
- ❖ **FTIR** - Perkin Elmer / Spectrum two
- ❖ **Prep HPLC** - Waters / Agilent / Shimadzu
- ❖ **Flash Chromatography** - Isolera / Biotage / Teledyne

WHY CHOOSE US

- ✔ **FDA** audited (Last inspection: [Jul, 2024])
- ✔ Robust **Data Integrity** controls
- ✔ Fully **cGMP-compliant**, aligned with **ICH** guidelines
- ✔ **OOX** management & **CAPA**

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