Stability study of sodium iodide (123 I) oral solution

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Sodium iodide (123 I) produced by the Nuclear Engineering Institute (IEN) is an oral radiopharmaceutical obtained from bombardment by proton irradiation of enriched xenon 124 and used in the evaluation of dysfunctions and tumors in the thyroid gland, with a half-life of 13.2 h [1]. It is stored at room temperature (15 - 30 ° C) and its activity is calibrated for the hospital to use the next day, being necessary to maintain its physical and chemical characteristics until the end of use.
The objective of this work was to evaluate the stability of the oral solution of sodium iodide (123 I) produced at the IEN, following ANVISA recommendations [2] and determine your shelf life. However, as a radiopharmaceutical with a half-life of 13.2 h, the stability study cannot be conducted in the same periods designated for conventional pharmaceutical products, and adaptations are necessary to circumvent mainly the particularities of its time of use and quantity produced in a batch. The stability of the sodium iodide solution (123 I) was evaluated in a climatic chamber, at a temperature of 40 ± 2ºC and humidity of 75 ± 5% RH, stored in a type I glass vial and lead shielding. Three consecutive batches were evaluated, with a radioactive concentration of approximately 500 MBq/mL, at 0 h (immediately after fractionation), 8 h, 16 h, 24 h, 32 h, 40 h and 48 h. The tests performed, based on the United States Pharmacopoeia [3] were as follows: appearance, pH (two methods), radiochemical purity, radionuclide identification and radionuclide purity. Their respective specifications are listed in Table 1. For conducting the study, two samples were separated: one for time 0 and another for the remaining 6 points, in which 1 mL was removed for each time of analysis.

Table 1 - Specification for sodium iodide (123I)

Test	Specification
Appearance	Clear and colorless
pH	7 - 10
Radiochemical purity (%)	≥ 95%
Radionuclide identification	Gamma-ray spectrum exhibits a major photoeletric peak having an energy of 0.159 MeV
Radionuclidic purity (%)	Not less than 90% of the total radioactivity is present as I 123

The results obtained in the 48 h of study are shown in Table 2.

Table 2 - Result of the 3 batches of sodium iodide (123 I) evaluated for the period of 48 h

Batch	Test	Time interval (h)						
		Time1 0 h	Time 2 8h	Time 3 16h	Time 4 24h	Time 5 32h	Time 6 40h	Time 7 48h
(1) I2002121	Appearance	Clear colorless	Clear colorless	Clear colorless	Clear colorless	Clear colorless	Clear colorless	Clear colorless
	pH (strip)	10	9	10	10	10	9	9
	pH (potentiometric)	9.6	9,8	9.9	10.0	9.3	9.8	9.3
	Radiochemical purity (%)	97,4	96,1	95,4	96,9	98,4	97,7	96,6
	Radionuclide identification	0.159	0.159	0.159	0.159	0.159	0.159	0.159
	Radionuclidic purity (%)	99,08	99,83	99,94	99,86	99,89	99,80	99,56
(2) I2002181	Appearance	Clear colorless	Clear colorless	Clear colorless	Clear colorless	Clear colorless	Clear colorless	Clear colorless
	pH (strip)	7	7	7	7	7	7	7
	pH (potentiometric)	7,08	7,02	7,35	7,37	7,12	7,07	7,13
	Radiochemical purity (%)	98,5	99,5	98,8	100	100	96,9	97,2
	Radionuclide identification	0.159	0.159	0.159	0.159	0.159	0.159	0.159
	Radionuclidic purity (%)	99,04	99,85	99,94	99,86	99,84	99,80	99,57
(3) I2002191	Appearance	Clear colorless	Clear colorless	Clear colorless	Clear colorless	Clear colorless	Clear colorless	Clear colorless
	pH (strip)	7	7	7	7	7	7	7
	pH (potentiometric)	7,44	7,13	7,13	7,15	7,13	7,26	7,43
	Radiochemical purity (%)	99,01	99,47	99,14	100	100	100	100
	Radionuclide identification	0.159	0.159	0.159	0.159	0.159	0.159	0.159
	Radionuclidic purity (%)	99,05	99,87	99,92	99,89	99,84	99,77	99,87

In view of the results obtained in the stability study, it can be concluded that the radiopharmaceutical sodium iodide (123 I) meets all the criteria for accepting the quality requirements in the period of up to 48 hours after synthesis.

References

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