ABSTRACT

The thesis preamble introduces validations of analytical methods, as an important process during pharmaceutical development and quality control in pharmaceutical manufacturing.

Method validation has essential influence on pharmacoeconomics and greatly shortens the time of placing the medicament to the market. The IMS principle greatly shortens analysis time, thus ensuring economic and innovation growth for pharmaceutical companies. Experimental part of this thesis was performed on the device IONSCAN – LS Smiths-Detection, USA in the branch of the Teva company in Opava, which introduces IMS to analytical procedures validation for cleaning validation in pharmaceutical manufacturing.

For measuring, the Naphazolini nitras standard was used and the Teflon dry method was applied. During the method development itself, in which I participated, the method usability range was found in the interval of mass concentrations from 0,06 – 0,80 mg / ml. The detection limit at the level of 0.02 ppm and the quantification limit at the level of 0.08 ppm were determined and linearity was verified. In the second part, I validated the analytical method for cleaning process validation. Sampling was performed by means of polyurethane swabs “Large Swab” from a metal plate of surface size 5 x 5 cm2. From this equipment, a swab will be made after product manufacturing. The swab will undergo the IMS Limit Test. Its result will determine whether the manufacturing equipment is ready for production of the following product, whether cleaning was sufficient. During the analytical method validation, an Israeli Validation Protocol was followed and the linearity, repeatability and swab recovery equaling to 93.59 – 135.81 % were verified.

Key words: validation, IMS, method development, analytical method validation, swabs, recovery