

# IDENTIFICATION OF COUNTERFEIT VIAGRA, CIALIS AND LEVITRA TABLETS USING HANDHELD RAMAN SPECTROSCOPY

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## Objective

The aim of this work was to identify counterfeit Viagra, Cialis and Levitra tablets using handheld Raman spectroscopy.

## Introduction

Counterfeit medicines impose a major health threat that leads to medicines' ineffectiveness as its easiest and lethal effects at its worst (1). Counterfeit medicines can be encountered anywhere over the wholesale supply chain. This stimulates the need to develop rapid and non-destructive methods for their analysis. Handheld Raman spectroscopy offers this advantage.

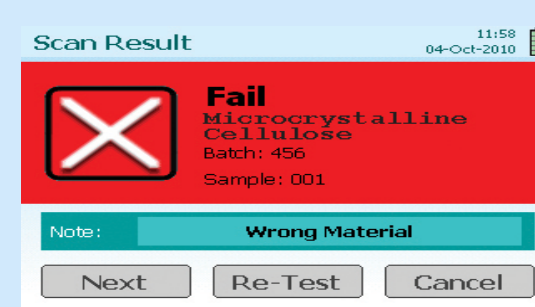
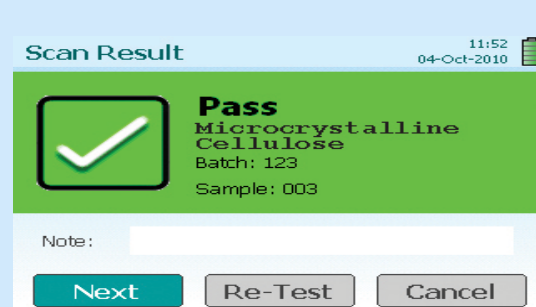
## Experimental

### Materials

A total of 44 Viagra (24 authentic and 20 counterfeit), 22 Cialis (14 authentic and eight counterfeit) and 19 Levitra (nine authentic and nine counterfeit) tablets were obtained through the Korean Food and Drug Administration (FDA).

### Instrumentation

The tablets were measured "as received" using a Thermo TruscanRM handheld Raman instrument.



## Method

For the in-built algorithm identification: a Raman signature (high quality spectrum) of each of authentic Viagra, Cialis and Levitra tablets were acquired using a handheld Thermo TruscanRM instrument. Then, the spectra of the test (authentic and counterfeit) tablets were matched against the known authentic tablets' signatures using the probability based algorithm.

For off-line identification, the spectra of the tablets were exported to Matlab and principle component analysis (PCA) was applied to their standard normal variate-second derivative (SNV-D2) spectra.

