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Newest Techniques in the Investigation Procedure of Counterfeit/Illegal Medicinal Products

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1. Introduction

The increasingly number of counterfeit and illegal medicinal products become ever more and more potential hazard for public health, thus investigation and analysing of these suspicious products is a very important point in the activity of the Official Medicine Control Laboratories (OMCLs). In Hungary the National Institute of Pharmacy and Nutrition (NIP) is responsible for providing expert opinion in the questions of suspected falsified pharmaceuticals.

2. Materials and methods

Usually the testing steps are the following:

- Visual examination of the packaging material, the leaflet, the appearance of product
- Comparison of the size, hardness, friability and weight of the product with the requirements
- Comparison of IR spectras with the original product's
- Identification of active substance with HPLC-UV-DAD-MS methods
- Other supplementary test to support the opinion in the question of falsification

3. Results

In the first part of the poster presentation there is a small statistical summary about the results of the suspicious falsified medicinal product legally authorised by Hungary, tested in recent years in the laboratory.

Besides this general information the main aim of this poster study is to demonstrate the investi-



Figure 1 Picture of the illegal site in a regular wine cellar



Figure 2 Picture of the tabletting machine

gation of one specific falsified medicinal product – Rivotril tablets – found in Hungary in an illegal site located in a regular wine cellar.

The fact of the falsification of the tested product has been confirmed by the result of the tests performed according to the authorisation documen-

tation and our own tests. Analyses were performed using LC-MS/MS, HPLC-DAD, FT-IR, hardness and friability tester instrument and the really important FT-IR, NIR microscope.

The tablets were almost perfectly counterfeited, but based on the different analytical results it could be stated without doubt that the samples were falsified products.

3. Conclusions

The conclusion of this study is that the counterfeited products show always better and better similarity with the original products, so the used methods and instrument have to be improved and developed in the fight against counterfeited products accordingly.
