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SIMULTANEOUS QUANTITATIVE ESTIMATION OF LISINOPRIL AND HYDROCHLOROTHIAZIDE RESIDUES USING HPLC FOR CLEANING VALIDATION

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Abstract. The aim of this study was to develop and validate direct - swab and indirect - rinse sampling procedures and a high performance liquid chromatography (HPLC) method for simultaneous quantitative estimation of residues of active pharmaceutical ingredients (API) – lisinopril and hydrochlorothiazide (HCT) in cleaning control samples collected from pharmaceutical manufacturing equipment surfaces after manufacturing of lisinopril/hydrochlorothiazide 20/25 mg uncoated tablets. The swab and rinse sampling procedures were developed and validated in order to obtain a suitable and good recovery (>80%). The acceptance limits of the above-mentioned APIs on the manufacturing equipment surfaces have been established based on pharmacological and toxicological criteria. The new, rapid, specific and selective, developed HPLC method for simultaneous quantitative determination of lisinopril and HCT residues was validated with respect to robustness, system suitability test, specificity, linearity-range, precision, limits of detection and quantitation. The stability of APIs solutions and membrane filter compatibility were studied as well. The method validation was carried out according to ICH Q2 guideline and United States Pharamcopeia requirements. The limit of detection and the limit of quantitation for lisinopril were 0.039 μg/mL and 0.155 μg/mL and for HCT - 0.012 μg/mL and 0.025 μg/mL, respectively.

Keywords: lisinopril, hydrochlorthiazide, swab sampling, rinse sampling, HPLC, validation.

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