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Long-term Stability Study for GERADOR-IPEN-TEC by IPEN-CNEN/SP

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Introduction

The aim of this work is to carry out a Long-term Stability Study (LT) for GERADOR-IPEN-TEC (Fig. 1) produced and distributed by IPEN-CNEN/SP, to confirm the product's shelf life of 14 days when stored at room temperature.

The eluate was obtained from ^{99}Mo-^{99m}Tc generator system in 0.9% sodium chloride solution (saline) and does not need further processing or purification and can be directly administered or used for the preparation of ^{99m}Tc-radiopharmaceuticals and also as $^{99m}TcO_4^-$

Figure 1: GENERATOR-IPEN-TEC

Some of ANVISA regulations applicable to the production of GERADOR-IPEN-TEC are:

1. Resolution RDC No. 658/2022 is the Good Manufacturing Practices applied to Medicines (GMP);
2. Normative Instruction IN No. 128/2022 is applied to Radiopharmaceuticals and complementary to RDC 658/2022;
3. Resolution RDC No. 318/2019 is applied to Stability Study of medicines and radiopharmaceuticals.

Methodology

✓ Protocol and report were developed in accordance with RDC 318/2019, including the items described in Table I.

Table I: Items of Stability Study Protocol and Report

STABILITY STUDY PROTOCOL	STABILITY STUDY REPORT
Name of the drug	Protocol version executed
Identification of the API by DCB and CAS	Name and address of the API manufacturer
Tests to be carried out	Batch number and size of the finished product
Specifications	Date of manufacture of the batch
Execution schedule	Batch and expiry date of the API used
Name and address of the API manufacturer	Batch of the bulk and/or intermediate product
Study conditions	Description of the primary packaging material
Name and address of the drug manufacturer	Study start date (day/month/year)
Manufacturing process, if there is more than one	Storage conditions
Batch size	Frequency of testing
Analytical Methods	
Indicative of Stability used for all tests	Stability specifications
Primary packaging material	Identification of equipment
	Production process
	Test results (raw data)
	Statistical evaluation
	Conclusion

Results and Discussion

Figure 2 shows scheme of the tests carried out and the results according to the acceptance criteria for eluate of GERADOR-IPEN-TEC, established by Brazilian Pharmacopoeia, 6th edition 2019.

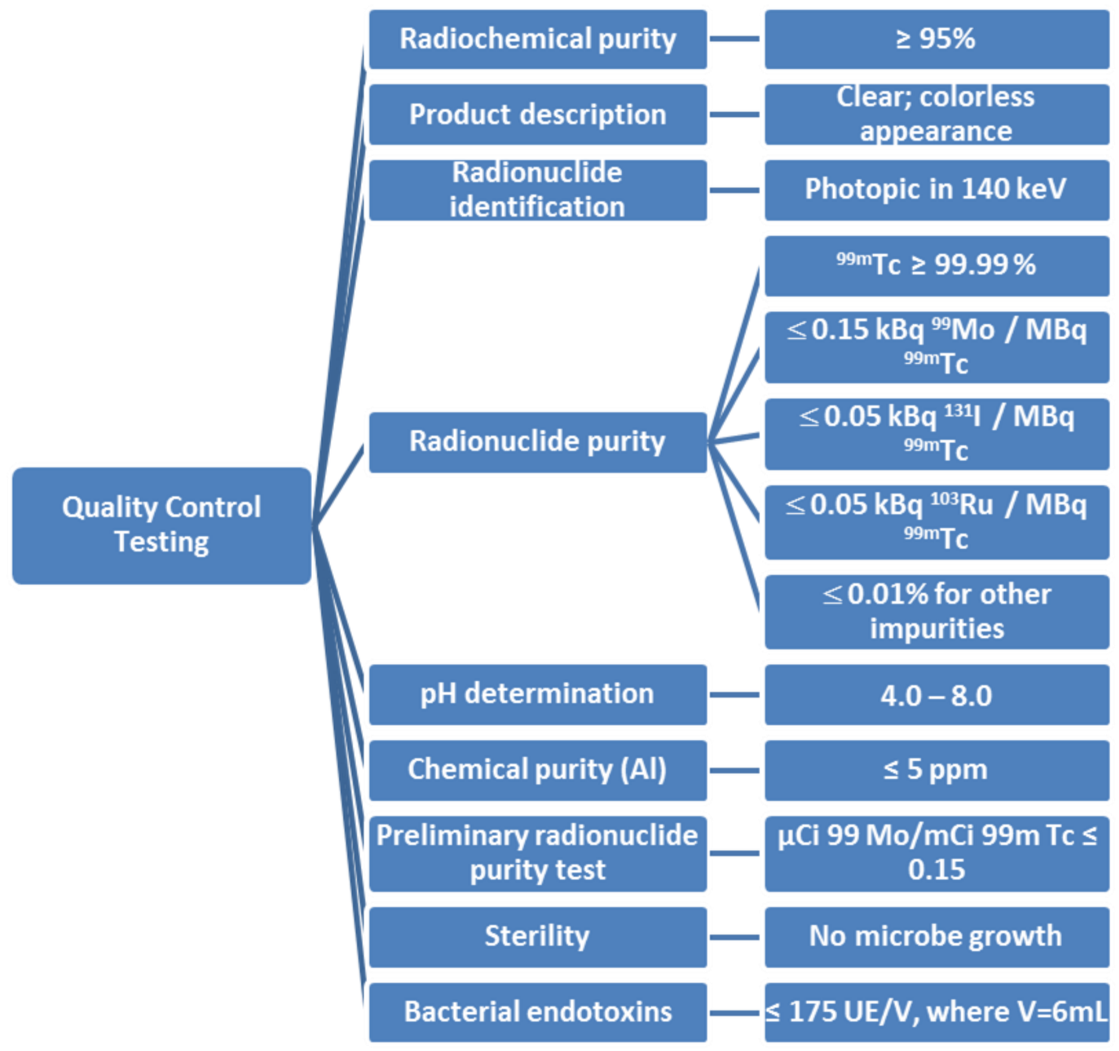

Figure 2: GENERATOR-IPEN-TEC: Tests and obtained results in Long Term Stability Study

- Radiochemical purity, pH, radionuclide purity, product description and radionuclide identification tests were carried out at 5 different times on alternate days, starting with the first eluate obtained on the day of production and were in accordance with the respective criterion.
- The preliminary radionuclide purity test was carried out in two daily elutions.
- For all the eluates, the chemical purity test to determine aluminum was carried out and the results were next to zero, bellow the limit of 5 ppm. The sterility and bacterial endotoxin tests were carried out on the initial day and the final day and the result were negative growth and negative gel formation to the dilution evaluated.

Conclusion

The LT Stability Study tested all the quality attributes that may have a potential impact on quality, efficacy, and safety, and which may change due to the influence of time, temperature, humidity or any other exposure factor.

The eluates from the 3 batches of GERADOR-IPEN-TEC analyzed showed results that met the radiopharmaceutical's specifications, confirming its shelf life of 14 days when stored at room temperature.

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