A LABORATORY EXPERIENCE IN ANALYSIS OF SEIZED MEDICINES IN THE REPUBLIC OF MACEDONIA

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INTRODUCTION

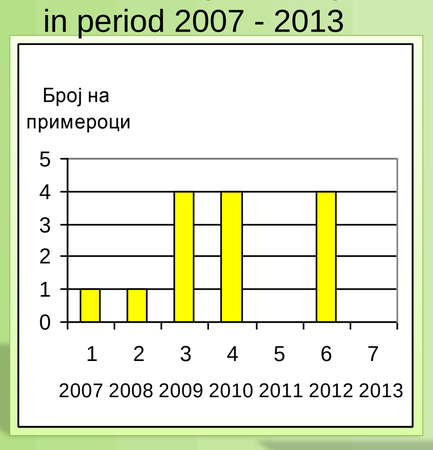
A counterfeit medicine is defined as a medicinal product which is manufactured by an illegal manufacturer or deliberately mislabeled with respect to identity of registered product. Once they enter the market, those medicines could pose a serious public health risk in a way that they do not deliver the desired effect and/or their use could lead to unexpected adverse effects, such as: anaphylaxis or developing resistance to the medicinal product. Therefore, fighting the entrance of counterfeit medicines in the country presents a significant national issue and requires a well-organized health system as well as market surveillance regulation.

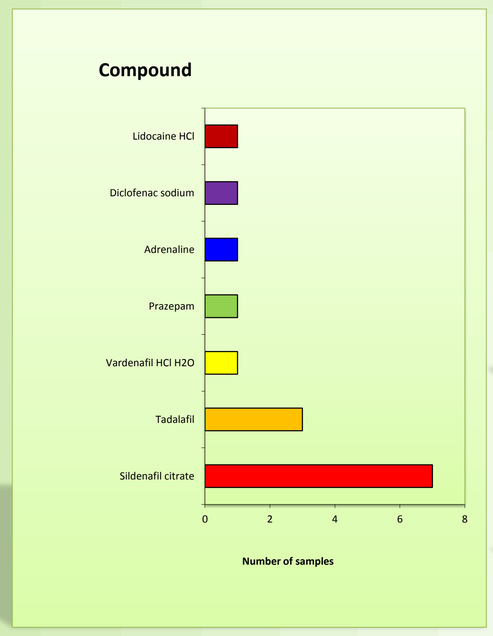
EXPERIMENTAL

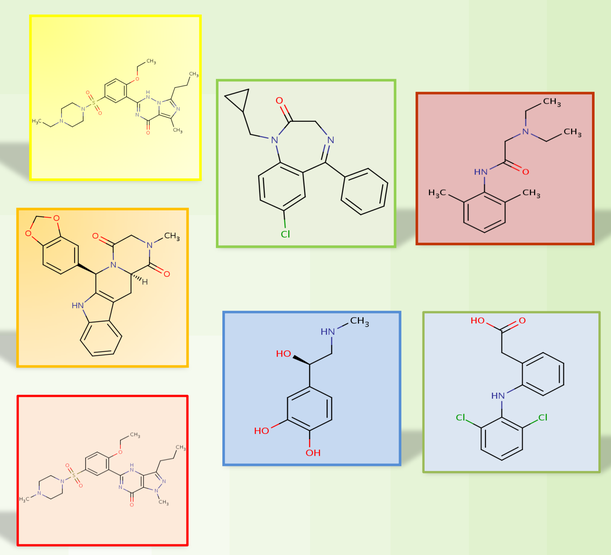
The Department for Medicines Quality Control at the Institute for Public Health of the Republic of Macedonia was actively involved in combating counterfeit drugs. In the period from 2007 – 2013, fourteen samples seized from the Customs of Macedonia were submitted to the Bureau of Medicines (Ministry of Health) to be analyzed in the Department for Medicines Quality Control. The identification and determination of the content of active substances was successfully achieved using laboratory methods from the registration documentation provided by the manufacturers of the licensed finished medicinal products or the internal HPLC methods validated previously and intended for control of the potentially counterfeit products.