## Results and Discussion

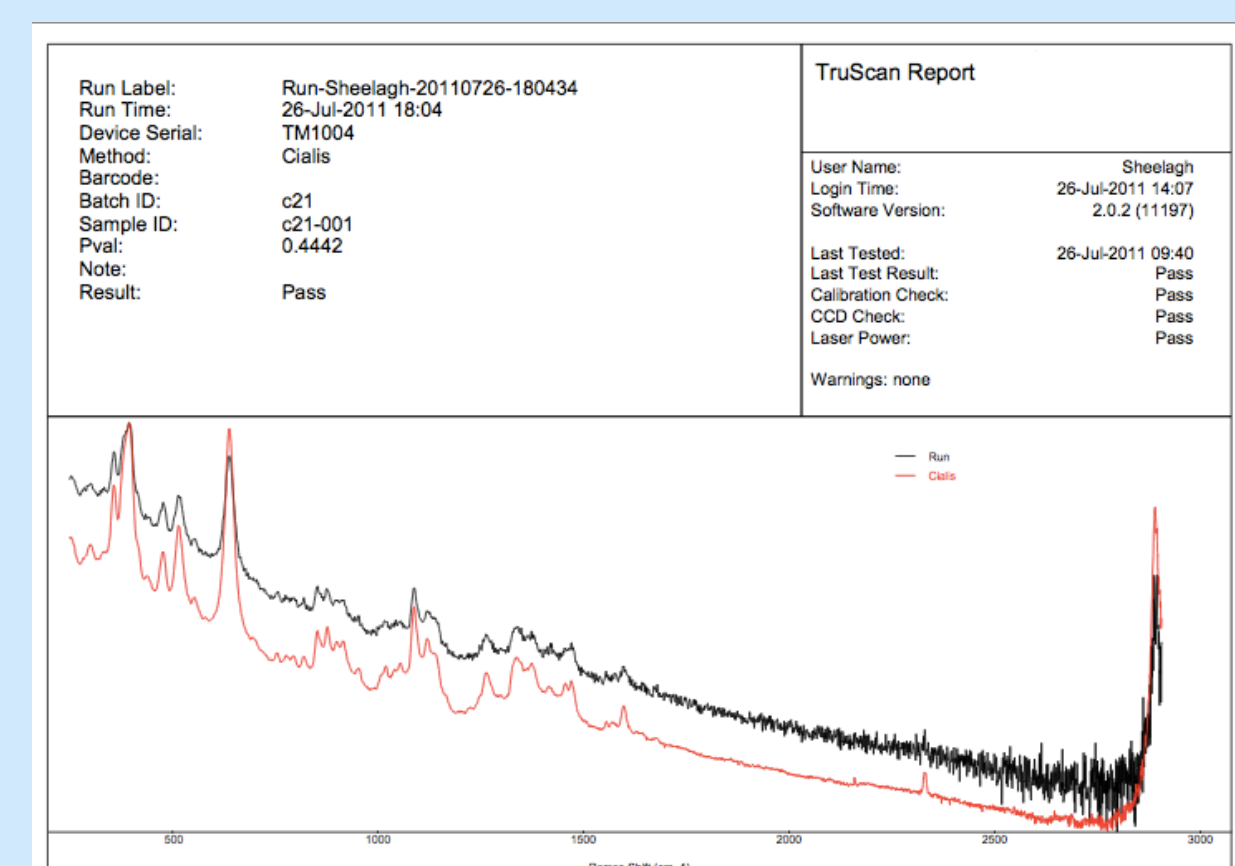
The comparison between both algorithms was inspected taking into account Type I and Type II errors. The first was encountered when an authentic tablet was misidentified; whereas the second occurred when a counterfeit tablet was identified as an authentic tablet.

### In-built identification algorithm

The in-built algorithm of the instrument utilised Bayes' theorem and calculated the probability value (pvalue) of how close the test spectrum was to the reference signature. A pvalue > 0.05 showed that the test tablet spectrum matched the method signature and thus was authentic. Otherwise, a pvalue < 0.05 showed that the test tablet was counterfeit. In the latter case, the in-built algorithm had the option of finding matches to the test spectrum in discovery mode to give a positive or a similar item match of reference material(s) stored in the library.

