Latin American Journal of Pharmacy
(formerly *Acta Farmacéutica Bonaerense)*
Lat. Am. J. Pharm. **31** (2): 315-20 (2012)

Short Communication
Received: October 21, 2011
Revised version: February 27, 2012
Accepted: March 3, 2012

Cleaning Validation Applied to the Production of Antiretroviral Drugs: Determination of Zidovudine and Lamivudine Residues on Manufacturing Equipment

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***SUMMARY*. This work evaluated the cleanliness of equipment involved in manufacturing the product LAFEPE Zidovudine (AZT) + Lamivudine (3TC) 300 mg + 150 mg coated tablets in a antiretroviral plant. A method for simultaneous determination of AZT+3TC in High Performance Liquid Chromatography HPLC-UV is selective and presented a linear range from 2.5 to 15 μg/mL, and Limit of Detection (LOD) (AZT: 0.13 μg/mL; 3TC: 0.15 μg/mL) and Limit of Quantification (LOQ) (AZT: 0.20 μg/mL; 3TC: 0.23 μg/mL). Recoveries of 82.00 and 83.00 % for the active AZT and 3TC, respectively, were obtained with the use of swab on stainless steel surfaces 316L. The method of cleaning and sampling was applied to three consecutive industrial batches and the results met the specification limits for contaminants.**

KEY WORDS: Cleaning validation, HPLC, Lamivudine, Swabbing recovery, Zidovudine.

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