White Paper

LABIO MEDICAL
BREATH DIAGNOSTICS

Drug development

Improving chemical analysis and reducing the time-to-market for the pharmaceutical industry

Read about our patented technology with endless potential in Life Science

OUR SERVICES

Chromatography
Breath Analysis
Drug Development
R&D Cooperation
Clinical Trials

CONTACT US

Stockholm Sweden
info@labio.se
www.labio.se

Analytical solutions

Pharmaceutical companies need analytical methods that could shorten the time-to-market for developing new drugs. Isomers are compounds with identical chemical formulae, but with different structures. Isomerism is very important in clinical pharmacology and pharmacotherapeutics. Drug isomerism has opened a new era of drug development. Identifying structural isomers helps pharmaceutical companies produce safer and more effective drug alternatives as well as new drugs. Many existing drugs have switched from racemic mixture to one of its isomers. Separating racemic mixtures into their respective enantiomers takes extra time, money and energy for the pharmaceutical industry meaning new innovative technologies would reduce the time-to-market.

The GC-UV method could be used to characterize leading candidate compounds that will be used in drug development and so see its pharmaceutical ingredients (API). The method could be used in clinical trials for its abilities to separate components and identify any impurities.

Guidelines

According to ICH Q3A (R2)[1] and other guidelines, impurities in any dosage form, or its pharmaceutical ingredients (API), must be identified during the drug development process. If not, the qualification of impurities will not succeed and have a major impact and new drugs cannot be considered qualified.

It is a balance between improving qualitative chemical analysis and reducing the time-to-market for drug development.

[1] https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-3-r2-impurities-new-drug-substances-step-5_en.pdf

Our patented GC-UV technology is a game-changer in the process and method development of drug developments in the pharmaceutical production and the stability of the pharmaceutical. The sensitivities are very high in identification limits, detection limits and classification limits. The method is suitable for the identification of structural isomers. Selective analysis can be carried out for most chemical classes.

Isomers

It is very important to be able to see structural isomers in drug development. Classification, identification, and quantification of compounds is important in chemical analysis and even more important for drug development. Most analytical instruments cannot see isomers during and analysis, but the sensitivities of the GC-UV technology is very high regarding to detection limits, identification limits and classification limits.

Our systems do not require a step-by-step procedure for performing a chemical analysis. And the procedure does not take hours to days to complete, but minutes.

It is not required for the operator of our system to do a manual computer-based search for unknowns, instead our system performs an automated report of the chemical analysis. The analysis is automatically compared to a reference library of chemical substances making the system well suited for identification and classification of unknowns.

Conclusion

It is important for the pharmaceutical industry to be able to make fast and qualitative chemical analyses. New analytical innovations as our GC-UV technology will support the pharmaceutical industry to achieve better and faster drug development.

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