

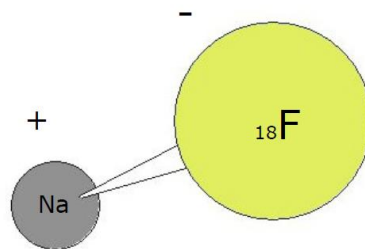


# AULA VIRTUAL de RADIOFARMACIA

Plataforma Virtual de Formación Continua en Radiofarmacia

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## Lectura recomendada



### Development and validation of an anion-exchange HPLC method for the determination of fluoride content and radiochemical purity in [ $^{18}\text{F}$ ]NaF

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$^{18}\text{F}$ -labeled sodium fluoride ( $[^{18}\text{F}]\text{NaF}$ ) is a useful bone imaging agent that has been demonstrated to be significantly more accurate than  $^{99\text{m}}\text{Tc}$ -labeled methylene diphosphonate for the detection of both sclerotic and lytic lesions in various malignancies. A reliable anion-exchange HPLC method equipped with suppressed conductivity and radioactive detectors has been developed in order to analyze the content of NaF and radiochemical purity in  $[^{18}\text{F}]\text{NaF}$  radiopharmaceuticals. The method described for fluoride analysis uses an isocratic elution of NaF in a Hamilton anion-exchange column using a mobile phase that consists of 7.5 mM sodium carbonate and 0.018 mM potassium thiocyanate. The flow rate was 1.0 ml/min. The method was validated in accordance with several parameters, including system suitability, specificity, precision, accuracy, linearity, robustness, limit of detection and limit of quantification. The results are described as follows: (1) The system suitability includes the tailing factor, theoretical plate number and resolution, which are 1.192534, 2729.6594 and 16.7415, respectively. (2) For specificity, the solvent peak and chloride ion did not interfere with the retention time of the fluoride. (3) The percentage coefficient of variation for analysis of precision, including repeatability and intermediate precision, is less than 2.0%. (4) Accuracy of method is within the range of 98%–102%. (5) The range of linearity is from 10 to 400  $\mu\text{g/ml}$ , with the correlation coefficient ( $R_2$ ) always being above 0.9985. (6) The data of method robustness are within acceptance criteria. (7) The limit of detection and limit of quantification are 0.0678 and 0.20  $\mu\text{g/ml}$ , respectively. All of the analysis results demonstrate that this method is highly sensitive, convenient, specific and suitable for quantification of NaF over a wide linear range. Therefore, the method can be successfully performed for routine analysis of fluoride content in  $[^{18}\text{F}]\text{NaF}$  radiopharmaceuticals and reduce the time required for analysis.



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



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