

Summary - Cleaning Validation – Visual Inspection and Quantitation

Visual inspection is the minimum requirement for all clean and test regimes required for Cleaning and Cleaning Validation. There are five aspects of visual inspection discussed in this procedure:

1. Visual inspection following or during manual cleaning.
2. Visual inspection of dedicated equipment
 - a. Interval cleaning
 - b. Campaign cleaning
3. Routine Visual inspection of multi-purpose equipment
4. Visual inspection during validation (e.g. most difficult to clean product approach)
5. Visual Quantitation
 - a. Laboratory Studies
 - b. Difficult-to-clean inactive raw materials

If visual inspection is the only verification of a changeover cleaning process on minor equipment, the limit of detection using visual inspection techniques should be quantified in the laboratory or referenced from recognized literature.

Depending upon the desired outcome of the cleaning activity the visual inspection can take on different emphasis to achieve the desired goals. Visual inspection will be a part of all cleaning procedures developed, and as such, each site should define the significant operations, responsibilities and expected results within site SOPs or individual cleaning instructions.

1. Visual Inspection following/during manual cleaning:

Manual intervention during the cleaning of major equipment is often required as part of a robust cleaning process.

The inspection should not substitute for the final visual inspection that would typically take place following analytical sampling. The final visual inspection determines the success or failure of the validation execution.

The purpose of inspection after manual cleaning is to measure the effectiveness of the manual methodology before resuming CIP cleaning. Rather, the inspection of these examples should follow the guidance of “final visual inspection” detailed below.

2 a. Visual Inspection of Dedicated Equipment – Interval Cleaning:

Product contact surfaces need not be free of visible residues if deemed appropriate by the cleaning evaluation activity.

The operations related to interval cleaning may be organized into their own cleaning instructions or it may be beneficial to incorporate interval cleaning activities into processing instructions (e.g., a post processing rinse).

2 b. Visual Inspection of Dedicated Equipment – Cleaning Between Campaigns:

Dedicated equipment campaign cleaning refers to the cleaning process performed between the end of one product campaign and the start of the next campaign of the same product. more emphasis during the cleaning process. The resource required to perform equipment disassembly on a routine basis, however, may justify the performance of a study to “validate” that the hard to clean areas are visibly clean for a number of consecutive cleanings as evidence that the visual inspection can be relaxed for subsequent cleaning.

3. Routine Visual Inspection of Multi-Purpose Equipment.

For routine visual inspection of multi-purpose equipment, or those inspections that occur as the last visual check of a system prior to release back to production of the next product, consideration of the following is suggested as part of the development of a multi-purpose cleaning methodology:

4. Visual Inspection during Validation.

During validation there may be reasons to perform more intensive equipment disassembly and visual inspection than during routine inspection. The routine cleaning procedure with any disassembly would be used in validation. - Those areas identified as difficult to clean by the cleaning evaluation exercise should be visually inspected with disassembly as necessary.

5. Visual Quantitation

If the only verification of cleaning changeover processes to be conducted on equipment is visual, then the visually detectable quantity must be known and documented.

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