



# AULA VIRTUAL de RADIOFARMACIA

Plataforma Virtual de Formación Continuada en Radiofarmacia

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## Lectura recomendada

### A Portable Test System for Determination of Bacterial Endotoxins in $^{18}\text{F}$ -FDG, $^{99\text{m}}\text{Tc}$ , and Lyophilized Reagents for Labeling with $^{99\text{m}}\text{Tc}$

Neuza T.O. Fukumori, Domingos G. de Campos, Adriana V.F. Massicano, Nilda P.S. de Pereira, Constancia P.G. da Silva and Margareth M.N. Matsuda  
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A rapid quantitative kinetic chromogenic test in an automated portable test system has been developed for in-process and end-product determination of bacterial endotoxins in water using the *Limulus* amoebocyte lysate. The aim of this work was to validate the method for  $^{18}\text{F}$ -FDG,  $^{99\text{m}}\text{Tc}$ , and the lyophilized reagents methylene diphosphonic acid (MDP) and pyrophosphate for labeling with  $^{99\text{m}}\text{Tc}$  radiopharmaceuticals with no interfering factors. **Methods:** Experiments were performed on 3 consecutive batches of  $^{18}\text{F}$ -FDG,  $^{99\text{m}}\text{Tc}$ , MDP, and pyrophosphate produced at the Nuclear Energy and Research Institute of São Paulo, Brazil, using a portable test system. The maximum valid dilution ( $\approx 500$ ) was calculated to establish the extent of dilution to avoid interfering test conditions. **Results:** Better results were obtained above a 1:5 dilution factor for  $^{18}\text{F}$ -FDG and  $^{99\text{m}}\text{Tc}$ , 1:20 for MDP, and 1:100 for pyrophosphate. The requirements of the test were satisfied ( $R \leq 0.980$ , recovery of product positive control between 50% and 200%, and coefficient variation of samples  $< 25\%$ ), and the endotoxin concentration was lower than the lowest concentration of the standard curve ( $0.05$  endotoxin unit  $\text{mL}^{-1}$ ) and therefore less than the established limit in pharmacopoeias. **Conclusion:** The portable test system is a rapid, simple, and accurate technique using the quantitative kinetic chromogenic method for bacterial endotoxin determination. For this reason, the test is practical for radiopharmaceutical uses and tends to be the method of choice for the pyrogen test. For  $^{18}\text{F}$ -FDG,  $^{99\text{m}}\text{Tc}$ , MDP, and pyrophosphate, the validation was successfully performed.



Colabora con Farmacéuticos Mundi (**FarmaMundi**) (<http://www.farmaceuticosmundi.org/>)



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