



INSTITUTE OF ISOTOPES CO. LTD.

H-1121 Budapest, Konkoly-Thege Miklós út 29-33.

☒ H-1535 Budapest, Pf. 851

T. +36 1 3922577

F. +36 1 3959247

www.izotop.hu



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

¹³¹ I	¹³¹ I sodium iodide non-sterile solution, drug substance
Product code:	I-RA-5
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 no reducing agents added.
Radioactive concentration:	≥ 100 MBq/ml
Radionuclidic impurities:	≤ 0.1 %
Radiochemical purity:	≥ 95 %
pH:	8-11
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:	≤ 111 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 non-sterile drug substance solution is manufactured from the ¹³¹I sodium iodide base solution, 175 GBq/mL active substance by dilution with 0.0001M NaOH according to the customer specified active concentration. It is specified according to the current edition of the European Pharmacopoeia Monograph 2121.

Composition

Components	Quantity	Quantity	Quantity
¹³¹ I sodium iodide	74 GBq/mL ± 10% (at the day of Production)	55.5 GBq/mL ± 10% (at the day of Production)	37 GBq/mL ± 10% (at the day of production)
Sodium bicarbonate	8.96 mg/mL	6.72 mg/mL	4.48 mg/mL
Sodium carbonate	1.78 mg/mL	1.33 mg/mL	0.89 mg/mL
Sodium hydroxide	3.15 µg/mL	3.36 µg/mL	3.58 µg/mL
Water for Injection	1.0 g/mL	1.0 g/mL	1.0 g/mL