RESULTS

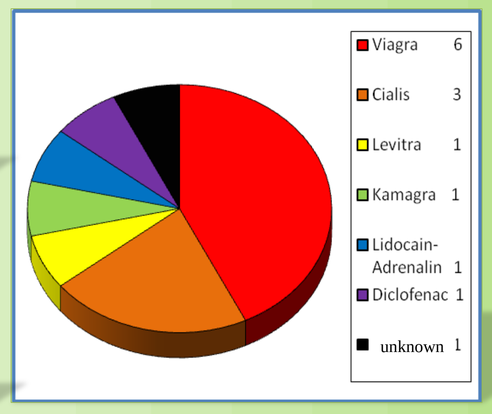
Number of samples analyzed in period 2007 - 2013

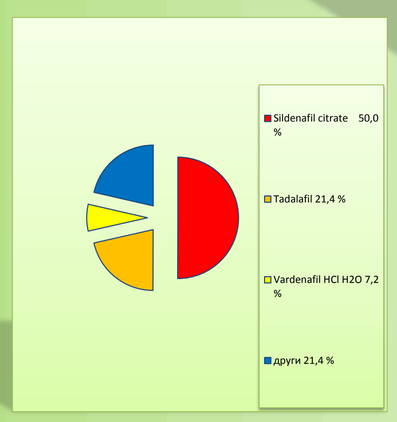


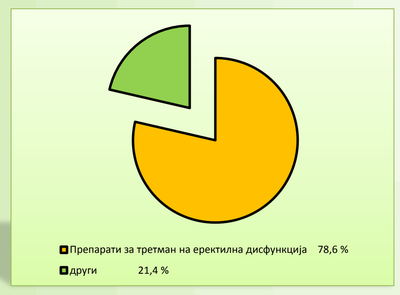


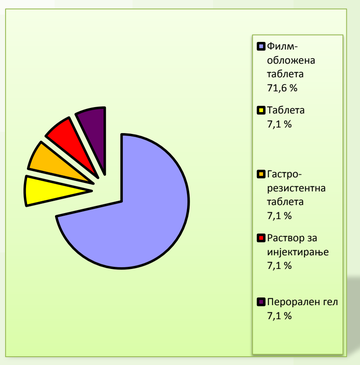


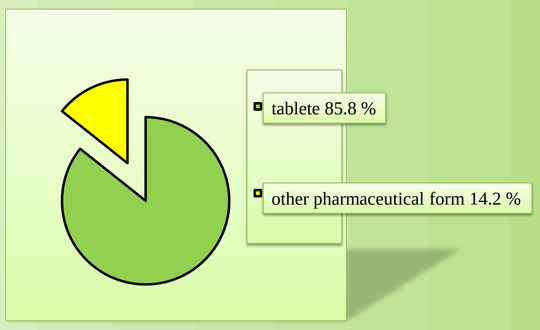
Samples classified by label



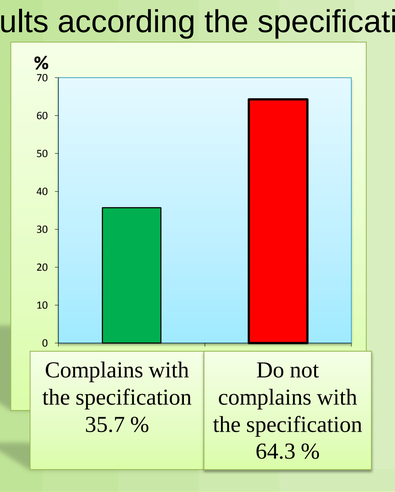








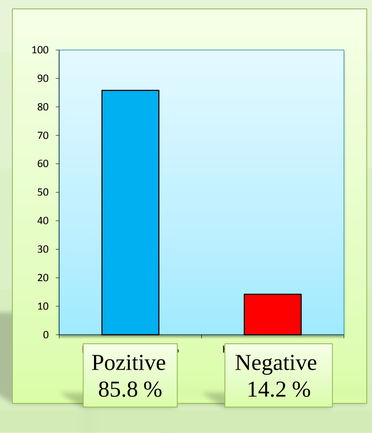
Results according the specification



Complains with the specification 35.7 %

Do not complains with the specification 64.3 %

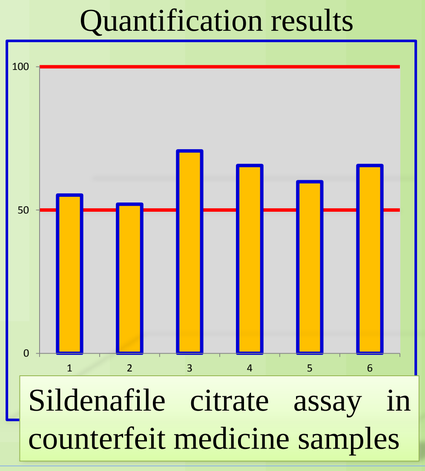
Identification results



Pozitive 85.8 %

Negative 14.2 %

Quantification results



Sildenafile citrate assay in counterfeit medicine samples

CONCLUSION

The most of the seized medicines were in pharmaceutical form of tablet.
The 14.2 % of samples were false labeled for the active compound.
The most frequently identified active substances were those for treatment of erectile dysfunction.
The most of the analyzed products contained the active substance outside the acceptable 95 % to 105 % margin of deviation from the declared value.
The assay results for sildenafil citrate in the seized tablets were in range 52.1 % - 70.6 % from the declared content.

PRESENTED PAPERS

1. Z. Poposka, M. Shishovska, Z. Arsova-Sarafinovska, Validated HPLC method for quantitation of tadanafil in pharmaceutical formulations and human serum, *V-mu Конгрес на Здружението на медицинските биохемичари на Македонија*, Poster Abstracts, PP-175, Ohrid, 2009.
