

## **T03. Recognition of the “high quality forgeries” among the medicines**

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Counterfeit drugs could be of different type, such as placebo, the medicines with lower concentration of active substances, the drugs that do not contain the proper concentrations or contain a wrong type of excipients, etc. The most difficult for revealing are 'the high quality fakes', which have a proper composition but produced by the underground manufactures with violation of technological regulations. We consider that methods that are based only on determination of an active substance do not suffice for our purposes due to a wide range of the counterfeit products. As NIR measurements carry information regarding not only chemical but also physical phenomena, NIR spectroscopy was chosen as an instrument. A well-known method of soft independent modeling of class analogy (SIMCA) with modified control limits was applied for the mathematical data processing.

Investigation of fifteen different types of medicines has shown that application of NIR measurements together with chemometric data processing is an effective approach. Proper discrimination should be free from human failures. For these purposes:

- Each medical product should be carefully investigated on the batch-to-batch variability.
- Selection of spectral region should be done individually for each type of medicine. The spectral region may essentially influence on the final classification results.
- It is equal important to recognize the forgeries as well as to avoid a misclassification for the genuine samples. Application of reliable acceptance limits is of great importance.

Several real-world examples illustrate the presentation.