**CLEANING VALIDATION ON MIXING AND FILLING MACHINES OF SEMISOLID LINE AREA**

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**Background and aims.** Cross-contamination in pharmaceutical manufacturing jeopardizes product quality and patient safety, necessitating stringent control measures, including effective cleaning validation. This study addressed contamination risks by identifying the worst-case product through systematic grouping, validating sensitive analytical methods for detecting trace residues and microbiological contaminants on stainless steel surfaces, and testing cleaning procedures on mixing and filling machines. This study was aimed to assess the effectiveness of cleaning procedures in eliminating Ketoconazole residue and microbial contamination, determine limit residue, conduct analytical method validation (AMV) and recovery studies.

**Methods.** This study was to determine product worst-case and residue limit, analytical method validation, residue recovery and microbiological recovery on stainless steel coupons, cleaning validation of mixing and filling machines washed with purified water and sanitized with 70% alcohol. Product worst-case residue and microbial contamination were sampled via swab and rinse methods.

**Results.** Ketoconazole was identified as the worst-case product with a limit of 10 ppm. AMV parameters met the criteria, with LOD 0.1 ppm and LOQ 1.1 ppm. Residue recovery averaged of 97.2% for swab and 95.8% for rinse methods, respectively. Microbiological recovery using the rinse method met the criteria for all microorganisms. Cleaning validation revealed the highest Ketoconazole residue was on the scraper (6.1 ppm) of mixing machine and connector (4.9 ppm) of filling machines, respectively. Microbiological cleaning validation showed that the highest microbial was on the swab method for mixing machine (17 CFU/25cm2) and filling machine (13 CFU/25cm2), respectively.

**Conclusion/Discussion.** Both swab and rinse methods were effective for residue recovery, and the rinse technique proved suitable for microbiological recovery. The cleaning procedures effectively removed Ketoconazole residue and microbial contamination below the specified limits. This validation is crucial for ensuring pharmaceutical product quality and preventing cross-contamination.

**References:**

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