



THE CLEANING VALIDATION

| CHAPTER 17 |

May 19, 2024

Reference Guidelines: ISPE | APIC | PDA | EMA

ESTABLISHING PROCESS PARAMETERS FOR A MANUAL CLEANING PROCESS



The purpose of this case study is to define appropriate parameters for manual cleaning of various equipment parts, utensils, and tools routinely used throughout manufacturing operations.

PARTS & TOOLS TO BE CLEANED:

- Scoops
- Spatulas
- Vessel with lid used in coating solutions
- Impeller blades
- Shaft
- Punches & Dies
- Hopper & lid

The wash room in the production area is designed with one -way flow: "dirty in" moving to "clean out", and is equipped with:

- Potable water line
- Pressurized hot potable water spray line.
- Sonicator
- Purified water spray line
- Clean dry compressed air line
- Heated drying rack area
- Timer
- In addition, there is an area where clean dry parts can be wrapped and labeled prior to being moved to the clean equipment storage area.

CLEANING PROCESS FOR TOOLS & SMALL PARTS:

- Removal of residue through mechanical force
- Sonication step
- Cleaning solution wash (Alkaline)
- Potable water rinse (to remove cleaning solution)
- Purified water final rinse
- Drying
- Visual Inspection
- Storing cleaned items

Cleaning Validation Manual

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