Near-infrared spectroscopy for the detection and quantification of bacterial contaminations in pharmaceutical products

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Accurate detection and quantification of microbiological contaminations remains an issue mainly due the lack of rapid and precise analytical techniques. Standard methods are expensive and time-consuming being associated to high economic losses and public health threats. In the context of pharmaceutical industry, the development of fast analytical techniques able to overcome these limitations is crucial and spectroscopic techniques might constitute a reliable alternative.

In this work we tested the ability of Fourier transform near infrared spectroscopy (FT-NIRS) combined with several chemometric methods as partial least squares discriminant analysis (PLSDA) and partial least squares (PLS) to detect and quantify bacteria (*Bacillus subtilis, Escherichia coli, Pseudomonas fluorescens, Salmonella enterica, Staphylococcus epidermidis*) in sterile saline solutions (NaCl 0.9%).

PLSDA models showed that FT-NIRS was able to discriminate between sterile and contaminated solutions for all bacteria as well as to identify contaminant bacteria. The PLS models allowed bacterial quantification (from 10-10^8 CFUs/mL) with limits of detection ranging from 5.1 to 9 for *E. coli* and *B. subtilis*, respectively. This methodology was also successfully validated in three pharmaceutical preparations (contact lens solution, cough syrup, topic anti-inflammatory solution).

Despite the need of some additional studies to strength the findings of this work, FT-NIRS seems to possess a high potential to be routinely used for the detection and quantification of bacterial contaminations in the pharmaceutical industry.