



# RESIDUAL SOLVENTS TESTING

*A Pharmaceutical Development Company.*

## INDUSTRY UPDATE

### ASSURE COMPLIANCE NOW WITH IRVINE'S COST EFFECTIVE IDENTIFICATION AND QUANTIFICATION OF IMPURITIES

Irvine 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\*.

#### Irvine's Expertise Encompasses:

- Strict compliance of ICH guidelines
- 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
- Validation of analytical methods
- Assistance in regulatory reporting
- Comprehensive and accurate reports

*We evaluate all dosage forms*

- Drug substances
- Excipients
- Drug products

#### Irvine's Multiple Points of Interaction:

- Joint review of DMF/physico-chemical properties of the API
- Meetings to ensure appropriate:
  - Technology – GC-FID or GC/MS
  - Limits, e.g., TDI
  - Procedure for method transfer/validation
  - Process – prescreening, routine testing, API qualification

#### Faster Analysis, Enhanced Sensitivity

Irvine 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 Irvine's state-of-the-art equipment that reduces the number of separation phases.

- Agilent GC/MS with Head Space Analyzer (6890N GC System™; 5975 inert XL Mass-Selective Detector™, G1701DA ChemStation software™)
- Combi PAL™ CTC Autosampler System for headspace and liquid injection

We invite you to visit us, audit our laboratories, discover our insight, and learn more about our passionate commitment to partnering excellence. To learn more, please visit [www.irvinepharma.com](http://www.irvinepharma.com) or call 877-445-6554.



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\*Residual solvents usually are determined using USP <467>, Organic Volatile Impurities. 6890N GC System,™ 5975 inert XL Mass-Selective Detector,™ and G1701DA ChemStation software™ are trade names of Agilent Technologies. Combi PAL™ is a trade name of CTC Analytics. © 2007 Irvine Pharmaceutical Services, Inc.