

**VALIDASI METODE ANALISIS KANDUNGAN SILDENAFIL SITRAT
DAN TADALAFIL SECARA SIMULTAN PADA JAMU KUAT PRIA
DENGAN MENGGUNAKAN METODE KROMATOGRAFI CAIR
KINERJA TINGGI (KCKT)**

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INTISARI

Sildenafil sitrat dan tadalafil merupakan obat keras yang sering ditambahkan dalam obat tradisional sebagai bahan kimia obat. Penggunaan Sildenafil sitrat dan tadalafil tanpa memperhatikan dosis dan cara penggunaan yang tepat dapat berbahaya bagi tubuh manusia. Karena itu dilakukan pengujian kandungan Sildenafil sitrat dan tadalafil pada obat jamu kuat yang beredar dipasaran. Penelitian ini bertujuan untuk menentukan parameter validasi metode kromatografi cair kinerja tinggi (KCKT) untuk analisis sildenafil sitrat dan tadalafil secara simultan pada sampel jamu kuat yang memenuhi persyaratan *Association of Official Analytical Chemist (AOAC)* dan *ICH (International Conference On Harmonisation)*. Validasi metode meliputi uji spesifisitas, linearitas, akurasi, presisi, kekuatan, batas deteksi (LOD), batas kuantifikasi (LOQ) dan ketidakpastian. Uji spesifisitas menunjukkan waktu retensi yang hampir sama antara standar, sampel dan sampel *spike* pada sildenafil sitrat dan tadalafil muncul pada R_t yang sama yaitu 1,764 dan 3,967. Persamaan linearitas diperoleh persamaan $y = 54.408,0541x + 77.586,1435$ dan $y = 105.555,4581x + 221.951,2206$. Nilai korelasi (r) yaitu $r=0,9999$ dan $r=0,9995$, uji akurasi nilai Perolehan kembali yaitu 105,53 % dan 92,79 %, uji presisi keterulangan didapatkan nilai RSD yaitu 1,36 % dan 1,44 % dan RSD horwitz 8,32 % dan 8,31 %, uji batas deteksi (LOD) untuk sildenafil sitrat dan tadalafil yaitu 2,14 ppm dan 3,24 ppm, batas kuantifikasi (LOQ) pada perhitungan sebesar 6,49 ppm dan 9,82 ppm. Nilai ketidakpastian yang didapatkan $162,751 \pm 2,255$ mg/g. Parameter validasi yang dilakukan telah memenuhi persyaratan yang ditetapkan *Association of Official Analytical Chemist (AOAC)* dan *ICH (International Conference On Harmonization)*

Kata kunci : Sildenafil sitrat, tadalafil, kromatografi cair kinerja tinggi (KCKT), jamu, validasi metode

**VALIDATION METHOD ANALYSIS SILDENAFIL CITRATE AND
TADALAFIL SIMULTANEOUSLY ON APHRODISIAC TRADISIONAL
MEDICINE BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY
(HPLC)**

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ABSTRACT

Sildenafil citrate and tadalafil are prescription drugs which are often added in traditional medicine as chemical drugs. The use of sildenafil citrate and tadalafil regardless of dosage and how the proper use can be harmful to the human body. Because it was examined content of Sildenafil citrate and tadalafil on the aphrodisiac herbal medicine on the market. This study aimed to determine the parameters of the validation method of high performance liquid chromatography (HPLC) for the analysis of sildenafil citrate and tadalafil simultaneously on a sample of aphrodisiac herbal medicine that meet the requirements of the Association of Official Analytical Chemist (AOAC) and ICH (International Conference On Harmonisation). Validation of test methods included specificity, linearity, accuracy, precision, robustness, limit of detection (LOD), limit of quantification (LOQ) and uncertainty. Specificity test showed that retention time of sildenafil citrate and tadalafil spiked with sample is almost equal with standar, Rt value obtained is 1.764 and 3.967. Linearity equation $y = 54.408,0541x + 77586.1435$ and $y = 105.555,4581x + 221,951.2206$. The correlation value (r) is $r = 0.9999$ and $r = 0.9995$, accuracy test Reacquisition value is 105.53% and 92.79%, precision test repeatability RSD value obtained is 1.36% and 1.44% Horwitz and RSD 8.32% and 8.31%, the test limit of detection (LOD) for sildenafil citrate and tadalafil are 2.14 ppm and 3.24 ppm, the limit of quantification (LOQ) in the calculation of 6.49 ppm and 9, 82 ppm. Uncertainty value obtained $162.751 \pm 8,00412$ mg / g. The parameter validation performed has fulfilled the requirements which set by Association of Official Analytical Chemist (AOAC) and ICH (International Conference On Harmonization)

Keyword : Sildenafil citrate, tadalafil, high performance liquid chromatography (HPLC), tradisional medicine, method of validation