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Jordan Research & Training Reactor 1st Sodium Iodide (NaI) Production

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Abstract— *The Jordan Research & Training Reactor (JRTR) is a part of the Jordanian nuclear program, that has been realized as the first nuclear critical facility. It is located in the north of Hashemite Kingdom of Jordan (HKJ), in the campus of Jordan Science & Technology University (JUST), 70 km far north of the Jordan capital city Amman.*

It was built in collaboration with Korean Atomic Energy & Research Institute and Daewoo Engineering (KDC) Consortium. As advanced model of open pool type reactor, and considered to be the safest research reactor model. The construction started in 2010 and commissioned in 2016.

JRTR got the operation license from the Jordanian regulatory Authority; Energy & Minerals Regulatory Commission (EMRC), in 2017 to operate and produce (I^{131}, Mo^{99m}, Ir^{192}).

In November 2017 we produced the first sample product of NaI-^{131}, and then the product subjected to the quality control for chemical and physical properties.

A sample of product was taken to the nuclear medicine unit at King Abdullah University Hospital (KAUH), and used in a phantom to do a virtual scan to test the product clinically, and the result was checked by the of NM unit, and it showed a very good uptake and spread throughout the phantom, and the images was very clear, which indicate that the product has good properties.

After that we started the medical registration process with Jordan Food and Drug Administration (JFDA) to be used as pharmaceutical product for human.

After the preparation and submission of the required documents, in March 2018 the Jordan Food and Drug Administration (JFDA) gave JRTR the Manufacturing License (ML) to be a pharmaceutical industrial facility, and in November 2018 JFDA gave JRTR the Product License to produce NaI-^{131}product in both dosage forms; oral solution and capsules for diagnostic and therapy usage. And since that time we at JRTR started to produce NaI^{131} commercially for our local hospitals and nuclear medicine centers.

I. Introduction

Iodine-131 (I 131); is an important radioisotope of iodine discovered in 1938 at the University of California. It has a radioactive decay half-life of about eight days. It can be produced by several nuclear processes like nuclear fission and target irradiation process (Tellurium dioxide TeO2). It is used for treatment and diagnosis of different thyroid gland diseases. There are two types of dosage forms for NaI131:

1. Hard gelatin capsules,
2. Oral solution.

In JRTR we produce the NaI-^{131} by using a dry distillation method, after taken the irradiated aluminum capsule filled with the target material Tellurium dioxide (TeO_2). The I^{131} is produced by the neutron activation reaction of tellurium as shown below.

$$^{130}\text{Te} + \text{n} \rightarrow {}^{131}\text{Te} \xrightarrow{T_{1/2}=25\text{min}} {}^{131}\text{I} + \beta$$

The procedure to produce $Na^{131}I$ solution from the irradiated tellurium in an oxide form (TeO_2) as shown in the Figure 1. To produce a high quality $Na^{131}I$ product, the source material, TeO_2 should be purified by a calcinations method before the irradiation in the reactor even though one uses a high quality grade such as 99.99%. After the calcinations procedure, fabrication of a target capsule is required. It is required to open a target capsule by using the target cutter and Capsule Opening Procedure' to introduce the irradiated TeO_2 in the production system. Distillation of ^{131}I from the irradiated TeO_2 is performed by using the production system at 760°C.

The collected I^{131} in the form of NaI-^{131} solution is required to be analyzed for its radioactivity, radionuclidic purity, radiochemical purity, visual inspection and pH measurement.

II. Quality Control and Methods

The final product is subjected to some quality control tests, to ensure that it is in compliance with the reference adopted in the process of production in the reactor which is European Pharmacopeia 9.0 published in 2017.

These tests are classified as below:

1. Visual Appearance.
2. Radiochemical Purity.
3. Radionuclide Purity.

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4. pH measurment.

