LabAnalysis
HIGH QUALITY CONTROLS

Delivering scientific excellence

STRESS TEST

Forced Degradation (or **Stress Test**) is a process that involves the degradation of active pharmaceutical ingredients or products formulated in a worse environmental condition compared to the condition of normal use of the products. Stress condition mostly involve the use of physical agents (heat, light) and chemical agents (moisture, acids, bases, oxidants). The stress test generates degradation products, known or unknown, which can be investigated to determine the pathways of drug degradation or to prevent it. The stress test also finds applications to support the validation of analytical methods to demonstrate that the method is "stability indicating", which means that is able to quantitatively detect the loss of content of the pharmaceutical active ingredient and the consequent increase in degradation products.

LabAnalysis, with its consolidated experience, acquired from the delivery of hundreds of forced degradation studies, and with a state-of-the-art analytical instrumentation, will perform any type of stress test on active pharmaceutical ingredients or products formulated to **support the submission of registration files all over the world** (our studies are regularly viewed by the main entities such as FDA, ANVISA, AIFA, etc).

For the realization of a stress study, LabAnalysis guarantees the:

- **Use of the best state-of-art technologies for the qualitative and quantitative evaluation of active pharmaceutical ingredients and their products of degradation.**
- **Numerical evaluation and rational discussion of mass balances.**
- **Transfer analytical methods adapting it to mass spectrometers to obtain useful structural information of the main degradation products obtained.**
- **Isolation and characterization of the higher impurities via NMR.**

LabAnalysis will share with the Client the technical approach of the forced degradation studies by drafting a **Study Protocol** containing information regarding the activity purpose, the analytical methods, the stress and processing conditions of the samples, the processing and presentation results, regulatory references. At the end of the experimental activity, LabAnalysis will draft a related **Study Report** containing all the experimental information, the numerical data obtained, the mass balances, the chromatographic traces and the considerations on the results.

Please don't hesitate to contact us for further information about the services you need. Our technical division will help you find the right solution for your analytical enquiries.

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