Zeneth

How to overcome the critical challenges faced **in forced degradation studies**

Your challenge

Our solution

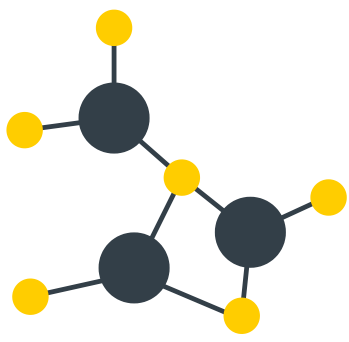
Selection of stress conditions

Appropriate stress conditions (e.g., heat, light, pH, oxidation) that accurately simulate real-world degradation without over-stressing the drug.

In Zeneth, you can set up the conditions for a prediction to evaluate the potential degradation chemistry of your planned study conditions. You can run multiple condition sets simultaneously on your API or drug product.

Identification of degradation products

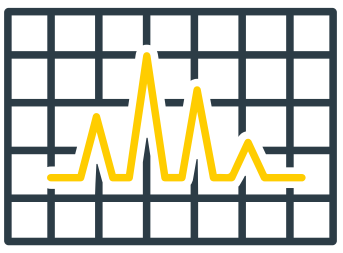
Characterisation of degradation products can be resource-intensive and requires knowledge of likely degradation pathways.



Zeneth provides a comprehensive overview of all the potential degradation chemistry possible of your API or drug product. By utilising the mass and/or substructure filters you can easily identify the degradant in your analytical results.

Method validation

Developing a reproducible, sensitive and specific stability indicating method, that is capable of separating the API from its degradation products.



It is important that we can identify all degradation products accurately. Zeneth assists with identification. Based on the properties of the identified compounds, chemists can ensure the stability indicating method is suitable.

Formulation components

Excipients may degrade or react with the API leading to complex impurity profiles. It is important that excipient compatibility studies are carried out.

Zeneth allows you to enter your formulations (API and excipients) and run your predictions under the selected conditions to give you an overview of the expected chemistry of the formulation as a whole.

Regulatory submission

Meeting regulatory requirements under guidelines such as ICH Q1A or RDC 964 requires scientific justification for chosen study conditions and validation of stability indicating methods.

By providing evidence to help justify the selection of conditions and the validity of stability indicating methods Zeneth is an invaluable tool for supporting regulatory submissions.

Our solution Zeneth can help overcome challenges associated with forced degradation studies

Read in more detail on the Lhasa blog

Get in touch

Visit our contact us page to request more information about Zeneth or to arrange a demo.

Lhasa Limited

www.lhasalimited.org