Nitto Avecia Pharma Services

residual SOLVENTS TESTING

Assure compliance now with Nitto Avecia Pharma Services' **cost effective** identification and quantification of impurities.

Nitto Avecia Pharma Services provides expert, rapid analysis of all three classes of residual solvents. Our USP/ICH compliant, state-of-the-art laboratory, and experienced team of scientists allow you to manage the large number of methods that may be involved in identification and quantification of impurities, including residual solvents.

OUR EXPERTISE ENCOMPASSES

- Detection, profiling and control support of residual solvents in drug substances, excipients, and drug products
  - Water-Soluble/Water-Insoluble raw materials and APIs
  - Screening for potential interference
  - Screening for identification of unknown peaks
  - Feasibility studies
- Strict compliance of ICH guidelines
- Development and validation of analytical methods
- Assistance in regulatory reporting
- Comprehensive and accurate reports
- Remediation of existing materials and products

OUR MULTIPLE POINTS OF INTERACTION

- Joint review of DMF/physico-chemical properties of the API and excipients
- Meetings to ensure appropriate:
  - Technology – GC-FID/TCD/ECD or GC/MS via direct injection or head-space sample introduction
  - Limits, e.g., TDI
  - Procedure for method transfer/validation
  - Process – prescreening, routine testing, API qualification

FASTER ANALYSIS, ENHANCED SENSITIVITY

Nitto Avecia Pharma Services remains committed to ongoing, effective upgrades in software and instrumentation so you can benefit from faster, more selective and sensitive testing. Currently, you benefit from Avecia Pharma's state-of-the-art equipment that reduces the number of separation phases.

Contact us at 877-445-6554 or visit www.aveciapharma.com.