The effect of the preparation conditions on the in vitro stability of \( ^{99m}\text{Tc} (\text{Sn}) \)-pyrophosphate kit solution has been examined. To extend the shelf-life of the preparation, different methods of protection were tested. Nitrogen purging stabilizes the kit for at least 6 h after labeling when the content of \( ^{99m}\text{Tc} \)-pertechnetate raises to about 5%. However, this method is ineffective in the presence of hydrogen peroxide. The protecting ability of two chemicals was also determined. Gentisic acid gave good results. In the presence of 50 \( \mu \text{g} \) of gentisic acid per ml of the kit the content of pertechnetate was 1-2\% throughout the examined time interval. To eliminate the influence of hydrogen peroxide (6 \( \mu \text{g} \) per ml of the kit) about 100 \( \mu \text{g} \) of gentisic acid is needed. \( \text{N,N'}\text{-diphenyl-p-phenylene-diamine} \) (DPPD) performs some protecting effect only when used in the samples protected by nitrogen purging. However its protecting ability is lower that in the case of gentisic acid.

INTRODUCTION

One of the important parameters of a labeled compound is its in vitro stability which should be sufficiently long to enable confident and cost-effective use of the
preparation. It is time-dependent, i.e. the ratio of the labeled compound decreases with time due to the decomposition of the complex and reoxidation of technetium to the heptavalent state. One of the factors which could accelerate the reoxidation, particularly in the case of kinetically labile complexes is the quality of $^{99m}$Tc-eluate. Additives such as copper as well as some other chemical impurities can affect the stability of the kit. Regular constituents of the eluate are also the products of radiolysis of water, i.e. free radicals and hydrogen peroxide.

The time-span during which the radiochemical purity is sufficiently high (usually $\geq$95%) dictates the shelf-life of the labelled compound. In principle it is difficult to predict the shelf-life of a labeled compound. It is usually determined experimentally for the product in its final form under the anticipated mode of preparation (levels of activity, kind and time of storage, etc.) and under strict adherence to Good Manufacturing Practice (GMP).

In this paper the stability of the bone-seeking agent $^{99m}$Tc(Sn)-pyrophosphate ($^{99m}$Tc(Sn)-PyP) was examined. The content of free pertechnetate was determined for the kit solution prepared under different experimental conditions. Examined and compared were the protection procedures performed by purging the reactant solutions by nitrogen and by the addition of two compounds of different chemical structure. The effect of hydrogen peroxide was examined by its addition (exogenous peroxide) to the kit solution. The relationship between the production of $^{99m}$Tc-pertechnetate and the concentrations of the stabilizers was determined.