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Cleaning Validation of Cefalexin Capsule

Nataraj H.M.[1], N. Vishal Gupta[1]*, G. Ravi[1]

[1]Department of Pharmaceutics, JSS College of Pharmacy, SS Nagara, Mysore, Jagadguru Sri Shivarathreeswara University, JSS Medical Institutions Campus, Mysore – 570015, Karnataka, India.

Abstract : Importance of cleaning validation in pharmaceutical industry is self-evident. It is enough to say that clean environment and clean operations are the heart of pharmaceutical activities. Cleaning is directly related to the safety and purity of pharmaceutical products and hence it becomes the most important and prime activity. The present topic deals with the cleaning validation of an oral antibiotic. The objective of the present research work is to study cleaning validation performed during changeover of Cefalexin product as oral formulation, determine the level detergent and microbial count at the manufacturing unit. For analysis of swab samples collected during cleaning validation of three different batches, many parameters were evaluated with particular acceptance limits. Among them the major evaluations such as UV analysis of drug residues and microbial count were carried out. In UV method the acceptance limit of previous product residues were calculated using maximum allowable carry over (MACO) technique. The samples were analyzed by the validated UV spectroscopic method at 262 nm. The detergent was analyzed by the validated UV spectroscopy at 650 nm. The results of analysis indicated that the levels of Cefalexin, detergent and microbial count were within the acceptance criteria. Hence it can be concluded that the cleaning methodology adopted for Cefalexin product does not leave any remains of previous batch which is confirmed by cleaning validation studies.

Key words : UV spectroscopy, Cefalexin, Microbial count, MACO.

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