CLEANING VALIDATION

BACKGROUND

Cleaning of production facilities requires a high degree of interdisciplinary know-how and is conducted in order to **remove potential residuals** of active ingredients, cleaning agents and degradation products. Cleaning validation serves as a **documented evidence** that the cleaning procedure has been carried out successfully and in a reproducible manner. It is conducted to **ensure the safety of products**, especially when manufactured in multi-use facilities.

CRITERIA AND CONCEPTS

In order to avoid **cross-contamination** in multi-use facilities, **acceptance criteria** are defined by ICH Q9 **for each and every active ingredient**.

After determination of the **critical values** a **worst case scenario** can be worked out to define the critical values of the cleaning validation procedure. Furthermore the building of apparatus and product groups is recommended to **minimize costs and efforts**.

RECOMMENDATION

The following considerations are recommended - determination of active ingredient with **highest toxicity, lowest solubility** and characteristics complicating its removal, as well as determination of the **manufacturing plants which are hardest to clean**.

TESTING METHOD

Advantages Swab-Test	Disadvantages Swab-Test
Collection of samples with low solubility	Will not cover the whole surface - critical spots often not accessible easily
Results can be assigned to a specific location	Low reproducability
Advantages Rinse-Test	**Disadvantages Rinse-Test**
Sampling of large surfaces	Relevant substances will be strongly diluted

METHOD DEVELOPMENT

- Conceptual design and optimization of sampling
- Analysis and qualification of the sampling process by staff on-site (incl. Training)
- Development of customized sample preparation
- Development and optimization of a highly sensitive and selective analysis method

METHOD VALIDATION

acc. to ICH Q2 guidelines

REFERENCE ANALYTICS TECHNOLOGY

In accordance with the requested critical values we can support you with a broad spectrum of analytical methods in order to ensure reliability of your cleaning procedure.

- GC
- HPLC
- LC-MS/MS

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