



B53 Analysis by HPLC-MS of Counterfeit and Imitations of Viagra®

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After attending this presentation, attendees will understanding the counterfeiting and imitations of the drug Viagra and other generic containing less active ingredient can pose significant risks.

This presentation will impact the forensic community and/or humanity by studying the qualitative and quantitative variability of the active principle in tablets sold in illicit market, checking the homogeneity of a batch, and distinguishing counterfeits and imitations from authentic Viagra®.

Goal: Pharmaceutical counterfeiting is becoming a serious problem both in developed and developing countries. The aims of this work are:

a) study the qualitative and quantitative variability of the active principle in tablets sold in illicit market; b) check the homogeneity of a batch; c) distinguish counterfeits and imitations from authentic Viagra®.

Methods: Instruments: HPLC-MS (Agilent Technologies LC 1100-MSD Trap XCD Plus); column Zorbax XDB-Phenyl 2.1x50 mm, 3.5 μ m.

Selected ion monitoring: m/z 377.2 (sildenafil), 368.2 (ethaverine)

Samples: Eighty-six tablets derived from judicial attachments of five different counterfeit drugs: Pesigra 50, Novagra 100, Kamagra 100, Vegatone 50, Viagra 100.

Results: The sildenafil citrate reported on the blister is quite different from measured quantity.

Analyzed tablets of Pesigra 50 contain from 9.27 mg to 14.20 mg of sildenafil citrate instead of reported 50 mg; Novagra 100 tablets contain from 16.65 mg to 26.16 mg instead of reported 100 mg; Kamagra 100 tablets contain from 16.00 mg to 24.59 mg instead of reported 100 mg; Vegatone 50 tablets contain from 5.43 mg to 10.92 mg instead of reported 50 mg; Viagra 100 tablets contains from 0.86 mg to 12.75 mg instead of reported 100 mg.

The method was validated for intraday and day to day precision, accuracy, LOD and LOQ.

Conclusions: Counterfeiting and imitations of the drug Viagra® and its generic, a treatment for erectile dysfunction, containing less active ingredients can pose significant risks.

Viagra®, Counterfeit Drugs, HPLC-MS