Cleaning Validation of Primary Packaging Equipment Line in Pharmaceutical Industry

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Cleaning validation is documented evidence that an approved cleaning procedure will consistently remove previous product or other residues on product contact equipment surfaces below scientifically set acceptable levels. The cleaning validation consequently ensures that the quality of the next product manufactured shall not be compromised by cross-contamination.[1,2]

The aim of this study was to validate the cleaning procedures of primary packaging equipment line IMA C80HS. Automated washing and drying machine DeLama were used for effectively washing and drying of disassembled packaging equipment parts. By performing a risk assessment considering solubility, toxicological effect and cleanability it was concluded that Alprazolam tablets 1mg is a worst-case product for primary packaging equipment line IMA C80 HS. Three consecutive cycles of cleaning and testing were executed after packaging of Alprazolam tablets 1mg. After each cleaning validation cycle swab and rinse samples were collected for physico-chemical analysis. The samples were analyzed with specific and validated HPLC method for quantification of residues from previous product. The column used was Zorbax Eclipse XDB C18, 150mm x 4.6mm i.d; 3.5µm; column temperature of 25 ºC; at a 1.0 mL/min flow rate and 254 nm detection. Mobile phase: mixture of ammonium acetate buffer solution pH=4.2 and methanol in ratio 35:65 %(*V*/*V*). The injection volume was 20µL.

The obtained data provide evidence that all results are within the acceptance criteria. The cleaning validation study confirms that the standard operating procedure for cleaning of primary packaging equipment parts is effective and reproducible and therefore approved as validated.

Keywords: cleaning validation, cross-contamination, risk assessment, HPLC method

References

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2. FDAGuidance for Industry Process Validation: General Principles and Practices, **2011**