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Specification of Sodium [¹³¹I]iodide solution, sterile drug substance

¹³¹ I	¹³¹I sodium iodide sterile solution, drug substance
Product code:	I-RA-7
Description:	Clear, colourless solution of ¹³¹ I sodium iodide containing iodine-131 in the form of sodium iodide in NaHCO ₃ /Na ₂ CO ₃ /NaOH buffer. Non-carrier and Sodium thiosulfate 0.5-2.0 mg/mL reducing agent added.
Radioactive concentration:	1.0- 55.5 GBq/ml
Volume:	0.2-10 ml
Radionuclidic impurities:	≤ 0.1 %
Radiochemical purity:	≥ 95 %
pH:	7-10
Expiry date:	21 days from manufacturing date
Storage:	Store at room temperature in its own container, in accordance with the regulations on radioactive materials.
Packaging:	In type I injection vial (6R or 10R), closed with brombutyl stopper and green aluminium cap in lead container (Type A packaging). 6R vial in KT1-KT6 and 10R vial in KT6B lead container.
Pack size:	≤ 29.6 GBq ± 10% (at the indicated calibration date)/vial.

Description

The largescale production of ¹³¹I based on the neutron irradiation of TeO₂ target followed by the separation of ¹³¹I using dry distillation technique. I-131 sterile drug substance solution is manufactured from the from I-131 sodium iodide base solution (175 GBq/mL, active substance specified according to the current edition of the European Pharmacopoeia Monograph 2121) by dilution with 50 mg/mL sodium hydrogen carbonate solution (Diluting agent 'A') and 20 mg/mL sodium thiosulphate solution (Diluting agent 'B') according to the customer specified active concentration.

Composition

Components	Quantity	Quantity	Quantity	Quantity
¹³¹ I sodium iodide	55.5 GBq/mL ± 10% (at the day of Production)	37 GBq/mL ± 10% (at the day of Production)	5.55 GBq/mL ± 10% (at the day of production)	1 GBq/mL ± 10% (at the day of production)
Sodium bicarbonate	16.72 mg/mL	14.48 mg/mL	10.67 mg/mL	10.12 mg/mL
Sodium carbonate	1.33 mg/mL	0.88 mg/mL	0.13 mg/mL	0.02 mg/mL
Sodium thiosulfate	0.5 mg/mL	0.5 mg/mL	2.0 mg/mL	2.0 mg/mL
Sodium hydroxide	0.63 µg/mL	0.42 µg/mL	0.06 µg/mL	0.01 µg/mL
Water for Injection	1.0 g/mL	1.0 g/mL	1.0 g/mL	1.0 g/mL