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^{99m}Tc-Ciprofloxacin Quality Control Method Development

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Structured Abstract

Background: Antibiotic resistance, which is a growing public health concern linked to overuse of antibiotics, results in about 700,000 deaths annually and could escalate to 9.5 million if resistance rises by 40%. Current imaging modalities like MRI and CT struggle with low sensitivity and specificity for bacterial infections. Nuclear medicine, especially using technetium-99m (^{99m}Tc) offers better solutions. The widespread use of ^{99m}Tc is due to its practical generation from ^{99}Mo and its availability. Radiolabeled antibiotics like ^{99m}Tc-ciprofloxacin, initially labeled with formamidine sulfuric acid (FSA) and later with stannous ion for stability, are effective for infection imaging, with ^{99m}Tc-ciprofloxacin marketed as "Infecton®".

Methods: To prepare ^{99m}Tc-ciprofloxacin, 19.9 mg ciprofloxacin was dissolved in acetic acid and HCl. It was then mixed with $SnCl_2$ dissolved in HCl. The solution was purged with nitrogen and adjusted to pH 6 with NaOH. After adding 0.5 ml of ^{99m}Tc, the solution was heated to 60°C and filtered through a 0.22 µm membrane. In this study, quality control involved Instant Thin-Layer Chromatography (ITLC-SG) using acetone and ethanol, ammonia as well as water mix as mobile phase. High-Performance Liquid Chromatography (HPLC) method also used with a Luna C18 column using a gradient flow with 0.1% trifluoroacetic acid (TFA) in water and acetonitrile. The radiochemical purity of ^{99m}Tc-ciprofloxacin (RCP) calculated by software.

Results: This study shows that the RCP varied significantly across different chromatographic techniques. Using ITLC-SG, the RCP was found to be 97% without nitrogen gas, and 57-94% with nitrogen gas. These findings highlight the impact of nitrogen gas on the stability and purity of the compound during the chromatographic process. In contrast, HPLC yielded a much higher RCP of 98-99%. This underscores the superior precision and efficacy of HPLC in separating and identifying the components of radiopharmaceuticals, ensuring minimal impurities. The HPLC method, though highly effective, is often more complex.

Conclusion: In conclusion, the findings of this study highlights the importance of quality control in radiopharmaceuticals, with HPLC offering superior accuracy for ^{99m}Tc-ciprofloxacin. Recommendations include robustness testing under varying conditions and using diverse analytical techniques.

Keywords: Nuclear medicine, Quality control, ^{99m}Tc-ciprofloxacin

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