Validation of an HPLC method for assessing the chemical and radiochemical purity for in-house produced [^{18}F]Sodium Fluoride radiopharmaceutical

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Background

- According to the current Ph. Eur., the HPLC method with a strong anion exchange column and both a UV/VIS detector and a radioactivity detector is recommended for assessing the chemical and radiochemical purity of [^{18}F]NaF.
- An isocratic HPLC ion-exchange method that utilizes a conductivity detector with a suppressor, along with a radioactivity detector, could be an effective alternative method.

Materials and methods

Method for assessing the chemical and radiochemical purity of [^{18}F] Sodium Fluoride

- Dionex ICS 1600 chromatographic system;
- Detector - radioactivity and conductivity;
- Dionex ADRS 6000 anionic suppressor;
- Analytical column - Dionex IonPac AS10;
- Guard column Dionex IonPac AG10;
- Mobile phase - 0.1M NaOH;
- Flow rate of 1 mL/min.

Results

Specificity

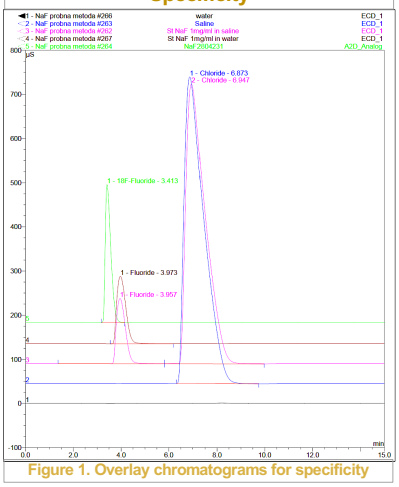
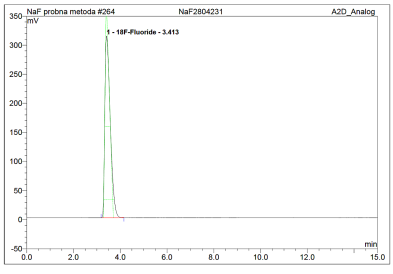
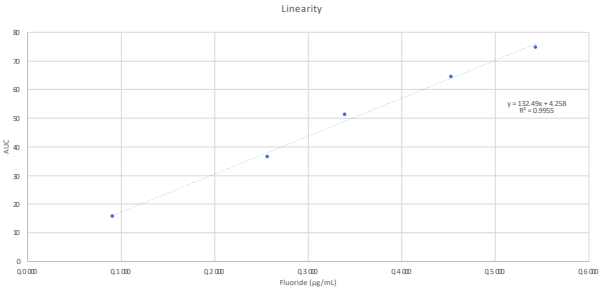


Figure 1. Overlay chromatograms for specificity



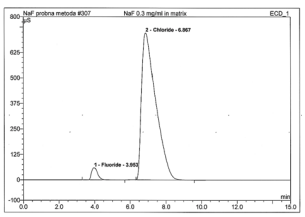
No.	Ret.Time min	Peakname	Height mV	Width min	Type	Resol. (EP)	Asym. (EP)	Plates (EP)
1	3.413	18F-Fluoride	312.462	0.425	BMB	n.a.	1.82	1029
n.a.	n.a.	Fluoride	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
n.a.	n.a.	Chloride	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Average:			312.462	0.425	n.a.		1.82	1029

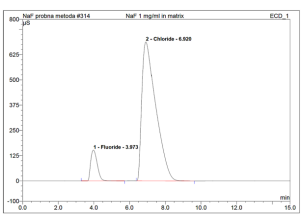
[^{18}F]NaF sample - radioactivity detector

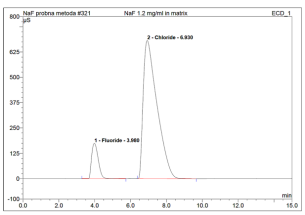


Precision (repeatability)		
No.	Method	System
1	65.927	65.464
2	65.946	65.600
3	65.98	65.645
4	66.02	65.792
5	66.095	66.216
6	66.176	66.003
Average	66.024	65.786
SD	0.095	0.279
RSD	0.15	0.42

Accuracy						
Spike St 30% C (µg/ml) recovery	1.	2.	3.	AVG	SD	RSD
	23.212	23.279	23.331	23.27	0.06	0.26
	0.143	0.143	0.144			
	105.501	105.874	106.164			
Spike St 100% C (µg/ml) recovery	1.	2.	3.	AVG	SD	RSD
	64.505	64.629	64.636	64.59	0.07	0.11
	0.455	0.456	0.456			
	100.604	100.811	100.822			
Spike St 120% C (µg/ml) recovery	1.	2.	3.	AVG	SD	RSD
	74.497	74.707	74.712	74.63	0.12	0.16
	0.5301	0.5317	0.5318			
	97.741	98.0329	98.0399			







Conclusion

The alternative analytical method developed for the routine assessment of [^{18}F]NaF chemical and radiochemical purity has been validated. This fast and straightforward method could be an effective alternative to the Ph. Eur. [^{18}F]NaF quality control method. Validation results have confirmed that the anion-exchange HPLC method is specific, linear within the defined range (0.1356 - 0.5424 µg/mL), precise, and accurate for evaluating the chemical and radiochemical purity of the [^{18}F]NaF radiopharmaceutical.