Radiopharmaceutical distribution device for pediatric cancer

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1. Introduction

For the treatment of neuroblastoma, a type of pediatric cancer, continuous and stable production of the radiopharmaceutical "I-131 mIBG (*meta*-iodobenzylguanidine)" is essential. With the current technology, the production process of I-131 mIBG is entirely dependent on manual labor, so there are concerns in production stability and radiation exposure to workers. In this study, we intend to develop a device that can withstand various adverse conditions caused under radiation conditions. This enables aseptic quantitative distribution of I-131 mIBG and minimizes uncertainties about product safety that may occur during the production process. In addition, the effect of minimizing the exposure of workers can be expected.

2. Purpose and Challenges to be solved

In the current production process, almost all processes are performed by hand, so there are various problems such as production stability resulting from human error and radiation exposure that occurs in the process of directly handling radioactive substances during manual work. Along with this, there is also a risk of biological contamination that can occur in the manual process.

Since this equipment is used in a radiation-exposed environment and has to handle I-131, a sublimable radioisotope, which has very difficult properties compared to other medical radioisotopes, the necessary requirements for radiation safety must be secured.

In addition, in order to develop a device capable of dispensing I-131 pharmaceuticals in a quantitative manner, it is necessary to ensure resistance that is not affected by performance even when exposed to radiation energy for a long period of time.

To do this, it is necessary to develop a device that has the simplest principle as possible and that can operate in a stable manner. And, since it is a device for the purpose of producing pharmaceuticals, it must comply with standards such as GMP applied in pharmaceutical-related regulations.

Lastly, in order to increase the efficiency of manpower and cost required for management and maintenance required for long-term use, a simple driving method that can minimize validation required for pharmaceutical production equipment should be applied.

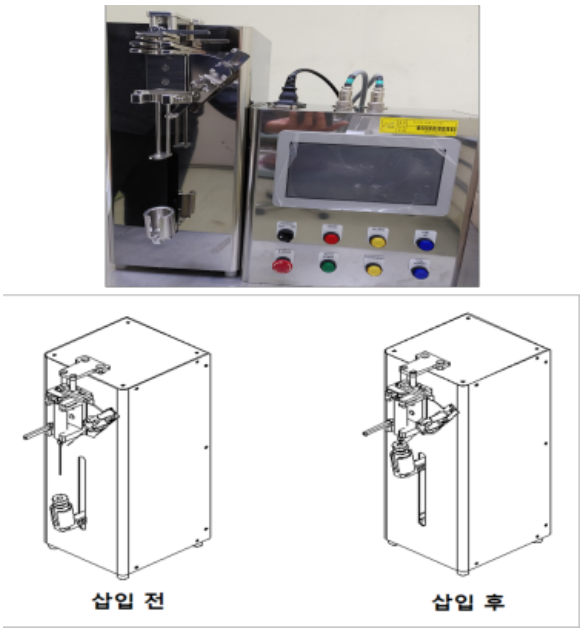

Fig. 1. Picture and drawing of device

3. Results and Conclusions

In order to solve the problem, a device that can be used in the distribution process has been developed.

This device is composed of a body part provided with a support surface, a vial mounting part that is mounted with a vial and capable of elevating or descending along the support surface, and a syringe mounting part capable of recovering or injecting I-131 mIBG solution contained in the vial. In particular, the vial mounting part includes a rotation function that enables the vial to rotate at a certain angle.

This device implements some automation without a computerized system and is not subject to computer validation under the pharmaceutical GMP regulations, and minimizes the burden on cleaning validation because the pharmaceitical solution is transferred only through a syringe and needle used for disposable use without a fixed transfer tube.

In addition, since the dispensing operation can be operated remotely from the outside of the hot cell, which is a radiation shielding space, the exposure of workers can be remarkably reduced, and the dispensing

is possible while maintaining the sterile state of the pharmaceitical solution.

Currently, preparation work is underway for the actual process use of this device, and it is expected that through this, it will be able to lay the foundation for stably supplying necessary medicines to pediatric cancer patients.

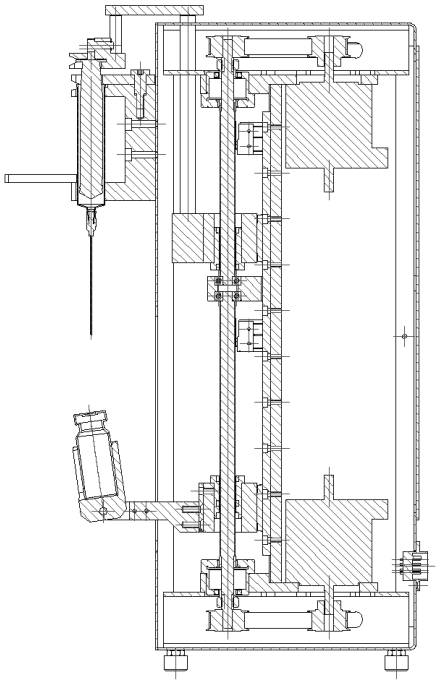

Fig. 2. Mechanical operation detail drawing

REFERENCES

[1] S. Voo, J. Bucerius, and F. Mottaghy Methods, Vol.55(3), p.238-245, 2011.