PHARMACEUTICAL IMPURITY REFERENCE STANDARDS & MORE

- Pharmaceutical Impurity Reference Standards
- Isolation and Purification
- Genotoxic Assessment of Impurities
- Computational Approach for Purge Assessment in API
- Determination of Carcinogenicity (TD50) & AI Values of Nitrosamines
- Investigation and Risk Assessment of Nitrosamine

Products

- Impurity Standards
- Isolation and Purification
- Isotope Labelled Compounds
- British Pharmacopoeia Standards
- United States Pharmacopoeia Standards
- European Pharmacopoeia (Ph. Eur.) Standards
- Japanese Pharmacopoeia Standards

OVERNIGHT SHIPPING IN US AND EU

Qualification of Impurity Standards

Both Veeprho and our clients strictly adhere to USP/EP monographs to ensure the highest degree of consistency and reliability in analytical data. This common framework guarantees directly comparable results between Veeprho's laboratories and those of our clients, minimizing the risk of discrepancies. Our Impurity Reference Standards facilitate this process by featuring comprehensive MASS, HNMR, IR, TGA, and HPLC data sets, all generated and reported in strict accordance with USP/EP monograph. This ensures consistent measurements of Relative Response Factor (RRF) and Relative Retention Time (RRT) for impurities, providing both Veeprho and our clients with a seamless and robust analytical process.

Isolation and Purification

of Unknown Impurity in API & Drug Product

At Veeprho, we pride ourselves on setting the industry benchmark in this complex but vital area. Leveraging state-of-the-art technologies and innovative methodologies, our adept scientists are proficient in separating and purifying impurities from drug substance and drug product, irrespective of the scale of operation. This expertise not only ensures the highest product quality but also provides essential data for regulatory compliance and safety evaluations."

Moving beyond conventional methods, we specialize in the structural elucidation of unknown impurities, often arising as degradation products of the parent compounds. To achieve this, we employ advanced 2-D NMR techniques like NOESY, DQF-COSY, TOCSY, and ROESY for homonuclear correlations, as well as HMQC, HSQC, and HMBC for heteronuclear correlations. These sophisticated techniques enable us to reveal the detailed spatial arrangement and molecular structure of these unknown impurities. As a result, we offer a nuanced, comprehensive understanding of these specific substances, providing a rock-solid foundation for ensuring product quality.

Services

We offer services on the genotoxicity assessment of impurities and purge factor assessment of toxic compounds including nitrosamine.

Computational Genotoxic Assesment of Impurity

as per ICH M7

We use (Quantitative) Structure-Activity Relationship ((Q)SAR) methods in line with the requirement of ICH M7 to predict impurity genotoxicity.

Assessment requires impurity and API chemical structures.

Reports include:
Impurity classification and expert summary
Scientific rationale for toxicology
Regulatory submission support

Report delivered in 1-2 working days.

Scientific Support for Investigation and Control of Nitrosamine

as per recent FDA guidelines

Our investigator offers guidance on nitrosamine related risk assessment for formulation to commercial batch processes.

Including:
API synthesis and formulation
Pilot batch production
Bio-batch stage
Post CMC+Bio, before FDA submission.

Computational Approach for Purge Assesment Toxic Compounds

Genotoxic Impurities, Nitrosamine and Their Precursors as per ICH M7

We offer a scientifically designed Computer Assisted Control Strategy for Genotoxic & Nitrosamine impurities as per ICH M7 & FDA guidance. During drug and starting material manufacturing, reactive reagents and toxic compounds are being used. The computational approach assesses their removal accurately.

This tool allows rapid, reproducible semiquantitative risk assessments. Assessment requires Route-of-Synthesis (ROS) and reaction conditions.

The Final Assessment Report includes:
Purge calculation with scientific rationale
Supporting evidence for regulatory submissions.

Determination of Carcinogenicity (TD50) & AI Values of Nitrosamines

We help determine nitrosamine Acceptable Intake (AI) values using QSAR modeling. This achieves direct structure-carcinogenicity TD50 value determination and identifies activating or mitigating features. Our experts offer FDA query support for submitted reports.

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