



SPECIFICATION

Lu-177 PSMA Doses

1. Scope

This specification describes the requirements for procuring 78 patient doses of Lu-177-PSMA-I&T (each dose containing 7 400 MBq, 200 mCi on the calibration date).

PSMA protein is over expressed in certain prostate cancers. Lutetium-177 (^{177}Lu)- PSMA-I&T is an approved radiopharmaceutical for clinical trial in Brazil by ANVISA for radioligand therapy of metastatic castration-resistant prostate cancers. Lutetium-177 (^{177}Lu)- PSMA-I&T specifically target and delivers radiation dose to PSMA-expressing cells and the surrounding microenvironment causing therapeutic effect. Lutetium-177 decays to a stable hafnium-177 with a physical half-life of 6.647 days by emitting beta-minus radiation with a maximum energy of 0.498 MeV (79%) and photon radiation (γ) of 0.208 MeV (11%) and 0.113 MeV (6.4%). The recommended treatment regimen of Lu-177-PSMA-I&T is 7 400 MBq intravenously every 6 weeks (± 1 week) for up to a total of 6 doses unless there is disease progression or unacceptable toxicity.

^{177}Lu -PSMA is revolutionizing the treatment of PCa, a disease highly prevalent in Brazil. IAEA will provide ^{177}Lu -PSMA doses for distribution to different nuclear medicine centers distributed in our country that will participate in training. IAEA will assist to strengthen, support and educate Brazilian physicians on the use of those RPs.

The following Nuclear Medicine Departments in Brazil are included as sites to be part of the project. The following NM departments:

- Quanta, Curitiba/PR
- IMEB, Brasília/DF
- Aliança, Belo Horizonte/MG"

The role of IAEA initiative can create a collaborative network in research and development in therapeutic radionuclides.

2. Definitions, Acronyms, and Abbreviations

PSMA = Prostate-specific membrane antigen

^{177}Lu = lutetium-177

SBMN – Brazilian Society for Nuclear Medicine

3. Packing

Clear, colourless type I glass vial, closed with a bromobutyl rubber stopper and aluminium seal. Each vial contains an sterile pyrogen free injection solution that can range from 7.5 mL to 12.5 mL corresponding to a radioactivity of 7 400 MBq $\pm 10\%$ at the date and time of administration. The



vial is enclosed within lead container with adequate protective shielding as per radiation protection regulation.

4. Quality Requirements

Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements, according to the Good Manufacturing Practices.

Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings. Preparation, receipt, storage, use, transfer and disposal of radiopharmaceutical are subject to the applicable regulations and/or appropriate licences from the competent regulatory agencies.

5. Testing and Acceptance

5.1 Doses, prior to shipment, must be calibrated to the guaranteed delivery dates and marking quality requirements.

5.2 The dose calibration values and date will be documented by the Contractor in an acceptance protocol that will be signed by the End User.

5.3 All relevant quality testing reports of the radiopharmaceutical batch should be documented and supplied with the consignment.

6. Installation and Training: Not applicable/ not required

7. Delivery and internal transportation- batches-timeframe (18 months). **Doses will be required in batches. The schedule is not fixed and depends on the patient studies.**

The injection should not be frozen. Stored in the original package in order to protect from ionising radiation (lead shielding). Handling, transportation storage and disposal of radiopharmaceuticals should be in accordance with national regulations on radioactive materials. The doses will be delivered to the selected participating hospitals in different regions of Brazil for 1.5 years (18 months) starting from the first delivered batch. All training and support for use will be provided by SBMN.

8. Deliverable Data Items

The Contractor shall provide the technical documentation of the item in the Portuguese language.