ELABORATION OF NEAR INFRARED SPECTROSCOPY MODEL FOR DETERMINATION OF WATER CONTENT IN FREEZE-DRIED IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

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Residual water is a critical parameter in assessing the quality of immunological veterinary medicinal products (IVMPs). In majority of the laboratories the Karl Fischer titration (KFT) is used for the determination of water content in IVMPs. However, the transfer of IVMP into titration cell without affecting the baseline drift and repeatability seems to be the main problem when using this method. In turn, Near Infrared Spectroscopy (NIRS) allows measurement of closed vials, therefore eliminating the impact of atmospheric conditions on the sample. The aim of the study was to create a calibration model based on the reference method (Karl Fischer titration) and its optimization. Five different IVMPs designated for two animal species (dogs and rabbits) were used. The model was constructed on the basis of 49 samples tested, each in triplicate (n=147). The spectra were divided in two sets: calibration and validation. Proper selection of samples and their processing allowed to obtain a model of high quality (Q-value>0.6).

Key words: Near Infrared Spectroscopy, Karl Fischer titration, IVMPs