

HOW EFFICIENTLY CAN TILMANOCEPT (LYMPHOSEEK®) SYRINGES BE PREPARED?

T. Martin, S. Espitallier, E. Castelli, M. Rugiero, D. Alberato, C. Maurel, N. Sapin, I. Benard-Thierry
Radiopharmacy department – Centre Antoine Lacassagne, 33 Avenue de Valombrose, 06189 Nice

Introduction:

Tilmanocept (Lymphoseek®) is used for isotopic identification of sentinel lymph nodes for patients surgically treated for malignancies. It is presented in a vial containing the kit for radiopharmaceutical preparation. The radiolabelling is carried out with 23.1MBq of ^{99m}Tc in a volume of 0.625mL in order to minimize the injection volumes. The preparation of 18.5MBq in 4 syringes of 4.63MBq by the radiopharmacy is complicated by :

- ✓ The small volumes and activities ;
- ✓ The decrease in activity of ^{99m}Tc ;
- ✓ The adsorption of the product on the walls of the vial ;
- ✓ The necessity to get the required amount to perform quality control of the preparation.



Aim:

- To describe an efficient and practical syringe preparation protocol to be implemented in our department.

Method:

1st step: Preliminary tests

- ✓ To explore the various sampling techniques in accordance with GMP.
- ✓ Without product.
- ✓ Syringe volumes and activities, ease and safe handling were compared.

2nd step: Define the best sampling technique.

3rd step: Application

- ✓ Radiopharmacy technicians (n=4) each prepared three sets of Tilmanocept syringes.
- ✓ Calculation of the difference to the target value ($\pm 10\%$).
- ✓ Time in minutes was counted as from the start of the syringes preparation.

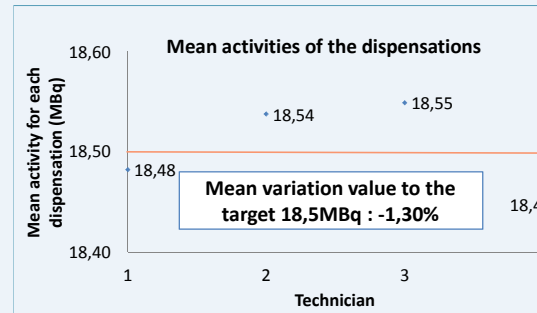
Results:

➤ Selected materials:

- Needle 21G 2'0,8 * 50mm (BD Microlance) ;
- Syringes 1mL (BD Plastipak) ;
- Needles 30G (BD Microlance).

➤ Sampling:

- Never flip the vial.
- Insert the 21G needle in the septum to reach the bottom of the vial.
- Sample the request activity for each syringe (4,63MBq in approximately 0,125mL).
- Some air was flared each time to safely disconnect the syringes.
- The syringes were equipped with 30G needles for assay and dispensation.
- Carry out quality control of the preparation (dilute if necessary).



- ✓ Global mean time of preparation: 10 \pm 1 min.
- ✓ No kit was wasted.
- ✓ Every quality control was performed.

Conclusion:

- Sampling technique: **Repeatable, Safe & Efficient** to prepare the Tilmanocept syringes.
- Difficulty faced: Obtain the correct value of 23.1MBq in the vial for the radiolabelling.
- For the medical team: Physician **satisfaction** to interpret scintigraphies.

⇒ This study showed the importance of adapting radiopharmaceutical practices to new situations to comply with Summary of Product Characteristics and GMP.