$$P(A|B) = \frac{P(B|A)P(A)}{P(B)}$$

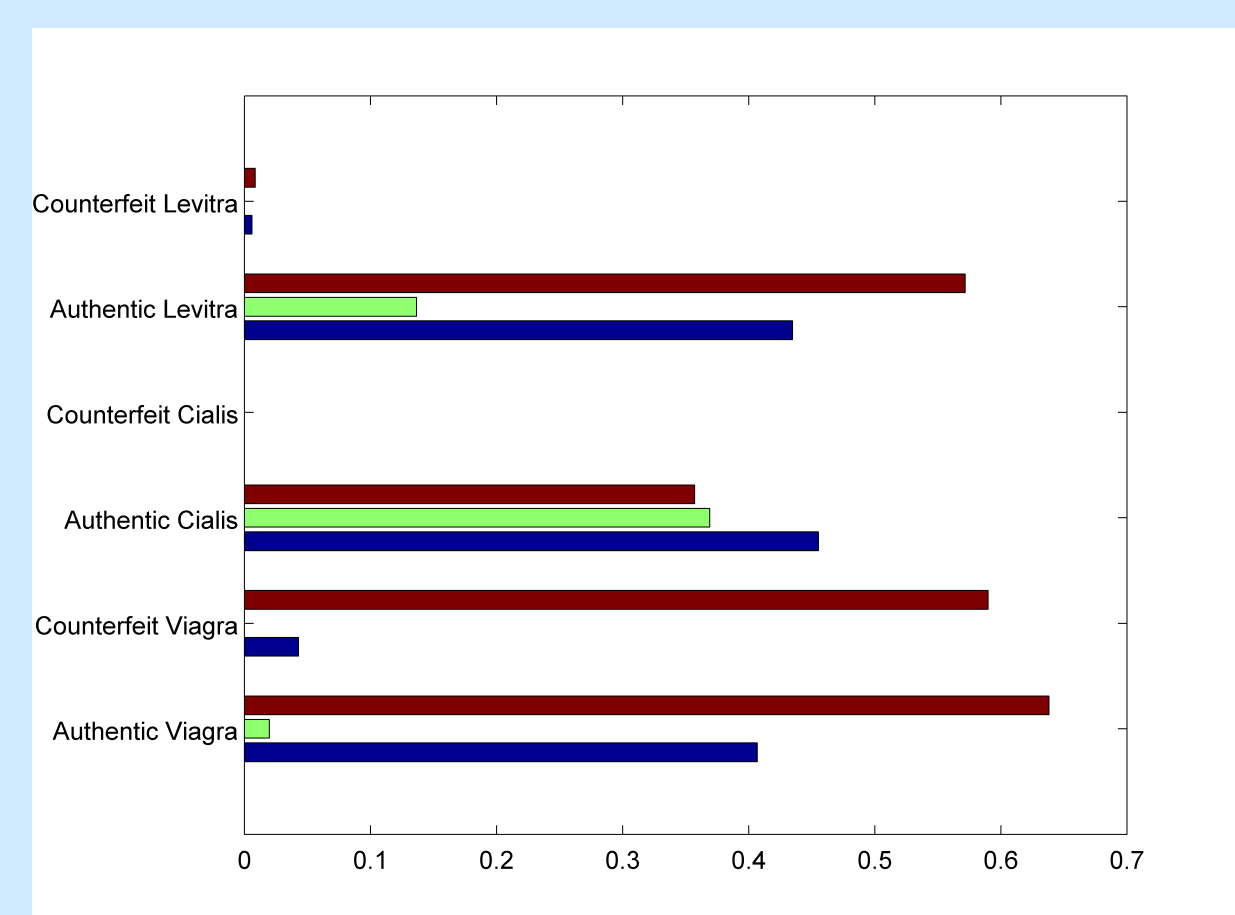
The results were displayed instantly showing the reference signature, the sample spectrum and the pvalue between both (Figure 1).



**Figure 1** Results sheet showing an authentic signature (red) and counterfeit spectrum of Cialis tablets measured with the Thermo Truscan RM (pvalue = 0.4442) .

