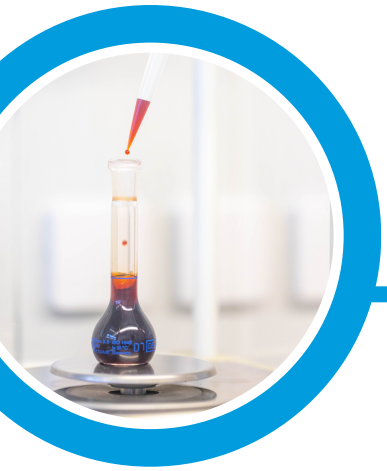

RESIDUAL SOLVENTS

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.

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

GMP COMPLIANT DETERMINATION

acc. Ph. Eur.

- Identification
- Quantification
- Limit test

GMP COMPLIANT METHOD VALIDATION

incl.

- Method set-up
- Validation or
- Transfer validation

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