DETERMINATION OF SILDENAFIL, VARDENAFIL AND TADALAFIL AND THEIR ANALOGUES IN ADULTERATED HERBAL MEDICINAL PREPARATIONS, HERBAL VITALITY PRODUCTS, SUPPLEMENTS AND FOODS AND BEVERAGES BY LIQUID CHROMATOGRAPH TANDEM MASS SPECTROMETRY (LC-MS/MS).

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ABSTRACT

A liquid chromatography tandem mass spectrometry (LC-MS/MS) method was developed for the simultaneous identification of Sildenafil, Tadalafil and Vardenafil and their analogues. The determination of these three ED drugs (Sildenafil, Vardenafil and Tadalafil) and their analogues (Hydroxyhomosildenafil, Norneosildenafil, Homosildenafil, Aminotadalafil, Thiosildenafil, Thiohomosildenafil, Hydroxythiohomosildenafil, Carbodenafil, Gendenafil, N-Desmethyl Sildenafil, N-DesethylVardenafil, Chloropretadalafil, Udenafil, Acetildenafil, N-DesmethylAcetildenafil, Hydroxyacetildenafil, Piperiacetildenafil, Noracetildenafil and Thiodimethylsildenafil) has been done in Research and Quality Assurance Division and Toxicology Section, Forensic Division at Headquarters, Petaling Jaya. Drugs were extracted from samples using methanol and separation was achieved using a Chromolith C18 column with a mixture of acetonitrile and acetate buffer.

This method can easily detect, confirm and quantify these analogues sildenafil concentrations in a single analysis. The chromatographic separation was achieved in less than 13 minutes, with the total run time of 15 minutes. From the validation study, the Limit of Detection (LoD) for coffee matrix ranged from 1.5 to 290ng/mL and from 1.2 to 10.1ng/mL in herbal matrix and ranged from 1.8 to 9.3ng/mL in candy matrix. And the average recovery for coffee matrix ranged from 51.21% to 118.57% and from 74.29% to 131.67% in herbal matrix and ranged from 82.86% to 104.29% in candy matrix.