Combat Nitrosamine Challenges with Comprehensive Analytical Solutions

As consumer safety becomes increasingly vital, the analysis of nitrosamine impurities in pharmaceuticals is critical. Classified as probable human carcinogens, nitrosamines pose significant health risks, prompting regulatory bodies like the U.S. Food and Drug Administration (FDA), Health Cananda and the European Food Safety Authority (EFSA) to implement strict guidelines.

At Aragen, our Analytical team follows a rigorous three-step approach-Risk Assessment, Confirmatory Testing, and Remediation Planning—to ensure that pharmaceutical products are safe for human use. By utilizing advanced methodologies and thorough testing, we adhere to global quality standards, safeguarding public health.

Our Capabilities

Risk Evaluation

- **GMP** and **non-GMP Screening:** Comprehensive analysis of raw materials, intermediates, drug substances, and drug products to detect nitrosamine impurities.
- **In silico Assessment:** Employing computational models to predict the formation and risk of nitrosamine impurities.
- **Confirmatory Testing:** Method development and validation for accurate detection and quantification of nitrosamine substances (NSAs).

Confirmatory Testing

- **Method Development & Validation:** Ensuring precise measurement and reliability for detecting nitrosamine substances (NSAs).
- **GMP Quantitative Tests:** Specialized testing for high-risk products to verify the absence of nitrosamines.

New Marketing Authorization and Batch Release: Comprehensive evaluation and testing of each batch to ensure compliance with regulatory standards prior to being marketed.

Comprehensive Analysis for Nitrosamines

- **Broad Range of Analytes:** Rigorous testing of various R&D, market products, NCEs etc.
- **Specialized and Targeted Testing:** Focused analysis for nitrosamine impurities in injectables, large volume parenteral, and peptide formulations.

Stability Storage & Testing: Long-term stability studies to track the presence of NSAs and nitrosamine drug substance related impurities (NDSRI) over time.

Query or Deficiency Handling: Rapid development and validation services to address urgent queries or deficiencies.

Cleaning Validation: Ensuring cleaning processes meet safety standards by testing for nitrosamine residues.

Why Aragen?

- **Experienced Team:** Dedicated team of 35 scientists with 5 to 20 years of experience in analytical testing of NSAs.
- **Advanced Instrumentation:** Equipped with latest analytical technologies such as LC-MS/M, GC-MS & GC-MS/MS for accurate and reliable results.
- **Regulatory Compliance:** In-depth knowledge of regulatory requirements and proficiency in handling audits from US FDA, Health Canada, and EU.
- **Proven Track Record:** Analyzed over 200 products, developing single methods to detect 7 NSAs.
- **GMP Compliance:** Conducting GMP analysis for batch release with methods achieving LOQ in low (ppm, ppb and ppt) ranges.
- **Cleaning Validation:** Thorough analysis of NSAs for cleaning validation purposes.

Let's begin the conversation

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