

Also for HPAPI and highly potent drugs now!

deconex[®] CLEAN

Evaluation of optimum cleaning processes

One headache less: deconex[®] CLEAN is your solution for integrated cleaning processes!

deconex[®] CLEAN takes into account the technical capabilities of your process equipment as well as the operating conditions. deconex[®] CLEAN is suitable for your cleaning tasks in the cGMP area and provides an important basis for cleaning validation.

Advantages of deconex[®] CLEAN

Scientific

- + Laboratory tests reflecting current practice
- + Comprehensive application database
- + Fully documented deconex[®] CLEAN Report

Compliant*

- + Part of the *rationale* according to cGMP
- + Basis for cleaning processes (SOP)
- + Basis for cleaning validation

Cost-saving

- + Fast process development
- + No interruption to production
- + Fast transfer to routine operation

* Annex 15 EU-GMP Guidelines

* ASTM E3106-2018 Standard Guide for Science-Based and Risk-Based Cleaning Processes Development and Validation

What is deconex® CLEAN?

deconex® CLEAN includes the development of new cleaning processes or the optimisation of existing processes through laboratory simulations using «worst-case» residues. All of these steps are carried out by specially qualified employees of Borer Chemie AG.

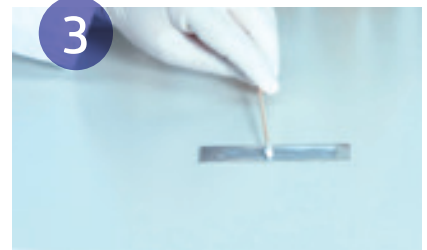
How does deconex® CLEAN work?



1 Interview with users, technical inventory, establishing aims, filling out the deconex® CLEAN checklist.



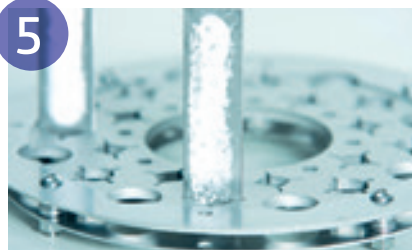
2 Sending the worst-case product samples with MSDS or sending test plates with original residues.



3 Preparation and conditioning of several test pieces and subsequent cleaning tests.



4 Detaching studies with cleaners using TACT (Time Action Concentration Temperature) with and without mechanical impact.



5 Transfer to development of automated cleaning processes, CIP simulation.



6 Assessment of the cleaning results by visual inspection and analytical methods.

7

7 Documentation of results in the deconex® CLEAN report. Basis for «on-site tests» for the performance survey.

8

8 Presentation of the results and an appropriate process proposal to the user. Clarification of the subsequent procedure.

9

9 Implementation of the new process on-site. Support for the cleaning validation.

We are pleased to also inspire you for our cleaning processes based on quality by design QbD and setting new standards for validated cleaning processes.



Please, contact us and benefit from our know-how!
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