ABSTRACT

The theoretical part deals with the problems of cleaning validation as one of the basic principles of quality assurance, which should secure the production of safe, effective and quality medicines. Validation of cleaning processes is required by good manufacturing practice, particularly to prevent contamination of raw materials, intermediate products, products and other materials. This work deals with the legislative control of validation, its organization and formalities. It also deals with the issue cleanliness in manufacturing facilities and its evaluation.

The experimental part was carried out in a pharmaceutical company Teva Czech Industries s.r.o in Opava. Analytical method for flutamide was developed and validated. The analytical method will be used to cleaning validation of the device in which it will be produced in the future. Validation of the analytical method included verification of validation characteristics such as accuracy, precision, specificity, linearity, detection and the limit of quantification and stability.

Keywords: pharmaceutical manufacturing, validation, cleaning