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Cleaning Validation: A Case Study Involving Dexamethasone Cream

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***SUMMARY*. In order to achieve a reliable degree of quality, the pharmaceutical industry needs to introduce a quality control system that includes validation of the cleaning of equipment. This study carried out cleaning validation on the dexamethasone cream production line. The validation study involved evaluation of the cleaning procedures for the dexamethasone cream production line. Samples were collected at thirteen points involving the reactor, the colloidal mill, the industrial blender, the mixer and the packaging machine, for each of the batches. Samples were collected for study of the residue of the principle active ingredient, of detergent, and for microbiological analysis. Cleaning was shown to be within the stipulated parameters (acceptable level = 9.95 μg/mL) for: residues of active ingredient, TOC, pH, conductivity and microbiological contamination. It was thus concluded that the strategy adopted for cleaning validation was simple, swift, and efficient and capable of being applied to other kinds of pharmaceutical products.**

KEY WORDS: Cleaning validation, Dexamethasone, Quality control, Semi-solids.

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