

Short description of a Freeze dryer unit CUB6031	 <b>IAEA</b> International Atomic Energy Agency	IAEA Specification Dated 29/11/2023
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## SPECIFICATION

### Freeze Dryer cGMP

#### 1. Scope

This specification describes the requirements for a cGMP freeze dryer (hereinafter referred to as the system), which will be employed in the facilities of the **clean area** in the Isotopes Centre, for the production of the freeze-dried kits of theranostic radiopharmaceuticals.

Planned application of the equipment is in accordance with the overall objective of the project (CUB 6031) "Production of theranostic radiopharmaceuticals in Cuba, as per current good manufacturing practice": Improve the quality of life and survival of cancer patients in Cuba. Task 2.1.1. EQ1: cGMP Freeze Dryer.

That goal of the project is closely related with the priorities embedded in the new Country Programme Framework for the period 2018-2023 (paragraph 1.3 "Human health and nutrition"):

- Enhance national radiotherapy and nuclear medicine capacities to manage patients with non-communicable diseases;

Besides, that aim is in accordance with the Sustainable Development Goal 03 of the National Socio-economic Development Plan for 2030: "Ensure healthy lives and promote well-being for all at all ages" and following priority of the Ministry of Health of the Republic of Cuba: "Non-communicable diseases and the risks, which influence on cancer and vascular diseases (cardiovascular, cerebrovascular, renal)"

#### 2. Applicable Documents

The following documents shall be applicable for this Specification to the extent specified hereinafter:

- 2.1. EudraLex The Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines to Good Manufacturing Practice (GMP) Medicinal Products for Human and Veterinary Use Annex 1 Manufacture of Sterile Medicinal Products (corrected version)

In the event of conflict between the documents listed above and the content of this Specification, the content of this Specification shall take precedence to the extent of the conflict.

#### 3. Definitions, Acronyms, and Abbreviations

cGMP: Current Good manufacturing practices

#### 4. Requirements



#### 4.1. Functional and Performance Requirements:

The system should be suitable for **aseptic production of pharmaceutical products as per cGMP criteria** providing minimum access control for building freeze drying cycle, visualization of process, batch report, data history.

The system should include **complete units** for automatic cleaning (**Cleaning in Place, CIP**), sterilization system (**Sterilization in Place, SIP; based on VHP (H<sub>2</sub>O<sub>2</sub> sterilization)**) in addition to basic components such as vacuum pump, compressor and system for heat transfer.

The System shall also meet the following functional and performance requirements:

- 4.1.1. Shelf area 0.5 m<sup>2</sup>;
- 4.1.2. Shelf dimensions (W x D) 380 x 450 mm;
- 4.1.3. N° of shelves 3 + 1;
- 4.1.4. Shelves clearance: 90 mm;
- 4.1.5. Chamber material: Stainless steel AISI 316L;
- 4.1.6. Condenser capacity: 30 kg;
- 4.1.7. Condenser temperature: -85 °C;
- 4.1.8. Shelves temperature range: from - 60 °C to +85 °C;
- 4.1.9. CIP (Clean in Place) system: piping and nozzles system in chamber and condenser. External drying unit: with liquid ring pump, water tank and plate heat exchanger
- 4.1.10. VHP disinfection (hydrogen peroxide vapor) – including piping and nozzles system, H<sub>2</sub>O<sub>2</sub> hydrogen peroxide tank with heating resistance, temperature probe and valves necessary for correct operation
- 4.1.11. Vial closing by pneumatic piston
- 4.1.12. Sealing of vials should be carried out under two conditions: vacuum conditions or with inert gas prior venting. Chamber aeration by HEPA filter + inlet for N<sub>2</sub>
- 4.1.13. Overall dimensions (W x D x H): 1,600 x 1,300 x 1,800 mm;
- 4.1.14. The equipment will be installed in a location with a controlled temperature (~ 22°C) and humidity < 60%, no condensation.
- 4.1.15. Allow the use of 2R, 10R and 15R vials
- 4.1.16. Break up the vacuum with filtered nitrogen and clean air.
- 4.1.17. Dry Air Compressor 5-10 bar, 220 VAC, 60 Hz is needed to be procured to guarantee the sustainability of the use of the freeze dryer
- 4.1.18. PC + external software control

#### 4.2. Technical Requirements

The System shall meet the following technical requirements:

4.2.1. The equipment should work with a power supply of AC 380 VAC; 3 phases + neutral + earth, 60 Hz;

4.2.2. Ports: USB, Ethernet 10/100/1000Mb, RS232, RS485 for communication and save tracing dates.

## 5. Marking

The System shall have all safety markings and user manual either in Spanish or in English language.

## 6. Packing

The System, for the shipment by air to the Isotopes Centre, Cuba, shall be packed in accordance with international standards that are applicable for the shipment by air of this kind of equipment.

## 7. Quality Requirements

7.1. The System shall be manufactured, shipped and installed in accordance with the Contractor's ISO quality assurance system or an equivalent quality assurance system.

7.2. The Contractor shall document the compliance with this quality assurance system.

## 8. Testing and Acceptance

8.1. The System, prior to shipment, shall be tested for conformance of the System with manufacturer's performance specifications (FAT) and the minimum requirements specified herein.

8.2. System, after installation, shall be tested by the Isotopes Centre (End-User) to demonstrate that the performance meets the manufacturer's performance specifications (SAT, IQ and OQ) and the minimum requirements specified herein as determined by the IAEA and the Isotopes Centre.

8.3. A report will be written by the Isotopes Centre and sent to IAEA in case of any compliance about the specifications of the equipment.

## 9. Installation and Training

9.1. The contractor shall Install the equipment at the end-user site.

9.2. The contractor shall provide three (days) local training course, for five (5) specialists.

## 10. Deliverable Data Items

The Contractor shall provide two complete sets of operation and servicing manuals and technical drawings in either Spanish or English language.