zeneth

Background

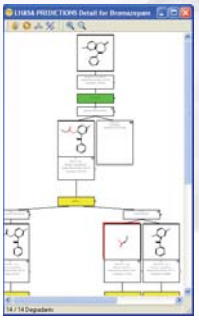
Within the pharmaceutical industry there is an abundant amount of knowledge about chemical degradation consisting of more than twenty years' worth of dispersed publications (chemistry, environmental, food/agricultural, organic chemistry, heterocyclic chemistry related publications) as well as proprietary knowledge held by experts and individual companies.

Lhasa Limited recognises that there is a strong case to amalgamate this knowledge into a predictive expert system, and is developing Zeneth, an expert decision support system to predict the forced degradation pathways of organic compounds. Results from the software can provide knowledge about the intrinsic stability of the drug and interactions with adjuvants or formulants. This information can be used in the early stages of drug development, thus reducing development time and costs.

Zeneth is based on existing Lhasa Limited Meteor technology. It uses a high-quality knowledge base and reasoning engine.

Uses & Benefits of Zeneth

- Provides a computational tool that can be useful to support regulatory submissions and compliance with International Conference on Harmonisation (ICH) Guidelines, Q1A and Q1B for stability and photostability testing of new drug substances and products.
- Contributes to QbD by assisting in the understanding of degradation processes which may take place during manufacture and storage.
- Acts as an educational tool providing an unbiased application of transformations.



Assigns likelihoods to degradant pathways based on the following reaction conditions:

1. Hydrolysis over a wide range of pH values
2. Oxidation through nucleophilic / electrophilic oxidation, autoxidation and electron transfer catalysts
3. Exposure to light
4. Elevated temperature and humidity

- Assists the elucidation of unknown degradant structures.
- Supports mass spectrometry and NMR studies by suggesting degradant structures, particularly useful where degradants are only present at trace levels.
- Helps develop strategies for selecting compatible formulations to better preserve stability by providing suggestions for how APIs and excipients degrade in formulations.
- Captures in-house expert knowledge that can be shared between internal users.
- May expose metabolites found in metabolism studies as degradants, thereby promoting synergy between discovery and development.

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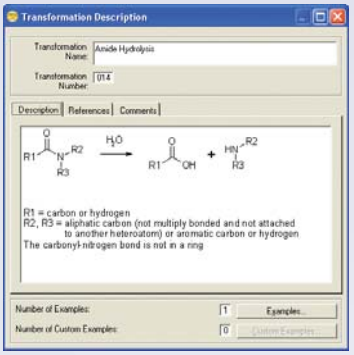
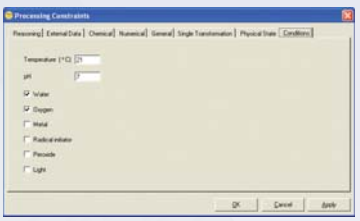
Why Lhasa Limited?

Lhasa Limited has an excellent reputation for collaboration with industry, academia and regulators to build expert knowledge systems that assist with informing early drug development, regulatory submissions, and advice for non-experts.

Lhasa Limited's experience in developing Meteor, software for metabolism prediction, provides an excellent building block to develop a chemical degradation knowledge base.



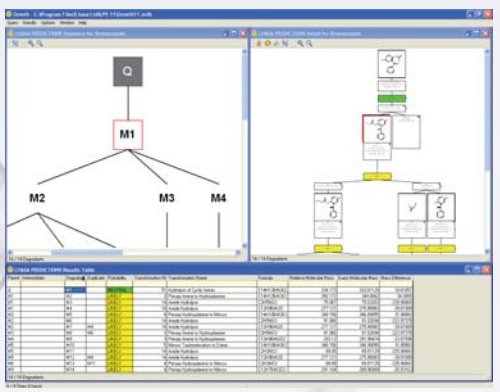


Detailed degradation pathway description.

How Can I Get Involved?

Lhasa Limited is seeking further sponsor organisations to join the Zeneth collaboration, which is bringing together expert knowledge, published and in-house data to derive generic structure-activity rules for degradation.

Data sharing between various reliable sources will lead to the development of a high-quality knowledge base for Zeneth, thereby increasing the reliability of results provided by the software.



Results display including sortable table.

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Shared knowledge, Shared Progress