

ABSTRAK

Nama : Mufthi Al Farizi Susandi

Program Studi : Farmasi

Judul : VALIDASI DAN PERBANDINGAN METODE PENETAPAN KEMURNIAN RADIOKIMIA [^{99m}Tc]Tc-MDP (*BONE SCAN*) DENGAN RTLC *SCANNER* DAN *DOSE CALIBRATOR* (*CUTTING METHOD*)

Penetapan kemurnian radiokimia [^{99m}Tc]Tc-MDP merupakan bagian penting dari pengendalian mutu sebelum penggunaan klinis, karena keberadaan pengotor seperti perteknetat bebas (TcO₄⁻) dan TcO₂ tereduksi dapat mengganggu distribusi biologis dan meningkatkan paparan radiasi non-target. Penelitian ini bertujuan memvalidasi dan membandingkan metode penetapan kemurnian radiokimia menggunakan RTLC *scanner* sebagai metode utama dan *dose calibrator* dengan teknik *cutting strip* sebagai alternatif. Sampel dianalisis menggunakan ITLC-SG dan kertas Whatman dengan sistem eluen yang sesuai untuk memisahkan masing-masing fraksi radiokimia. Validasi dilakukan meliputi spesifisitas, akurasi, presisi, linearitas, rentang, LOD, dan LOQ sesuai pedoman ICH Q2(R2), IAEA, dan EANM. Hasil menunjukkan kedua metode memenuhi kriteria validasi dan menghasilkan nilai kemurnian yang sebanding serta konsisten. RTLC *scanner* unggul dalam kecepatan, pembacaan otomatis berbasis kromatogram, dan ketelitian kuantitatif, sedangkan metode *cutting strip* lebih sederhana, ekonomis, dan mudah diterapkan pada fasilitas dengan keterbatasan instrumen. Dengan tingkat kesesuaian hasil yang baik, sehingga metode *cutting strip* berpotensi menjadi alternatif dalam pengendalian mutu [^{99m}Tc]Tc-MDP.

Kata Kunci : *Cutting method*, *Dose calibrator*, Kemurnian radiokimia, RTLC, [^{99m}Tc]Tc-MDP, Validasi metode

ABSTRACT

Name : Mufthi Al Farizi Susandi
Study Program : Farmasi
Title : *VALIDATION AND COMPARISON OF METHODS FOR DETERMINING THE RADIOCHEMICAL PURITY OF [^{99m}Tc]Tc-MDP (BONE SCAN) USING AN RTLC SCANNER AND A DOSE CALIBRATOR (CUTTING METHOD)*

Radiochemical purity determination of [^{99m}Tc]Tc-MDP is a critical component of quality control prior to clinical administration, as radiochemical impurities such as free pertechnetate (TcO₄⁻) and reduced TcO₂ may alter biodistribution and increase non-target radiation exposure. This study aimed to validate and compare radiochemical purity testing using an RTLC scanner as the primary method and a dose calibrator with the cutting strip technique as an alternative approach. Samples were analyzed using ITLC-SG and Whatman paper with appropriate mobile phase systems to separate individual radiochemical fractions. Method validation included assessment of specificity, accuracy, precision, linearity, range, limit of detection (LOD), and limit of quantification (LOQ) in accordance with ICH Q2(R2), IAEA, and EANM guidelines. The results demonstrated that both methods met the validation criteria and produced comparable and consistent radiochemical purity values. The RTLC scanner provided advantages in rapid analysis, automated chromatogram-based quantification, and high analytical precision, whereas the cutting strip method offered procedural simplicity, lower operational cost, and broader applicability in facilities with limited RTLC instrumentation. The good agreement between methods indicates that the cutting strip technique has potential as a reliable alternative for quality control of [^{99m}Tc]Tc-MDP.

Keywords: *Cutting method, Dose calibrator, Method validation, Radiochemical purity, RTLC, [^{99m}Tc]Tc-MDP*