

CLEANING TABLET TOOLS

BACKGROUND

Compression tools such as tablet punches are extensively used in pharmaceutical drug tableting operations. These are typically multi-product operations, and cleaning and cleaning validation are important to prevent cross-contamination.

The drug product is often more tenaciously adhered onto the punches due to the high pressure punching operation. This makes the cleaning process more challenging. Since the tableting process is among the last stages of processing, the acceptance criteria are usually very stringent. Also, punches are manufactured from special types of tool steels due to the extreme stresses and high wear involved. These metals are not as corrosion resistant as the 316 grade stainless steel used in other pharmaceutical manufacturing operations. Therefore, when aqueous cleaning agents are used, careful selection of cleaning agents, cleaning processes, and cleaning parameters is required.

OBJECTIVE

A large pharmaceutical manufacturer was interested in evaluating STERIS cleaning agents for their S-7, D-3, and 440-C grade steel punches. The alkaline detergent used earlier was from another company and caused staining of the punches.

FIELD EVALUATION

The cleaning equipment used by the company was a three-tank Sonicor ultrasonic machine. Prior experience suggested that a highly alkaline cleaning agent was inappropriate for substrates such as S-7 and D-3 steel. Based on the chemistry of soils involved and the substrate, STERIS product DA 7645 was suggested as the primary cleaning agent. DA 7645 is a detergent system with a 1% solution pH of about 9.6. Cleaning trials were done on a limited scale on the tablet punches to establish performance and compatibility with the substrates. Based on the trials, the following cleaning procedure was established.

1. One quart of DA 7645 was added to the ultrasonic wash tank.
2. The machine then automatically added about 40 gallons of cold potable water to the wash tank, and the solution was heated in the wash tank. The temperature setting for the wash tank was 125°F (51°C).
3. A basket of tooling was introduced into the ultrasonic wash tank and sonicated for 2-1/2 minutes.
4. The basket was then automatically cycled to the rinse tank and rinsed by immersion at a set point temperature of 120°F (48°C) for 1 minute.
5. The basket then passed to the drying chamber and was dried with fresh air at 135°F (57°C) for 5 minutes, and then deposited on the other staging area.
6. Immediately after the cycle was completed, all tooling surfaces were wiped using a clean disposable cloth dampened with Septihol™, a 70 percent isopropanol solution made by STERIS.
7. The tooling was inspected for any corrosion and product residue, and then stored.

RESULTS

After the cleaning process, the surfaces were thoroughly inspected for visual residue. The surfaces were swabbed at various locations and the samples were tested for the active component using existing protocols. The residue levels obtained for the active component met the acceptance criterion. This cleaning procedure has since been successfully validated. The tools have not shown any signs of visual staining or rusting since the use of this revised SOP.

For further information, please contact:



STERIS Corporation
 5960 Heisley Road
 Mentor, OH 44060-1834 • USA
 440-354-2600 • 800-444-9009
 www.steris.com

STERIS offices provide support throughout the world:

Belgium	32 2 523 2488
Canada	800 661 3937
France	33 1 4488 2688
Germany	49 2233 6999 0
Italy	39 0141 590429
Japan	81 78 252 1901
Latin America	305 442 8202
Netherlands	31 111 643444
Nordic	358 9 25851
Singapore	65 841 7677
Spain	34 91 658 5920
United Kingdom	44 1 276 683 300