Pharmaffiliates
CREATING STRONGER BONDS

Analytical Research & Development

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

21 CFR Part 11 Compliance with GxP System

TC-16273 RC-1037 USFDA INSPECTED DSIR RECOGNIZED ISO 14001:2015 ISO 45001:2018 ISO 9001 • 17025 • 17034

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 Sub stances & 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 ElmerClarus 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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