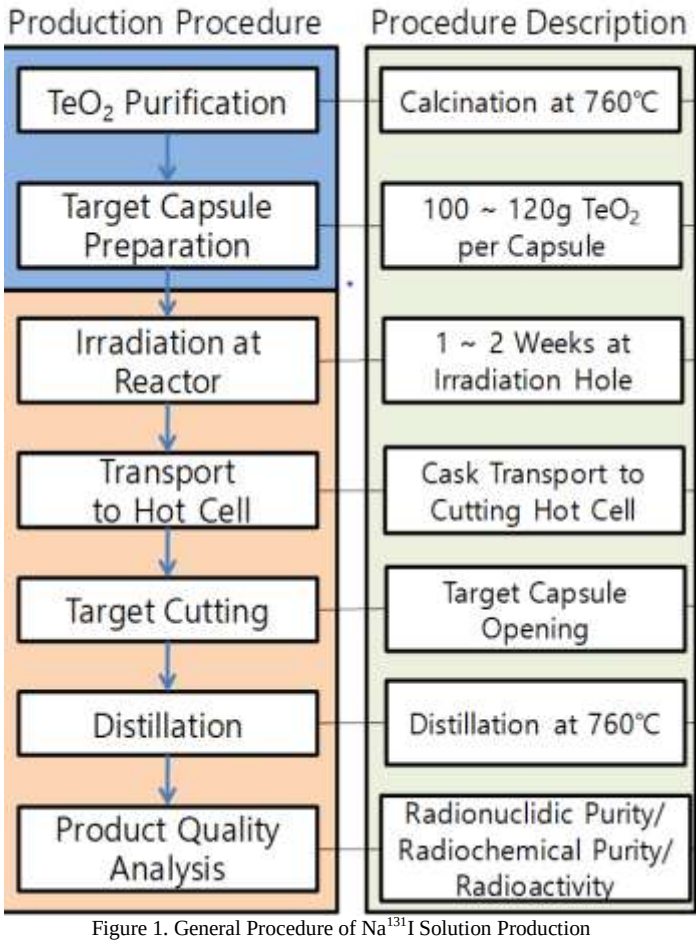

Figure 1. General Procedure of $Na^{131}I$ Solution Production

III. Detailed Explanation of Quality Control Process

1. Visual Appearance

To inspect the clarity, the presence of sediments and the color of the final solution product.

2. Radiochemical Purity

To check the portion of the total radioactivity (NaI-^{131}) in the sample which is present as the wanted radiolabelled species (NaI-^{131}) in comparison with un-desirable chemical percentage.

Radiochemical purity is important in radiopharmacy since it can give an image about the bio distribution of desirable radiolabelled species (NaI-^{131}) regarding to other unwanted products.

In our Laboratories we use the High Performance Liquid Chromatograph (HPLC) Chromaster, from Hitachi with Diode Array Detector (DAD) and GABI Nova Radio Counting System

- The mobile phase we use in this procedure is

NaCl 1.461 g/250ml
Octylamine 162.5mcl/250ml
Acetonitrile 12.5ml/250 ml
(HPLC grade)
pH to be 7

- Test solution:
  KI 100mg/100ml
  KIO_3 200mg/100ml
  $NaHCO_3$ R 1g /100ml

- Reference solution A
  KI 2.62mg/100ml
  KIO_3 2.45mg/100ml

3. Radionuclide Purity

It is a test to check the ratio, expressed as a percentage, of the radioactivity of the desired radionuclide to the total radioactivity of the source.

We use HPGE instrument, High-purity Germanium (HPGe) Detectors - CANBERRA Industries

4. pH Measurement

To avoid cross contamination when we use the pH meter instrument, we decide to use the pH detection strips.

The sample is concentrated not diluted from the first scrubber solution.

After the sample underwent these tests, the batch will be released and dispensed as radiopharmaceutical isotope and to be ready for human use.

The QC tests results for some of the first batches of NaI-^{131} product were as in the following table:*

Production Date	Radionuclide Purity (≥99.9 %)	Radiochemical Purity (≥95 %)	pH Result (7≤pH ≥10)	QC Test Date
17 Dec 2018	99.9%	99.8%	10.0	17 Dec 2018
2 Jan 2019	100%	99.7%	9.50	2 Jan 2019
20 Jan 2019	100%	99.4%	9.50	20 Jan 2019
19 Feb 2019	100%	99.1%	9.00	19 Feb 2019
23 Feb 2019	100%	96.1%	9.50	24 Feb 2019
5 March 2019	100%	99.4%	9.50	6 March 2019
20 March 2019	100%	99.8%	9.50	21 March 2019

- Visual appearance of the samples: Colorless, clear solution.

IV. Discussion

After the completion of these tests and compare the results with approved and documented references, - which is European Pharmacopeoa (Eu. Ph) in our SOP- we can say that our product is rely with the Eu Ph references which means that we can release this drug's batch to be used in the nuclear medicine center in Hashemite Kingdom of Jordan for the human use.

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In March 2019 the Jordan Food & Drug Administration conducted an evaluation survey for the feedback of JRTR NaI^{131}, with several Nuclear Medicine centers in Jordan, and the results was promising, the images was clear, the body feedback of the product was in normal range, the uptake of product in normal scale.

This concludes that the JRTR is a qualified center for the production of good quality NaI^{131} that can be used as radiopharmaceutical isotopes for human use.

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