Reference Analytics GmbH

Thomas-Alva-Edison Straße 1
7000 Eisenstadt
+43-2682-62220-24
office@reference-analytics.com

reference analytics

Residual solvents

Background

Residual solvents are residues from the synthesis of active pharmaceutical ingredients, from semi-finished products or from raw materials, which cannot always be removed completely during the production processes. These remaining residual solvents are in part, highly toxic, and present a substantial health risk. For that reason critical values in final products need to be specified, controlled and observed.

Specification of the critical values is conducted by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use – abbreviated ICH-guidelines.

Our Service

GMP compliant determination of residual solvents according to Pharm. Eur. 10.0/2.4.24 incl.

⇒ Identification

⇒ Quantitation

⇒ Limit test

GMP compliant method validation in special cases incl.

⇒ Method set-up

⇒ Validation

⇒ Transfer validation

Classes

Residual solvents are subdivided into three different classes in accordance with their toxicity and resulting risk potential, and thus, increased analytical complexity.

Classes of residual solvents

Class 1	Residual solvents that should be avoided
Class 2	Residual solvents that should be limited
Class 3	Residual solvents with low toxic risk

Methods

Our state-of-the-art HS-GC-MS will allow accurate and reliable analysis for most of the residual solvents within very low detection limits. However - there can be a lot of special requirements - please contact us in case of any questions.

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