

IMPURITIES

Quantex Laboratories offers comprehensive impurities testing for both small and large molecule drug products. Impurity identification is a necessary activity during the development of any new pharmaceutical product. Every synthesis of a molecule produces a characteristic suite of impurities. Regulatory agencies set the nominal action limit for identification of impurities at the 0.1% abundance level. Similar action limits are applied for degradants observed during stability and purposeful degradation studies.

Impurities fall into several broad classes, including process-related impurities, degradant-related impurities and residual solvents. Reactants and catalysts that are employed in the synthesis of APIs or reaction by-products formed during synthesis, have the potential to remain as impurities in finished APIs. Some of these compounds, if present, may have genotoxic properties, and as a result have the potential of being carcinogenic, mutagenic or teratogenic agents. Consequently, the toxicity of these compounds make it necessary that they not be present or be limited to extremely low levels in an API. Recently, in response to such concerns, the European Medicines Agency (EMA) released industry guidance on acceptable limits of potential genotoxic impurities in APIs.

We can assist with impurity profile characterization, identification of process related impurities and in tracing the source of impurities. Degradant related impurities can be characterized or identified by performing degradation studies under acidic, basic, oxidative, and various heat and light conditions. By using mass spectrometry, which is a powerful analytical tool capable of providing the substantive structural information, the identification of impurities and degradants of various drug substances can be accomplished. Impurities and degradant products can be identified by LC-MS, LC-MS/MS and/or GC-MS. Residual solvents can be identified by direct injection, static headspace or dynamic headspace GC and GC-MS.

Analytical techniques used for impurities, degradants and residuals are:

- Fraction collection for isolation of impurities, degradants & residuals
- GC-MS with direct injection
- GC-MS with static headspace and/or dynamic headspace for residual solvents
- LC-MS for quantitative analysis of known impurities
- LC-MS/MS for quantitative analysis of known impurities
- GC-MS for accurate mass and structural elucidation
- LC-MS for accurate mass and structural elucidation
- HPLC with various detectors such as PDA, ELSD, electrochemical, etc.
- Ion chromatography
- ICP and ICP-MS for metals analysis (catalysis & process related metals)



Our State-of-the-Art Instrumentation includes:

- HPLC: (PDA, electrochemical, ELSD, etc.)
- LC-MS with APCI & ESI
- LC-MS/MS with APCI & ESI
- GC-MS: direct injection, headspace capability with EI and CI ionization source
- HRGC-HRMS
- Flame AA
- GFAA
- ICP & ICP-MS
- Mercury analyzer
- IC
- CE

Our services include support for:

- API Impurities
- Degradation products
- Excipient impurities
- Residual solvents
- Process impurities
- Stability degradants & impurities
- Residual catalysts (Palladium, Platinum, etc.)



AN EXTENSION OF YOUR TEAMSM

For more information on our capabilities please contact our Business Development group at
(609) 655-4047, extension 304.

3000 Eastpark Boulevard • Suite 100 • Cranbury, New Jersey 08512 USA • TEL: 609.655.4047 • FAX: 609.655.4374 • Email: info@quantexlabs.com