### Accuracy of in-built algorithm

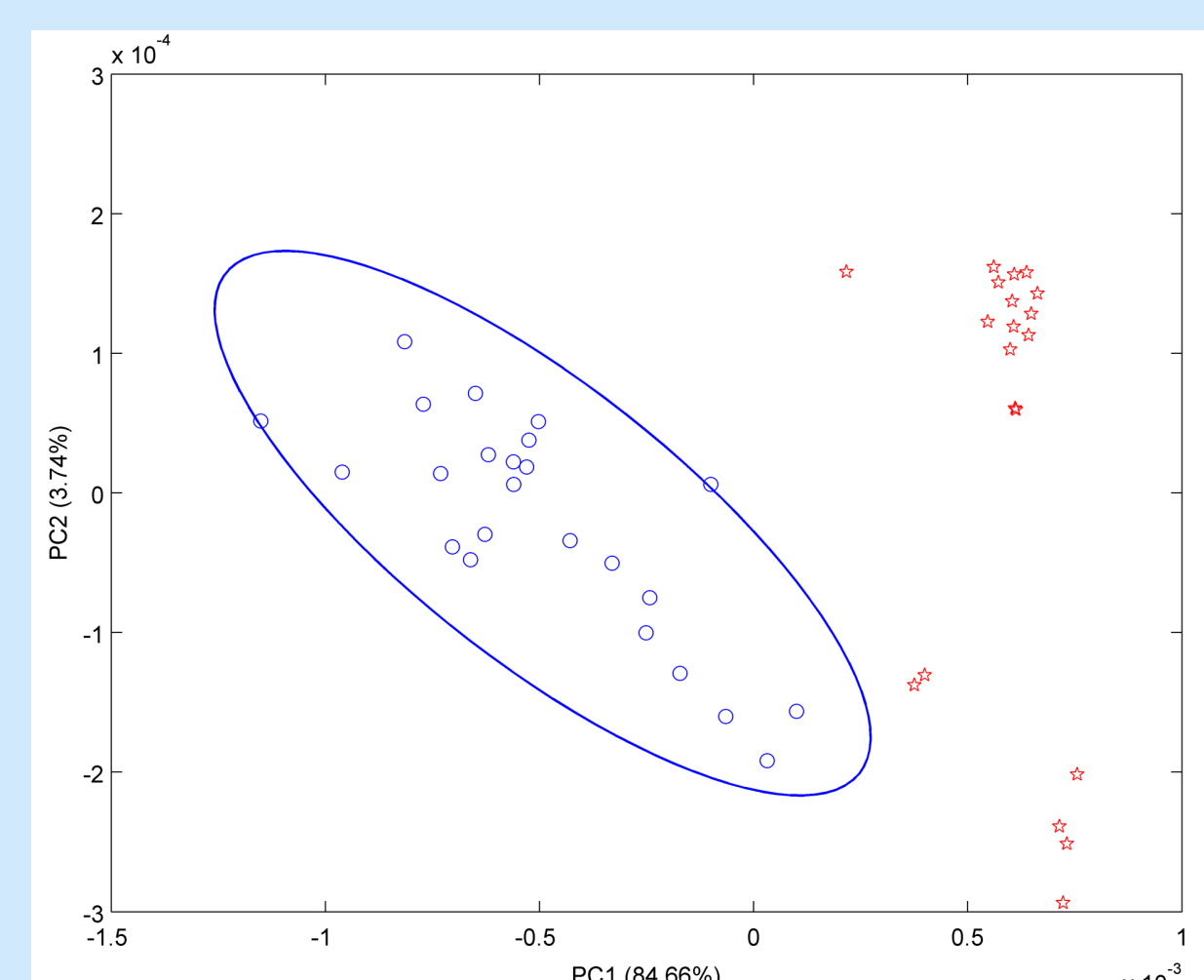
The Viagra tablets showed type I errors for two out of the 24 authentic tablets; and type II error for one counterfeit tablet. On the other hand, no type I and type II errors were observed for the authentic and counterfeit Cialis and Levitra tablets (Figure 2).



**Figure 2** Mean (blue), minimum (green) and maximum (red) pvalues of authentic and counterfeit Viagra, Cialis and Levitra tablets obtained through the in-built identification algorithm.

### Accuracy of PCA

PCA was able to identify all the counterfeit tablets and differentiate them from the authentic tablets with no Type I or Type II errors (Figure 3).



**Figure 3** PCA scores plot of authentic (blue) and counterfeit (red) Viagra tablets Raman spectra with the 95% equal frequency ellipses around the authentic tablets.

## Conclusion

PCA was showed to be more accurate than the in-built instrumental algorithm for identifying counterfeit Viagra, Cialis and Levitra tablets.