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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 worst case concept

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.

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

Choosing a suitable testing method can be challenging too:

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

Our Service

Development of a suitable cleaning validation method can be time consuming and expensive. Reference Analytics will be pleased to support you in this process.

We offer flexible sample analysis customized to your individual cleaning validation project incl.

⇒ 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:

- According to ICH Q2 guidelines

Methods

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.