Development of a Remotely Operated Dispensing Unit for the Production of $^{131}$I Therapeutic Capsules

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Introduction

Radiotherapy with particulate emitting radioisotopes in the form of radiopharmaceuticals is used in nuclear medicine centres for treating hyperthyroidism and various type of cancers. The radioisotope $^{131}$I is one such radionuclide used for the above application. At present sodium iodide solution is given to the patient as oral administration form for the treatment of thyrotoxicosis. A method has been developed by the (MBPP), BRIT to produce 5 mCi of therapeutic capsules required for thyrotoxicosis treatment. In order to produce these capsules on a regular basis, it is essential to design and fabricate a machine having the following qualifications:

I. Machine should be operated in remotely controlled shielded facilities.
II. Accurate pipetting of $^{131}$I solution of volume 5 ml in to the syringe from a 20 mm USP type glass vial containing the stock solution.
III. Dispensing of $^{131}$I solution of volume 50µl within an accuracy of ±2 % in to a gelatin capsule of 7mm (φ) x 15 mm(l).
IV. Encapsulation of the gelatin capsule by appropriate pneumatic system with specially designed tong.
V. Transferring of the gelatin capsule containing $^{131}$I in to a glass vial for the assay of activity.

Remotely Operated Machine

A survey was made for commercially available equipment which can be used with minor modification to meet our specification. No suitable equipment could be found to fulfill the requirements of adopting within the limited space available in the shielded fume hood, high precision pipetting and type of operation in capsule making. It was therefore decided to design and fabricate a remotely controlled machine in the Group facility workshop of Isotope Applications Division. The schematic diagram of the machine designed is shown in Figure 1.

The first operation envisages the filling up of sodium sulphate powder in to the gelatin capsules. The capsule holding mechanism essentially consists of capsule and cap holding ring type device. The empty capsules are fed into the slot (circular pocket) either manually or mechanically. Rotation of the ring generates vacuum in the applicator and pulls the cap of capsules, thereby gets opened. When the capsule gets opened, it is to be filled with sodium sulphate powder.
The next operation is to dispense accurate amount of $^{131}$I solution into the capsule containing sodium sulphate powder. The capsule containing sodium sulphate powder is transferred into the dispensing slot of the pipetting station with the help of a specially designed remote tong which moves in vertical direction but not in the horizontal direction. The operation of the capsule lifting tong is performed by a button pressing system.

The pipetting station consists of an indexing table of circular shape which is an integral part of the unit. This indexing table has an arrangement of 10 equidistant circular pockets to hold gelatin capsules of sizes 7 mm(φ) x 15 mm(l). This indexing table rotates in both clockwise and anticlockwise direction by a warm and warm gear wheel arrangement made at the bottom of the plate. The circular motion is actuated by a knob which protrudes outside the unit.
the shielded wall and can be operated remotely by hand.

Pipetting of $^{131}\text{I}$ solution (Na$^{131}\text{I}$ in Na$_2\text{S}_2\text{O}_3$) from the stock solution contained in a 20mm USP type glass vial is carried out employing suction mechanism with the help of a needle syringe. The needle of the syringe is pushed downward into the glass vial containing radioactive solution. The solution is sucked in to the glass cylinder of the syringe. The upward and downward movement of the syringe is achieved by lead screw and bracket mechanism. In one rotation, a predetermined volume of the solution can be dispensed in to the syringe. Total amount of solution to be pumped out can be ascertained by performing the number of rotations. In order to perform the operation remotely, a knob has been provided which can perform the pipeting operation. When the knob is rotated clockwise, the solution is sucked into the needle from the glass vial. Before the installation of the machine, this operation was checked repeatedly and it was observed that reproducibilities of volume sucked is obtained.

The next task is to dispense the above sucked radioactive solution in to the capsule. A locator arrangement has been made to align the capsule and needle in position after which activity is dispensed into the capsule. Dispensing of 50µl of $^{131}\text{I}$ solution with an accuracy of ±2% into the capsule was carried out using the above mentioned mechanism but in reverse direction i.e. anticlock wise with the same instrumental set up. Adequate care needs to be taken while performing this operation so that the needle does not touch the powder in the capsule. In such an event, the powder in the capsule gets sucked into the syringe and will lead to an error in the precision of pipetting. Once the dispensing of the last drop is over, it is essential to suck the reminder of the radioactive solution into the cylinder of the syringe. This can be accomplished by rotating the corresponding knob clockwise, which should be limited to 3-4 number of turns only. More number of rotations will lead to bubble formation inside the syringe and will affect precision of pipetting in the subsequent operation.

The gelatin capsule is next encapsulated by fixing of cap. A knob has been arranged in such a way that when it is rotated in clockwise direction, the position of the capsule can be raised whereas as rotation in anticlockwise direction will lower its position. This arrangement helps to adjust the position of the capsule to any predetermined height. A suitable provision has been incorporated in the machine to encapsulate the gelatin capsule by fixing the cap. The ring type device generates vacuum in the applicator and holds the cap of capsules. The vacuum is generated by means of a pneumatic cylinder piston system. When the applicator holding the cap is positioned above the capsule, vacuum is released and after this compressed air is passed through the same cylinder piston, the cap gets fixed on the capsule tightly.
The next operation is the transfer of capped capsule into a glass vial. This operation is performed using the same applicator with vacuum arrangement. The filled capsule is sucked into the applicator and brought in to the mouth of the USP 20 ml vial. Once the vacuum is released, the filled capsule falls into the vial. Two such capsules were placed in a single vial kept inside a lead pot for the assay of activity. Each vial containing capsule was labeled suitably indicating the batch No., radioactivity content and reference data.

Once this operation of dispensing is over for a batch, the remaining radioactive liquid left in the cylinder of the syringe is collected back in the stock solution and can be used. Subsequently, the needle of the syringe is washed with double distilled water to prevent blockage and pipetting error in the subsequent batch.

The machine has been installed at the Radiopharmaceutical Laboratory, MBPP Vashi complex, BRIT. After installation, the unit has been tested. It is now being used for the regular production and supply of $^{131}$I therapeutic capsules for treatment of hyperthyroidism.

**Acknowledgment**

The authors are thankful for the technical support provided by all the staff members of Group facility workshop, Isotope Applications Division, BARC, during the assembly and installation of the equipment. The authors would like to thank Dr A. Dash of Radiopharmaceuticals Division for his help in the preparation of manuscript of this paper. The guidance of Dr. M. R. A. Pillai, Head, Radiopharmaceuticals Division, BARC, and Dr. N. Ramamoorthy, Associate Director, Isotope Group, BARC, throughout the project is gratefully acknowledged. The authors would also like to thank Mr Gursharan Singh, Head, Isotope Applications Division, BARC, and Mr M.L. Dutta, Head Engineering Services Section of IAD for their keen interest and providing necessary administrative support during the course of this work.

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This paper was adjudged as a prize winning paper in the poster session II in the 13th Annual Conference of Indian Nuclear Society (INSAC-2002) on “Nuclear Technology – Catalyst for National Development” held at Mumbai during October 9-11, 2002

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Founder’s Day Special Issue