2. Z. Poposka, M. Shishovska, Z. Arsova–Sarafinovska, D. Doneva, K. Starkoska, Z. Mustafa, Performance evaluation of various HPLC columns in sildenafil and tadanafil analysis, *4th BBBB Bled International Conference on Pharmaceutical Sciences*, Poster Abstracts, P025, Bled, 2011.
3. Z. Poposka, M. Shishovska, K. Starkoska, Z. Arsova–Sarafinovska, Validated HPLC method for determination of sildenafil in pharmaceutical dosage forms, *5th Congress of Pharmacy of Macedonia with International Participation*, Poster Abstracts, PP-29, Ohrid, 2011.
4. Z. Poposka, Sh. Memeti, M. Shishovska, Z. Mustafa, K. Starkoska, Z. Arsova–Sarafinovska, Identification of counterfeit medicines for erectile dysfunction by validated RP-HPLC method, 5th BBBB International Conference on Pharmaceutical Sciences, Poster Abstracts, PP038, Athens, 2013.

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1. Z. Poposka, M. Shishovska, Z. Arsova–Sarafinovska, D. Doneva, K. Starkoska, Z. Mustafa, Performance evaluation of different HPLC columns in sildenafil and tadanafil analysis, 4th BBBB -Bled International Conference on Pharmaceutical Sciences New Trends in Drug Discovery, Delivery Systems and Laboratory Diagnostics, Bled, Slovenia, *European Journal of Pharmaceutical Sciences*, **44** (Suppl. 1), 74-75, (2011). (http://dx.doi.org/10.1016/j.ejps.2011.08.002)
2. Z. Poposka, Sh. Memeti, M. Shishovska, Z. Mustafa, K. Starkoska, Z. Arsova–Sarafinovska, Identification of counterfeit medicines for erectile dysfunction by validated RP-HPLC method, 5th BBBB International Conference on Pharmaceutical Sciences, *European Journal of Pharmaceutical Sciences*, **50** (Suppl. 1), 53, (2013). (http://dx.doi.org/10.1016/j.ejps.2013.09.012)

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