SynZeal®

Certified Pharmaceutical Reference Standards

High purity Nitrosamine Standards for analytical testing

www.synzeal.com

About SynZeal

SynZeal is a research-driven company that provides full technical support in synthetic, analytical and medicinal chemistry. We are committed to the delivery of high-quality pharmaceutical reference standard for impurities, process impurities, degradants, metabolites, drug glucuronides, stable isotopes & nitrosamines and services provided to pharmaceutical companies at various stages of product development.

SynZeal is well equipped with a wide range of state-of-art, fully qualified analytical instruments. Our experienced, highly qualified and professionally competent team has a proven track record of delivering the most complex products in a defined timeframe. SynZeal certificate of analysis includes all the characterization and purity data required for regulatory compliance. All analytical data is peer reviewed and undergoes thorough technical QC review and quality assurance prior to release.

Key Differentiators

- State-of-art R&D Infrastructure
- Exhaustive inventory of 10000+ products
- Diversified Product Range
- Quick turnaround time for complex product
- Comprehensive & regulatory compliant documentation
- ISO 9001:2015 & ISO 17025
- EP/USP Traceable Standards
- Dynamic team of professionals
- Excellent Logistic Framework
- Unparalleled Technical Support

Nitrosamines - It's beginning

The discovery of nitrosamine impurities in marketed drugs has led to a significant regulatory response demanding evaluation of all synthetic and formulation routes for the potential presence of nitrosamine impurities. Nitrosamines are formed through a common chemical reaction of a secondary or tertiary amine with a nitrosating agent. These reactions were known to generate during API manufacturing, finished product manufacturing, packaging, or storage. However, it is now evident that the possibility for nitrosamine impurity content is broader than simply the presence of nitrites and amines in the synthesis.

Hence a more comprehensive approach is required for the risk assessment of the possibility of nitrosamines formation. Expert assessment is a fundamental part of the evaluation of the mutagenic potential of impurities under the guideline.

SynZeal Expertise

The detection and quantification of traces of nitrosamines in drug products can be challenging and necessitates the use of highly pure and well-characterized pharmaceutical reference standards to meet regulatory requirements. SynZeal offer an exhaustive range of nitrosamine products to comply with the directives of regulatory agency. Our extensive range of products supports our customers in identifying and quantify traces of nitrosamines impurities confidently.

SynZeal Advantages

- Trusted partnership with global pharmaceutical companies
- 1000+ nitrosamines covering an extensive range of APIs
- Complex products access for respective Nitrosamines
- Stability data of synthesized Nitrosamines
- Access to stable isotope product nitrosamines
- Capability of synthesis from mg to multi g scale
- Process Safety Study for the Nitrosamines preparation
- Controlled substance Nitrosamine products
- Strong commitment to EHS measures for synthesis, analysis & handling

SynZeal Research Private Limited

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Nitrosamines Catalogue

D-Labelled Catalogue

SynZeal Products

Visit us at www.synzeal.com or e-mail to standards@synzeal.com