Affek, K., Zaleska-Radziwill, M., Lebkowska, M. Determination of Safe Concentration Limits of Pharmaceuticals in the Aquatic Environment Based on Ecotoxicological Studies. *Ochrona Srodowiska* 2013, Vol. 35, No. 4, pp. 51–56.

Abstract: The results of ecotoxicological research on determination of safe concentration limits of 5-fluorouracil (anticancer drug) in water were discussed. A method for determination of safe concentrations of pharmaceuticals according to the EMA (European Medicines Agency) guidelines was employed for this purpose. The procedure was verified in microcosm, multispecies model ecosystem studies. The experiments demonstrated that concentrations determined in water by the EMA recommended method cannot be considered safe. Additionally, the coefficient AF=10 (acc. to EMA recommendations) cannot form the basis for estimates of safe concentration limits of pharmaceuticals in aquatic biocenoses. The bioequivalence studies showed that so-called safe 5-fluorouracil concentration led to decrease in Shannon-Wiener index value in regard to microbentos. It was found that ecotoxicological risk assessment for the presence of pharmaceutical in surface waters should be based on chronic test set supported with molecular studies and multispecies microcosm testing. It should be noted that safe concentrations of pharmaceuticals that cause no risk to aquatic biota and humans should form the basis for the process optimization in regard to wastewater treatment and elimination of medicines from potable water.

Keywords: Water quality, 5-fluorouracil, safe concentration, microcosm.